PATHOMECHANICS OF THE TIBIAL NERVE IN ASSOCIATION WITH LUMBAR RADICULOPATHY

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ABSTRACT

Dysfunctional neural pathomechanics are thought to be an underlying feature of numerous spinal pathologies and peripheral nerve disorders, and have been shown to have a direct effect on patient pain and functional ability levels. In particular, a reduction in the ability of a peripheral nerve to slide and glide is associated with increased pain and disability and often occurs with lumbar disc herniation due to compression of the nerve root in the intervertebral canal. Consequently, tibial nerve pathomechanics are an essential consideration with respect to lumbar radiculopathy, however, this association has not been widely investigated. In particular, there is limited research involving neural pathomechanics in symptomatic patients who have been diagnosed with intervertebral disc disease. The research studies undertaken for this PhD all involved symptomatic patients with intervertebral disc disease, some who had undergone lumbar decompression surgery and others who had not received any surgical intervention. However, all participants had a confirmed diagnosis of lumbar spinal pathology. To my knowledge, each of the five studies undertaken for this PhD are all innovative studies involving the investigation of tibial nerve pathomechanics in symptomatic patients.

The first aim of this thesis was to assess tibial nerve mobility in patients following lumbar decompression surgery, to determine if there was a relationship between nerve excursion and the development of Failed Back Surgery Syndrome (FBSS). A novel method of assessing and measuring tibial nerve excursion via diagnostic ultrasound at the popliteal fossa behind the knee had previously been developed and validated by our research group and this method was utilised throughout the research studies. The first three studies all involved patients who had previously undergone lumbar decompression and subsequently developed FBSS, with the

first study identifying that FBSS was associated with decreased tibial nerve mobility. The second study investigated the effect of a nerve mobilisation exercise on nerve mobility in post-lumbar surgical patients who were suffering from FBSS. This study identified that a single session of a nerve mobilisation exercise could improve tibial nerve mobility and reduce tibial nerve mechanosensitivity as determined by a straight leg raise (SLR) test. The third study aimed to determine the strength of correlation between both the leg pain experienced by patients post-lumbar decompression surgery and the patient-reported global rate of change scale (GRCS) with specific biomechanical and clinical variables; lumbar flexion, hip flexion, nerve excursion (painful leg), straight leg raise angle (painful leg) and back pain (VAS). This study identified that there was a strong correlation between tibial nerve movement and lumbar flexion with both leg pain and GRCS, with hip flexion and back pain also significantly associated with post-surgical leg pain and GRCS. This has clear clinical implications for the management of patients following lumbar decompression surgery as the identified variables are all potentially modifiable by clinical interventions.

The final two studies involved patients who had not undergone any lumbar surgery but whom all had a diagnosis of a single-level lumbar disc herniation and were all experiencing leg pain associated with the disc herniation. These studies aimed to investigate the potential effects of lumbar traction on leg pain and/or tibial nerve mobility. Study four investigated tibial nerve mobility during traction, measured at 5 minutes and then 30 minutes during continuous mechanical lumbar traction, and observed significantly increased tibial nerve excursion during traction in patients with a recently confirmed diagnosis of a lumbar disc herniation. These results suggested that traction could be a beneficial intervention with regard to improving tibial nerve mobility in symptomatic lumbar disc herniation patients that have not undergone surgery. These results led to the development of study five which consisted of a viability study to investigate the effects of a course of eight sessions of sustained, mechanical lumbar traction, with and without a nerve mobilisation exercise, on nerve mobility, leg pain, back pain, SLR angle, Oswestry Disability Index (a back and/or leg pain specific disability score) and the global rate of change scale (GRCS) in patients with a recently confirmed single-level lumbar disc herniation in patients aged 18-60 years inclusive.

Study five identified that both treatment groups; traction and traction with a nerve mobilisation exercise, resulted in a significant increase in nerve mobility in patients with a confirmed diagnosis of a single-level lumbar disc herniation. In addition, leg and back pain levels were significantly reduced following treatment in both groups, SLR angle and GRCS significantly improved and ODI score significantly decreased in both traction treatment groups. However, there was no difference in outcomes between the two treatment groups which suggested that traction alone can improve symptoms in people with a herniated lumbar disc and it is not necessary to perform a nerve mobilisation exercise during the traction.

All five studies in this thesis present innovative research that, to my knowledge, has not been previously investigated or reported. The findings of the five studies are relevant to clinical practice and also to the design of future research trials to further investigate the effect of sustained mechanical traction on people with a confirmed diagnosis of a lumbar disc herniation.

CLINICAL IMPLICATIONS:

1. Tibial nerve ‘glide and slide’ mobilisation exercises should be included as part of the rehabilitation and recovery programme following lumbar decompression surgery.
2. Back pain should be controlled following lumbar decompression surgery.
3. Lumbar and hip mobility exercises should be included as part of the rehabilitation and recovery programme following lumbar decompression surgery.
4. Sustained mechanical traction should be considered as an intervention to reduce leg pain and improve tibial nerve mobility in patients with a confirmed diagnosis of a single-level lumbar disc herniation.
5. It is recommended that a mechanical traction intervention for a single-level lumbar disc herniation adheres to the standard protocol specified in this study:
    - Type of Traction: Sustained Mechanical
    - Number of Traction Sessions: 8
    - Sustained Traction Time: 30 minutes
    - Traction Load: 30-45% of patient body weight (increasing by 5% each session over 4 sessions)

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AUTHORS DECLARATION

I hereby declare that this PhD thesis submission is my own work and that, to the best of my knowledge, contains no work written by another person or previously published.

At no time during the registration for the degree of Doctor of Philosophy has the author been registered for any other University award. Work submitted for this research degree at Chichester University has not formed part of any other degree either at Chichester University or at another establishment.

Signed: 

Date: 18th February 2023

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ABBREVIATIONS

BMI	Body Mass Index
DRAM	Distress Risk Assessment Method
FBSS	Failed Back Surgery Syndrome
GRCS	Global Rate of Change Scale
HF	Hip Flexion
ICC	Intraclass Correlation Coefficient
LBP	Lower Back Pain
LF	Lumbar Flexion
MCID	Minimal Clinically Important Differences
ODI	Oswestry Disability Index
PCC	Pearson Correlation Coefficient
SLR	Straight Leg Raise
VAS	Visual Analogue Scale

CHAPTER ONE. INTRODUCTION

1.1 BACKGROUND

Low back pain (LBP) is a major health problem that is thought to occur in 60-90% of people at some time during their lifespan (Güevenol *et al.* 2000), with an estimated cost of care and related production losses estimated to be £10668 million in the UK (1998 figure) (Maniadakis and Gray 2000). There has been a significant increase in hospital admissions due to LBP throughout the period 1999-2013, with numbers increasing from 127.09 per 100,000 population to 216.26 per 100,000 population in 2013. However, the growth in number of surgical procedures has not been as great, with the number of admissions having increased at a rate of 3.5 times greater than the number of surgical interventions (Sivasubramaniam *et al.* 2015). Consequently, there is a greater demand for conservative treatment of LBP to manage this increasing patient load. However, there is currently a lack of evidence to support many conservative interventions for LBP, therefore, research to support and validate potential treatments for the non-surgical management of LBP would allow more effective, evidence-based treatment and management of this growing patient group.

LBP is a generic term which covers a range of different pathologies that can lead to back pain. LBP resulting from degenerative lumbar spine pathology is considered to be one of the most common non-fatal medical conditions throughout the world resulting in significant levels of long-term disability (Hoy *et al.* 2012; Vos *et al.* 2012). In the UK back pain resulting from spinal degenerative conditions is one of the main causes of doctor visitations, hospitalisation and social care intervention (Maniadakis and Gray 2000). Consequently, it places a significant financial burden on healthcare resources and providers, patients and society.

Although much of the literature regarding spinal degenerative pathologies reference back pain as a symptom these conditions frequently involve clinical symptoms and pain beyond the lower back. Radiculopathy has been described as a loss of sensory or motor function along the distribution of a spinal nerve and the term radicular pain describes a pain that radiates down one or both legs (Berry *et al.* 2019; Lin *et al.* 2014). However, there is a lack of consensus across the literature regarding the definition and use of the terminology lumbar radiculopathy and other terminologies including sciatica, radicular pain, nerve root pain and referred pain are often used interchangeably and inconsistently to describe the same condition (Lin *et al.* 2014). Indeed, back pain guidelines across different countries use varying and inconsistent terminology. The European Back Pain Guidelines refer to nerve root pain and radicular pain (Airaksinen *et al.* 2006; van Tulder *et al.* 2006), whereas the guidelines for the diagnosis and treatment of low back pain from the American College of Physicians and the American Pain Society refer to sciatica and radiculopathy (Chou *et al.* 2007). However, the International Association for the Study of Pain (IASP) do not recommend the use of the term sciatica as it does not differentiate between different types of leg pain or other associated symptoms (Merskey 1986). Instead they define lumbar radiculopathy as a loss of motor function and/or sensation along the distribution of a spinal nerve, which is defined by objective neurological signs rather than pain, and radicular pain as leg pain caused by a nerve root or its ganglion (Bogduk 2009). Although it is common for radiculopathy and radicular pain to occur together they can also present independently of each other.

Lumbar radiculopathy is caused by irritation of a specific lumbar nerve root, usually resulting from a compressive force, with disc herniation thought to be the most common cause (Bogduk 2009). Patients often describe the pain associated with lumbar radiculopathy as burning, sharp or an electric sensation, and is estimated to affect 3-5% of the population including both men and women (Heliövaara *et al.* 1987; Tarulli and Raynor 2007). Indeed, lumbar intervertebral disc disorder is one of the most frequently diagnosed pathologic conditions affecting the spine with a reported lifetime occurrence as high as 40% (Manchikanti *et al.* 2009a). A herniated disc is often referred to as a bulging, prolapsed or slipped disc and is the most common cause of radiating leg pain and paraesthesia which results from the compression of spinal nerve roots (Gibson and Waddell 2007b; Mitchell *et al.* 2017b), with surgery for radicular pain and radiculopathy (including discectomy) estimated to cost over £100 million per year in the UK (Legrand *et al.* 2007). In addition, it has been proposed that impaired peripheral nerve mobility and mechanics play a significant role in many peripheral neural disorders (Dilley *et al.* 2008) (Hough *et al.* 2007) (Greening *et al.* 2005). Microscopic discectomy is the most common surgical treatment for lumbar intervertebral disc disorder and involves the excision of the disc herniation, subsequently relieving pressure on the nerve root in the central or lateral intervertebral canal. However, despite technically successful surgery up to 32% of patients continue to experience radiculopathy and pain following surgery (Dasenbrock *et al.* 2012; Dewing *et al.* 2008), which can eventually lead to the development of chronic persistent leg pain; a condition referred to as Failed Back Surgery Syndrome (FBSS).

In addition to surgical intervention traction is a proposed treatment in the management of lumbar disc herniation and associated lumbar radiculopathy and radicular pain. Indeed, traction has been in use as a treatment for lumbar disc herniation since the time of Hippocrates (460 BC–370 BC) (Saunders 1979) with several studies identifying significant benefits of mechanical traction when used to treat a lumbar disc herniation (Apfel *et al.* 2010;

Chow *et al.* 2017; Hahne *et al.* 2010; Mitchell *et al.* 2017b; Ozturk *et al.* 2006; Prasad *et al.* 2012). It has been a commonly used intervention for back pain and sciatica since the 1950's (Crisp *et al.* 1955) (Parsons and Cumming 1957) and was reported as a clinical treatment option for LBP by 41% of physiotherapists in the UK (Harte *et al.* 2005). However, the 1996 Clinical Guidelines for the Management of Acute Low Back Pain reported that traction does not appear to be effective for low back pain or radiculopathy based on consistent findings from multiple studies (Waddell 1996), similarly, current NICE guidelines for low back pain, radicular pain and radiculopathy do not recommend the use of traction (de Campos 2017; National Guideline 2016). Although, it has been suggested that the reports of little or no benefit from traction could be due to poor patient selection criteria or inadequate traction protocols (Güevenol *et al.* 2000). Stratified medicine involves identifying specific clinical sub-groups with a distinct mechanism of a disease. This allows the identification of treatments that will be effective for a particular patient group to ensure that the right patient gets the right treatment at the right time (Medical Research Council, 2017). In terms of traction as a treatment for back pain, it is only likely to be effective for patients with disc pathology as observed in the biomechanics and physiology studies that have identified clinically beneficial outcomes from mechanical traction (Apfel *et al.* 2010; Chung *et al.* 2015; Hahne *et al.* 2010; Ozturk *et al.* 2006; Prasad *et al.* 2012), therefore suggesting it should not be used as an intervention for non-disc related spinal pathologies. Varying traction loads and type (intermittent or continuous) can be applied and it is proposed that an insufficient load (Güevenol *et al.* 2000) or intermittent traction application (Clarke *et al.* 2006; Schimmel *et al.* 2009; Wegner *et al.* 2013) could also be potential reasons for a lack of treatment effect.

1.2 AIMS AND OBJECTIVES

The aims of this research were:

1. To add to the body of evidence regarding peripheral nerve pathomechanics in relation to leg pain associated with lumbar radiculopathy.

2. To investigate tibial nerve pathomechanics in patients with spinal pathology and associated leg pain pre and post-lumbar spinal surgery.

3. To investigate the effect of an ultrasound-guided neural mobilisation exercise on the straight leg raise (SLR) angle for patients with failed back surgery syndrome (FBSS) and persistent leg pain.

4. To identify any significantly relevant biomechanical and clinical factors associated with leg pain and the patient-reported outcome Global Rate of Change Scale (GRCS) in patients post-lumbar decompression surgery.

5. To investigate the effect of a mechanical traction intervention, with and without a neural mobilisation exercise, on tibial nerve excursion in patients with a disc herniation confirmed by MRI.

6. To specify a standardised protocol for the clinical use of mechanical traction in the treatment of leg pain associated with lumbar disc herniation.

1.3 SIGNIFICANCE OF THIS DOCTORAL RESEARCH

This PhD research aimed to add to the body of evidence and in particular enhance knowledge of tibial nerve pathomechanics in association with lumbar radiculopathy, with the hope of developing specific treatment strategies for patients diagnosed with a lumbar disc herniation, who either have or have not, had lumbar decompression surgery. Each of the five studies of this PhD involve innovative research and techniques that have not previously been investigated in symptomatic patients with a confirmed diagnosis of a single-level lumbar disc herniation. In particular, tibial nerve mobility in patients with a lumbar disc herniation, both pre and post lumbar decompression, has not previously been investigated or reported on.

The findings from this research will have significance for clinicians involved in the treatment of patients with lumbar radiculopathy and related peripheral nerve pain. In particular, it will be relevant for the treatment and management of patients with leg pain associated with intervertebral disc disease and disc herniation. Information from this research will increase understanding of the pathomechanics of the tibial nerve in patients pre and post-lumbar surgery. In addition, the influence of mechanical traction on tibial nerve pathomechanics of patients with a confirmed diagnosis of a lumbar disc herniation will also be further understood. The research will also present a specific protocol for the application of lumbar mechanical traction to allow ease of replication in future studies and also for use in clinical practice for the treatment of patients with a confirmed diagnosis of a lumbar disc herniation.

1.4 THESIS PRESENTATION

This thesis is presented in an academic paper-based style consisting of an initial review of the relevant literature concerning neurodynamics, lumbar intervertebral disc disease, Failed Back

Surgery Syndrome (FBSS), mechanical traction, neural mobilisation, ultrasound imaging of nerve movement and outcome measures used in the research studies, and then subsequently comprised of the following papers:

1. Decreased tibial nerve movement in patients with failed back spinal surgery syndrome

2. Immediate effect of ultrasound-guided neural mobilisation on straight leg raise angle for patients with failed back surgery syndrome and persistent leg pain

3. Factors associated with patient-reported outcomes in post-operative spinal patients

4. Comparison of tibial nerve excursion before, during and after sustained lumbar traction in people with a confirmed lumbar disc herniation

5. The effect of mechanical traction, with or without neural mobilisations, on leg pain and tibial nerve mobility in patients with a single-level lumbar disc herniation

I believe that all the papers present innovative research techniques and procedures that have not been previously undertaken or documented in the literature. In particular, previous research has not involved assessment of tibial nerve excursion via ultrasound imaging in people with a confirmed diagnosis of a lumbar disc herniation or in people who have undergone lumbar spinal surgery. In addition, no previous study regarding mechanical lumbar traction has attempted to specify a standardised protocol for use in the clinical setting and for future research.

An overall summary of the research and thesis is then provided with conclusions drawn and clinical implications specified. Finally, recommendations are made for areas of future research.

RESEARCH FLOW CHART

STUDY ONE (N=74)
POST LUMBAR SPINAL SURGERY
GP 1: CONTINUING LEG PAIN (FBSS)
GP 2: NO CONTINUING LEG PAIN (NON FBSS)
MEASUREMENT OF TIBIAL NERVE MOBILITY

REDUCED TIBIAL NERVE MOVEMENT OBSERVED IN FBSS PATIENTS
HOW COULD TIBIAL NERVE MOVEMENT BE IMPROVED?

STUDY TWO (N=32)
POST LUMBAR SPINAL SURGERY
PATIENTS WITH CONTINUING LEG PAIN (FBSS)
SINGLE NERVE MOBILISATION EXERCISE
IMMEDIATE EFFECT ON SLR ANGLE

INCREASED SLR FOLLOWING NERVE MOBILISATION IN PATIENTS WITH FBSS
WHAT OTHER CLINICAL VARIABLES ARE ASSOCIATED WITH FBSS?

STUDY THREE (N=74)
STATISTICAL CORRELATION ANALYSIS
POST LUMBAR SPINAL SURGERY
PATIENTS WITH FBSS + NON FBSS
ASSESSED – LEG PAIN, BACK PAIN, LUMBAR FLEXION,
HIP FLEXION, SLR, GRCS

CLINICAL IMPLICATIONS FOR THE MANAGEMENT OF FBSS POST SPINAL SURGERY
WHAT ABOUT PRE-SURGERY, DISC HERNIATION PATIENTS?

STUDY FOUR (N=17)
PATIENTS WITH CONFIRMED DISC HERNIATION
SINGLE TRACTION SESSION
MEASUREMENT OF TIBIAL NERVE MOBILITY AFTER 5 MINS AND 30 MINS OF MECHANICAL TRACTION
EFFECT OF TRACTION ON TIBIAL NERVE MOBILITY

SUSTAINED LUMBAR TRACTION IMPROVED TIBIAL NERVE MOBILITY
WHAT ARE THE POTENTIAL EFFECTS ON NERVE MOBILITY AND OTHER CLINICAL VARIABLES OF A COURSE OF TRACTION IN DISC HERNIATION PATIENTS?

STUDY FIVE (N=50)
BIOMECHANICAL STUDY TO INVESTIGATE A COURSE OF TRACTION ON LEG PAIN AND TIBIAL NERVE MOBILITY IN PATIENTS WITH CONFIRMED DISC HERNIATION
GP 1: TRACTION
GP 2: TRACTION + NERVE MOBILISATION
GP 3: CONTROL

CHAPTER TWO. LITERATURE REVIEW

2.1 INTRODUCTION

The aim of this literature review is to evaluate the main theoretical and clinical concepts presented throughout this thesis, including a discussion of the concept of neurodynamics, which is defined as the integrated biomechanical, physiological and morphological functions of the nervous system which consists of various structures including the brain and cranial nerves, the spinal cord, nerve roots, peripheral nerves and all related connective tissues (Shacklock 1995, Shacklock, 2005 #1353). Neurodynamics is an important area of consideration for this thesis and warrants theoretical explanation and understanding of the physiological structures and processes involved during the investigation of the pathomechanics of the sciatic nerve in relation to lumbar radiculopathy. It provides a theoretical background and understanding that was essential for the design and development of the studies undertaken during this thesis. Consideration of the information within this literature review was important in the development of an understanding of the concepts employed to achieve the objectives of this PhD thesis.

An understanding of the development and progression of lumbar intervertebral disc disease as well as the associated post-surgical complication of failed back surgery syndrome were fundamental to the development of the studies involved in this thesis as both conditions are potentially associated with lumbar radiculopathy. The first three studies of the thesis involved patients with both lumbar intervertebral disc disease and failed back surgery syndrome, while all the participating subjects in the final two studies had a diagnosis of lumbar intervertebral disc disease. Consequently, this literature review will examine the pathogenesis of lumbar intervertebral disc disease and the occurrence of failed back surgery syndrome post lumbar spinal surgery.

The existing evidence regarding mechanical traction is equivocal and its use is not currently recommended by NICE guidelines as a treatment for sciaticia. The research evidence regarding mechanical traction will be discussed in regard to lumbar radiculopathy including an evaluation of the evidence to support its use in the 4^{th} and 5^{th} studies of this thesis.

The implications of impaired nerve mobility will be examined and the evidence regarding the use of neural mobilisation exercises to improve nerve mobility will be discussed in relation to lumbar radiculopathy. In addition, the use of diagnostic ultrasound imaging to determine and assess nerve mobility will be examined and explained, specifically with respect to the sciatic/tibial nerve. Finally, the outcome measures utilised throughout the five studies undertaken for the completion of this PhD will be documented and evaluated to aid clarity and comprehension of the methodology employed for each study.

2.2 NEURODYNAMICS

Neurodynamics refers to the integrated biomechanical, physiological, and morphological functions of the nervous system which consists of numerous different structures including the brain and cranial nerves, the spinal cord, nerve rootlets and roots, peripheral nerves and all related connective tissues (Shacklock 2005). The terminology was first introduced by Shacklock in 1995 to describe the interactions between the mechanical and physiological mechanisms of the nervous system (Shacklock 1995). Shacklock referred to the body as a container of the nervous system with the musculoskeletal system being the mechanical interface to the nervous system which consists of central and peripheral mechanical components. The central components being formed by the cranium, and spinal and radicular canals containing the neuraxis, cranial nerves, meninges and nerve root, and the peripheral component consisting of the nerve bed which has contact with the surrounding musculoskeletal structures of the body. As the body (or container) moves, the mechanical interface must undergo changes to accommodate the movement, which subsequently exerts forces on the neural structures (Shacklock 1995). To ensure that optimal communication is maintained throughout the structures of the body at all times the nervous system is constantly required to adapt to the forces and mechanical loads that are continually placed on it. To do so the neural structures need to be able to undergo mechanical changes such as elongation, sliding, cross-sectional changes, angulation and compression (Ellis and Hing 2008; Shacklock 1995). Such changes help to protect the nervous system, however, if they fail to occur it is left vulnerable to increased mechanosensitivity (Dilley *et al.* 2005), decreased neural mobility (Kobayashi *et al.* 2010), reduced nerve conduction (Brown *et al.* 1993), intraneural oedema (Lundborg *et al.* 1983; Yayama *et al.* 2010), hypoxia and ischaemia (Jung *et al.* 2014), inhibition of axonal transport (Rydevik *et al.* 1980) and fibrosis (Hunter 1991; Millesi *et al.* 1990), all of which may cause neurodynamic alterations and biomechanical dysfunction to occur. Subsequently, this may lead to the development of pathophysiology within neural tissues resulting in pain and disability (Ellis and Hing 2008; Gilbert *et al.* 2015b; Shacklock 1995).

Traditionally, the nervous system was considered a hierarchical structure consisting of input–processing-output, with sensory nerves feeding into the central system and motor nerves feeding out (Butler 2000). However, this rather simplistic overview of the system has now changed with the knowledge that the nervous system is actually an evolving system capable of adaptation and learning new patterns of activity. Knowledge of the nervous system and associated structures throughout the human body is constantly progressing with increased research and information aiding the development of the most effective treatments for associated neural disorders and dysfunctions.

2.2.1 NERVE BIOMECHANICS

To facilitate the normal functioning of neural structures in unloaded, loaded and compressed positions peripheral nerves have various biomechanical properties that allow accommodation of the mechanical forces that are constantly placed upon the nervous system. These biomechanical properties include the ability of the nerve to change length (strain), to slide and glide relative to surrounding tissues (excursion) and the ability to withstand pressure or compression from surrounding structures (Topp and Boyd 2012).

To maintain normal neural function peripheral nerves need to withstand tensile load with reduced intraneural vascularity (Ogata and Naito 1986), axoplasmic flow (Dahlin *et al.* 1986) and nerve conduction (Wall *et al.* 1992) being observed to occur with only a 5-10% increase in nerve strain (Coppieters *et al.* 2006; Phillips *et al.* 2004). Normal movement requires the elongation of peripheral nerves; a straight leg raise requires the sciatic nerve to adapt to length changes in the surrounding tissues of at least 12%, raising an arm overhead causes the tissues surrounding the median nerve to lengthen by up to almost 20% to which the median nerve must adapt (Butler 2000). This capacity to lengthen is due to the viscoelastic properties of neural tissue; with a mixture of elastin and collagen fibres present throughout the connective tissue layers (Phillips *et al.* 2004). These viscoelastic properties also allow the nerve to recoil to its original length once the tensile stress is reduced (Dilley *et al.* 2003; Nee *et al.* 2010).

Peripheral nerves are constructed of hundreds of individual nervous fibers that are organised into fasicles that are surrounded and supported by connective tissue layers. There are sensory and motor fibres with sensory fibres having a diameter of 4-10µm and motor fibre being of a smaller diameter ranging from 2-6µm. Most peripheral nerves are bimodal in that they contain both sensory and motor fibres which are intermingled through the length of the nerve. The nerve is surrounded by three layers of connective tissue which structurally support and nourish the nerve. The outer layer is the epineurium which is a longitudinal structure along the nerve length that provides resistance and elongation to the nerve trunk. The perineurium is the middle layer which consists of a sheath of several layers of flat cells that are thought to act as a metabolic blood-nerve barrier involved in the regulation of the endoneuronal environment. The innermost layer is the endoneurium which consists of connective tissue which surrounds the intrafascicular nerve fibres (Berthold *et al.* 2005; Teixeira *et al.* 2016). The neural connective tissue layers also aid neural strain with the collagen fibres of the epineurium and endoneurium allowing the accommodation of elongation forces (Topp and Boyd 2006), with the perineurium able to withstand 18-22% strain before any structural failure occurs (Sunderland and Bradley 1961).

The ability of a nerve to slide and glide in relation to surrounding tissues and structures is termed excursion and allows a nerve to adapt to changes in the nerve bed length elicited by limb movements (Dilley *et al.* 2007; Erel *et al.* 2003). A consistent pattern of excursion has been observed in peripheral nerves which involves a convergence of nerve movement towards a moving joint when the nerve path length is elongated, with the nerve gliding towards the moving joint (Topp and Boyd 2006). When the nerve path is shortened, the reverse occurs and the nerve will diverge away from the moving joint (Topp and Boyd 2012). Excursion can result in shearing forces being imposed upon the nerve, these forces being greater with faster movements (Yoshii *et al.* 2009).

The layers of connective tissue supporting the peripheral nerves play an important role in nerve excursion facilitation, with the outer mesoneurium sheath; a connective tissue sheath which is continuous with the underlying epineurium, allowing sliding of the nerve in relation to the surrounding tissues and the external epineurium allowing neural excursion relative to the mesoneurium and nerve bed (Butler 2000; Mackinnon 2002; Shacklock 2005). In addition, the epineurium and endoneurium facilitate the internal sliding with individual nerve fascicles and fibres sliding against each other (Abe *et al.* 2004; Butler 2000; Shacklock 2005).

Neural tissue also has to withstand pressure increases from surrounding tissues, with certain functional positions exerting neural pressure three to six times higher than the pressure exerted in a relaxed position (Pechan and Julis 1975). Excessive neural compression has been shown to detrimentally affect neurophysiological features such as intraneural blood flow, nerve conduction and axoplasmic flow (Gelberman *et al.* 1983). The main resistance to compressive forces is provided by the epineurium which acts as a shock-absorber (Rydevik *et al.* 1980; Sunderland 1989), with both connective tissue density and fascicle numbers being observed to be greater in regions of increased mechanical load (Mackinnon 2002; Rempel and Diao 2004a). Neural compression has been shown to influence intraneural vascularity with impaired blood flow observed in animals at 20-30mmHg and total ischaemia at 60-80mmHg (Ogata and Naito 1986; Rydevik *et al.* 1991). However, no impairment in nerve conduction was observed until higher levels of compression (75-100mmHg) were applied (Olmarker *et al.* 1990; Rydevik *et al.* 1991). Consequently, this has implications for optimal neural health and function in the presence of nerve compression, with nerve root compression frequently seen in patients with intervertebral lumbar disc disease (Gibson and Waddell 2007b; Mitchell *et al.* 2017b).

If the magnitude of the stress exerted on the neural tissue exceeds the capacity the tissue can withstand, either acutely or cumulatively over time, then it is likely that an injury to the neural tissue will occur (Topp and Boyd 2006). Such an injury may alter the biomechanical properties of a nerve and subsequently reduce the capacity of the nerve to accommodate and tolerate the mechanical stresses placed upon the neural structures during normal movement and physical function resulting in mechanosensitivity (Topp and Boyd 2012).

2.2.2 NERVE PATHOLOGY

Increased pressure on a nerve results in compression of neural blood vessels which subsequently leads to impaired blood flow and potential epineurial arterial ischemia. In turn, this can cause capillary leakage, intraneural and extraneural oedema and further intraneural pressure (Tang *et al.* 2015). A relatively mild neural injury can result in epineural oedema, whereas long term compression may cause changes to the diffusion barriers of the perineurium and microvasculature resulting in endoneural oedema, inflammation, fibrosis, demyelination and axonal degeneration (Rempel and Diao 2004a). There are no lymphatic vessels around the endoneurium, consequently, the excess fluid associated with endoneural oedema is unable to drain away and can lead to fibrosis, adhesions and reduced intrafasicular gliding, with fibrosis eventually causing intraneural thickening, nerve enlargement and subsequent extraneural compression from external adjacent structures (Gilbert *et al.* 2015b). A dose-response pattern has been observed between neural compression pressure and axonal degeneration (Rempel and Diao 2004b).

Mechanosensitivity refers to how sensitive nerves are to mechanical stresses and is thought to be a protective response to potentially harmful increased tissue load stress that results in increased neural sensitivity (Topp and Boyd 2012). It is generally accepted that this heightened sensitivity is associated with stimulation of the nocioceptive nervi nervorum fibres by excessive mechanical or chemical stimuli (Ogata and Naito 1986). Nervi nervorum are unmyelinated or poorly myelinated fibers that are located in peripheral nerves sheaths, and they are thought to be involved in the transmission of sensory information and the environmental regulation of peripheral nervous system structures (Teixeira *et al.* 2016).

Structural and functional abnormalities of the nervi nervorum are thought to contribute to the development, maintenance and exacerbation of neuropathic pain, as well as abnormality of the impulse generation site along the length of neural axons (Bell and Weddell 1984) (Gelberman *et al.* 1981). In addition, nervi nervorum are thought to be vulnerable to nervous tissue injuries caused by friction and chronic compressive syndromes and their stimulation may contribute to neuropathic chronic pain conditions (Bove and Light 1997).

In addition, nerve root compression has been shown to induce inflammatory responses that can also cause mechanosensitivity (Dilley and Bove 2008). As a result of increased mechanosensitivity the physical stresses exerted on a nerve during normal movement may elicit a painful or symptomatic response. Neural mechanosensitivity is generally identified clinically by the administration of neurodynamic tests which use a series of joint movements to selectively and progressively stretch a specific nerve tract (Boyd *et al.* 2009; Byl *et al.* 2002). Neurodynamic tests progressively lengthen the nerve bed and nerve whilst the level of mechanosensitivity is assessed with regard to a symptomatic response. Specific nerve neurodynamic tests have been shown to increase neural strain from 8.2-11% (Byl *et al.* 2002; Topp and Boyd 2006) with mechanosensitivity being observed to occur at only 3% strain in rats with experimentally induced neuritis (Dilley *et al.* 2005). With respect to sciatic and tibial nerve mechanosensitvity, the Straight Leg Raise (SLR) test is a validated neurodynamic test commonly used in research and clinical practice to assess the sensitivity and irritability of the sciatic and tibial nerves. The test applies tension to the sciatic and tibial nerve by elongation of the nerve bed at the ankle, hip and knee which is achieved via passive ankle dorsiflexion, knee extension and hip flexion (Rade *et al.* 2017).

2.3 LUMBAR INTERVERTEBRAL DISC DISEASE ETIOPATHOGENESIS

Back pain is considered to be the most disabling condition globally and as such presents a significant healthcare and socioeconomic problem to the majority of the world (James *et al.* 2020), with healthcare costs in the United Kingdom alone estimated to be £1632 million (Maniadakis and Gray 2000). In addition to the direct healthcare costs, indirect costs with respect to employment and production losses due to back pain, are estimated to be £10668 million (UK 1998 figure) (Maniadakis and Gray 2000) giving a combined estimated cost of back pain of £12300 million to the UK economy.

Lumbar intervertebral disc disorder is the most frequently diagnosed pathologic condition affecting the spine (Suthar *et al.* 2015) with a reported lifetime occurrence as high as 40% (Manchikanti *et al.* 2009b). Intervertebral disc herniation is defined as a localised displacement of disc material beyond the margins of the intervertebral disc space (Hahne *et al.* 2010) and is a cell-mediated response to progressive structural failure (Adams 2006). Intervertebral discs (IVD) are pads of fibrocartilage composed of an outer, collagen-dense annulus fibrosus, an inner nucleus pulposus consisting of a proteoglycan and water gel held together by a network of collagen and elastin fibres, and a cartilaginous endplate consisting of a thin horizontal layer of hyaline cartilage which is avascular in the adult (Adams 2006; Dowdell *et al.* 2017; Mitchell *et al.* 2017b). The discs sit between each spinal vertebrae and makeup approximately one-third of the height of the spinal column, with a healthy lumbar intervertebral disc being usually 7-10mm thick and 40mm in diameter (Urban and Roberts 2003). Their main function involves the transmission of mechanical loading in the spinal column, which occurs from body weight and muscle activity, to allow bending and torsion of the spine (Pathak and Conermann 2022). The nucleus pulposus is highly hydrated due to high osmotic pressure, which helps to maintain disc height and distribute loading across the vertebral endplate (Samartzis and Cheung 2011). The IVD is an avascular structure with nutrition driven by a diffusion gradient of glucose, oxygen, and other macromolecules (Dowdell *et al.* 2017). The discs resist spinal compression, spreading the load evenly across the vertebral bodies and permit limited movement between the vertebra (Adams 2006). Shear forces and loads act on the spine throughout the day causing a decrease in the water content of the disc by about 14% (Kuo *et al.* 2014). During sleep and periods of non-weight bearing, water and nutrients are drawn back into the nucleus of the disc to re-establish hydrostatic homeostasis (Malko *et al.* 2002). This increase in nutrient supply promotes cell growth within the disc consequently inhibiting cellular degeneration (Kuo *et al.* 2014). Fragmentation of proteoglycans within the nucleus starts during childhood and with increasing age there is a decrease in proteoglycan and water content within the nucleus, as well as an increase in stiffness and weakness of the annulus (Adams 2006). Degeneration within IVDs occurs much earlier than any other connective tissue in the body (Urban and Roberts 2003) and has been observed as early as 11 years of age and a decrease in blood supply to vertebral endplates is thought to occur with increasing prevalence from about the age of 20 years (Dowdell *et al.* 2017). Indeed, disc degeneration has been observed via MRI in asymptomatic patients, with a prevalence ranging from 37% in 20-year-olds to 96% in 80-year-olds, suggesting that disc degeneration is part of the normal ageing process (Brinjikji *et al.* 2015b). However, MRI findings have identified that disc degeneration, disc bulge, protrusion and extrusion occur more frequently in adults under the age of 50 years with symptomatic back pain than in asymptomatic individuals (Brinjikji *et al.* 2015a). Annular tears increase in frequency after the age of 10 years, reaching a peak in middle age, and are especially common in the lower lumbar spine. Such tears can lead to disc herniation or prolapse which occur most frequently between the age of 30-40 years, usually due to excessive or repetitive mechanical loading (Adams 2006). Various factors can cause a disc to become weakened, including genetic inheritance, increasing age, reduced disc nutrition and increased loading, which can subsequently result in structural failure of the disc during normal daily living activities (Adams 2006). A herniated disc is often referred to as a bulging, prolapsed or slipped disc. It is the leading cause of radiating leg pain and paraesthesia (sciatica) which results from the compression of spinal nerve roots (Gibson and Waddell 2007b; Mitchell *et al.* 2017b).

Peripheral nerves such as the tibial nerve must bend, stretch and glide along their length within the nerve tissue bed to accommodate movement of the adjacent joints whilst maintaining the transmission of electrical impulses (Ellis and Hing 2008). Nerve root impingement could compromise the ability of a peripheral nerve to stretch and glide causing reduced neural mobility and subsequent increased neural tension and associated loss of function, pain or neural fibrosis (Hunter 1991; Millesi *et al.* 1990). Nerve movement limitations due to adhesions at the level of the spinal nerve root have been directly observed intra-operatively (Kobayashi *et al.* 2010), while nerve entrapment neuropathies have been shown to have an effect on both myelinated and unmyelinated nerve fibres distal to the site of compression (Schmid *et al.* 2014a). In addition, increased mechanosensitivity (Dilley *et al.* 2005), a reduction in nerve conduction (Brown *et al.* 1993), inhibited axonal transportation (Rydevik *et al.* 1980) and neural oedema (Lundborg *et al.* 1983; Yayama *et al.* 2010) have been observed following peripheral nerve compression. Vascular changes have also been observed in spinal nerve roots in patients with radiculopathy associated with disc herniation which are thought to be caused by compromised venous flow due to the mechanical compression which ultimately results in ischaemic damage and neural fibrosis (Cooper *et al.* 1995). These changes can result in shortening and tightening of the nerve which subsequently affect the biomechanical properties of the nerve (Topp and Boyd 2012), leading to mechanosensitivity symptoms including a painful response to nerve stretch during joint movements (Dilley *et al.* 2005). An innovative study which investigated the effect of the addition of nucleus pulposus material to cauda equina nerve roots in pigs, observed that it resulted in several degenerative nerve root changes including a reduction in nerve conduction velocity, axonal vascularisation and fibre atrophy. These observations suggest that disc herniation may induce neural injury by biochemical mechanisms in addition to mechanical compression (Olmarker *et al.* 1993).

Lumbar disc herniation can be treated by conservative or surgical intervention, with surgery indicated if conservative therapy fails or is considered unavoidable when a motor deficit intensifies or when a cauda-equina syndrome develops (Gibson and Waddell 2007c). Cauda equina syndrome is caused by the compression or injury of several lumbar and sacral nerve roots resulting in a combination of clinical symptoms including motor deficit, bladder and/or bowel dysfunction, saddle anaesthesia of the perineum (Lavy *et al.* 2009). It is a medical emergency and usually requires urgent surgical decompression. Microscopic discectomy is the most common surgical intervention for lumbar intervertebral disc disorder, which results in excision of the lumbar disc herniation and subsequent relief of pressure on the nerve root at the central or lateral canal. Surgery for sciatica (including discectomy) has been estimated to cost over £100 million per year in the UK so is a considerable healthcare cost (Legrand *et al.* 2007). Following successful discectomy surgery, it is hoped that normal nerve mechanics will be restored. However, chronic persistent leg pain can occur in up to 32% patients following discectomy (Dasenbrock *et al.* 2012; Dewing *et al.* 2008).

2.4 LATERAL RECESS SYNDROME ETIOPATHOGENESIS

Lateral recess syndrome, a variant of spinal stenosis, is a progressive degenerative condition that commonly affects older adults and leads to significant pain and functional disability, which can result in activity and participatory restrictions and have a negative effect on psychosocial wellbeing (Chad 2007). In addition to disc herniation it is one of the most commonly diagnosed and surgically treated pathologic conditions affecting the spine (Lurie *et al.* 2003). Spinal stenosis is especially common in the elderly population, with the prevalence as high as 66.6% in people with back pain in the 60-69 year old age group (Kalichman *et al.* 2009). Lateral recess syndrome is caused by facet and ligamentous hypertrophy that narrows the lateral lumbar spinal canal and compresses the spinal nerves root. Surgical intervention for lateral recess syndrome results in global decompression of the central canal, lateral canal, and neural foramina across single or multiple levels which is cost effective and largely successful (Turner *et al.* 1992). However, a number of studies reported postoperative residual leg pain in 17 - 41% people with lateral recess syndrome following decompression (Atlas *et al.* 1996; Turner *et al.* 1992).

2.5 FAILED BACK SURGERY SYNDROME

In the UK in 2012 lumbar decompression surgery was performed on approximately 24,000 patients throughout the duration of the year (Weir *et al.* 2017a). Unfortunately, despite undergoing technically successful surgery it is estimated that 10-40% of these patients would continue to experience pre-surgical radiculopathy and/or radicular pain, a condition which is commonly referred to as Failed Back Surgery Syndrome (FBSS) (Eldabe *et al.* 2010). Incidence levels of FBSS do appear to vary across different surgical procedures, with rates of 35-36.2% reported following lumbar decompression (Cornefjord *et al.* 2000; Fokter and Yerby 2006) and a rate of 25% reported following lumbar microdiscectomy (Asch *et al.* 2002). As the total number of lumbar spinal surgeries in 2012 was estimated at approximately 24,000 it would be expected that at least 6000 of those patients would develop FBSS following their surgery.

FBSS is characterised by continued radiculopathy and radicular pain following surgery, which is often resistant to pharmacological intervention (Eisenberg *et al.* 2005). The pain and radicular symptoms experienced by patients with FBSS often inflicts limitations on people's ability to work as well as having a detrimental effect on their quality of life, with FBSS patients reporting much lower health-related quality of life scores than patients with other causes of neuropathic pain (Eldabe *et al.* 2010). It has been reported that post microscopic discectomy up to 15% of young, active participants with no overt re-herniation or lumbar pathology fail to return to work (Dewing *et al.* 2008). In addition, FBSS results in significantly increased post-surgical healthcare costs that are estimated to be over 50% greater than lumbar surgery patients with no persistent pain. Indeed, the estimated cost of short-term care (2 years) for this patient group is approximately £26.4 million, with the cost of care over the 10 years following surgery predicted to be approximately £70.3 million for each annual cohort of post-lumbar surgery patients (Weir *et al.* 2017a). Therefore, FBSS presents a huge financial cost to healthcare providers, as well as to the patients themselves and the wider society, in terms of work hours lost and other subsequent effects on the socioeconomic environment. In addition, many of these patients are left living with persistent pain and functional limitations that often have a large detrimental impact on their professional and personal lives.

A greater understanding of the causes of FBSS and potential interventions for the condition is required as currently there are limited treatment options available despite the fact it affects over 20% of lumbar surgery patients and contributes greatly to long-term healthcare costs. There appears to be a lack of consensus regarding the occurrence and definition of the condition, with some of the literature referring to this disorder as persistent postoperative pain (PPP) (Weir *et al.* 2017a). Consequently, there is a need for specific evidence-based treatment and management guidelines to allow the most beneficial outcomes for these patients.

2.6 MECHANICAL TRACTION

2.6.1 History

The word traction is a derivative of the Latin word 'tractico' meaning a process of pulling or drawing. It is thought that traction has been used as a treatment for spinal pathologies and pain relief since the time of Hippocrates (460 BC–370 BC) (Saunders 1979). Hippocrates described five types of spinal deformities: kyphosis, scoliosis, concussion fractures, vertebral dislocations and fractures of the spinous processes and invented several devices for the treatment of these spinal deformities; the Hippocratic ladder, the Hippocratic board and the Hippocratic bench, which were all based on principles of axial traction (Vasiliadis *et al.* 2009). The Hippocratic ladder aimed to reduce spinal curvatures and involved the patient being shaken (succession) whilst being tied on a ladder; head up if the deformity was near the neck, and head down if the deformity was at a lower level of the spine, with the weight of the trunk acting as the traction force (Vasiliadis *et al.* 2009). The Hippocratic table involved the patient having leather straps to his body, allowing traction to be applied in cephalic and caudal directions whilst at the same time direct pressure was manually applied to the area of deformity by hands, feet or sitting on the patient (Xarchas and Bourandas 2003).

In 1950 James Cyriax developed a traction device that involved the patient lying prone or supine on a couch with wide bands placed around the pelvis and mid-thorax, which were attached to hooks at each end of the table. Traction of between 80-200lb (36-90kg) was then applied for around 30 minutes, with treatment given daily for 8 treatments. If after 8 treatments no relief of symptoms was experienced by the patient then the treatment was discontinued (Parsons and Cumming 1957). A study of 100 cases treated with the Cyriax traction device was conducted in 1956 and concluded that the treatment greatly reduced the period of disability and the incidence of laminectomy, with 74 of the patients achieving complete relief from their symptoms (Parsons and Cumming 1957). Since then traction has been widely used for the treatment of lower back pain with differing reported rates of success (Clarke *et al.* 2007; van der Heijden *et al.* 1995).

2.6.2 Traction and Disc Herniation

Spinal traction is a conservative treatment which has been frequently used to reduce the pain and discomfort associated with disc herniation (Güevenol *et al.* 2000). However, current NICE guidelines for lower back pain and sciatica do not recommend the use of traction (National Guideline 2016), although these recommendations are for generalised sciatica, for which the causes could be multi-factorial, rather than specific to disc pathology. Conversely, several studies have identified significant benefits of mechanical traction when used to treat back pain caused specifically by disc pathology (Apfel *et al.* 2010; Chow *et al.* 2017; Hahne *et al.* 2010; Mitchell *et al.* 2017b; Ozturk *et al.* 2006; Prasad *et al.* 2012). Consequently, the evidence for the use of traction remains inconclusive. This is thought to be potentially due to a lack of methodological rigor and a limited application of clinical parameters, therefore, it is proposed that further research in the area is required that should address methodologic quality and the appropriateness of the intervention (Harte *et al.* 2003; Harte *et al.* 2005; Prasad *et al.* 2012). It is also suggested that reports of little or no benefit from traction could be due to poor patient selection criteria (Güevenol *et al.* 2000). Stratified medicine involves identifying specific clinical sub-groups with a distinct mechanism of a disease. This allows identification of treatments that will be effective for a particular patient group to ensure that the right patient gets the right treatment at the right time (Medical Research Council, 2017). In terms of traction as a treatment for back pain it is only likely to be effective for patients with disc pathology as observed in the biomechanics and physiology studies that have identified clinically beneficial outcomes from mechanical traction (Apfel *et al.* 2010; Chung *et al.* 2015; Hahne *et al.* 2010; Ozturk *et al.* 2006; Prasad *et al.* 2012) so should not be used as an intervention for non-disc related spinal pathologies. Varying traction loads and type (intermittent or continuous) can be applied and it is suggested that an insufficient load (Güevenol *et al.* 2000) or intermittent traction application (Clarke *et al.* 2006; Schimmel *et al.* 2009; Wegner *et al.* 2013) could also be potential reasons for a lack of treatment effect.

Despite evidence to suggest that mechanical traction is not a beneficial intervention in the treatment of lower back pain there is also research that has identified traction as a successful intervention in the treatment of disc herniation. Consequently, mechanical traction could be beneficial to patients awaiting discectomy surgery by decreasing pain levels and potentially reducing the need for surgery (Apfel *et al.* 2010; Chow *et al.* 2017; Hahne *et al.* 2010; Mitchell *et al.* 2017b; Ozturk *et al.* 2006; Prasad *et al.* 2012). It has been proposed that traction therapy can increase the flow of nutrients into the disc helping to promote disc cell growth and it has been observed to enhance nutrient transportation and cell viability, consequently, relieving the degeneration process (Kuo *et al.* 2014). In addition, traction is proposed to decompress the nerve root by the production of negative intradiscal pressure that helps to retract protruded disc matter (Güevenol *et al.* 2000). The use of MRI has identified changes in disc shape, reduced herniation of the nucleus pulposus, separation of the adjoining disc and nerve root and widening of the facet joints during and following 30 minutes of continuous traction (Chow *et al.* 2017; Chung *et al.* 2015). Traction has also been shown to decrease pain levels associated with discogenic back pain with one study showing an average decrease in pain from 6.2 (SD 2.2) to 1.6 (SD 2.3, $p < 0.001$) on an 11-point verbal rating scale (0-10)(Apfel *et al.* 2010).

In addition, traction has been shown to reverse the need for surgery in patients with disc herniation, with surgery avoided in 79.6% of patients receiving inversion traction compared with 22.2% in the control group (Prasad *et al.* 2012). Inversion traction is a form of traction whereby the patient is strapped to a tilt table by the ankles and then positioned head down, consequently the traction force is created by the body weight of the patient. Although this form of traction has been shown to potentially decrease the need for spinal surgery in a small group of patients (Prasad *et al.* 2012) poor tolerance to inversion traction has also been reported due to anxiety and feelings of congestion (Güevenol *et al.* 2000).

Traction dosage is an important consideration with a traction of less than 25% of body weight described as low dose or sham traction, and a load of 60% body weight shown to cause a reduction of residual intradiscal pressure of 25% (Prasad *et al.* 2012). However, disc changes have been shown to be more pronounced with a traction dosage of 44-50% of body weight (Chow *et al.* 2017). Consequently, although a reduction of intradiscal pressure has been shown to be beneficial to the intervertebral disc (Guehring *et al.* 2006; Sato *et al.* 2002), it is deemed prudent to use a traction load below 50% to reduce the potential risk of inducing disc changes and damage. Traction can be applied continuously or intermittently with 30 minutes of continuous traction being observed to result in increased height of the intervertebral space of all lumbar discs (Chow *et al.* 2017). Suggested treatment times for traction vary, however, increased disc reduction ratio has been observed with increasing treatment time up to 30 minutes (Chung *et al.* 2015) and on average a treatment time of 30 minutes is recommended. Recommended frequency is 2-3 times per week for a minimum of 3 weeks (Harte *et al.* 2003). Consequently, it is hypothesised that an intervention of a mechanical traction applied at a force of 45% of body weight continuously for 30 minutes, 2 times per week for 4 weeks would have a significant beneficial effect including reducing pain rating and the likelihood of surgery.

2.6.3 Risk of Traction

Few risks of traction have been reported however the European guidelines for the management of chronic nonspecific low back pain report a potential risk of adverse effects including raised blood pressure and respiratory constraints with heavy traction; specified as lumbar traction forces greater than 50% of total patient body weight (Airaksinen *et al.* 2006; van den Hoogen *et al.* 1995). Inversion therapy is an alternative to mechanical traction that has also been shown to be an effective intervention for patients with intervertebral disc disease (Mendelow *et al.* 2021; Prasad *et al.* 2012). However, inversion traction is not always well tolerated, with reports that patients undergoing inverted traction experienced pain where the ankles were anchored to the bed as well as anxiety (Güevenol *et al.* 2000). In addition, adverse cardiovascular responses have also been reported in patients undergoing inversion traction therapy, including increased systolic blood pressure and increased ophthalmic arterial pressure (Zito 1988).

2.7 NEURAL MOBILISATION

Neural mobilisation is a clinical treatment technique that aims to restore optimal physiological movement and function to peripheral nerves in which neurodynamics have been compromised, and is often used in clinical practice to manage patients with nerve root compression and associated pain (Bertolini *et al.* 2009; Brown *et al.* 2011; Gilbert *et al.* 2015b). Neural mobilisation was originally defined as an intervention that directly or indirectly affects the neural structures and surrounding tissues (Butler 2000; Shacklock 2005). It is used to address adverse neurodynamics with the objective of restoring the dynamic balance between the movement of neural tissues in relation to surrounding mechanical structures (Ellis and Hing 2008), and is recommended in clinical practice guidelines as an intervention for patients with neck and arm pain related to neural compression (Childs *et al.* 2008). Neural mobilisation exercises are thought to decrease intrinsic pressures on neural tissues which allows enhanced axoplasmic flow and consequently optimal physiological functioning (Bertolini *et al.* 2009; Ellis and Hing 2008). It is proposed that neural mobilisation results in benefits to the neural tissues including the reduction of nerve adhesions and associated facilitation of nerve gliding, increased neural vascularisation, dispersal of noxious fluids, decreased intraneural and extraneural oedema and improved axoplasmic flow; restoring the ability of the nervous system to tolerate normal compressive, tensile and frictional forces (Ellis and Hing 2008, Gilbert, 2015 #660).

One of the main proposed benefits of neural mobilisation is the restoration of nerve mobility by the promotion of nerve excursion to reduce neural fibrosis and tethering (Akalin *et al.* 2002; Bialosky *et al.* 2009; Brown *et al.* 2011; Coppieters and Alshami 2007; Pinar *et al.* 2005). In addition, it has been proposed the neural mobilisation may also maximise the viscoelastic properties of neural tissue and consequently improve the extensibility of the tissue (Mendez-Sanchez *et al.* 2010; Shacklock 1995; Shacklock 2005). It has also been suggested that the neural sliding action induced by nerve mobilisation may also produce a mechanical 'milking effect' upon the nerve which may enhance intraneural circulation and the subsequent removal of waste products and oedema (Akalin *et al.* 2002; Coppieters *et al.* 2004; Coppieters and Butler 2008). Neural oedema is thought to impair nerve excursion, consequently, a reduction in neural oedema may also facilitate improved neural excursion. A mechanical pumping effect created by joint movements has also been suggested to aid neural fluid dispersal (Brown *et al.* 2011), therefore, it is proposed that both extraneural and intraneural effects may be involved in the physiological effects observed with neural mobilisation.

2.7.1 Neural Mobilisation Techniques

There are two different types of nerve mobilisation techniques; sliders and tensioners. Sliders consist of a specific sequence of joint movements that aim to produce a sliding of neural structures by increasing nerve length at one joint whilst simultaneously reducing nerve length at another joint (Efstathiou *et al.* 2015), resulting in nerve excursion without any associated neural tension. However, tensioners aim to stretch the neural tissues by combining joint movements that result in elongation of the nerve bed at both ends (Coppieters *et al.* 2009).

Sliders have been shown to produce greater amounts of nerve excursion compared with tensioners and subsequently are most frequently used to facilitate nerve excursion (Coppieters and Alshami 2007; Coppieters and Butler 2008; Coppieters *et al.* 2009; Ellis 2012).

In addition, a sliding technique is considered to be less aggressive on the neural tissue and consequently more appropriate for acute neural injuries and post-surgery as they are less likely to exacerbate mechanosensitivity and radicular pain (Coppieters and Butler 2008). However, it has been proposed that a tensioning technique may be more effective at altering intraneural pressure which can be beneficial for the reduction of intraneural swelling (Coppieters and Butler 2008).

2.7.2 Mechanical And Physiological Effects

In vivo studies with rats have shown numerous benefits of neural mobilisations following an induced neural chronic construction injury, including reduced neural oedema (Schmid *et al.* 2012), decreased neuropathic pain symptoms (Giardini *et al.* 2017) and axonal regeneration (da Silva *et al.* 2015). In addition, neural sliding and gliding of upper quadrant peripheral nerves have been demonstrated in both human cadaveric and in vivo studies (Alshami *et al.* 2008; Babbage *et al.* 2007; Coppieters *et al.* 2009), with beneficial outcomes reported in the treatment of carpal tunnel syndrome (Ballestero-Pérez *et al.* 2017; Rozmaryn *et al.* 1998).

Sciatic and tibial nerve excursion have been observed during neural mobilisation exercises (Coppieters *et al.* 2015; Ellis *et al.* 2008), with a neural mobilisation exercise involving ankle dorsiflexion performed alone (Boyd *et al.* 2012) or in conjunction with cervical extension (Ellis *et al.* 2008), shown to facilitate distal tibial nerve excursion (Ellis *et al.* 2008). In addition, spinal position (slump or upright in sitting) was observed to have no effect on tibial excursion (Ellis *et al.* 2017). Consequently, it is recommended that a neural mobilisation exercise to improve tibial nerve excursion can be performed with ankle dorsiflexion or a combination of ankle dorsiflexion and cervical flexion, with spinal position determined by patient preference and comfort.

Studies investigating neural mobilisation exercises in people with lumbar radiculopathy and persistent leg pain, have reported both positive and negative effects, with most studies involving patients who have not undergone any surgical procedure for their condition. A relatively recent meta-analysis of 40 studies identified a significantly positive effect of neural mobilisation exercises on both pain and disability when compared to exercise and/or to exercise plus lumbar mobilisation in people with nerve related back pain (Basson *et al.* 2017). Several studies have identified positive clinical outcomes with neural mobilisation exercises combined with other treatment techniques (Murphy *et al.* 2006; Savva and Giakas 2013). However, combining the neural mobilisation exercises with other treatment techniques meant it was not possible to determine the effectiveness of the neural mobilisation alone. One study investigating the effect of neural mobilisation exercises on various sub-groups of patients with low back and leg pain determined that neural mobilisation exercises were most effective for improving pain and physical function in patients with peripheral nerve sensitivity; as classified by a positive straight leg raise (SLR) nerve provocation test (Schäfer *et al.* 2011), with a positive response to a neurodynamic test being suggestive of increased peripheral neural mechanosensitivity (Nee *et al.* 2012; Walsh and Hall 2009a).

Although a lack of neural mobility is believed to be potentially influential in the development of various neuropathies, there is a lack of evidence to support the hypothesis that neural mobilisation increases nerve excursion in patients presenting with limited nerve mobility.

Indeed, only one previous study has investigated the effect of a neural mobilisation exercise on patients with lumbar radiculopathy post-spinal surgery (Scrimshaw and Maher 2001) and found that the addition of a neural mobilisation exercise to standard post-operative care did not result in improved patient outcomes. However, that study included all lumbar decompression post-operative patients without differentiating between patients with a successful surgical outcome and those with remaining leg pain despite having surgical decompression (Scrimshaw and Maher 2001). It was also suggested by the authors that the prescribed neural mobilisation protocol may have been insufficient, either too vigorous or too cautious, to improve patient outcome. In turn, this highlighted the lack of consensus throughout the literature regarding optimal protocols and procedures for the prescription of nerve mobilisation exercises. Consequently, this supports the requirement of further research to investigate the proposed benefits of neural mobilisation exercises in people with reduced neural mobility.

However, it has been suggested that in patients with acute symptoms nerve mobilisation exercises should be performed within the patients comfort range to avoid exacerbating any existing mechanosensitivity, focusing on nerve gliding mobilisation techniques (Butler 1989; Shacklock 2005; Totten and Hunter 1991), and as the mechanosensitivity decreases over time then nerve tensioning techniques could potentially be included (Herrington 2006; Talebi *et al.* 2010). Consequently, in patients with acute peripheral nerve sensitivity and irritable symptoms, it is suggested that sliders are a more appropriate nerve mobilisation technique than tensioners as they are less likely to aggravate any existing neural symptoms and are more likely to enhance nerve mobility (Ellis 2012, Coppieters, 2008 #776, Coppieters, 2006 #775). As this thesis was predominantly concerned with the assessment of tibial nerve mobility in patients with existing lumbar radiculopathy and associated pain, it was deemed most appropriate to use a slider nerve mobilisation exercise to avoid further exacerbating tibial nerve mechanosensitivity and worsening any existing pain and neural symptoms.

2.8 ULTRASOUND IMAGING OF NERVE MOVEMENT

2.8.1 Ultrasound Principles And Techniques

As a diagnostic tool ultrasound (US) was initially utilised in the field of cardiology to observe heart echoes in the late 1940s and early 1950s which led to the development of echocardiology (Persson *et al.* 2012). Since then ultrasound machines have progressed from being large, cumbersome machines that produced poor-quality images to portable, sophisticated instruments producing high-quality images (Chiou *et al.* 2003; Newman and Rozycki 1998; Walker 2004). Ultrasound imaging is now a commonly used technique to provide real-time and in-vivo musculoskeletal imaging in a non-invasive, flexible and cost-effective manner (Alshami *et al.* 2022; Ellis *et al.* 2008; Ellis *et al.* 2021).

Ultrasound imaging involves the transmission of sound waves that are the echoed back from a source of contact, with the waves being reflected back in a specific manner dependent on the physical properties of specific tissues (Walker *et al.* 2004). Tissues with a low density reflect back fewer sound waves to the transducer whereas those with a greater density reflect back more sound waves. High density tissues such as bone have a bright white visual appearance (hyperechoic) whereas tissues with a lower density such as blood/liquid appear visually darker (hypoechoeic) (Sconfienza *et al.* 2012).

2.7.2 Ultrasound Imaging Of Peripheral Nerves

With the development of high-frequency transducers and the continual improvements in ultrasound image quality which now allows nerve visualisation with excellent resolution, US imaging is widely used for the investigation and assessment of peripheral nerves which has proved to be reliable, effective, non-invasive and well tolerated (Goedee *et al.* 2013).

It is now possible to visualise subtle anatomical details and to identify a wide range of pathologies affecting nerves via US imaging (Beekman 2004) (Sconfienza *et al.* 2012). As many peripheral nerves run superficially ultrasound allows non-invasive examination of nerves along the length of the nerve trunk in both static and dynamic states (Goedee *et al.* 2013; Martinoli and Bianchi 2007).

A normal nerve has a fairly uniform appearance which reflects their histologic composition. In longitudinal section a nerve will normally appear as an elongated structure with multiple hypoechoic parallel linear areas that correspond to the neuronal fascicles that run longitudinally and are separated by hyperechoic bands (Sconfienza *et al.* 2012). The size and number of fascicles vary in individual nerves depending on distance from origin, amount of pressure the nerve is subjected to and the occurrence of nerve branching (Martinoli and Bianchi 2007).

In transverse section a peripheral nerve appears as a honeycomb-like structure consisting of hypoechoic spots embedded within a hyperechoic background, the hypoechoic spots corresponding to the longitudinal fascicles within the nerve and the hyperechoic background the interfasicular epineurium (Martinoli and Bianchi 2007; Sconfienza *et al.* 2012). When viewed longitudinally peripheral nerves appear as hypoechoeic tubes which can be differentiated from surrounding soft tissues as numerous hypoechoic lines (nerve fascicles) enclosed between two bolder hyperechogenic lines (epineurium) (Hough *et al.* 2000a; Hough *et al.* 2000b; Martinoli *et al.* 2000).

2.8.3 Ultrasound Imaging Of The Sciatic/Tibial Nerve

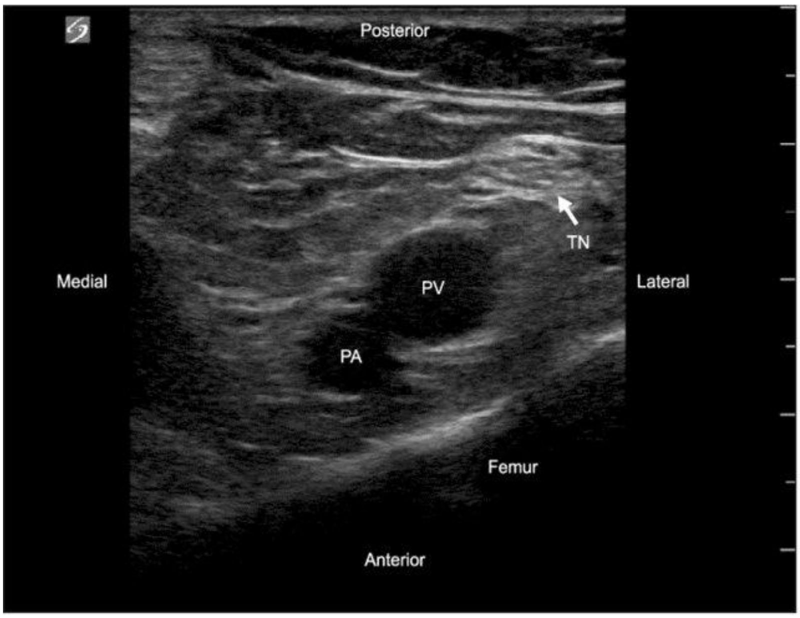
Nerve roots exiting the lumbar and sacral spine cannot be imaged via ultrasound due to the depth of their course and the interposition of bony structures, therefore, imaging the nerve as it exits from the spine is not a viable option (Beekman 2004; Hoddick *et al.* 1984). Subsequently, investigation of the sciatic/tibial nerve by ultrasound needs to be undertaken somewhere along the course of the nerve after it exits the vertebral foramen. Successful ultrasound imaging of the sciatic nerve requires precise anatomical knowledge regarding position of the nerve and their relationship with surrounding structures. Ultrasound imagery of the sciatic nerve has been reported by numerous authors using a range of different locations along the main nerve and its associated branches (Chan *et al.* 2006; Gray *et al.* 2004; Heinemeyer and Reimers 1999; McCartney *et al.* 2004; Schwemmer *et al.* 2004; Sinha and Chan 2004; Tsui and Finucane 2006). The tibial nerve is relatively easy to locate at the back of the knee as it passes through the popliteal fossa, in between the mass of the hamstrings and gastrocnemius muscles, coursing immediately adjacent to the popliteal artery and vein which can be easily identified by ultrasound. On identification of the blood vessels the tibial nerve can be observed running adjacent to the vessels (figure 2.1). The addition of body movements can allow peripheral nerves to be more easily visualised (Coppieters *et al.* 2009), with ankle dorsiflexion seen to produce superficial and longitudinal movement of the tibial nerve (Schafhalter-Zoppoth *et al.* 2004). The observation of these anatomical landmarks, along with the addition of lumbar and hip flexion or ankle dorsiflexion to facilitate neural mobility, enabled identification and visualisation of the tibial nerve via ultrasound imaging for the purpose of the research involved in this thesis.

The ultrasound transducer was placed at the back of the patients knee in the popliteal fossa. Initially the transducer was positioned vertically to allow the identification of the popliteal artery and vein and tibial nerve in transverse section where the tibial nerve could be readily identified as a round to oval hyperechoic structure (figure 2.1). The transducer was then rotated into a horizontal position to allow visualisation of the blood vessels and tibial nerve in the longitudinal plane from which nerve movement could be recorded and evaluated (Figure 2.2). Nerve movement was recorded via a pre-set cine-loop function on the ultrasound machine which recorded nerve movement over an 4 second period. The cine-loop was then reviewed by the researcher to determine that the nerve remained in view throughout the sequence. If an unsatisfactory image sequence was observed the transducer was repositioned and the measurement repeated. When a satisfactory cine-loop was obtained, it was saved to the hard drive for subsequent off-line analysis. This was repeated 3 times for each assessment. This data was stored on the ultrasound machine and then uploaded to a password protected google drive for anonymous, secure storage.

The image sequences of the diagnostic ultrasound cine-loops were analysed in MATLAB (MathWorks, Natwick, MA, USA) (Shum *et al.* 2013) using a frame-by-frame normalised cross-correlation approach. The tracking programme used a pattern-matching algorithm based on the greyscale pattern present in each of the five selected region of interests to find the best match region of interests in sequential frames. Dilley et al. (2001) developed a frame-by-frame cross-correlation approach based on 2-D speckle tracking principles that allows direct calculation of the nerve movement in two dimensions. 2-D speckle tracking techniques allow both longitudinal excursion and axial components of nerve movement to be recorded. From these two values, the hypotenuse movement can then be calculated, which represents the true longitudinal excursion component. Successful in vivo tracking of parts of the sciatic nerve tract using a speckle tracking approach was reported by Ellis et al. (2008) and the same technique was used by Shum et al (2013) to measure the tibial branch of the sciatic nerve at the popliteal fossa during functional movement. Consequently the speckle tracking approach for measuring nerve excursion was considered an appropriate methodology for this doctoral research. Displacement of the nerve in the longitudinal (lateral) and axial (deep/superficial) dimensions were registered for each frame-by-frame matching comparison. The programme also calculated the hypotenuse excursion from the vector combination of longitudinal and axial movement. To minimize bias, the researcher was blinded to each participant's information or grouping during offline data analysis.

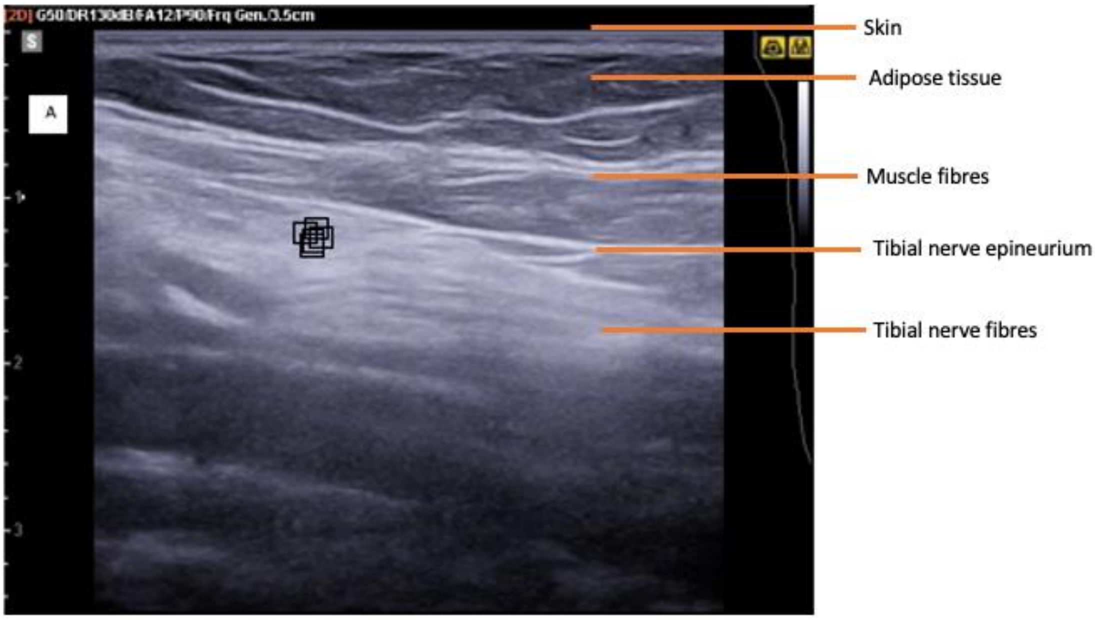
Figure 2.1 : Transverse view of the tibial nerve at the popliteal fossa

(Hannaford *et al.* 2021)



TN – tibial nerve, PA – popliteal artery, PV - popliteal vein

Figure 2.2 : Longitudinal view of the tibial nerve at the popliteal fossa



This image was taken at the popliteal fossa and was collected as part of this doctoral research

2.9 RESEARCH STUDY OUTCOME MEASURES

There are numerous different assessment tools that are used throughout clinical practice and research for the assessment of radicular pain and radiculopathy including pain severity outcome measures, functional/disability measures, quality of life measures and mental health assessment tools (Longo *et al.* 2010). Ideally, outcome measures used in clinical research should also be appropriate for use in a clinical setting to encourage and promote transfer of knowledge and findings from the research setting to clinical practice. To allow significant conclusions to be drawn regarding the effectiveness of specific interventions, the outcome measures selected should demonstrate appropriate scientific rigor and clinical relevance.

Outcome measures used in the five studies involved in this PhD were selected by examination of previous research and literature with consideration of the specific research aims and variables that were being examined. In addition, the clinical appropriateness of each outcome measure was also considered as it is vitally important that research to support assessment and treatment in a healthcare profession such as physiotherapy utilises methods that can be transferred into clinical practice. Consequently, clinical relevance was a consideration when selecting the outcome measures to allow the potential use of our testing methods and assessment and treatment procedures to be replicated by physiotherapists in clinical practice. All outcome measures utilised have been previously validated and were deemed the most appropriate measures for the specific purpose of each study.

2.9.1 Nerve Excursion

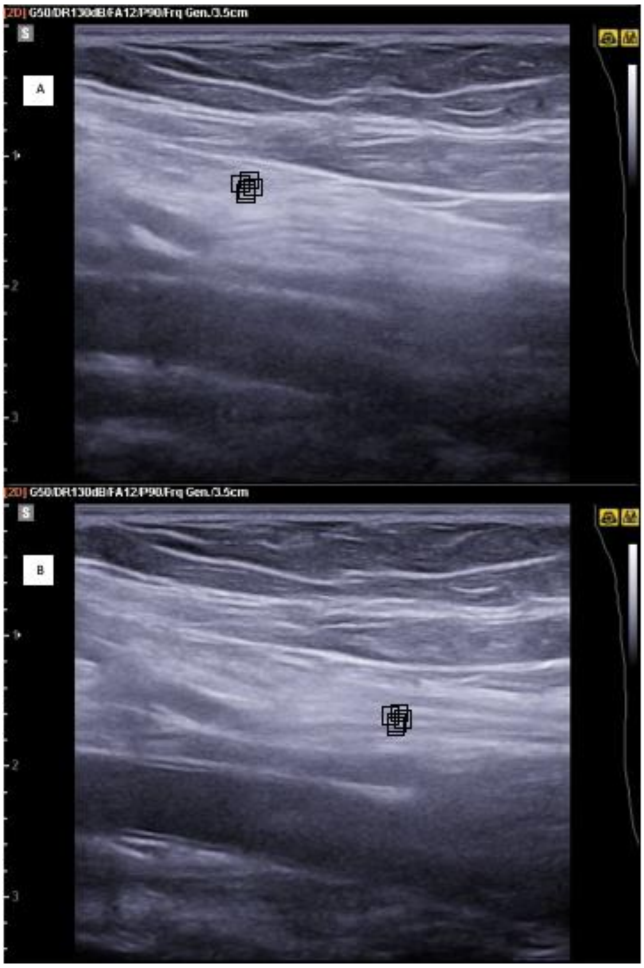
Tibial nerve excursion was used as an outcome measure in each of the studies involved in this PhD thesis and was, indeed, one of the major areas of interest and consideration. Although sciatic and tibial nerve mobility has been investigated in previous research studies (Ellis *et al.* 2008; Ellis *et al.* 2017; Ellis *et al.* 2021; Ellis 2012) these previous studies have all involved asymptomatic patients. The aim of this thesis was to investigate tibial nerve mechanics in patients with a spinal pathology who presented with lumbar radiculopathy and radicular pain, both before and after lumbar decompression surgery. As such, assessment of tibial nerve mobility was the main objective variable measured across all the studies.

As previously discussed tibial nerve mobility was assessed via the use of ultrasound recordings of linear arrays centre frequency at 7.5Mhz (Model: HL5-9ED, Medison Co., Ltd, Seoul, South Korea). The data was then analysed offline to determine the actual movement of the tibial nerve. Ultrasound imaging provides a reliable and valid method of visualising musculoskeletal structures throughout the body in 'real time' allowing nerve excursion to be imaged as the movement occurs (Ellis *et al.* 2021; Ridehalgh *et al.* 2015; Shum *et al.* 2013). Our research group has developed an innovative technique to visualise and measure movement of the tibial nerve at the popliteal fossa behind the knee during forward bending movement of the lumbar spine. In asymptomatic patients, a mean tibial nerve movement of 12.2 ± 2.2mm has been observed during forward bending. There is excellent test-retest reliability of the nerve movement magnitude recorded at the popliteal fossa (ICC=0.97) which suggests that the measure is sufficient for detecting group differences in nerve excursion (Shum *et al.* 2013).

The image sequences of the diagnostic ultrasound cine-loops were analysed in MATLAB (MathWorks, Natwick, MA, USA) (Shum *et al.* 2013) using a frame-by-frame normalised cross-correlation approach as described by Dilley et al. (2001). The tracking programme used a pattern-matching algorithm based on the greyscale pattern present in each of the selected regions of interest (ROI) to find the best match region of interest in sequential frames. The cine-loop of nerve movement was observed to identify a location on the image sequence where nerve tissue could be seen moving throughout the complete sequence (figure 2.3). Five overlapping ROIs were then selected within this area on the nerve as described by the approach initially presented by Dilley et al. (2001). The tracking programme used a pattern-matching algorithm based on the greyscale pattern of each of the selected ROIs to find the best match ROIs in sequential frames with displacement of the nerve in the longitudinal (lateral) and axial (deep/superficial) dimensions registered for each frame-by-frame matching comparison. The programme also calculated the hypotenuse excursion from the vector combination of longitudinal and axial movement. Total longitudinal, axial and hypotenuse excursion were calculated from the sum of these displacements throughout the image sequence for each of the selected ROIs with the median value for hypotenuse excursion taken as being representative of nerve movement occurring in that image sequence. To minimize bias, the researcher was blinded to each participant’s information or grouping during offline data analysis.

Tibial nerve excursion was assessed during lumbar and hip flexion or during ankle dorsiflexion, which on analysis of the data produced a calculation of total nerve movement. To allow comparison and evaluation of nerve mobility regardless of associated joint movement which will obviously vary between patients, a normalised nerve movement calculation was determined by dividing the total nerve movement by the sum of the lumbar spine and hip flexion angles: Normalised tibial nerve movement (mm/º) = Tibial nerve movement (mm) / Total lumbar spine and hip flexion angle (º) during each forward bending movement. This calculation allowed comparison between subjects regardless of individual joint mobility levels.

Figure 2.3 Initial and final frame of a typical nerve movement sequence.



(A) The first frame of the image sequence with the location of the selected regions of interest (ROI) in the nerve represented by the five overlapping boxes.

(B) The final frame of the image sequence with the new positions of the five boxes indicating the magnitude of nerve excursion for the selected ROIs in this particular subject.

The substantial proximal movement of the tibial nerve observed at the popliteal fossa during forward bending is consistent with the requirement of the nerve tract to accommodate increases in the nerve bed length evoked by hip and lumbar spine flexion. To my knowledge, the use of ultrasound imaging to measure nerve mobility in symptomatic patients both pre and post-lumbar surgery and during mechanical lumbar traction has not been previously investigated. The use of ultrasound imaging in symptomatic surgical and non-surgical patients offers an effective technique to assess nerve mobility that can be used for future research and in clinical practice as a patient assessment and feedback tool.

2.9.2 Straight Leg Raise Test

Straight Leg Raise (SLR) test is a validated outcome measure to assess the mechanosensitivity of the sciatic and tibial nerve, with a positive SLR angle following lumbar surgery being correlated with inferior surgical outcomes (Jonsson and Stromqvist 1995; Jönsson and Strömqvist 1999) and a negative SLR test 4 months post lumbar decompression surgery being predictive of excellent surgical outcome (Rebain *et al.* 2002).

The SLR test has been shown to be a sensitive test for detecting sciatic nerve sensitivity and irritability, however, it does lack specificity, with a positive result failing to identify the cause of nerve irritation or compression and it can also be positive in conditions other than lumbar radiculopathy. In addition, the interpretation of the test relies on the patient's subjective report of symptoms, such as pain or tingling. This subjectivity can introduce variability in the results and may be influenced by the patient's pain perception. The SLR test is also susceptible to type I errors (false positives) whereby patients present with leg pain but have no nerve compression and type II errors (false negatives) whereby patients do have nerve compression but do not present with leg pain. Consequently, it is important that the SLR test is used in conjunction with other outcome measures that assess leg pain and sciatic nerve mobility in patients with lumbar radiculopathy. In some cases, the SLR test can induce or exacerbate pain in patients, so care must be taken to avoid excessively irritating the nerve and potentially exacerbating a patients pain.

The SLR test applies tension to the sciatic and tibial nerve by elongation of the nerve bed at the ankle, hip and knee which is achieved via passive ankle dorsiflexion, knee extension and hip flexion (Rade *et al.* 2017). A significantly reduced SLR angle has also been observed in patients with FBSS and associated radicular pain following lumbar decompression compared to a group of non-FBSS post lumbar decompression patients (Shum *et al.* 2019). Consequently, SLR test was considered an appropriate outcome measure for the assessment of sciatic/tibial nerve mobility in both surgical and non-surgical symptomatic patients involved in the research studies conducted for this PhD. The SLR test was conducted with the patient in supine lying with the leg passively raised as far as could be tolerated. The non-painful leg was assessed first, followed by assessment of the painful leg. The maximum angle between the raised leg and the longitudinal axis of the trunk was measured by use of a digital goniometer.

2.9.3 Global Rate Of Change Scale

In clinical practice patients are frequently asked to rate whether their health condition has improved or deteriorated over time or following a specific intervention. In addition, many research studies also use patient-rated change as an outcome measure to determine the effectiveness of a specific intervention. The Global Rate of Change Scale (GRCS) provides an assessment method of obtaining information regarding patient perceived change in health status or condition that is quick to administer and efficient. Following a specific intervention, the GRCS requires the patient to identify the change in their health condition on a numerical scale (Kamper *et al.* 2009; Wang *et al.* 2019). The magnitude of the change is scored on a 15-point scale (-7 to +7) with an increase of 5 or more being defined as a clinically important improvement (Stratford *et al.* 1994). The GRCS identifies the perceived rate of change for a particular health condition, however, it does not identify any specific variables that contribute to the change.

The GRCS was used in two of the research studies included in this PhD to assess how the study participants perceived the effectiveness of the treatment they had received. The first study involved the assessment of patient rate of change following lumbar decompression surgery. Further analysis was then performed to determine the specific variables that influenced the GRCS. The second study involved the use of the GRCS as an outcome measure following a traction intervention in people with a confirmed diagnosis of a herniated lumbar intervertebral disc. In both studies, the GRCS was considered an appropriate and effective outcome measure that could also be beneficial for patient assessment in a clinical setting.

2.9.4 Pain Visual Analogue Scale

The Pain Visual Analogue Scale (VAS) is a validated patient-reported outcome measure that is one of the most commonly used instruments to assess pain in clinical practice (Ferreira-Valente *et al.* 2011; Thong *et al.* 2018) and the measure most frequently used to assess pain intensity in LBP research studies (Chiarotto *et al.* 2019). It has been deemed as a valid assessment tool that can reliably predict disability in patients with LBP (Shafshak and Elnemr 2021) and has the advantage of being a quick and convenient outcome measure both to administer by the clinician or researcher and to complete by the patient. In addition, it provides a quantitative measure of pain, which can be helpful for tracking changes over time and comparing pain levels across individuals or groups. It consists of either a horizontal or vertical line that is usually 10 centimetres long with a verbal descriptor at each end specifying two extremes of pain status, such as 'no pain' and 'worst possible pain'. The patient is asked to identify the point on the scale that best refers to their current level of pain. A horizontal line has been shown to produce a more uniform distribution of scores (Wewers and Lowe 1990) and is more frequently used than a vertical line. Consequently, in these studies a horizontal line VAS was used with a 10-point linear numerical scale, with the participant requested to mark the appropriate number on the line that reflected their level of back pain and leg pain.

Although a validated outcome measure that is frequently used both in research and clinical settings the pain VAS outcome measure does have several limitations that should be considered including the fact that the measure relies on the patient's subjective perception of pain which can vary greatly between individuals and the fact that the scale does not provide any information regarding the quality or characteristics of the pain, consideration of these factors can potentially be beneficial for diagnosis and treatment planning.

It has been suggested that for patients with chronic low back pain, the minimally clinically important change (MCIC) for pain on a visual analogue scale should at least be 20mm (Ostelo and de Vet 2005).

2.9.5 Lumbar Flexion And Hip Flexion

Lumbar flexion and hip flexion were used as outcome measures in three of the studies involved in this PhD to assess patients with and without FBSS post-lumbar decompression surgery, as well as non-surgical patients with a confirmed diagnosis of a herniated lumbar disc. It was measured within physiological ranges using the three-dimensional inertia measurement unit (ProMove 3D, Inertia Technology, The Netherlands). The study participants were asked to bend forwards, backwards, sideways and to rotate to both sides whilst in a standing position. Markers were placed on 4 standardised landmarks on the posterior thigh, sacrum and L1 spinous process. Signals were Analog to Digital converted (200Hz sampling frequency) and stored for offline analysis.

2.9.6 Oswestry Disability Index

The Oswestry Disability Index (ODI) was originally developed in 1976 by John O'Brien, in a specialist back pain referral clinic and was designed as a measure for both assessment and outcome (Roland and Fairbank 2000). It is a valid and reliable back or leg pain specific outcome measure that is widely used to assess functional ability and pain severity in the clinical management of spinal pathologies across numerous different countries suggesting that results can be reliably compared across studies (Garg *et al.* 2020; Longo *et al.* 2010). The ODI is sensitive to changes in a patient's condition over time which makes it a beneficial assessment tool for tracking patient progress in clinical trials and research studies (Carlesso *et al.* 2021), and it has been shown to be capable of identifying the severity of a functional disability although the its discriminative ability is most effective at higher levels of disability (Saltychev *et al.* 2017). However, all the subjects involved in these PhD research studies were patients with a confirmed diagnosis of a spinal pathology with lumbar radiculopathy symptoms so presented with a high level of disability with respect to their spinal pathology.

The ODI consists of a self-administered questionnaire that evaluates the activities of daily living across 10 sections; pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life (if applicable), social life and travelling, and the effect that the back or leg pain has on those activities and the patient's ability to manage in everyday life (Longo *et al.* 2010). The ease of administration of the questionnaire makes it a highly practical and convenient method for assessing the functional impact of back or leg pain in both a clinical and research setting. In addition, it is recommended for use in patients who have persistent pain or disability and has been shown to be an effective at detecting changes over time

(Roland and Fairbank 2000). Consequently, it was deemed an appropriate outcome measure for this research as most subjects recruited for the studies involved in this PhD presented with persistent radicular pain. Patients chose the answer to the question that most closely describes their symptoms and/or the effect the back or leg pain has on their life on that particular day. The questionnaire is self-administered by the patient and can normally be completed in under 5 minutes and can be scored in under 1 minute, making it an efficient tool for both patient and researcher or clinician. There is no agreement across the literature regarding a minimally clinically important change (MCIC) of the Oswestry Disability Index with changes varying from 4 to 17 points and 30-50% being suggested as being clinically relevant (Fairbank and Pynsent 2000; Schwind *et al.* 2013).

However, Schwind, Learman et al. (2013) suggest that despite the ODI being a valid and reliable measure of disability status in patients with low back pain and/or leg pain, a minimally important clinical score is likely to be specific to each individual patient and subsequently, a standard MCID for the ODI cannot be specified.

2.9.7 Distress And Risk Assessment Method

The Distress and Risk Assessment Method (DRAM), which is a combination of the Modified Zung depression scale and the Modified Somatic Perception Questionnaire to assess depression and somatisation of anxiety, has been demonstrated to be a valid and reliable outcome tool for identifying LBP patients and pre/post lumbar surgery patients who will benefit from psychological intervention (Hobby *et al.* 2001). This outcome measure was administered to all patients who participated in the studies in an attempt to identify any subjects who would be indicated for psychological interventions to address their back and leg pain rather than a physical intervention such as traction. It has been suggested that screening for distress prior to spinal surgery is likely to identify patients at risk of poor surgical outcome (Trief *et al.* 2000), although Hobby et al. (2001) observed that lumbar discectomy surgical outcome was not affected by preoperative psychological disturbance and concluded that patients with a herniated lumbar intervertebral disc should not be denied surgery on the basis of preoperative psychological assessment (Hobby *et al.* 2001). It was deemed pertinent to include this outcome measure in the interest of patient welfare as the DRAM is an effective screening tool to identify patients for whom psychological intervention could be warranted. However, it is recognised that further research is required to examine whether psychological intervention prior to surgery or other non-surgical treatment for spinal pathologies would improve the patient's functional outcome (Trief *et al.* 2000).

2.10 CONCLUSION

The aim of this literature review was to evaluate the main theoretical and clinical concepts presented throughout this thesis and to critically appraise the outcome measures that were deemed most appropriate for the fulfilment of the research requirements and aims, whilst being clinically relevant and potentially transferable to the physiotherapy profession.

The term neurodynamics was initially introduced by Shacklock in 1995 (Shacklock 1995) and since then has formed the basis for much research in the field of nerve biomechanics and nerve pathology. All the studies documented in this PhD thesis are based on Shacklock's initial concept of neurodynamics, in particular the influence of nerve mobility on peripheral pain in patients with lumbar radiculopathy which was the main area of consideration throughout this PhD.

Back pain is reported to be the most disabling condition throughout the world and therefore presents a significant global healthcare and socioeconomic problem (James *et al.* 2020). In the UK alone healthcare costs were estimated to be £1632 million (Maniadakis and Gray 2000), with indirect costs in relation to employment and production losses estimated to be £10668 million (UK 1998 figure) (Maniadakis and Gray 2000), giving a combined estimated cost of back pain to the UK economy of £12300 million. Consequently, research investigating assessment and treatment methods that could improve outcomes for patients with spinal pathology could be beneficial to patient care outcomes as well as having positive socioeconomic implications.

The outcome measures used throughout the five studies reported in this thesis were selected by examination of the existing literature in the field and also with consideration of the clinical relevance of the measures. The measures selected were all valid and reliable tools that have been widely used across previous research studies investigating spinal pathology, lumbar radiculopathy and patient outcomes following lumbar surgery and are widely used in both research and clinical practice. They are all well documented outcome measures that can easily be replicated and applied in any further research to aid continuity and transferability of research findings.

Although the assessment of tibial nerve mobility via diagnostic ultrasound has been previously documented (Chan *et al.* 2006; Gray *et al.* 2004; Heinemeyer and Reimers 1999; McCartney *et al.* 2004; Schwemmer *et al.* 2004; Sinha and Chan 2004; Tsui and Finucane 2006) there have been no previous studies investigating tibial nerve mobility in patients with a confirmed diagnosis of lumbar radiculopathy and consequently this thesis contributes new evidence to the clinical field of lumbar radiculopathy.

CHAPTER THREE. DECREASED TIBIAL NERVE MOVEMENT IN PATIENTS WITH FAILED BACK SPINAL SURGERY SYNDROME AND PERSISTENT LEG PAIN.

3.1 PRELUDE

The initial research in support of this thesis was conducted in conjunction with the spinal unit at Royal Exeter and Devon (RD&E) hospital to investigate tibial nerve mobility in relation to surgical outcomes following lumbar decompression, as it is estimated that following technically successful surgery 10-40% of patients will still continue to experience pre-surgical leg pain and other associated symptoms (Weir *et al.* 2017b). The spinal surgical team at the RD&E were keen to identify any specific factors that may contribute to the continuation of leg pain post-spinal surgery; a condition referred to as Failed Back Surgery Syndrome (FBSS), as it is obviously distressing and frustrating to the patient, surgeon and other healthcare providers if a surgical technique does not result in the desired outcome.

This study was the first in a series of investigations involving pathomechanics of the tibial nerve in association with lumbar radiculopathy. It involved the assessment of lumbar decompression patients who presented with and without persistent leg pain following surgery, with the aim of assessing the mobility of the tibial nerve to determine if tibial nerve mobility could be related to surgical outcome.

3.2 ABSTRACT

3.2.1 Purpose

To measure and compare the total and normalised tibial nerve movement during forward bending in patients with and without Failed Back Surgery Syndrome (FBSS) and persistent leg pain following anatomically successful lumbar decompression surgery and demonstrated no psychological stress. Nerve pathomechanics may contribute to FBSS with persistent leg pain following anatomically successful lumbar decompression surgery.

3.2.2 Methods

Tibial nerve movement during forward bending was measured in two groups of patients following anatomically successful lumbar decompression surgery. FBSS group (N=37) consisted of patients with persistent leg pain following lumbar surgery and non-FBSS (N=37) were patients with no remaining leg pain following lumbar surgery. Total and normalised tibial nerve movement at the popliteal fossa was measured by a previously validated ultrasound imaging technique (Shum, 2013) and compared between the two groups, and also between the painful and non-painful leg within the FBSS group.

3.3.3 Results

Both the mean total and normalised tibial nerve movement were significantly decreased in the FBSS group in both legs when compared to the non-FBSS group ($P<0.05$). The total and

normalised tibial nerve movement was also more restricted in the painful leg ($P<0.05$) when compared to the non-painful side within the FBSS group.

3.2.4 Conclusion

This was the first study to quantify the decreased total and normalised tibial nerve mobility in FBSS patients with persistent leg pain when compared with non-FBSS patients following anatomically successful lumbar decompression surgery. Further research could investigate the efficacy of intervention, such as nerve mobilisation in this particular group of patients with failed back surgery syndrome and limited nerve mobility.

3.3 INTRODUCTION

Lumbar surgery is performed on approximately 23,592 patients each year in the United Kingdom (Weir *et al.* 2017b). However, it is estimated that 10-40% of these patients will continue to experience pre-surgical symptoms and pain despite anatomically successful surgery for either lumbar intervertebral disc disorder (Suthar *et al.* 2015) or lateral recess syndrome (Lurie *et al.* 2003); a condition referred to as Failed Back Surgery Syndrome (FBSS)(Eldabe *et al.* 2010). A recent study estimated the incidence of FBSS at 20.8% within 2 years of lumbar surgery (Weir *et al.* 2017b), although incidence levels vary across surgical procedures, with rates of 35-36.2% reported following lumbar decompression (Cornefjord *et al.* 2000; Fokter and Yerby 2006) and a rate of 20-25% reported following lumbar microdisectomy (Asch *et al.* 2002). FBSS results in continued pain, functional limitations and reduced ability to work (Weir *et al.* 2017b), with FBSS patients with persistent leg pain reporting much lower health-related quality of life scores(EQ-5D scores of 0.16 ± 0.3) than other causes of neuropathic pain (Eldabe *et al.* 2010). FBSS results in significantly increased post-surgical healthcare costs that are estimated to be over 50% greater than lumbar surgery patients with no continued pain (Weir *et al.* 2017b). Furthermore, FBSS exacts a high societal cost with up to 15% of young, active participants failing to return to work despite having no overt re-herniation or lumbar pathology post-microdiscectomy (Dewing *et al.* 2008).

Lumbar intervertebral disc disorder is the most frequently diagnosed pathologic condition affecting the spine (Suthar *et al.* 2015) with a reported lifetime occurrence as high as 40% (Manchikanti *et al.* 2009a). Lateral recess syndrome; a variant of spinal stenosis, is another commonly diagnosed and surgically treated pathologic spinal disorder (Lurie *et al.* 2003), with symptoms estimated to occur in approximately 20% of adults aged over 65 years (Fritsch *et al.* 2017), and 66.6% of people with back pain aged 60-69 years (Kalichman *et al.* 2009).

Nerve root impingement resulting in peripheral nerve pain is a common characteristic of both intervertebral disc disorder and lateral recess syndrome. Peripheral nerves such as the tibial nerve must bend, stretch and glide along their length within the nerve tissue bed to accommodate movement of the adjacent joints whilst maintaining the transmission of electrical impulses (Ellis and Hing 2008). Nerve root impingement could compromise the ability of a peripheral nerve to stretch and glide causing reduced neural mobility and subsequent increased neural tension and associated loss of function, pain or neural fibrosis (Hunter 1991; Millesi *et al.* 1990). Nerve movement limitations due to adhesions at the level of the spinal nerve root have been directly observed intra-operatively (Kobayashi *et al.* 2010), while nerve entrapment neuropathies have been shown to have an effect on both myelinated and unmyelinated nerve fibres distal to the site of compression (Schmid *et al.* 2014b). In addition, increased mechanosensitivity (Dilley *et al.* 2005), a reduction in nerve conduction (Brown *et al.* 1993), inhibited axonal transportation (Rydevik *et al.* 1980) and neural oedema (Yayama *et al.* 2010) (Lundborg *et al.* 1983) have been observed following peripheral nerve compression.

Nerve movement can be observed and measured by diagnostic ultrasound imaging. An innovative technique was developed to measure tibial nerve movement at the knee during forward bending movement of the spine (Shum *et al.* 2013). During forward bending, a mean tibial nerve movement of 12.2 ± 2.2mm measured at the popliteal fossa was found in asymptomatic participants, which has been shown to be a reliable measurement (Shum *et al.* 2013). The substantial proximal movement of the tibial nerve during forward bending is consistent with the requirement of the nerve tract to accommodate increases in the nerve bed length evoked by hip and lumbar spine flexion (Ellis *et al.* 2008). It was hypothesised that reduced nerve movement could potentially contribute to the persistent leg pain of FBSS.

The aim of this study was to compare tibial nerve movement between FBSS and non-FBSS patients following lumbar surgery, and between the painful and non-painful leg within the FBSS group. It was hypothesised that people with FBSS and persistent leg pain will present with reduced tibial nerve movement when compared to people without persistent leg pain following lumbar surgery. A second hypothesis was that there would be significant differences in the tibial nerve movement between the painful and non-painful side in people with FBSS.

3.4 MATERIALS AND METHODS

Ethical Approval

Ethical approval was granted by the National Health Service (NHS) Health Research Authority, United Kingdom. A total of seventy-four patients with and without post-operative leg pain following discectomy or lumbar decompression were recruited.

Sample Size

Previous work in the field of tibial nerve mobility has shown that during forward bending in 24 asymptomatic participants the sciatic nerve moved at the popliteal fossa by 12.2 ± 2.2 mm

(Shum *et al.* 2013). However, no data regarding nerve movement in symptomatic participants has been previously published. Based on a 15% difference in the tibial nerve movement between the FBSS and non-FBSS group following lumbar surgery and the observed standard deviation of 2.2mm at 95% power and 5% alpha, 32 participants per group were required in this study.

3.4.1 Particpiants

People with (N=37) or without (N=37) postoperative residual leg pain following lumbar discectomy or decompression completed this study with the following eligibility criteria:

Inclusion criteria:

Patients aged 18-80 years who underwent lumbar microdiscectomy or single level lumbar decompression surgery, 6-12months post-operation.

Patients who have persistent postoperative residual leg pain as defined by:

The severity of leg pain score being 5 or more on Numerical Rating Scale of Pain (Dworkin *et al.* 2005).

Less than 5 points improvement in the Global Rating of Change Scale, in which a clinically important improvement is defined as 5 or more (Stratford *et al.* 1994).

A positive straight leg raise (SLR) sign (specified as 65° or less movement of the straight leg relative to the longitudinal axis of the trunk) that the test reproduced unilateral symptoms in the tested leg (Shum *et al.* 2005; Sweetman *et al.* 1974).

Exclusion Criteria:

Participants were excluded if they suffered from long standing ischaemic neuritis or any other surgery-related complications (e.g. inadequate spinal decompression, postoperative instability, neural injury) as they may lead to postoperative residual leg pain. These exclusions were identified by the surgeon during their post-operative assessments. Patients were also excluded if identified as at risk by the Distress and Risk Assessment Method (Hobby *et al.* 2001; Trief *et al.* 2000), which has been shown to be an accurate assessment tool of psychological disturbance in patients with low back pain (Greenough and Fraser 1991; Hobby *et al.* 2001; Main *et al.* 1992).

Seventy-four patients were recruited for the study in accordance with the eligibility criteria. Participants were divided into two groups dependent on surgical outcomes:

Non-FBSS group (N = 37): Participants with no or minimal residual leg pain during forward bending; defined as (A) greater than 50% improvement three months after the operation as defined on a visual analogue scale; and (B) a negative straight leg raise sign when the maximum angle between the straight leg and the longitudinal axis of the trunk is 66° or more (Rebain *et al.* 2002; Tafazzoli and Lamontagne 1996).

FBSS group (N = 37): Participants with post-operative residual leg pain during forward bending; defined as (A) either unchanged or less than 50% improvement three months after operation as defined on a visual analogue scale; and (B) a positive straight leg raise sign when the maximum angle between the straight leg and the longitudinal axis of the trunk is 65° or less, with unilateral symptoms reproduced in the tested leg (Rebain *et al.* 2002; Tafazzoli and Lamontagne 1996).

Subjects were assessed at the spinal unit of a local hospital on one occasion, three to nine-months post-surgery with the following outcome measures: tibial nerve mobility, lumbar spine and hip range of movement, straight leg raise (SLR) angle, global rate of change following surgery and level of psychological stress. Patients were assessed in a single session with no follow up treatment or assessment. All patients completed a consent form and were made aware that the assessment did not have any effect on any further treatment they would potentially require or receive.

3.4.2 Outcome Measures

Tibial nerve mobility: Ultrasound recordings of linear arrays centre frequency at 7.5Mhz (Model: HL5-9ED, Medison Co., Ltd, Seoul, South Korea) during forward bending were taken behind the knee region in order to track movement of the tibial nerve using a similar technique developed from previous research (Aebi 2011; Coppieters *et al.* 2009; Shum *et al.* 2013). The image sequences of the diagnostic ultrasound cine-loops were analysed using a frame-by-frame normalised cross-correlation approach implemented in MATLAB (MathWorks, Natwick, MA, USA) (Shum *et al.* 2013). The tracking programme used a pattern-matching algorithm based on the greyscale pattern present in each of the selected region of interests to find the best match region of interests in sequential frames. Displacement of the nerve in the longitudinal (lateral) and axial (deep/superficial) dimensions were registered for each frame-by-frame matching comparison. The programme also calculated the hypotenuse excursion from the vector combination of longitudinal and axial movement. To minimize bias, the researcher was blinded to each participant's information or grouping during offline data analysis.

Tibial nerve excursion was assessed during lumbar and hip flexion, which on analysis of the data produced a calculation of total nerve movement. To allow comparison and evaluation of nerve mobility regardless of associated joint movement which obviously varies between patients, normalised nerve movement was calculated by dividing the total nerve movement by the sum of the lumbar spine and hip flexion angles: Normalised tibial nerve movement (mm/º) = Tibial nerve movement (mm) / Total lumbar spine and hip flexion angle (º) during each forward bending movement. This calculation allowed comparison between subjects regardless of individual joint mobility levels.

Tibial nerve mobility assessment was performed with the patient in standing, they were asked to bend forwards as far as was comfortable for them and during this movement nerve mobility was visualised and recorded via an ultrasound probe positioned in the popliteal fossa at the back of the knee. The movement was repeated three times and the video recordings of the nerve movement saved to the ultrasound machine.

Spinal and hip range of movement: These were measured within physiological ranges. Lumbar spine and hip movement and coordination were measured using the three-dimensional inertia measurement unit (ProMove 3D, Inertia Technology, The Netherlands) when the participants were asked to bend forwards, backwards, sideways and rotate to both sides in a standing position. Markers were placed on 4 standardised landmarks on the posterior thigh, sacrum and L1 spinous process. Signals were Analog to Digital converted (200Hz sampling frequency) and stored for offline analysis.

Straight leg raise (SLR) angle: A standardised passive SLR test was performed and the maximum angle between the straight leg and the longitudinal axis of the trunk measured using an inclinometer. SLR sign was considered to be positive if the lift angle was 65° or less, with unilateral symptoms reproduced in the tested leg (Rebain *et al.* 2002; Tafazzoli and Lamontagne 1996).

Global rate of change: The improvement between before and after surgical intervention was measured with the Global Rating of Change Scale with a 15-point scale (-7 to +7), in which a clinically important improvement was defined as 5 or more (Stratford *et al.* 1994). Participants were asked to rate their severity of back pain and leg pain using a simple 10cm visual analogue scale (Jensen *et al.* 1996).

Psychological stress level: This was measured by the Distress and Risk Assessment Method (Hobby *et al.* 2001; Trief *et al.* 2000), which is a combination of the Modified Zung depression scale and the Modified Somatic Perception Questionnaire to assess depression and somatisation of anxiety. The Distress and Risk Assessment Method has been shown to be accurate in the assessment of psychological disturbance in patients with low back pain (Greenough and Fraser 1991; Hobby *et al.* 2001; Main *et al.* 1992).

3.4.3 Statistical Analyses

Descriptive statistics were produced of the mean and standard deviation of the angle of SLR and longitudinal, axial and hypotenuse nerve excursion magnitude. Statistical analysis was performed with SPSS software (Version 22.0). Intra-class correlation coefficient ($ICC_{3,k}$) with 95% confidence interval was calculated to determine intra-rater reliability of the three repeat measures of nerve mobility during forward bending.

Application of the Kolmogorov-Smirnov test ($p=0.065$) determined the data to be parametric, therefore, T-tests and paired T-tests were conducted with the level of significance set at 0.05. T-tests were used to compare the outcome measures between the non-FBSS and FBSS groups. Paired T-test was used to compare the tibial nerve movement between the painful leg and the non-painful leg within the FBSS group. Effect size was calculated from the observed differences in tibial nerve mobility of the painful leg and non-painful leg between the two subject groups; non-FBSS and FBSS and between the painful leg and non-painful leg in the FBSS group. The effect size indicates if an intervention or treatment has a greater effect than zero and when there is an effect, how large that effect is. Effect size values range from 0 to +1, with values of 0.2 considered to be small, 0.5 moderate and +0.8 large (Serdar *et al.* 2021). Reporting the effect size aids in the evaluation of the clinical importance of a study as it describes the strength of the relationship between the investigated variables rather than just the presence of a significance difference between variables. In addition, it allows the magnitude of the research findings to be quantified in a standardised metric regardless of the scale of measurement that was used in the research which assists comparison across studies and the planning of future research (Lakens 2013; Serdar *et al.* 2021; Tomczak and Tomczak 2014). A large effect size suggests high clinical relevance of an outcome measure and as such are used to indicate the practical significance of research findings (Lakens 2013).

3.5 RESULTS

The ICC (3,k) values for the longitudinal, axial, and hypothalamic axes of the nerve movement were 0.991, 0.985, and 0.992, respectively. This suggest that the measurement of nerve mobility was highly repeatable.

Subject characteristics are presented in table 3.1. No participants dropped out of the study during the one-off assessment.

Table 3.1. Subject characteristics

	Non-FBSS	FBSS with Persistent leg pain	Effect Size (Cohen's *d*)
Age (years)	55.6 ± 13.2	54.4 ± 12.5	
Height (cm)	169.3 ± 6.6	169.1 ± 7.1	
Weight (kg)	73.7 ± 12.7	70.8 ± 9.7	
Post operation days	146.1 ± 36.2	145.4 ± 36	
Pre-operation pain scale (VAS)	8.7 ± 1.6	8.9 ± 1.1	0.14
Global rating of change scale (-7 to +7)	6.1 ± 2.1	2.2 ± 2.1 [a]	1.85
Severity of back pain (VAS)	0.3 ± 0.7	1.8 ± 3.1 [a]	0.66
Severity of leg pain (VAS)	0.8 ± 1.4	5.9 ± 1.8 [a]	3.16
Modified Somatic Perception Questionnaire	0.8 ± 1.6	1.2 ± 2	0.22
Modified Zung depression scale	6.1 ± 5.3	5.8 ± 4.4	0.06
Lumbar flexion during forward bending (°)	71.9 ± 8.2	26.6 ± 5.3 [a]	6.56
Hip flexion during forward bending (°)	29.2 ± 4.7	17.2 ± 4.2 [a]	2.69
Straight leg raise angle (painful side, °)	76.5 ± 7.0	42.0 ± 16.2 [a]	2.76
Straight leg raise angle (non-painful side, °)	77.6 ± 5.7	74.5 ± 12.8	0.31

[a] $P < 0.05$, significant differences in painful side between Non-FBSS and FBSS group (t test).

Table 3.2. Comparison of nerve mobility between the Non-FBSS group and FBSS group in the painful leg and non-painful leg.

	Non-FBSS group		FBSS group	
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Painful Leg	Non-painful Leg	Painful Leg	Non-painful Leg
Total Longitudinal tibial nerve movement (mm)	10.4 ± 2.1	11.3 ± 2.0	1.8 ± 0.7 [a]	3.8 ± 1.0 [b,c]
Total Axial tibial nerve movement (mm)	4.5 ± 0.5	3.7 ± 0.2	0.2 ± 0.1 [a]	1.2 ± 0.1 [b,c]
Total Hypotenuse tibial nerve movement (mm)	11.4 ± 1.9	11.9 ± 1.8	1.9 ± 0.7 [a]	4.1 ± 0.9 [b,c]
Normalized Longitudinal tibial nerve movement (mm/º)	0.1022 ± 0.0208	0.1114 ± 0.019	0.0411 ± 0.01075 [a]	0.0892 ± 0.023 [b,c]
Normalized Axial tibial nerve movement (mm/º)	0.0441 ± 0.00500	0.0384 ± 0.0037	0.0043 ± 0.00502 [a]	0.0311 ± 0.011 [b,c]
Normalized Hypotenuse tibial nerve movement (mm/º)	0.1127 ± 0.0181	0.1186 ± 0.0178	0.0419 ± 0.01101 [a]	0.0946 ± 0.0228 [b,c]

[a] P < 0.05, significant differences in painful side between Non-FBSS and FBSS group (t test). Effect size (Cohen's d) = 3.69 (normalised longitudinal tibial nerve movement), 7.94 (normalised axial tibial nerve movement), 4.72 (normalised hypotenuse tibial nerve movement).

[b] P < 0.05, significant differences in the non-painful side between Non-FBSS and FBSS group (t test).

Effect size (Cohen's d) = 1.05 (normalised longitudinal tibial nerve movement), 0.88 (normalised axial tibial nerve movement), 1.17 (normalised hypotenuse tibial nerve movement).

[c] P < 0.05, significant differences between painful and non-painful side within the FBSS group (paired t-test).

Effect size (Cohen's d) = 2.67 (normalised longitudinal tibial nerve movement), 3.13 (normalised axial tibial nerve movement), 2.94 (normalised hypotenuse tibial nerve movement).

The angle of SLR in the painful leg was significantly more limited in FBSS group (42.0° ± 16.2°) when compared to non-FBSS group (76.5° ± 7.0°) with very high effect sizes of tibial nerve movement of 2.76 (Table 3.1, P < 0.05).

During the forward bending movement, the flexion range of movement of the lumbar spine and hip were significantly reduced in FBSS group when compared with the non-FBSS group, with both lumbar flexion and hip flexion having very high effect sizes; 6.56 and 2.69 respectively (Table 3.1, P < 0.05).

During the forward bending movement, normalised tibial nerve movements in the longitudinal, axial and hypotenuse planes were significantly reduced in both the painful leg and the non-painful leg in the FBSS group when compared to the non-FBSS group (Table 3.2, $P < 0.05$). Effect sizes for longitudinal, axial, and hypotenuse nerve mobility measurements in the painful leg between the FBSS and non-FBSS groups were very high at 3.69, 7.94 and 7.24 respectively. Effect sizes for longitudinal, axial, and hypotenuse nerve mobility measurements in the non-painful leg between the FBSS and non-FBSS groups were still high at 1.05, 0.88 and 1.17 respectively, although far lower than for the painful leg.

Within the FBSS group, the movements of the tibial nerve were significantly reduced in the painful leg when compared to the non-painful leg (Table 3.2, $P < 0.05$) during the limited forward bending movement of both the lumbar spine and hips (Lumbar flexion: 26.6° ± 5.3°; Hip flexion: 17.2° ± 4.2°). Effect sizes for longitudinal, axial, and hypotenuse nerve mobility were very high at 2.67, 3.13 and 2.94 respectively.

3.6 DISCUSSION

Despite anatomically successful lumbar decompression surgery FBSS is estimated to occur in 20.8% of patients within 2 years of surgery (Weir *et al.* 2017b), with these FBSS patients reported to suffer for an average of 4.7 years (Thomson and Jacques 2009). Consequently, FBSS is a significant problem to patients, healthcare providers and society. Further understanding of neural pathomechanics and any involvement in FBSS will potentially contribute to the development of an appropriate intervention for this problematic condition. This study examined nerve pathomechanics in two groups of post-lumbar surgical patients; one group with successful clinical outcome (non-FBSS) and the other group with FBSS presenting with persistent leg pain following successful anatomical decompression. Tibial nerve movement during forward bending was compared between the two patient groups, and between the painful and non-painful leg in the FBSS patients, using the previously validated ultrasound imaging technique. This is the first study involving non-invasive in-vivo measures of the magnitude or timing of strain occurring in the tibial nerve during spinal and hip movements in FBSS and non-FBSS patients following lumbar decompression.

The results of the study suggest tibial nerve mobility is reduced in the painful leg of patients with FBSS compared with tibial nerve mobility in the painful leg of patients without FBSS following lumbar decompression surgery. In addition, tibial nerve mobility is also reduced in the painful leg compared with the non-painful leg of FBSS patients. Furthermore, the angle of SLR in the painful leg was significantly more limited in FBSS group compared to the non-FBSS group and in the painful leg compared with the non-painful leg of the FBSS group. The flexion range of movement of the lumbar spine and hip were also significantly reduced in FBSS group when compared with the non-FBSS group. There was a large effect size observed across all the significant variables suggesting that the findings are highly clinically relevant. Effect size reporting allows the evaluation of the clinical relevance of the effects of an intervention or treatment. Although calculating statistical significance determines the presence or absence of an effect, it does not evaluate the size of the effect and the clinical relevance of any observed statistically significant outcomes. Effect size reporting allows the practical significance of results to be determined rather than just the statistical significance (Lakens 2013; Serdar *et al.* 2021; Tomczak and Tomczak 2014). Cohen's *d* was used to calculate the effect size of the different variables in the t-test and paired t-test calculations with values ranging from 0 to +1; values of 0.2 are considered a small effect size, 0.5 a medium effect size and +0.8 a large effect size (Serdar *et al.* 2021).

The observed movement of the tibial nerve in non-FBSS patients is consistent with the requirement of the nerve tract to accommodate increases in the nerve bed length evoked by hip and lumbar spine flexion during forward bending identified in previous studies (Shum *et al.* 2013). In the FBSS group, the reduced tibial nerve excursion could potentially cause increased nerve tension leading to loss of function and pain (Millesi *et al.* 1990), as demonstrated in the results of this study. Nerve root restrictions can lead to distal alterations in sciatic nerve movement and strain during forward bending as this section of the nerve tract is forced to accommodate more changes in nerve bed length, a finding observed in animal and cadaveric studies (Goddard and Reid 1965; Smith *et al.* 1993). However, it could be expected that the elimination of nerve root impingement following decompression lumbar surgery would result in the return of normal peripheral nerve movement. All patients with remaining residual pain had a post-operative MRI which failed to identify any remaining restrictions of the nerve root in the lumbar spine.

Prolonged nerve root compression has been shown to cause inflammatory changes to the nerve fibres that can result in perineural scarring, nerve fibrosis and intraneural oedema (Brown *et al.* 2011; Lemke *et al.* 2017). These changes can result in shortening and tightening of the nerve which subsequently affect neural biomechanical properties (Topp and Boyd 2012), leading to mechanosensitivity symptoms including a painful response to nerve stretch during joint movements (Dilley *et al.* 2005). Indeed, mechanosensitivity has been observed to occur at only 3% strain in rats with experimentally induced sciatic nerve restrictions (Dilley *et al.* 2005). It is suggested that the reduced tibial nerve mobility observed in the FBSS group resulted from nerve adhesions caused by inflammatory and biomechanical changes to the nerve that occurred during nerve root compression prior to surgery. Following successful lumbar decompression surgery, it is hoped that normal nerve mechanics will be restored, however, in some instances it appears that this fails to happen and neural mechanosentitivity persists post-surgery.

It is proposed that persistent altered nerve mechanics could be responsible for the limited joint range of motion observed at the lumbar spine and hip in the FBSS patients, which subsequently lead to other nerve changes that produce long term neuropathic pain. Within the FBSS group tibial nerve movement was significantly reduced in the painful leg compared with the non-painful leg at the same limited forward bend position. However, the straight leg raise angle of the non-painful leg was negative (greater than 65 degrees) indicating there was no movement restriction of the sciatic/tibial nerve in the non-painful leg, suggesting that the limiting factor of the lumbar spine and hip movement was the altered nerve mechanics in the painful leg. Consequently, it is proposed that the significantly reduced lumbar flexion and hip flexion observed in the FBSS group resulted from decreased mobility and associated increased mechanosensitivity of the sciatic/tibial nerve of the painful leg. In addition, a decrease in the ability of peripheral nerves to bend, stretch and glide may limit the transmission of electrical impulses (Ellis and Hing 2008) and the dispersion of intraneural fluid (Gilbert *et al.* 2015a). Such limited nerve movement may cause the persistent leg pain in the FBSS group as observed in this study.

It is hypothesised that the persistent postoperative leg pain could be caused by tightening and/or shortening of the sciatic/tibial nerve due to prolonged movement restrictions prior to surgery which then results in decreased nerve mobility. If the persistent pain is at least partly due to decreased nerve movement and increased mechanosensitivity, this could potentially be resolvable with appropriate post-surgical treatment. However, persistent post-operative neuropathic pain could also be caused by initial nerve damage, which could lead to permanent neural symptoms with minimal improvement of symptoms expected.

It is well recognised that biological, psychological and social factors can all be influential in the development of low back pain (Apeldoorn *et al.* 2012) with non-specific low back pain defined as low back pain that cannot be attributed to a specific pathology (Brunner *et al.* 2013). Psychological interventions have been shown to be beneficial in the management of idiopathic chronic low back pain in patients who do not have surgically remediable pathology. The Distress and Risk Assessment Method (DRAM) has been shown to be an effective tool for identifying patients that will benefit from psychological intervention (Hobby *et al.* 2001). Both patient groups in this study demonstrated no significant differences in both Zung Self-Rating Depression Scale and Modified Somatic Perception Questionnaire which are part of DRAM assessment suggesting that the FBSS patients with chronic persistent postoperative leg pain of this study were not indicated for any psychological interventions. This implies that the persistent leg pain of the FBSS patient group was unlikely to be associated with psychosocial factors but rather due to a mechanical cause such as altered nerve biomechanics. Further research could investigate potential causes of the observed restricted neural mobility including the influence of pain, and whether removal of pain via a spinal nerve block may result in improved neural mobility in patients with persistent leg pain of FBSS. Further research could also investigate the efficacy of intervention, such as nerve mobilisation in this particular group of patients with failed back surgery syndrome and limited nerve mobility.

The limitation of this study was that the assessor was not blinded to the grouping of the participants during the clinical assessments and ultrasound recordings as it was obvious that the participants in the FBSS group with persistent leg pain would normally present with a more limited lumbar and hip movement and limited straight leg raise angle. However, the researcher was blinded to each participant's information or grouping during offline data analysis of the nerve movement data and spinal and hip movement analysis. Participants were also only assessed on one occasion, three to nine-months post-surgery. It was unknown if the participants in the FBSS group with persistent leg pain would have improved their clinical and biomechanical outcome measures if reassessed over time.

3.7 CONCLUSION

To my knowledge this is the first study to compare the tibial nerve mobility produced by forward bending in patients with and without failed back surgery syndrome following anatomically successful lumbar decompression who demonstrated no psychological stress. There is no published record of any other data being collected regarding sciatic/tibial nerve mobility in symptomatic patients and as such, this study contributes new evidence to the field of nerve mobility and nerve mobilisation and the potential role it may play in the development of FBSS.

Tibial nerve movement was significantly reduced in FBSS patients with persistent leg pain compared with non-FBSS patients following anatomically successful lumbar decompression surgery. In addition, the tibial nerve excursion was more significantly reduced in the painful leg when compared to the non-painful leg in FBSS patients with persistent leg pain. Further research could investigate the efficacy of intervention, such as nerve mobilisation exercises in this particular group of patients with failed back surgery syndrome and limited nerve mobility.

CHAPTER FOUR. IMMEDIATE EFFECT OF ULTRASOUND-GUIDED NEURAL MOBILISATION ON STRAIGHT LEG RAISE ANGLE FOR PATIENTS WITH FAILED BACK SURGERY SYNDROME AND PERSISTENT LEG PAIN.

4.1 PRELUDE

The aim of the initial study; decreased tibial nerve movement in patients with failed back spinal surgery syndrome, was to compare tibial nerve movement between FBSS and non-FBSS patients following lumbar surgery, and between the painful and non-painful leg within the FBSS group. It is estimated that despite technically successful lumbar decompression surgery 20.8% of patients will develop FBSS within 2 years of surgery (Weir *et al.* 2017a), consequently, FBSS presents a significant problem to patients, healthcare providers and the wider society (Eldabe *et al.* 2010). Identification of any specific factors that may contribute to the development of FBSS would further develop our knowledge and understanding of this condition and potentially advance the development of treatment options for this debilitating condition. Indeed, if such risk factors could be identified and addressed the probability of developing FBSS could theoretically be decreased.

The study identified that following anatomically successful lumbar decompression surgery, patients with persistent leg pain (the FBSS group) had significantly reduced tibial nerve mobility compared with patients with no post-surgical persistent leg pain. In addition, patients with persistent leg pain had reduced tibial nerve movement in the painful leg compared with the non-painful leg. Consequently, the study suggests that reduced tibial nerve mobility could be a contributing factor to the development of FBSS. Previous studies have demonstrated that nerve mobility can be improved by undertaking nerve mobilisation exercises (Coppieters *et al.* 2015; Ellis 2012), therefore, it was hypothesised that improving nerve mobility in the painful leg following spinal surgery could potentially reduce leg pain and the risk of developing FBSS.

The straight leg raise (SLR) test is one of the most common clinical tests used to assess and diagnosis sciatic nerve mobility and mechanosensitivity (van der Windt *et al.* 2010), with a positive SLR angle following lumbar surgery being correlated with inferior surgical outcomes (Jönsson and Strömqvist 1999). In the previous study; decreased tibial nerve movement in patients with failed back spinal surgery syndrome, a significantly reduced SLR angle was observed in the group of patients with FBSS and associated leg pain compared to the group of non-FBSS patients, with the FBSS patients also presenting with a significantly reduced SLR angle of the painful leg in comparison to the non-painful leg. In view of the previous study's findings, SLR angle was considered an appropriate clinical outcome measure to assess the mechanosensitivity of the tibial nerve in FBSS patients with persistent leg pain. In addition, the results of the previous study led to the proposed hypothesis for this next study that an increase in nerve mobility in patients with FBSS would result in an increased SLR angle.

Neural mobilisation is a clinical technique that is frequently used as a treatment for patients with sciatica and nerve mechanosensitivity, with the aim of restoring optimal mobility to peripheral nerves in which neurodynamics have been compromised (Bertolini *et al.* 2009; Brown *et al.* 2011; Gilbert *et al.* 2015b). A neural mobilisation exercise aims to facilitate the gliding and sliding of neural structures through a specific sequence of repeated joint movements that reduce nerve length at one joint whilst simultaneously increasing nerve length at another joint (Ellis *et al.* 2008). The second study investigated the immediate effect of an ultrasound-guided neural mobilisation on the straight leg raise angle of patients with FBSS and persistent leg pain following lumbar decompression surgery.

4.2 ABSTRACT

4.2.1 Purpose

To investigate the immediate effect of ultrasound-guided neural mobilisation on straight leg raise angle in patients with Failed Back Surgery Syndrome (FBSS) and persistent leg pain following lumbar decompression surgery. Patients with FBSS and persistent leg pain, presenting with limited straight leg raise angle and without any psychological disturbance or stress, may benefit from a session of ultrasound-guided neural mobilisation to improve straight leg raise angle.

4.2.2 Methods

Straight leg raise (SLR) angle was measured before and after a single session of twenty ultrasound-guided neural mobilisation exercises in 32 patients with FBSS and associated persistent leg pain following anatomically successful lumbar decompression surgery, with caudal and cephalad tibial nerve movement being verified and recorded at the popliteal fossa during the neural mobilisation.

4.2.3 Results

Following a single session of repeated ultrasound guided nerve mobilisation exercises there was a significant positive strong correlation between pre-mobilisation SLR and normalised nerve movement ($R = 0.753$, $p < 0.05$), and a significant negative moderate correlation

between both normalised nerve movement and improvement in SLR ($R = -0.412$, $p < 0.05$) and between pre-mobilisation SLR and improvement in SLR ($R = -0.492$, $p < 0.05$).

4.2.4 Conclusion

Ultrasound-guided mobilisation could be a treatment invention in improving the neural mobility in patients with FBSS with persistent leg pain following lumbar decompression surgery.

4.3 INTRODUCTION

Failed back surgery syndrome (FBSS) is a condition in which patients continue to experience pain and pre-surgical radicular symptoms following spinal surgery (Thomson 2013). It is estimated that approximately 20.8% of patients will experience FBSS within 2 years of lumbar surgery, despite technically successful surgery, with resulting post-surgical healthcare costs estimated to be over 50% greater than patients with no continued pain (Weir *et al.* 2017b). Consequently, FBSS poses a significant problem in terms of patient care and healthcare costs.

Nerve root impingement leading to altered neurodynamics, muscle weakness and peripheral nerve pain is a common pre-surgical characteristic of lumbar pathology patients. Despite successful surgical nerve root decompression continued peripheral nerve pain is frequently experienced by FBSS patients (Tharmanathan *et al.* 2012). The leg pain experienced by these patients is frequently resistant to pharmacological intervention (Eisenberg *et al.* 2005), and the effectiveness of non-pharmalogical treatments is currently unclear. Indeed, there is uncertainty regarding the diagnosis and management of FBSS, with a paucity in the evidence regarding potential treatment options (Tharmanathan *et al.* 2012).

Peripheral nerves are required to bend, stretch and glide along the length of the nerve bed to accommodate movement in adjacent joints whilst maintaining the transmission of electrical impulses (Ellis and Hing 2008). Surgical nerve root decompression aims to restore normal neurodynamics, subsequently removing peripheral neuropathic pain and functional limitation. However, tibial nerve movement was found to be significantly decreased in people with FBSS when compared to people with no persistent radicular symptoms following lumber decompression (Shum *et al.* 2019). The total and normalised tibial nerve movement was also more restricted in the painful leg when compared to the non-painful side within the FBSS group during the same forward bending movement (Shum *et al.* 2019).

Mechanosensitivity of peripheral neural tissue is thought to be a protective response to potentially harmful increased tissue load stress that results in increased neural sensitivity (Topp and Boyd 2012). It has been proposed that such heightened sensitivity could be associated with the stimulation of nociceptive properties identified in nerve fibres; the nervi nervorum, which are fibres located in peripheral nerve sheaths that are involved in the transmission of sensory information and the

innervation of the connective tissue of nerves themselves (Gelberman *et al.* 1981; Ogata and Naito 1986) as well as abnormality of the impulse generation site along the length of neural axons (Bell and Weddell 1984). In addition, nerve root compression has been shown to induce inflammatory responses that are can also cause mechanosensitivity (Dilley and Bove 2008). As a result of increased mechanosensitivity the physical stresses exerted on a nerve during normal movement may elicit a painful or symptomatic response.

Mechanosensitivity of the tibial nerve can be assessed by a straight leg raise (SLR) test with a positive SLR angle following lumbar surgery being correlated with inferior surgical outcomes (Jönsson and Strömqvist 1999) and a negative SLR test 4 months post lumbar decompression surgery being predictive of excellent surgical outcome (Rebain *et al.* 2002). The SLR test applies tension to the sciatic and tibial nerve by elongation of the nerve bed at the ankle, hip and knee which is achieved via passive ankle dorsiflexion, knee extension and hip flexion (Rade *et al.* 2017). A significantly reduced SLR angle was observed in a group of patients with FBSS and associated leg pain following lumbar decompression compared to a group of non-

FBSS post lumbar decompression patients (Shum *et al.* 2019). In addition, the FBSS patients presented with a significantly reduced SLR angle of the painful leg in comparison to the non-painful leg. In view of these previous findings SLR angle was considered an appropriate clinical outcome measure to assess the mechanosensitivity of the tibial nerve in FBSS patients with persistent leg pain.

It is recognised that patients with FBSS should be distinguished from patients presenting with other forms of pain, however, there is a need for more evidence-based guidance for the management of this specific patient group (Tharmanathan *et al.* 2012). Based on the findings of some previous studies on the reduced neural mobility in people with FBSS but without any psychological disturbance (Shum *et al.* 2019), it has been suggested that reduced tibial nerve mobility could contribute to the persistent leg pain of FBSS. Consequently, improving tibial nerve mobility could potentially reduce the symptoms of persistent leg pain in patients with FBSS. Neural mobilisation is a clinical treatment technique that aims to restore optimal physiological movement and function to peripheral nerves in which neurodynamics have been compromised. A neural mobilisation exercise consists of a specific sequence of joint movements that aim to produce a sliding of neural structures by increasing nerve length at one joint whilst simultaneously reducing nerve length at another joint (Ellis and Hing 2008).

This study aimed to assess the clinical effect of a single session of an ultrasound-guided 'slider' neural mobilisation, with caudal and cephalad tibial nerve movement being verified at the popliteal fossa by ultrasound imaging, on patients with FBSS and persistent radicular leg pain. SLR angle was measured before and after a single session of twenty ultrasound-guided neural mobilisation exercises in patients with FBSS and associated persistent leg pain, following anatomically successful lumbar decompression surgery. Tibial nerve mobility was observed and recorded during the nerve mobilisation exercise.

4.4 MATERIALS AND METHODS

Ethical Approval

Ethical approval was granted by the relevant research ethics panel. Informed consent was received from the participants and the rights of the participants were protected.

A total of 32 patients with post-operative leg pain associated with FBSS following technically successful lumbar decompression (as determined by MRI) were included in the study. The 32 subjects consisted of twenty patients with intervertebral disc disease and ten patients with lateral recess syndrome. Subjects were assessed on one occasion in specialist spinal unit of a general hospital.

Sample Size

Previous work has shown that the SLR angle in 37 participants with FBSS and persistent leg pain was 42.0 ± 16.2˚ (Shum *et al.* 2019). Based on a 10% improvement in the SLR angle following neural mobilisation for participants with FBSS and persistent leg pain at 80% power and 5% alpha, 29 participants were required in this study.

4.4.1 Participants

Thirty two people with postoperative residual leg pain following lumbar decompression (N=32) completed this study (Table 1) with the following eligibility criteria:

Patients aged 18-70 years who underwent lumbar microdiscectomy or single level lumbar decompression surgery, 6-12months post-operation.

Patients who have persistent postoperative residual leg pain were recruited if they have met the following criteria:

The severity of leg pain score being 5 or more on Numerical Rating Scale of Pain (Dworkin *et al.* 2005).

Less than 5 points improvement in the Global Rating of Change Scale, in which a clinically important improvement is defined as 5 or more (Stratford *et al.* 1994).

A positive straight leg raise (SLR) sign (specified as 65° or less movement of the straight leg relative to the longitudinal axis of the trunk) that the test reproduced unilateral symptoms in the tested leg (Shum *et al.* 2005).

Exclusion Criteria:

Participants were excluded if they suffered from long-standing ischaemic neuritis or any other surgery-related complications (e.g. inadequate decompression, postoperative instability, neural injury) as they may lead to postoperative residual leg pain. Patients were also excluded if identified as at risk by the Distress and Risk Assessment Method, which has been shown to be an accurate assessment tool of psychological disturbance in patients with low back pain (Hobby *et al.* 2001).

4.4.2 Outcome Measures

Tibial nerve mobility was assessed by diagnostic ultrasound at the popliteal fossa during forward bending using the same technique as previously described in chapter 3. Nerve displacement in the longitudinal axial and hypotenuse planes were calculated off-line by a researcher who was blinded to participant information to minimise bias. The assessment was performed with the patient in standing and bending forwards as far as was comfortable. During this forward bend movement tibial nerve movement was visualised and recorded via an ultrasound probe positioned in the popliteal fossa at the back of the knee. The movement was repeated three times and the video recordings of the nerve movement saved to the ultrasound machine. Normalised nerve movement was calculated by dividing the total nerve movement by the sum of the lumbar spine and hip flexion angles: Normalised tibial nerve movement (mm/º) = Tibial nerve movement (mm) / Total lumbar spine and hip flexion angle (º) during each forward bending movement. This calculation of normalised nerve movement allowed comparison between subjects regardless of individual joint mobility levels. The tibial nerve mobility assessment was performed with the patient in standing and bending forwards as far as was comfortable. Nerve mobility was visualised and recorded via an ultrasound probe positioned in the popliteal fossa at the back of the knee during the forward bend. The forward bend was repeated three times and the video recordings of the nerve movement saved to the ultrasound machine.

Straight leg raise (SLR) angle was assessed before and after a single session of twenty ultrasound-guided neural mobilisation exercises for the tibial nerve. The patient was positioned in supine lying with the painful leg passively raised as far as could be tolerated and a standardised passive SLR test was performed and the maximum angle between the straight leg and the longitudinal axis of the trunk measured using a digital goniometer.

Following the SLR measurement the leg was lowered by 10 degrees to avoid any discomfort during the neural mobilisation exercise. The leg was then supported and a neural mobilisation exercise was repeated twenty times. Distal gliding of the tibial nerve has been observed in response to neural mobilisation exercises involving ankle dorsiflexion both performed alone (Boyd *et al.* 2012) or in conjunction with cervical extension (Ellis and Hing 2008). In this study, each cycle of tibial neural mobilisation was achieved by simultaneous cervical flexion and ankle plantar flexion followed by cervical extension and ankle dorsiflexion. Twenty cycles of neural mobilisation exercises were completed by each participant. During the neural mobilisation exercise tibial nerve movement was observed at the popliteal fossa via diagnostic ultrasound, which gave objective feedback to both the researcher and the patient regarding the effectiveness of the exercise to induce tibial nerve movement.

The level of psychological stress was measured by the Distress and Risk Assessment Method (Hobby *et al.* 2001), which is a combination of the Modified Zung depression scale and the Modified Somatic Perception Questionnaire used to assess depression and somatisation of anxiety. The Distress and Risk Assessment Method has been shown to be a valid and reliable outcome tool for identifying LBP patients and pre/post lumbar surgery patients who will benefit from psychological intervention (Hobby *et al.* 2001).

4.4.3 Data analysis

Kolmogorov–Smirnov test was run before data analysis and there was a significant deviation from normality ($P < 0.05$). Therefore, the non-parametric statistical test of Wilcoxon Signed-ranked was used to compare the SLR angle before and after neural mobilisation. Effect size (Cohen's *d*) was calculated from the observed difference in SLR angle before and after the performance of the nerve mobilisation exercise. Effect size values range from 0 to +1, with values of 0.2 considered to be small, 0.5 moderate and +0.8 large (Serdar *et al.* 2021). Effect size is commonly used in the medical world to determine the clinical relevance of significant research findings, with a large effect size suggestive of a high clinical relevance of an outcome measure. Consequently, effect size calculations are frequently reported in medical literature to indicate the practical significance of research findings (Lakens 2013).

Correlation analysis

Pearson correlation analysis was performed between pre-mobilisation SLR, pre-mobilisation normalised nerve movement and improvement in SLR angle (two-tailed) to determine if there was a significant linear correlation between the variables.

4.5 RESULTS

Subject characteristics are presented in Table 4.1. Thirty two post-operative participants consented and completed the study, twenty-two participants had undergone lumbar discectomy for lumbar disc disorders and ten participants had undergone lumbar decompression for spinal stenosis. Participants were assessed on one occasion at an average of 146.8 days post-operation. Tests of SLR angle were positive for all participants (Median : 42.5º, Mean ± Standard deviation: 37.5º ± 12º, Table 4.3). All participants presented with a high pain score on their persistent leg pain (Mean ± Standard deviation: 6.3 ± 1.5, Table 4.1).

Table 4.1. Subject characteristics (Mean ± Standard deviation)

Post operation days	146.8 ± 35.1
Age (years)	51.6 ± 16.4
Height (cm)	168.9 ± 7.3
Weight (kg)	70.4 ± 9.3
Post-operative pain rating (back)	1.9 ± 3.1
Post-operative pain rating (leg)	6.1 ± 1.6
Global rating of change scale (-7 to +7)	2.2 ± 1.9
Lumbar flexion during forward bending (°)	25.9° ± 5.2°
Hip flexion during forward bending (°)	16.9° ± 4.2°
Normalised nerve movement (mm/º) (Painful side)	0.0412 ± 0.0116
Normalised nerve movement (mm/º) (Non-painful side)	0.0931 ± 0.0235

The scores of the Modified Zung depression scale of all participants were below 17 (Table 4.2). The results of the Distress and Risk Assessment Method suggested that the level of psychological stress was considered to be normal (Main *et al.* 1992).

Table 4.2. Level of Psychological stress in Subjects

Distress and Risk Assessment Method (DRAM)	Normal: N =32 At risk or displayed any distressed scores: N =0
Modified Somatic Perception Questionnaire	1.3 ± 2.1
Modified Zung depression scale	6.1 ± 1.6

Interpretation of scores

The suggested cut-offs

Normal	modified Zung <17
At risk	modified Zung 17-33 and MSPQ <12
Distressed Depressive	modified Zung >33
Distressed Somatic MSPQ	modified Zung 17-33 and MSPQ >12

SLR angles were significantly increased post-mobilisation (Median = 60.0º) when compared to pre-mobilisation (Median = 42.5º), Z = -4.8, $P < 0.05$ (Table 4.3), with a large effect size of 1.21 suggesting a strong clinical relevance of this observation.

Table 4.3. Angle of the SLR test (º)

N = 32	Mean	Standard Deviation
Pre-mobilisation	40.2	12.4
Post-mobilisation	46.3*	14.1
Effect size (Cohen's *d*)		1.21

*P<0.05, significant difference in the SLR angle between pre-mobilisation and post-mobilisation

There was a significant positive strong correlation between pre-mobilisation SLR and normalised nerve movement ($R = 0.753$, $p < 0.05$) (Table 4.4). There was a significant negative moderate correlation between improvement in SLR and normalised nerve movement ($R = -0.412$, $p < 0.05$). There was also a significant negative moderate correlation between pre-mobilisation SLR and improvement in SLR ($R = -0.492$, $p < 0.05$) (Schober *et al.* 2018).

Table 4.4. Correlation between pre-mobilisation SLR angle (º), improvement in SLR (º) and normalised nerve movement (R, 2-tailed)

	Pre-mobilisation SLR (º)	Normalised nerve movement (mm/º)
Pre-mobilisation SLR (º)	-	R = 0.753 p = 0.000
Improvement in SLR(º)	R = -0.492 p = 0.004	R = -0.412 p = 0.019

4.6 DISCUSSION

This is the first study to assess the effect of a neural mobilisation exercise in patients with FBSS and persistent leg pain presenting with a positive SLR test following technically successful lumbar decompression. The study aimed to determine if a single session of an ultrasound-guided repeated neural mobilisation exercise could improve straight leg raise angle of the painful leg in these patients with FBSS. Following a single session of twenty ultrasound-guided repeated neural mobilisation exercises, a significant 40% improvement of the median SLR angle (17.5º) was observed.

To facilitate normal spine and hip forward flexion the tibial nerve is required to accommodate an increase in nerve bed length, with a mean tibial nerve movement of 12.2 ± 2.2mm observed in asymptomatic subjects (Shum *et al.* 2013). Prior to lumbar decompression, it is expected that peripheral nerve mobility will be limited due to nerve root compression in the intervertebral foramen. Successful decompression surgery should remove this nerve root compression and allow the restoration of normal peripheral neurodynamics. However, despite technically successful lumbar decompression reduced tibial nerve movement has been observed in patients with FBSS and persistent leg pain (Shum *et al.* 2019). Neural mobilisation is a recognised clinical treatment technique that aims to restore optimal physiological movement and function to peripheral nerves in which neurodynamics have been compromised, and as such could be a potentially beneficial treatment for patients with FBSS and persistent leg pain.

The theoretical proposed benefits of neural mobilisation include enhanced neural gliding and sliding, increased neural vascularity and improved axoplasmic flow (Ellis and Hing 2008). In vivo studies with rats have shown numerous benefits of neural mobilisations following an induced neural chronic construction injury, including reduced neural oedema, decreased neuropathic pain symptoms and axonal regeneration (Giardini *et al.* 2017). In addition, neural sliding and gliding of upper quadrant peripheral nerves have been demonstrated in both human cadaveric and in vivo studies (Babbage *et al.* 2007) with beneficial outcomes reported in the treatment of carpal tunnel syndrome (Ballestero-Pérez *et al.* 2017).

Studies investigating neural mobilisation exercises in people with lumbar radiculopathy and persistent leg pain, have reported both positive and negative effects, with most studies involving patients who have not undergone any surgical procedure for their condition. A relatively recent meta-analysis of 40 studies identified a significantly positive effect of neural mobilisation exercises on both pain and disability when compared to exercise and/or to exercise plus lumbar mobilisation in people with nerve-related back pain (Basson *et al.* 2017). However, several studies have combined neural mobilisation with other treatment techniques (Čolaković and Avdić 2013; Savva and Giakas 2013) which meant it was not possible to determine the effectiveness of the neural mobilisation alone. One study investigating the effect of neural mobilisation exercises on various sub-groups of patients with low back and leg pain determined that neural mobilisation exercises were most effective for improving pain and physical function in patients with peripheral nerve sensitivity; as classified by a positive nerve provocation test including a SLR test (Nee and Butler 2006). This observation was also supported by the findings of previous studies in which all patients who experienced a positive effect from a nerve mobilisation exercise had presented with a positive

SLR nerve provocation test, with a positive response to a neurodynamic test being suggestive of increased neural mechanosensitivity (Nee and Butler 2006; Shum *et al.* 2019).

Only one previous study investigated the effect of a neural mobilisation exercise on patients with lumbar radiculopathy post spinal surgery (Scrimshaw and Maher 2001) and found that the addition of a neural mobilisation exercise to standard post-operative care did not result in improved patient outcomes. However, that study included all lumbar decompression post-operative patients without differentiating between patients with a successful surgical outcome and those with remaining leg pain following surgical decompression (Scrimshaw and Maher 2001). In contrast, this study only included post-surgical patients with remaining leg pain whom all presented with a significantly reduced SLR angle despite a surgically successful lumbar decompression and demonstrated that a session of ultrasound-guided neural mobilisation improved the SLR angle. The observed significant improvement in SLR angle following the neural mobilisation exercise had a very high effect size (1.21) suggesting that this observed improvement in SLR angle is of strong clinical relevance.

There was a significant positive strong correlation between pre-mobilisation SLR and normalised nerve movement ($R = 0.753$, $p < 0.05$), and a significant negative moderate correlation between both normalised nerve movement and improvement in SLR ($R = -0.412$, $p < 0.05$) and between pre-mobilisation SLR and improvement in SLR ($R = -0.492$, $p < 0.05$).

A positive strong correlation was observed between pre-mobilisation SLR and normalised nerve movement ($R = 0.753$, $p < 0.05$). In addition, there was a negative moderate correlation between improvement in SLR and normalised nerve movement ($R = -0.412$, $p < 0.05$) as well as a negative moderate correlation between pre-mobilisation SLR and improvement in SLR (R

= -0.492, $p < 0.05$) (Schober *et al.* 2018). These results suggest a strong association exists between nerve mobility and SLR angle with an increase in nerve mobility likely to result in an increased SLR angle. However, the negative moderate correlations observed between both normalised nerve movement and improvement in SLR, and pre-mobilisation SLR and improvement in SLR suggest that as nerve movement increases improvement in SLR decreases, and that as pre-mobilisation SLR increases the improvement in SLR decreases. Consequently, in patients that present with a greater magnitude of nerve mobility, there will be a smaller level of improvement seen in the SLR angle post-mobilisation. Similarly, if a greater pre-mobilisation SLR angle is recorded then the level of improvement seen in the SLR post-mobilisation will be smaller. Consequently, a lower starting point for both variables; pre-mobilisation SLR angle and nerve mobility, will allow the potential for a greater improvement in post-mobilisation SLR angle.

4.7 CONCLUSION

This was the first study to investigate the effect of a single session of repeated ultrasound-guided neural mobilisation exercises for the tibial nerve on the SLR angle of the affected leg in people with FBSS and associated persistent leg pain. The observed increase in SLR angle suggests that a repeated ultrasound-guided tibial neural mobilisation exercise increases straight leg raise angle in people with persistent leg pain of FBSS. Further research is required to determine if neural mobilisation would improve clinical outcome measures including nerve mobility and whether the improvement can be maintained over time. In addition, future studies could determine the effect of ultrasound-guided neural mobilisation exercises on pain and function in FBSS patients with associated leg pain.

4.7.1 Limitations

Although a significant immediate improvement in SLR angle was identified in this study the absence of a control group is obviously a limitation. In addition, only the immediate effect on the SLR angle was measured so any potential long term effect remains unknown. A further follow up assessment could have ideally been included in the research protocol but was not included due to time and financial restrictions. Although straight leg angle was measured before and after the nerve mobilisation exercise and tibial nerve mobility was observed via diagnostic ultrasound during the nerve mobilisation exercise no measurement of tibial nerve mobility was recorded due to time limitations. Consequently, a further limitation is the lack of measurement of nerve mobility via diagnostic ultrasound before, during and after the nerve mobilisation exercise.

Further studies could measure tibial nerve mobility before, during and after the application of a nerve mobilisation exercise as well as assessing nerve mobility and SLR angle following a course of neural mobilisation for patients with FBSS and include a follow up assessment.

4.7.2 Future Implications

The findings of this study support the feasibility of future research to further investigate the effect of neural mobilisation exercises on neuropathomechanics in FBSS patients with persistent leg pain. It is proposed that a randomised controlled trial to assess the effectiveness of a course of ultrasound-guided neural mobilisation exercises at improving neural mobility, and consequently decreasing pain and increasing function, in FBSS patients with persistent leg pain and increased peripheral nerve sensitivity, would aid the development of an evidence-based treatment strategy for this patient group.

CHAPTER FIVE. AN INVESTIGATION INTO THE CORRELATION BETWEEN BIOMECHANICAL AND CLINICAL VARIABLES IN RELATION TO LEG PAIN IN PATIENTS FOLLOWING LUMBAR SPINAL DECOMPRESSION.

5.1 PRELUDE

The second study investigated the immediate effect of an ultrasound-guided neural mobilisation on the straight leg raise angle of patients with FBSS and persistent leg pain following lumbar decompression surgery. Following a single session of twenty ultrasound-guided repeated neural mobilisation exercises a significant 40% improvement of the median SLR angle (17.5º) was observed. This study suggests that nerve mobilisation is potentially an effective intervention to improve SLR angle and nerve mobility in patients with failed back surgery syndrome and persistent leg pain. This study specifically assessed SLR angle which is known to be commonly limited in patients with radicular pain or persistent leg pain, and the results demonstrated that an immediate improvement in SLR angle can be achieved by a single session of nerve mobilisation exercises. However, SLR angle is not the only assessment variable associated with persistent leg pain and it was deemed pertinent to investigate which biomechanical and clinical factors are associated with persistent leg pain in patients post-lumbar decompression surgery. Identifying such variables would have direct clinical implications if these variables could be influenced and improved with specific interventions.

5.2 ABSTRACT

5.2.1 Purpose

To determine the strength of correlation between the leg pain experienced by patients post-lumbar decompression surgery and specific biomechanical and clinical variables; lumbar flexion, hip flexion, nerve excursion (painful leg), straight leg raise angle (painful leg), leg pain (VAS), back pain (VAS), Global Rate of Change Scale (GRCS).

Understanding the relationship between clinical and biomechanical factors and post-surgical leg pain would enhance the knowledge and understanding of spinal surgery outcomes and potentially facilitate the development of appropriate clinical interventions to improve surgical outcomes.

5.2.2 Methods

The study involved the retrospective analysis of data collected from seventy four post-lumbar decompression and discectomy surgery patients at an orthopaedic unit of a local hospital.

Statistical analysis was performed to determine the correlation between specific biomechanical and clinical variables and leg pain in patients following lumbar decompression surgery. Lumbar flexion, hip flexion, nerve excursion (painful leg), straight

leg raise angle (painful leg, back pain (VAS), Global Rate of Change Scale (GRCS) were all correlated with leg pain (VAS) using the Pearson correlation coefficient (PCC).

5.2.3 Results

There was a significant correlation between leg pain and lumbar flexion, hip flexion, SLR, nerve excursion (painful side), back pain and GRCS, with nerve excursion and lumbar flexion having the strongest correlation.

There was a significant correlation between GRCS and lumbar flexion, hip flexion, SLR, nerve excursion (painful side), back pain and leg pain, with leg pain, nerve excursion and lumbar flexion having the strongest correlation.

5.2.4 Conclusion

These findings have important clinical implications for the management of FBSS and associated leg pain, considering that the influential variables are all potentially modifiable factors.

5.3 INTRODUCTION

Nerve root impingement resulting in radicular pain is a normal characteristic of both intervertebral disc disorder and spinal stenosis, with disc herniation being responsible for approximately 90% of cases (Fokter and Yerby 2006; Koes *et al.* 2007). Spinal decompression surgery aims to remove the nerve root impingement and consequently the associated leg pain. However, despite technically successful decompression surgery 10-40% of patients experience continued post-surgical peripheral pain; commonly referred to as failed back surgery syndrome (FBSS) (Weir *et al.* 2017b). FBSS presents a significant problem to patients who continue to experience pain, functional limitations, lower quality of life scores and reduced ability to work (Eldabe *et al.* 2010; Thomson and Jacques 2009), with the pain experienced often being resistant to pharmacological intervention (Eisenberg *et al.* 2005). In addition, it is estimated that healthcare costs associated with FBSS are over 50% greater than those of patients with no post-surgical continued pain (Weir *et al.* 2017a). Consequently, FBSS presents a considerable healthcare problem in terms of patient outcome and financial costs, with further understanding of the contributing factors required. In particular, it would be beneficial to identify any specific biomechanical factors correlated with FBSS and associated leg pain, and consider if these factors could be positively influenced to improve lumbar surgical outcomes.

Clinical outcome following lumbar decompression surgery can be assessed by a variety of outcome measures including patient-reported measures. Patient-reported outcomes are increasingly used in both medical research and clinical practice to assess intervention outcome and determine any clinically relevant change in a patient's condition (Wang *et al.* 2019). One such measure is the Global Rate of Change Scale (GRCS) which requires the patient to identify the change in their health condition on a numerical scale, following a specific intervention (Kamper *et al.* 2009); the magnitude of the change being scored on a 15-point scale (-7 to +7) with a clinically important improvement defined as an increase of 5 or more (Stratford *et al.* 1994). Although the GRCS identifies the perceived rate of change of a particular health condition, it does not identify any specific variables that contribute to the change. In order to improve patient outcomes following lumbar decompression surgery it would be beneficial to determine which variables have a significant effect on the GRCS.

If these variables are potentially modifiable before and/or after surgery, then their identification would allow the implementation of an appropriate treatment plan to facilitate improvements in these specific variables, and consequently improve surgical outcome and the post-surgical GRCS score. Following lumbar decompression surgery, the main contributing factors to FBSS are the continued presence of back and/or leg pain, and as such these pain levels will obviously influence the GRCS. However, any correlation between persistent pain and GRCS post-lumbar surgery with other quantifiable biomechanical and clinical outcomes has not been previously investigated or reported.

The main objective of this study was to identify any correlation between both leg pain and GRCS and other biomechanical and clinical variables, specifically lumbar flexion, hip flexion, nerve excursion (painful leg), straight leg raise angle (painful leg), back pain (VAS) using the Pearson correlation coefficient (PCC). The identification of specific variables associated with post-surgical persistent pain would enhance the knowledge and understanding of spinal surgery outcomes and potentially facilitate the development of appropriate clinical interventions to improve surgical outcomes.

5.4 MATERIALS AND METHODS

The study involved the retrospective analysis of data collected from post-lumbar decompression and discectomy surgery patients at the spinal unit of an orthopaedic hospital (Shum *et al.* 2019).

5.4.1 Participants

A total of 74 subjects who had undergone lumbar discectomy or decompression surgery were included in the analysis for this study. Patients were selected with the following eligibility criteria:

Inclusion criteria:

Patients aged 40-80 years who had undergone lumbar decompression or discectomy**,** with unilateral radiculopathy, with or without post-surgical persistent leg pain.

Exclusion Criteria:

Patients were excluded if they suffered from long-standing ischaemic neuritis or any other surgery-related complications (e.g. inadequate decompression, postoperative instability, neural injury) as they may lead to postoperative residual leg pain. Patients were also excluded if identified as at risk by the Distress and Risk Assessment Method (Hobby *et al.* 2001; Trief *et al.* 2000), which has been shown to be an accurate assessment tool of psychological disturbance in patients with low back pain (Greenough and Fraser 1991; Main *et al.* 1992; Trief *et al.* 2000).

5.4.2 Outcome Measures

The Global Rate of Change Scale (GRCS) allows the patient to rate the change in their health status or condition following a specific treatment or intervention (Kamper *et al.* 2009). Patient-reported outcome tools are frequently used in research and clinical practice to evaluate treatment outcomes and identify any clinically relevant change to a patient's condition (Wang *et al.* 2019). The patient scores their rate of change on a 15-point numerical scale (-7 to +7), with an increase of 5 or more defined as a clinically relevant improvement (Stratford *et al.* 1994).

Tibial nerve mobility was assessed via ultrasound recordings of linear arrays centre frequency at 7.5Mhz (Model: HL5-9ED, Medison Co., Ltd, Seoul, South Korea). The measurement was taken behind the knee in the popliteal fossa during a forward bend movement, using a technique documented and validated by previous research (Coppieters *et al.* 2009; Shum *et al.* 2013; Shum *et al.* 2011). The image sequences of the diagnostic ultrasound cine-loops were analysed in MATLAB (MathWorks, Natwick, MA, USA) (Shum *et al.* 2013) using a frame-by-frame normalised cross-correlation approach. The tracking programme used a pattern-matching algorithm based on the greyscale pattern present in each of the selected region of interests to find the best match region of interests in sequential frames. Displacement of the nerve in the longitudinal (lateral) and axial (deep/superficial) dimensions were registered for each frame-by-frame matching comparison. The programme also calculated the hypotenuse excursion from the vector combination of longitudinal and axial movement. To minimize bias, the researcher was blinded to each participant's information or grouping during offline data analysis.

Lumbar flexion and hip flexion were both measured within physiological ranges using the three-dimensional inertia measurement unit (ProMove 3D, Inertia Technology, The Netherlands). Markers were placed on 4 standardised landmarks on the posterior thigh, sacrum and L1 spinous process. Signals were Analog to Digital converted (200Hz sampling frequency) and stored for offline analysis. To minimize bias, the researcher was blinded to each participant's information or grouping during offline data analysis.

Straight leg raise (SLR) angle was assessed with the patient positioned in supine lying and the painful leg passively raised as far as could be tolerated to perform a standardised passive SLR test. The maximum angle between the straight leg and the longitudinal axis of the trunk was measured using a digital goniometer.

The Visual Analogue Scale (VAS) is a validated patient-reported outcome measure that is one of the most frequently used pain assessment tools in clinical practice and LBP research (Chiarotto *et al.* 2019; Ferreira-Valente *et al.* 2011; Thong *et al.* 2018) and has been shown to be a valid and reliable assessment tool for the prediction of disability in patients with LBP (Shafshak and Elnemr 2021). Each patient was asked to identify the appropriate number on a 10-point linear numerical scale that best referred to their level of pain in both the back and their painful leg. It has been suggested that for patients with chronic low back pain, the minimally clinically important change (MCIC) for pain on a visual analogue scale should at least be 20mm (Ostelo and de Vet 2005).

5.4.3 Statistical Analysis

The main objective of this study was to identify the strength of correlation between both leg pain and GRCS and other biomechanical and clinical variables. The Pearson correlation coefficient (PCC) was used to determine if there was a correlation between both leg pain and patient-reported GRCS and other biomechanical and clinical variables; lumbar flexion, hip flexion, nerve excursion (painful leg), straight leg raise angle (painful leg), back pain (VAS).

5.5 RESULTS

There was a significant correlation ($P < 0.01$) between leg pain and all specified variables (Table 5.1). A very strong negative correlation was identified between leg pain and both lumbar flexion and tibial nerve excursion (of the painful leg). Hip flexion, SLR and GRCS all demonstrated a moderate negative correlation with leg pain, whilst the correlation between leg pain and back pain was only fair in a positive direction.

There was a significant correlation between GRCS and all specified variables, however, the strength of correlation was lower than that of the correlation identified between leg pain and each of the variables. A moderate negative correlation was identified between GRCS and leg pain and a moderate positive correlation with lumbar flexion, SLR and tibial nerve excursion (of the painful leg). The correlation observed between GRCS and both back pain and hip flexion was only fair; in a positive direction for hip flexion and a negative direction for back pain.

Table 5.1. Correlation between biomechanical and clinical variables in relation to leg pain and GRCS

Correlations

		Lumbar Flexion	**Hip Flexion**	**SLR painful side**	**Nerve excursion painful side**	**VAS leg**	**VAS back**	**GRCS**
	N	74	74	74	74	74	74	74
VAS leg	Pearson Correlation	-.833**	-.729**	-.772**	-.851**		.442**	-.768**
	Sig. (2-tailed)	.000	.000	.000	.000		.000	.000
	R^2	0.69	0.53	0.60	0.72		0.20	0.59
GRCS	Pearson Correlation	.649**	.564**	.609**	.647**	-.768**	-.343**	
	R^2	0.42	0.32	0.37	0.42	0.59	0.12	
	Sig. (2-tailed)	.000	.000	.000	.000	.000	.003	
	N	74	74	74	74	74	74	

**. Correlation is significant at the 0.01 level (2-tailed).

5.6 DISCUSSION

The statistical analysis aimed to investigate the strength of any correlation between both leg pain and patient-reported GRCS and several specific biomechanical and clinical variables. The findings have potentially important clinical implications for the management of FBSS and associated leg pain, considering that the correlated variables are all potentially modifiable factors.

Correlation does not imply causation but describes a relationship between variables that would not be expected to occur by chance alone (Akoglu 2018). When analysing a correlation between variables it is important to consider the strength of the correlation. The strength of the correlation is determined by the correlation coefficient (r) whereas the significance (p-value) shows the probability that this correlation may occur by chance. A significant correlation suggests that the correlation is unlikely to be due to chance. The correlation coefficient ranges from -1 to +1, zero means there is no correlation and 1 denotes a perfect correlation. The positive or negative sign of the correlation shows the direction of the correlation, with a negative r denoting an inverse relationship between the variables. The correlation strength is interpreted differently across the literature with variations in the specified strength for the same r value reported between authors and across fields of study. Consequently, it is important that the actual value and direction of r is reported to allow full clarity of interpretation of the results. It has been recommended that for use in medical research the following r value descriptions of strength are reported; 1 perfect, 0.8-0.9 very strong, 0.6-0.7 moderate, 0.3-0.5 fair, 0.1-0.2 poor and 0 none (Akoglu 2018; Chan 2003).

Leg pain has a very strong negative correlation with lumbar flexion and nerve excursion and a moderate negative correlation with hip flexion, SLR and GRCS. However, the strength of the positive correlation between leg pain and back pain was only fair.

GRCS has a moderate positive correlation with lumbar flexion, SLR and nerve excursion (painful side) and a moderate negative correlation with leg pain. The correlation between GRCS and both hip flexion and back pain was only fair; in a positive direction for hip flexion and a negative direction for back pain.

These results suggest that lumbar flexion and tibial nerve excursion (of the painful leg) are the variables that are most highly correlated with leg pain in patients following lumbar spinal surgery, with the observed inverse correlation suggesting that increased lumbar flexion and tibial nerve excursion are associated with a reduction in leg pain. In addition, both these variables show a moderate positive correlation with GRCS, suggesting that increased lumbar flexion and tibial nerve excursion are also associated with an improved patient-reported GRCS.

SLR angle was shown to have a moderate correlation with both leg pain (negative correlation) and GRCS (positive correlation). Previous research has reported SLR angle to be closely associated with both tibial nerve mobility (Shum *et al.* 2019) and hip flexion (Rade *et al.* 2017), however, this study identified a weaker correlation between SLR and both leg pain and GRCS than either nerve mobility or hip flexion. With regard to the assessment of lumbar radiculopathy and disc herniation the SLR test has been shown to have reasonably good sensitivity ranging from 0.67 (Rabin *et al.* 2007) to 0.91 (Devillé *et al.* 2000a), however, with a reported specificity of only 0.26 (Devillé *et al.* 2000b) it is suggested that its value as a diagnostic tool is limited. Considering the low specificity level of the SLR test and the lower strength of correlation observed between SLR and both leg pain and GRCS, than lumbar flexion and tibial nerve mobility, it is suggested that lumbar flexion and tibial nerve mobility may be more relevant variables to consider in patients who have undergone lumbar surgery.

Lumbar flexion is an important movement of daily function and routinely assessed in the clinical evaluation of back pain and referred leg pain (Shum *et al.* 2013). It has been shown to produce proximal excursion of the lumbosacral nerve roots and sciatic nerve in both in vitro and cadaveric studies (Breig and Marions 1963; Coppieters *et al.* 2006; Louis 1981; Shum *et al.* 2013), and therefore can be considered an influential variable on nerve biomechanics (Coppieters *et al.* 2015). Indeed, significantly reduced lumbar flexion has been identified in people with lower back pain compared with those with no lower back pain (Laird *et al.* 2019; Shum *et al.* 2005; Wong and Lee 2004), as well as in patients with referred leg pain (Pearcy *et al.* 1985; Shum *et al.* 2010). On statistical analysis, lumbar flexion had one of the strongest correlations of all the variables with both leg pain and GRCS, with it being very strongly correlated with leg pain and moderately correlated with GRCS. Consequently, interventions aimed at increasing lumbar flexion may be beneficial for decreasing leg pain and improving the patient-reported outcome GRCS following lumbar decompression surgery.

Nerve root compression can negatively affect the dynamics of peripheral nerves resulting in reduced neural mobility and increased neural tension that are associated with mechanosensitivity, pain, loss of function and possible neural fibrosis (Hunter 1991; Millesi *et al.* 1990) (Dilley *et al.* 2005; Yayama *et al.* 2010). Lumbar decompression surgery aims to restore normal neurodynamics by removing the compression of the affected nerve roots, however, despite technically successful surgery reduced excursion of the tibial nerve has been observed in patients with FBSS and associated persistent leg pain post-surgery, with nerve excursion significantly reduced in the painful leg compared with the non-painful leg (Shum *et al.* 2019). The failure of the surgery to restore normal nerve excursion leads to continuation of the neural tension and mechanosensitivity, consequently, physical stresses exerted on the neural structures during normal movement may elicit a symptomatic or painful response (Topp and Boyd 2012). In addition, neural oedema and inflammation have been observed in nerve injuries associated with lower back pain (Gilbert *et al.* 2015c), which can lead to associated structural nerve damage including fibrosis and adhesions, and subsequently, reduced neural gliding and increased mechanosensitivity (Dilley *et al.* 2005; Lemke *et al.* 2017; Lundborg *et al.* 1983). Neural inflammation and reduced nerve mobility have also been observed to disrupt axoplasmic transport and limit the transmission of electrical impulses along the nerve, as well as reducing the dispersion of intraneural fluid (Brown *et al.* 2011; Dilley and Bove 2008; Gilbert *et al.* 2015a; Gilbert *et al.* 2015c) causing further neural mechanosensitivity. This previous research suggests that a nerve must be able to slide and glide to facilitate optimal neural function, which is further supported by this study and the identification of tibial nerve excursion as one of the variables most strongly correlated with both leg pain and GRCS. These results support previous findings and suggest that improving tibial nerve mobility could be beneficial in reducing leg pain and subsequently improving patient outcome following lumbar decompression surgery.

Back pain was also correlated with leg pain and GRCS but less strongly than lumbar flexion and tibial nerve excursion. However, previous studies investigating lumbar flexion and back pain have identified differences in lumbar flexion between subjects with non-specific lower back pain and those with no back pain, with a smaller lumbar flexion range of motion observed in patients with LBP (Laird *et al.* 2019) suggesting an association between lumbar flexion and back pain. In addition, patients with back pain plus a positive SLR test demonstrated reduced lumbar flexion and increased muscle moment effects during flexion compared with patients presenting with LBP but a negative SLR test, which suggests there may be a greater association between lumbar flexion and back pain in the presence of radicular pain as indicated by a positive SLR test (Shum *et al.* 2010). Although this current study identified back pain as being more weakly correlated with leg pain following lumbar surgery than either lumbar flexion or nerve mobility, with the consideration of previous evidence it is suggested that the alleviation of back pain would be beneficial in the management of leg pain and improving patient outcome

5.7 CONCLUSION

As far as we are aware this is the first study that has examined specific biomechanical and clinical factors associated with FBSS and associated leg pain in patients post-lumbar decompression surgery. Identification of significant biomechanical and clinical factors associated with continuing pain in post-operative spinal patients could allow the development of appropriate clinical interventions to improve surgical outcomes following lumbar surgery and decrease the occurrence of FBSS.

The results of the study suggest that the main biomechanical and clinical variables correlated with leg pain and GRCS in patients following lumbar decompression are lumbar flexion and tibial nerve excursion. In addition, back pain, hip flexion, and straight leg raise angle of the painful leg are also correlated with both leg pain and GRCS. Therefore, it is proposed that interventions to improve lumbar flexion, tibial nerve mobility, back pain and hip flexion could have a beneficial effect on leg pain and GRCS following lumbar decompression surgery. These results have clinical implications for the management of patients undergoing lumbar surgery and those post-surgical patients experiencing FBSS with associated leg pain.

5.7.1 Study Strengths and Limitations

This study includes the use of objective measurements to determine the strength of correlation between both leg pain and patient-reported GRCS and specific biomechanical and clinical variables. However, as always in the provision of patient-centred care each patient will have individual needs and preferences and not all treatments will be suitable or beneficial for all patients. Low back pain and radicular pain are complex conditions that can be affected by varying, interacting physical and psychosocial factors (Hartvigsen *et al.* 2018), consequently, it could be potentially misleading to attempt to oversimply the causes of FBSS. However, there is currently a lack of consistent evidence-based guidelines regarding the treatment and management of FBSS and this study provides some preliminary evidence regarding specific biomechanical variables that are potentially influential on patient outcomes following lumbar decompression and the potential development of FBSS.

5.7.2 Clinical Relevance

Lumbar flexion, tibial nerve movement, hip flexion and back pain are all potentially modifiable variables that could influence the presence of continuing leg pain and associated patient-reported GRCS following lumbar surgery. Consequently, it is suggested that if back pain is controlled, lumbar flexion and hip flexion improved via mobility exercises and tibial nerve mobility increased with nerve mobilisation exercises, leg pain could potentially be reduced. In addition, improving tibial nerve mobility and hip flexion should also result in an improved SLR angle.

5.7.3 Future Research

Further research should investigate specific interventions to improve lumbar flexion, hip flexion, tibial nerve movement and back pain, and the subsequent effect on FBSS and associated leg pain, with a view to implement such interventions before and/or after lumbar surgery.

CHAPTER SIX. ANALYSIS OF TIBIAL NERVE EXCURSION DURING SUSTAINED LUMBAR TRACTION IN PEOPLE WITH A CONFIRMED LUMBAR DISC HERNIATION

6.1 PRELUDE

The results of the previous study investigating factors associated with patient-reported outcomes (GRCS) and persistent leg pain in post-operative spinal patients, suggest that the significant biomechanical and clinical factors that contribute to an improvement in patient Global Rate of Change Score (GRCS) and leg pain are lumbar flexion, hip flexion, SLR angle, nerve excursion (painful side) and back pain, with nerve excursion and lumbar flexion being the variables with the strongest correlation with both GRCS and leg pain.

These results have direct clinical implications for the management of patients undergoing lumbar surgery and those post-surgical patients experiencing FBSS. Lumbar flexion, hip flexion, SLR angle, tibial nerve movement and back pain are all potentially modifiable variables that could influence the presence of continuing leg pain and associated patient-reported outcome following lumbar surgery. Consequently, in patients with persistent leg pain following lumbar decompression surgery, it is suggested that leg pain could be reduced by the use of treatments and interventions aimed at decreasing back pain, increasing lumbar and hip flexion and improving tibial nerve mobility.

Although it is suggested that such interventions could be beneficial following lumbar decompression surgery there is limited evidence for the use of any interventions to improve leg pain prior to surgery whilst the nerve root is compressed. Many patients requiring spinal decompression have long wait times for surgery, particularly following the COVID-19 pandemic, there have been continually increasing surgical wait times and a significant reduction in new patient referrals to surgery (Hampton *et al.* 2021). Consequently, any conservative intervention that can potentially reduce pain and facilitate the continuation of normal daily activities would be highly beneficial to patients who are suffering from pain and disability associated with lumbar disc herniation, as well as those patients who are awaiting spinal surgery.

Back pain, lumbar flexion and tibial nerve mobility are all associated with leg pain. If these variables could be influenced prior to surgery it may improve surgical outcome or even potentially reduce the need for surgery.

Nerve mobilisation exercises have been shown to improve tibial nerve mobility (Basson *et al.* 2017; Ellis *et al.* 2021). However, prior to decompression surgery the effectiveness of a nerve mobilisation exercise will be limited due to the fact that the nerve root is mechanically compressed so unable to glide during a nerve mobilisation exercise (Rade *et al.* 2017).

An increase in lumbar intervertebral disc height has been observed following sustained mechanical traction in asymptomatic patients (Chow *et al.* 2017). In patients with lumbar nerve root compression due to a herniated disc an increase in disc height under traction could potentially reduce the disc protrusion and consequently reduce the nerve root compression. Therefore, the next study was designed to investigate tibial nerve mobility during sustained traction in patients with a confirmed diagnosis of a herniated disc and the presence of pain in one or both legs. The study design involved a repeated measures experimental design to investigate tibial nerve excursion before and during sustained lumbar traction in patients with a confirmed diagnosis of a single-level lumbar disc herniation. Nerve excursion was elicited via a nerve mobilisation exercise and the nerve movement observed during the exercise was recorded via ultrasound imaging. Statistical analysis of the results involved the undertaking of a paired t-test to determine any statistically significant differences between tibial nerve excursion before mechanical traction and after thirty minutes of sustained mechanical traction, as well as the calculation of the intraclass correlation coefficient [($ICC_{3,k}$)] to determine the reliability of the measurements in nerve movement.

6.2 ABSTRACT

6.2.1 Purpose

A biomechanical study with a repeated measure design was conducted to compare tibial nerve excursion following five minutes and then thirty minutes of sustained mechanical lumbar traction in people with a confirmed diagnosis by MRI of a single-level lumbar disc herniation. It was hypothesised that people with lumbar intervertebral disc herniation and associated leg pain/symptoms will experience improved tibial nerve movement following thirty minutes of sustained lumbar traction compared with tibial nerve movement following five minutes of sustained lumbar traction due to decreased compression of the nerve root by the herniated disc.

6.2.2 Methods

A biomechanical study with a repeated measurement protocol this study compared the effects of a tibial nerve mobilisation exercise performed under mechanical traction, after five minutes and after thirty minutes, on tibial nerve mobility in patients with a single-level lumbar disc herniation confirmed by MRI. Seventeen participants with a confirmed diagnosis of a single-level lumbar herniated disc were recruited for the study. Each participant performed a nerve gliding mobilisation exercise to facilitate nerve mobility five minutes after the start of a sustained mechanical traction session and then again following thirty minutes of sustained traction. Tibial nerve mobility was assessed during the nerve mobilisation exercise at the popliteal fossa via a previously validated ultrasound imaging technique.

6.2.3 Results

Paired t-test statistical analysis identified that tibial nerve movement was significantly increased ($p<0.001$) following thirty minutes of sustained lumbar traction ($M=2.98$, $SD=1.04$) compared with the nerve movement observed following five minutes of lumbar traction ($M=2.49$, $SD=0.86$). Nerve mobility, achieved via a nerve gliding mobilisation exercise, is improved with sustained mechanical traction in patients with a confirmed diagnosis of a single-level lumbar disc herniation.

6.2.4 Conclusion

This was the first study to assess tibial nerve movement via ultrasound imaging during sustained lumbar traction, in patients with a confirmed diagnosis of a single-level lumbar disc herniation. This has potential clinical implications regarding the management and treatment options for patients with lumbar disc herniation as the results suggest that the use of sustained mechanical lumbar traction may facilitate an improvement in tibial nerve mobility.

6.3 INTRODUCTION

Low back pain (LBP) is the most commonly diagnosed musculoskeletal problem throughout the world (Hoy *et al.* 2012), and as the main cause of work absenteeism and activity limitation (Maher *et al.* 2017), places a huge medical and financial burden on health care systems and society. One of the most frequently diagnosed variations of LBP is radicular pain or sciatica (Konstantinou and Dunn 2008), which is defined as pain radiating from the lower back and/or buttocks distally to one or both lower limbs along the distribution of the sciatic nerve (Pesonen *et al.* 2019). It is estimated that lumbar disc herniation is responsible for 85-90% of radiculopathy cases (Koes *et al.* 2007) and is the most commonly diagnosed pathologic condition affecting the spine (Suthar *et al.* 2015).

Impingement of the sciatic nerve root in the intervertebral canal by a herniated disc can result in decreased peripheral nerve excursion along the distribution of the sciatic nerve (Kobayashi *et al.* 2010; Pesonen *et al.* 2019), with sciatic nerve excursion being shown to be reduced by 66.6% n people with lumbar intervertebral disc herniation (Rade *et al.* 2017). Nerve excursion can be assessed via ultrasound imaging, with decreased peripheral nerve excursion being identified in several peripheral nerve disorders presenting with radiculopathy and radicular pain, including deep gluteal pain syndrome (Knudsen et al. 2015; Carro et al. 2016), post-operative leg pain post lumbar discectomy/decompression (Shum et al. 2019) and lumbosacral nerve root pain in people with intervertebral disc herniation (Kobayashi et al. 2003; Pesonen et al. 2019).

In the event of a lumbar disc herniation, compression and subsequent tethering of the nerve root occurs in the intervertebral canal. In the presence of such nerve root compression the nerve will not be able to slide and glide but instead will be put under increased stretch and strain which could result in exacerbated radicular symptoms including neural mechanosensitivity and pain (Boyd *et al.* 2012; Dilley *et al.* 2005).

Mechanical lumbar traction has been used as a treatment option for LBP for many years (Clarke *et al.* 2007; van der Heijden *et al.* 1995) despite the fact that there is a lack of consensus across the literature regarding its effectiveness (Alrwaily *et al.* 2018; Harte *et al.* 2005; Madson and Hollman 2015; Tanabe *et al.* 2021; Wegner *et al.* 2013). Indeed, the Royal College of General Practitioners concluded that there was little evidence to recommend traction for nonspecific LBP and the NICE Guidelines (no.59) state that traction should not be offered for low back pain or sciatica (National Collaborating Centre for Primary 2009; National Guideline 2016). Despite these recommendations, a survey of physiotherapists in the UK reported that 41% of respondents used mechanical traction as an intervention for LBP (Harte *et al.* 2005) and in a similar study amongst physical therapists in the US, 76.6% of respondents reported using traction in their clinical practice, although, it should be noted that the response rate for the US study was only 25.5% (Madson and Hollman 2015).

Despite the controversy regarding traction as an effective intervention for LBP, numerous studies support the use of manual traction as a conservative treatment for radicular symptoms and pain associated with spinal pathology (Apfel *et al.* 2010; Güevenol *et al.* 2000; Hahne *et al.* 2010; Mitchell *et al.* 2017b; Ozturk *et al.* 2006; Prasad *et al.* 2012), with sustained mechanical traction having been observed to increase lumbar intervertebral disc height in asymptomatic patients (Chow *et al.* 2017). It has been suggested that traction facilitates the distraction of vertebral bodies and facet joints with a consequent widening of the vertebral foramen (Kane *et al.* 1985). In addition, it has been proposed that traction may have a direct effect on the intervertebral disc, resulting in an increase in disc height and the potential reduction of any disc protrusions (Chow *et al.* 2017). However, traction type, duration and intensity protocols have varied greatly across the studies, with a lack of specification and standardisation of traction procedures and variables (Alrwaily *et al.* 2018). Furthermore, few studies have included participants with a confirmed diagnosis of intervertebral disc disease.

Traction methods and protocols vary greatly and can consist of mechanical traction or inversion therapy, and sustained or intermittent traction. The applied traction force is another procedural variable that can differ significantly between studies, as well as treatment duration and frequency. Schimmel et al (2009) concluded that intermittent mechanical traction therapy (sixty seconds of distraction followed by thirty seconds of partial relaxation) did not provide any additional clinical benefit to a standard graded exercise programme in patients with low back pain. However, a sustained mechanical traction force has been observed to have a direct effect on the disc height of asymptomatic patients (Chow *et al.* 2017), with a significant increase in percentage disc height observed across all lumbar discs following thirty minutes of sustained mechanical traction.

The lack of agreement across the research regarding the effectiveness of lumbar traction for the treatment of LBP could potentially be exacerbated by a lack of standardisation regarding traction type and specified protocol parameters, the application of other treatment techniques/modalities in addition to traction, as well as widespread variations regarding patient selection and a lack of stratification based on patient pathology and symptoms (Alrwaily *et al.* 2018; Harte *et al.* 2005; Madson and Hollman 2015; Tanabe *et al.* 2021;

Wegner *et al.* 2013). Evaluation of the literature reporting beneficial effects of traction in the treatment of lumbar disc herniation suggested that mechanical traction sustained for at least 30 minutes with a load of 45% of body weight produced the most preferential outcomes. There is no data to suggest the most beneficial number of sessions or frequency of treatment and indeed an increase in disc height in asymptomatic subjects has been observed following a single session of sustained mechanical traction (Chow *et al.* 2017). However, most previous studies have involved differing numbers of repeated traction sessions over varying periods of time (from 1-22 sessions, over 1-42 days) (Apfel *et al.* 2010; Chow *et al.* 2017; Güevenol *et al.* 2000; Ozturk *et al.* 2006; Prasad *et al.* 2012), so following evaluation of the existing research and consideration of the time/travel demands placed on the participants it was decided that 8 sessions over 4 weeks (2 sessions a week) would be an appropriate number of sessions to be both effective and achievable in terms of time and travel expense for the participants.

6.4 MATERIALS AND METHODS

A biomechanical study with a repeated measure design was conducted to compare tibial nerve excursion following five minutes and then thirty minutes of sustained mechanical lumbar traction in people with a confirmed diagnosis by MRI of a single-level lumbar disc herniation. In line with existing literature which has demonstrated beneficial effects following lumbar traction (Apfel *et al.* 2010; Chow *et al.* 2017; Chung *et al.* 2015; Hahne *et al.* 2010; Mitchell *et al.* 2017b; Ozturk *et al.* 2006; Prasad *et al.* 2012), continuous mechanical traction was applied by the traction unit (Tru-trac Traction Unit, Chattanooga^{TM}) on a friction-free rolling top traction table (Plinth 2000 Ltd), with the aim of applying 30% of body weight via mechanical traction sustained for thirty minutes, with bilateral hip flexion of 45 degrees.

6.4.1 Participants

Inclusion Criteria:

- Patients aged between 18 and 60 years (both inclusive)
- Diagnosis, confirmed by MRI, of a single level unilateral lumbar disc protrusion causing the appropriate nerve root impingement (within 6 months of diagnosis).
- Patients who have residual leg pain as defined by a positive straight leg raise (SLR) sign (specified as less than 66° movement of the straight leg relative to the longitudinal axis of the trunk that the test reproduced unilateral symptoms in the tested leg)

Exclusion Criteria:

- Presence of the following red flag features – bladder/bowel dysfunction, history of cancer, thoracic night pain, previous history of lumbar surgery, saddle anaesthesia
- Significant cardio-respiratory disorder
- Pregnancy
- Weight more than 20% of ideal norms for height and age or more than 140kg

Characteristics of the tested subject sample are shown in Table 6.1.

Ethics Approval and Participant Consent

Ethics approval was granted by the Plymouth Marjon University Research Ethics Panel and written informed consent was obtained from all participants.

Table 6.1 Subject characteristics

	Mean ± Standard deviation	Range
Age	44.1 ± 9.4	32 - 60
Height	170.4 ± 10.0	154 - 190
Weight	80.0 ± 19.8	56 - 130
VAS (back)	6.4 ± 2.0	3 - 10
VAS (leg)	7.5 ± 1.9	4 - 10
Oswestry Disability Index	17.8 ± 6.9	6 - 28
Zung Self-Rating Depression Scale	13.8 ± 3.6	4 - 16
Lumbar Range of motion (°)	24.5 ± 5.3	16.2 - 31.9
Hip Range of motion (°)	16.1 ± 4.7	8.9 - 23.7
Total lumbar hip Range of motion (°)	40.6 ± 7.2	29.8 – 55.6
SLR of Painful side (°)	54.2 ± 12.5	33 - 80
SLR of Non-Painful side (°)	73.7 ± 9.9	53 - 90
Gender	Male: N = 9 Female: N =8	

6.4.2 Outcome Measures

Tibial nerve excursion was assessed via ultrasound recording of linear arrays, centre frequency 7.5Mhz (Model: HL5-9ED, Medison Co., Ltd, Seoul, South Korea). Measurements were taken during a nerve mobilisation technique following five minutes of lumbar traction and then again following thirty minutes of sustained lumbar traction. The measurement was taken behind the knee at the popliteal fossa whilst the patient performed a nerve mobilisation exercise. This involved extending the knee of the painful leg to a tolerable position which was then maintained and supported whilst the participant completed a nerve gliding mobilisation exercise via simultaneous ankle plantarflexion and cervical flexion, followed by ankle dorsiflexion and cervical extension. This technique has been previously demonstrated to facilitate distal gliding of the tibial nerve (Ellis and Hing 2008). During the neural mobilisation exercise maximum tibial nerve movement was recorded at the popliteal fossa via diagnostic ultrasound. The image sequences of the diagnostic ultrasound cine-loops were then analysed offline in MATLAB (MathWorks, Natwick, MA, USA) (Shum *et al.* 2013) using a frame-by-frame normalised cross-correlation approach. The tracking programme used a pattern-matching algorithm based on the greyscale pattern present in each of the selected region of interests to find the best match region of interests in sequential frames. Displacement of the nerve in the longitudinal (lateral) and axial (deep/superficial) dimensions were registered for each frame-by-frame matching comparison. The programme also calculated the hypotenuse excursion from the vector combination of longitudinal and axial movement. To minimize bias, the researcher was blinded to each participant's information or grouping during offline data analysis.

6.4.3 Statistical Analysis

A paired-t test was used to detect statistically significant differences within patients between tibial nerve excursion following five minutes of mechanical traction and then after thirty minutes of sustained mechanical traction. Effect size was calculated from the recorded differences in nerve movement following five minutes and thirty minutes of traction using Cohen's *d* equation. Effect size indicates if an intervention has a greater effect than zero and when there is an effect, how large that effect is, values range from 0 to +1, with values of 0.2 considered to be small, 0.5 moderate and +0.8 large (Serdar *et al.* 2021). Effect size is used to evaluate the clinical relevance of research outcomes with a large effect size suggesting strong clinical relevance (Lakens 2013). In addition, the intraclass correlation coefficient [($ICC_{3,k}$)] was also calculated to determine the reliability of the nerve excursion measurements. Intraclass correlation coefficient (ICC) is a widely used measure of reliability that reflects the degree of correlation and the agreement between measures, however, it is important for effective reliability analysis that the appropriate form of ICC is conducted with the 'model', 'type' and 'definition' selection specified (Koo and Li 2016). This study involved a two-way random-effects model, single-rater and absolute agreement definition for the ICC calculation.

6.5 RESULTS

Paired t-test analysis identified a significant difference ($p<0.001$) between nerve excursion following five minutes of lumbar traction (M=2.49, SD=0.86) and after thirty minutes of sustained lumbar traction (M=2.98, SD=1.04), suggesting that sustained lumbar traction has a significant effect on tibial nerve excursion (table 6.2). The effect size was large for the longitudinal and hypotenuse nerve movement measurements; 1.877 and 1.785 respectively, but only small (0.156) for the axial nerve movement (table 6.2).

Table 6.2. Paired t-test analysis, nerve excursion at 5 mins under traction (pre) and at 30 mins under traction (post)

	Mean ± Standard deviation	**Mean ± Standard deviation**	**p**	**Effect size (Cohen's *d*)**
	Following five minutes of lumbar traction	Following thirty minutes of lumbar traction		
Longitudinal Nerve movement (mm/°)	2.45 ± 0.85	2.95 ± 1.03	0.000*	1.877
Axial Nerve movement (mm/°)	0.4 ± 0.21	0.42 ± 0.21	0.429	0.156
Hypotenuse Nerve movement (mm/°)	2.49 ± 0.86	2.98 ± 1.04	0.000*	1.785

*significant difference in longitudinal and hypotenuse nerve movement between five minutes and thirty minutes of lumbar traction (p = 0.000).

The mean $ICC_{3,k}$ for measuring the longitudinal, axial and hypotenuse movement of the tibial branch of sciatic nerve were found to be 0.990, 0.977 and 0.996 respectively following five minutes of traction and 0.996, 0.988 and 0.999 respectively (see Table 6.3) after thirty minutes of traction. These results suggest the measurements of nerve excursion are highly reliable.

Table 6.3. Reliability Analysis of the Tibial Nerve Excursion

	ICC(3,K)	ICC(3,K)
	Following five minutes of lumbar traction	Following thirty minutes of lumbar traction
Longitudinal	0.990	0.996
Axial	0.977	0.988
Hypotenuse	0.996	0.999

6.6 DISCUSSION

The evidence to support the use of traction as an effective treatment for LBP is inconclusive (Clarke *et al.* 2007; van der Heijden *et al.* 1995) and the use of traction is not recommended by the Royal College of General Practitioners and NICE clinical guidelines for the treatment of LBP (National Collaborating Centre for Primary 2009; National Guideline 2016). However, some studies suggest that mechanical traction may be effective for the treatment of patients who experience pain associated with intervertebral disc disease, disc herniation and radicular pain (Apfel *et al.* 2010; Güevenol *et al.* 2000; Hahne *et al.* 2010; Mitchell *et al.* 2017b; Ozturk *et al.* 2006; Prasad *et al.* 2012). Our previous study identified a significant correlation between leg pain in patients with intervertebral disc disease and tibial nerve mobility (Cinnamond and Shum, 2023, chapter 4, submitted and under review), which supports previous findings that increased nerve mobility correlated with a decrease in pain in a group of symptomatic patients (Thoomes *et al.* 2021). Consequently, it was hypothesised that leg pain in patients with a lumbar disc herniation could potentially be reduced if tibial nerve mobility was increased. Although nerve mobilisation exercises have been observed to result in improved nerve mobility (Basson *et al.* 2017; Ellis 2012; Nee and Butler 2006), the effectiveness of the mobilisation exercise is likely to be reduced in the presence of a lumbar disc herniation due to compression of the nerve root in the intervertebral foramen preventing the nerve from being able to slide and glide during the mobilisation exercise. In fact, a nerve mobilisation exercise performed whilst the nerve root is compressed due to a disc herniation is likely to put the nerve under increased strain and stretch which could further exacerbate the leg pain (Boyd *et al.* 2012) (Dilley *et al.* 2005). Therefore, for a nerve mobilisation exercise to be beneficial, the nerve root compression must first be reduced or removed. Sustained mechanical traction has been shown to increase intervertebral lumbar disc height in asymptomatic patients (Chow *et al.* 2017), consequently, it was hypothesised that sustained mechanical lumbar traction in patients with a lumbar disc herniation could potentially facilitate improved neural mobilisation by a reduction in nerve root compression.

This study compared tibial nerve excursion whilst performing a nerve mobilisation exercise following five minutes of lumbar traction and after thirty minutes of sustained mechanical lumbar traction in people with a confirmed lumbar disc herniation. The traction protocol was devised from the examination of previous studies that had reported positive effects of traction on patients with back and leg pain associated with intervertebral disc disease, disc herniation, radiculopathy and radicular pain (Apfel *et al.* 2010; Güevenol *et al.* 2000; Hahne *et al.* 2010; Mitchell *et al.* 2017b; Ozturk *et al.* 2006; Prasad *et al.* 2012). It was determined that sustained mechanical traction for thirty mins, at a load of between 30-45% of body weight was likely to produce the most beneficial outcome. Significantly increased tibial nerve excursion was observed during a nerve mobilisation exercise following thirty minutes of sustained mechanical traction compared with the nerve excursion observed after five minutes of lumbar traction. This suggests that sustained mechanical traction could be beneficial for improving tibial nerve mobility which, in turn, could have a positive effect on leg pain associated with a lumbar disc herniation. The effect size was very large for the longitudinal and hypotenuse nerve movement measurements; 1.877 and 1.785 respectively, suggesting strong clinical relevance of these nerve movement observations.

Previous research reported an increase in lumbar intervertebral disc height in asymptomatic patients following thirty minutes of sustained mechanical lumbar traction (Chow *et al.* 2017).

Consequently, it is hypothesised that the increased nerve mobility observed during this study resulted from a reduction in the disc herniation and associated compression on the nerve root, due to an increase in disc height that has been observed to occur following sustained lumbar traction.

6.7 CONCLUSION

To our knowledge, this was the first study to investigate the effect of sustained mechanical traction on tibial nerve mobility in patients with a confirmed diagnosis of a single-level lumbar disc herniation. Results from this study suggest that nerve excursion, achieved via a nerve gliding mobilisation exercise, is improved with sustained mechanical traction in patients with a confirmed diagnosis of a single-level lumbar disc herniation.

6.7.1 Limitations

This was a study to identify any immediate effect of a single session of traction on the excursion of the tibial nerve. Consequently, it did not determine if the increased mobility was maintained over time or if neural excursion could be further increased with repeated traction sessions. Further research is recommended to determine the cumulative effects of repeated traction treatment sessions on nerve mobility and also to determine if the increase in nerve excursion is maintained over time.

6.7.2 Clinical Relevance

The results suggest that sustained mechanical traction can potentially improve tibial nerve mobility during a nerve mobilisation exercise in patients with a confirmed diagnosis of a single-level lumbar disc herniation. This has potential clinical implications for the management and treatment options for patients with lumbar disc herniation, as the results suggest that the use of sustained mechanical traction may facilitate an improvement in tibial nerve mobility. Our previous study identified that persistent leg pain in patients post-lumbar decompression surgery is significantly correlated with lumbar flexion, tibial nerve movement and back pain. Consequently, if tibial nerve mobility can be improved by sustained lumbar traction, it could potentially help reduce leg pain associated with lumbar disc herniation. Further research is recommended to determine the effect of improving nerve mobility on leg pain associated with disc herniation, as well as any potential cumulative effects on nerve mobility of repeated traction treatment sessions.

CHAPTER SEVEN. THE EFFECT OF MECHANICAL TRACTION, WITH OR WITHOUT NEURAL MOBILISATIONS, ON LEG PAIN AND TIBIAL NERVE MOBILITY IN PATIENTS WITH A SINGLE LEVEL LUMBAR DISC HERNIATION.

7.1 PRELUDE

The final study included in this thesis was designed as a feasibility study to investigate the effect of sustained mechanical traction, with or without neural mobilisations, on leg pain and tibial nerve mobility in patients with a single-level lumbar disc herniation. The National Institute for Health and Care Research (NIHR) define a feasibility study as research designed to investigate whether a full-scale trial would be feasible. This study was completed as part of this PhD thesis prior to the undertaking of a full RCT study. Sample sizes ranging from 24-50 have been recommended as appropriate for a feasibility study (Julious 2005; Lancaster *et al.* 2004; Sim and Lewis 2012), consequently, the number of participants recruited for this study (n=50) could be deemed to be sufficient.

In people with lumbar intervertebral disc herniation and associated leg pain/symptoms, tibial nerve movement is limited due to mechanical compression of the nerve root by the disc herniation (Gibson and Waddell 2007a; Kobayashi *et al.* 2010; Millesi *et al.* 1990; Mitchell *et al.* 2017a; Pesonen *et al.* 2019), with a 66.6% reduction of sciatic nerve excursion observed in people with lumbar intervertebral disc herniation (Rade *et al.* 2017). However, an increase in lumbar intervertebral disc height following sustained mechanical traction has been observed in asymptomatic patients (Chow *et al.* 2017). Consequently, it was hypothesised that sustained mechanical traction in patients with a lumbar disc herniation, could potentially reduce leg pain and increase tibial nerve mobility by decreasing the protrusion of the herniated disc and associated compression of the nerve root. The effect of sustained mechanical traction with and without the addition of a neural mobilisation exercise was investigated in patients with a confirmed diagnosis of a single-level lumbar disc herniation.

This was the first study of our knowledge designed to investigate the effects of sustained mechanical traction, with and without a nerve mobilisation exercise, on tibial nerve mobility and leg pain in patients with a confirmed diagnosis of a single-level lumbar disc herniation.

The study recruited subjects with a confirmed diagnosis of a single-level lumbar disc herniation who were then randomly assigned into one of three groups:

- Traction + Usual physiotherapy exercises (n=20)
- Traction + Nerve mobilisation + Usual physiotherapy exercises (n=15)
- Control (Usual physiotherapy) (n=15)

7.2 ABSTRACT

7.2.1 Purpose

This study investigated the effects of sustained mechanical traction, with and without a nerve mobilisation exercise, on tibial nerve mobility and leg pain in patients with a single-level lumbar disc herniation.

7.2.2 Methods

Participants were randomly assigned to one of two intervention groups; Group 1 Traction: (n = 20), Group 2: Traction + Nerve Mobilisation (n = 15) or a Control group (n = 15). The intervention groups received eight sessions of traction, with or without nerve mobilisation exercises performed during traction. Subjects in Group 2 performed three sets of twenty nerve mobilisation exercises during the thirty-minute traction session. Control subjects continued with any treatment they were already receiving. An initial assessment was completed prior to the subjects commencing treatment and the assessment repeated on completion of the eight sessions of traction. The following outcome measures were assessed:

Patient details - age, height, weight; back and leg pain (visual analogue scale - VAS); straight leg raise (SLR) angle; lumbar spine and hip biomechanics – lumbar flexion, extension, lateral flexion, rotation; tibial nerve mobility; Oswestry Disability Index (ODI); Psychosocial Testing - Zung Self-Rating Depression Scale and Modified Somatic Perception Questionnaire; Global Rate of Change Scale (GRCS). The GRCS was included in the final assessment only.

Tibial nerve mobility was assessed at the popliteal fossa by a previously validated ultrasound imaging technique.

7.2.3 Results

No significant differences across any of the outcome measures were identified between the two intervention groups and the control group in the initial assessment.

A significant improvement in GRCS was observed in both intervention groups with no significant difference between the two treatment groups (traction only group: 4.73 ± 1.49 and traction plus nerve mobilisation group: 5.64 ± 0.92). There was no significant change observed in the control group (-0.15 ± 2.04).

Tibial nerve movement in the painful leg improved significantly in both intervention groups (traction group: pre: 0.054 ± 0.011 mm/°; post: 0.104 ± 0.040 mm/° and traction plus nerve mobilisation group: pre: 0.052 ± 0.009 mm/°; post: 0.110 ± 0.015 mm/°), with no significant differences observed between the traction and traction plus nerve mobilisation group.

No significant improvement in tibial nerve movement in the non-painful leg was observed between the traction group (pre: 0.092 ± 0.025 mm/°; post: 0.117 ± 0.039 mm/°), traction plus nerve mobilisation group (pre: 0.100 ± 0.019 mm/°; post: 0.122 ± 0.018 mm/°) and control group (pre: 0.099 ± 0.026 mm/°; post: 0.103 ± 0.027 mm/°).

Significant improvement in straight leg raise angle of the painful leg was observed in both the traction group (pre: 49.0 ± 14.3°; post: 70.9 ± 5.4°) and traction plus nerve mobilisation group (pre: 48.5 ± 9.3°; post: 75.8 ± 5.0°) when compared to the control group (pre: 58.3 ± 13.6°; post: 60.0 ± 13.5°). There were no significant differences observed between the traction and traction plus nerve mobilisation group.

Significant improvement in leg pain severity was observed in both the traction group (pre: 7.1 ± 2.4; post: 2.5 ± 2.8) and traction plus nerve mobilisation group (pre: 7.5 ± 1.8; post: 1.6 ± 2.0) when compared to the control group (pre: 7.0 ± 2.3; post: 5.9 ± 2.8). There were no significant differences observed between the traction and traction plus nerve mobilisation group.

Significant improvement in leg pain severity was observed in both the traction group (pre: 6.6 ± 2.8); post: 3.3 ± 2.4) and traction plus nerve mobilisation group (pre: 6.0 ± 1.9; post: 2.5 ± 2.5) when compared to the control group (pre: 6.0 ± 2.4; post: 5.6 ± 2.9). There were no significant

Significant improvement in ODI was observed in both the traction group (pre: 18.3 ± 7.4); post: 10.0 ± 8.6) and traction plus nerve mobilisation group (pre: 20.2 ± 6.9; post: 7.4 ± 5.8) when compared to the control group (pre: 16.5 ± 5.7; post: 15.3 ± 5.2). There were no significant differences observed between the traction and traction plus nerve mobilisation group.

7.2.4 Conclusion

Results from this study suggest that sustained mechanical traction can reduce leg pain and increase tibial nerve mobility in patients with a confirmed diagnosis of a single-level lumbar disc herniation.

7.3 INTRODUCTION

As the most frequently diagnosed musculoskeletal condition worldwide (Hoy *et al.* 2012), and the main cause of work absentee and activity restriction (Maher *et al.* 2017), low back pain (LBP) is a significant global health concern. Sciatica is a commonly diagnosed variation of LBP involving the presence of pain along the distribution of the sciatic nerve (Pesonen *et al.* 2019), with lumbar disc herniation and associated nerve root compression, estimated to be the cause of 85-90% of sciatica cases (Koes *et al.* 2007). Indeed, lumbar disc herniation is the most frequently diagnosed spinal pathology (Suthar *et al.* 2015). Nerve root compression at the intervertebral foramen has the effect of decreasing peripheral nerve mobility (Kobayashi *et al.* 2010), leading to increased neural tension, mechanosensitivity, pain and an associated loss of normal function (Dilley *et al.* 2005; Hunter 1991; Millesi *et al.* 1990).

Although there is conflicting evidence to support its effectiveness, traction has been used as a treatment for LBP for many years (Clarke *et al.* 2007; van der Heijden *et al.* 1995). Indeed, it was reported to be used as a treatment option for LBP by 41% of physiotherapists in the UK (Harte *et al.* 2005) despite the Royal College of General Practitioners concluding that there was little evidence to recommend traction for nonspecific LBP and the NICE Guideline (no.59) stating that traction should not be offered for low back pain or sciatica (National Collaborating Centre for Primary 2009; National Guideline 2016). The lack of consensus across the body of evidence regarding the effect of lumbar traction on LBP is likely to be exacerbated by the fact that there have been widespread variations and a lack of standardisation regarding patient selection, including their characteristics and symptom stratification, as well as traction type and protocol parameters (Alrwaily *et al.* 2018; Harte *et al.* 2005; Madson and Hollman 2015; Tanabe *et al.* 2021; Wegner *et al.* 2013). However, there are numerous studies supporting the effectiveness of manual traction as a conservative treatment for LBP and radicular pain (Apfel *et al.* 2010; Güevenol *et al.* 2000; Hahne *et al.* 2010; Mitchell *et al.* 2017b; Ozturk *et al.* 2006; Prasad *et al.* 2012) with sustained mechanical traction having been observed to increase lumbar intervertebral disc height in asymptomatic patients (Chow *et al.* 2017).

Inversion therapy is an alternative to mechanical traction and has been shown to be an effective treatment for patients with intervertebral disc disease, significantly reducing the need for surgery (Mendelow *et al.* 2021; Prasad *et al.* 2012). A prospective randomised controlled trial observed reduced symptoms and need for surgery in patients with lumbar disc protrusions following 6 weeks of daily self-administered inversion therapy (Mendelow *et al.* 2021). These results provide promising evidence to support the use of traction as an effective intervention for lumbar intervertebral disc disease. However, inversion traction is not always well tolerated, with Güevenol et al (2000) reporting that almost all patients undergoing inverted traction experienced anxiety as well as pain at the ankles. Adverse cardiovascular responses including increased systolic blood pressure and increased ophthalmic arterial pressure have also been reported with inversion therapy (Zito 1988). In addition, inversion traction cannot be maintained for a sustained duration and there is no precise control over the traction force exerted as it is determined by gravity and the weight of the patient. With mechanical traction the treatment parameters can be standardised with the applied traction force accurately specified and controlled, gradually increased over a set time period and sustained for a pre-determined length of time.

Considering the existing evidence, it is proposed that in the presence of a lumbar disc herniation, sustained mechanical traction resulting in increased intervertebral disc height could potentially reduce the disc protrusion and associated nerve root compression, therefore allowing the nerve to be mobilised.

Nerve mobilisation is often part of a comprehensive physiotherapy intervention that aims to improve the mobility of peripheral nerves, such as the tibial nerve. Nerve mobilisation techniques involve the application of gentle manual pressure to the nerve in a specific direction in order to increase its mobility and reduce any restrictions or adhesions that may be present. Studies have shown that nerve mobilisation can improve tibial nerve mobility in asymptomatic individuals with Ellis (2012) reporting that a specific nerve mobilisation technique called "slide and glide" improved tibial nerve mobility in asymptomatic participants. In addition, an increase in nerve mobility has been shown to correlate with a reduction in pain and disability in a group of symptomatic patients (Thoomes *et al.* 2021). However, in the presence of a lumbar disc herniation and subsequent nerve root compression, the effectiveness of a nerve mobilisation exercise is likely to be reduced or completely removed. In fact, a nerve mobilisation exercise will put the nerve under increased strain, potentially exacerbating radiculopathy symptoms and pain (Boyd *et al.* 2012) (Dilley *et al.* 2005). Consequently, for a nerve mobilisation exercise to be effective in the presence of a disc herniation the nerve root compression needs to be reduced or removed to allow mobilisation of the nerve. This study was designed to investigate the effects of sustained mechanical traction, with and without a nerve mobilisation exercise, on tibial nerve mobility and leg pain in patients with a single-level lumbar disc herniation. To our knowledge it is the first study of its kind to assess the effects of mechanical traction on nerve mobility measured via ultrasound imaging in patients with a confirmed diagnosis of lumbar disc herniation.

7.4 MATERIALS AND METHODS

A randomised feasibility study was conducted to investigate the effect of a course (eight sessions) of sustained mechanical lumbar traction on leg pain and tibial nerve excursion in people with a single-level lumbar disc herniation confirmed by MRI.

In line with existing literature which has demonstrated beneficial effects following lumbar traction (Apfel *et al.* 2010; Chow *et al.* 2017; Chung *et al.* 2015; Hahne *et al.* 2010; Mitchell *et al.* 2017b; Ozturk *et al.* 2006; Prasad *et al.* 2012), continuous mechanical traction was applied by the traction unit (Tru-trac Traction Unit, Chattanooga™) on a friction free rolling top traction table (Plinth 2000 Ltd), with the aim of applying a maximum of 45% of body weight of mechanical traction. A continuous mechanical lumbar traction was applied for 30 minutes with bilateral hip flexion of 45 degrees. Traction force was set at 30% of patient body weight for the first session and increased by 5% each session up to a maximum of 45% at session 4, which was then maintained for the remaining sessions.

Ethics Approval and Participant Consent

Ethics approval was granted by the Plymouth Marjon University Research Ethics Panel and written informed consent was obtained from all participants.

7.4.1 Participants

Participants were recruited as an intervention group for a study to investigate the effects of mechanical traction on leg pain and tibial nerve mobility in patients with a confirmed diagnosis of a single-level herniated disc in the lumbar spine.

Inclusion Criteria:

Patients aged between 18 and 60 years (both inclusive)

Diagnosis, confirmed by MRI, of a single-level unilateral lumbar disc protrusion (study recruitment within 6 months of diagnosis)

Patients who have residual leg pain as defined by a positive straight leg raise (SLR) sign (specified as less than 66° movement of the straight leg relative to the longitudinal axis of the trunk that the test reproduced unilateral symptoms in the tested leg)

Exclusion Criteria:

Presence of the following red flag features – bladder/bowel dysfunction, history of cancer, thoracic night pain, previous history of lumbar surgery, saddle anaesthesia

Significant cardio-respiratory disorder

Pregnancy

Weight more than 20% of ideal norms for height and age, or more than 140kg

Participants were randomly assigned to one of two intervention groups; Group 1 Traction: (n = 20), Group 2: Traction + Nerve Mobilisation (n = 15) or a Control group (n = 15). The intervention groups received eight sessions of traction, with or without nerve mobilisation exercises performed under traction, conducted by a Chartered Physiotherapist. Subjects continued with any existing physiotherapy or other treatment they were already receiving prior to participation in the study. Subjects in Group 2 performed three sets of twenty nerve mobilisation exercises during the thirty-minute traction session – at one minute, fifteen minutes and thirty minutes. Control subjects continued with any treatment they were already receiving.

7.4.2 Outcome Measures

All subjects underwent an initial assessment at the start of the study prior to commencing their traction sessions and then a final assessment following completion of their eight traction sessions. Control subjects underwent an initial assessment and were then reassessed four weeks later. All assessments were undertaken by the same assessor; a Chartered Physiotherapist. The assessments consisted of the following objective measurements:

- Patient details - age, height, weight
- Back and leg pain (VAS)
- Tibial nerve mobility
- Lumbar spine and hip biomechanics – lumbar flexion, extension, lateral flexion, rotation
- SLR angle
- Oswestry Disability Index (ODI)

- Psychosocial Testing - Zung Self-Rating Depression Scale and Modified Somatic Perception Questionnaire
- Global Rate of Change Scale (GRCS) – this was included in the final assessment only

The Visual Analogue Scale (VAS) is a validated patient-reported outcome measure that is one of the most commonly used instruments to assess pain in clinical practice (Ferreira-Valente *et al.* 2011; Thong *et al.* 2018). It is the measure most frequently used to assess pain intensity in LBP research studies and predict disability (Chiarotto *et al.* 2019) and has been deemed as a valid assessment tool that can reliably predict disability in patients with LBP (Shafshak and Elnemr 2021). Each patient was asked to identify the appropriate number on a 10-point linear numerical scale that best referred to their level of pain in both the back and their painful leg.

Tibial nerve mobility was assessed via ultrasound recordings of linear arrays centre frequency at 7.5Mhz (Model: HL5-9ED, Medison Co., Ltd, Seoul, South Korea) in all subject groups. The measurement was taken behind the knee in the popliteal fossa during a forward bend movement, using a technique documented and validated by previous research (Coppieters *et al.* 2009; Shum *et al.* 2013; Shum *et al.* 2011). For Group 2 participants tibial nerve mobility during traction was observed at the same anatomical site whilst the patient performed a nerve mobilisation exercise. This involved extending the knee of the painful leg, and with the leg supported in a comfortable and tolerable position, twenty nerve mobilisation exercises were performed via simultaneous ankle plantarflexion and cervical flexion followed by ankle dorsiflexion and cervical extension; a method that has previously been observed to facilitate distal gliding of the tibial nerve (Ellis and Hing 2008). During the neural mobilisation exercise tibial nerve movement was observed and recorded at the popliteal fossa via diagnostic ultrasound.

The image sequences of the diagnostic ultrasound cine-loops were analysed in MATLAB (MathWorks, Natwick, MA, USA) (Shum *et al.* 2013) using a frame-by-frame normalised cross-correlation approach. The tracking programme used a pattern-matching algorithm based on the greyscale pattern present in each of the selected region of interests to find the best match region of interests in sequential frames. Displacement of the nerve in the longitudinal (lateral) and axial (deep/superficial) dimensions were registered for each frame-by-frame matching comparison. The programme also calculated the hypotenuse excursion from the vector combination of longitudinal and axial movement. To minimize bias, the researcher was blinded to each participant's information or grouping during offline data analysis.

Lumbar spine and hip biomechanics were measured within physiological ranges using the three-dimensional inertia measurement unit (ProMove 3D, Inertia Technology, The Netherlands) whilst the subjects were asked to bend forwards, backwards, sideways and rotate to both sides in a standing position. Markers were placed on 4 standardised landmarks on the posterior thigh, sacrum and L1 spinous process. Signals were Analog to Digital converted (200Hz sampling frequency) and stored for offline analysis.

Straight leg raise (SLR) angle was assessed with the patient positioned in supine lying and the leg passively raised as far as could be tolerated to perform a standardised passive SLR test. The maximum angle between the straight leg and the longitudinal axis of the trunk was measured using a digital goniometer.

The Oswestry Disability Index (ODI) is a validated, self-administered questionnaire that evaluates the activities of daily living across 10 sections; pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life (if applicable), social life and travelling, and the effect that the back or leg pain has on those activities and the patient's ability to manage in everyday life (Longo *et al.* 2010). It is widely used to assess functional ability and pain severity in the clinical management of spinal pathologies and is recommended for use in patients who have persistent pain or disability (Garg *et al.* 2020; Longo *et al.* 2010). In addition, it has been shown to be an effective at detecting changes over time (Roland and Fairbank 2000). It is easy to administer and quick to score, making it an efficient assessment tool for both patient and clinician.

The Distress and Risk Assessment Method (DRAM) has been shown to be an effective tool for identifying patients that will benefit from psychological intervention (Hobby *et al.* 2001). In an attempt to identify any subjects who would be indicated for psychological interventions to address their back and leg pain rather than a physical intervention such as traction, this questionnaire was administered to all study participants at the initial assessment.

The Global Rate of Change Scale (GRCS) allows the patient to rate the change in their health status or condition following a specific treatment or intervention (Kamper *et al.* 2009). Such patient-reported outcome tools are commonly used in research and clinical practice to evaluate treatment outcomes and identify any clinically relevant change to a patient's condition (Wang *et al.* 2019). The patient scores their rate of change on a 15-point numerical scale (-7 to +7), with an increase of 5 or more defined as a clinically relevant improvement (Stratford *et al.* 1994).

7.4.3 Statistical Analysis

Mixed analysis of variance (ANOVA) was performed to evaluate the effects of time (before and after intervention) and time-treatment group interaction on the outcome measures of straight leg raise angle, tibial nerve excursion (painful and non-painful leg), lumbar flexion range of motion, hip flexion range of motion and leg pain (VAS) and back pain (VAS).

The within-subject factor would be time, before and after a course of 8 sessions of mechanical traction (with and without a nerve mobilisation exercise) intervention.

The between-subject factor would be the types of intervention including:

- Traction + Usual physiotherapy exercises
- Traction + Nerve mobilisation + Usual physiotherapy exercises.
- Control (Usual physiotherapy)

7.5 RESULTS

An initial assessment was completed by all subjects prior to undergoing any intervention to determine baseline data. No significant differences across any of the outcome measures were identified between the two intervention groups and the control group.

Table 7.1. Comparison of baseline data between intervention and comparison groups pre-intervention (Mean ± Standard deviation)

	Traction only	**Traction plus nerve mobilisation**	**Control**	**P**
Gender	Male 8 Female 7 **Total : 15**	Male 5 Female 6 **Total: 11**	Male 5 Female 8 **Total: 13**	
Age (years)	42.2 ± 11.1	43.8 ± 9.4	45.6 ± 9.2	0.669
Height (cm)	167.7 ± 9.8	169.4 ± 9.1	167.1 ± 11	0.852
Weight (kg)	79.3 ± 18.6	75.7 ± 12.7	82.2 ± 21.3	0.684
Straight Leg Raise Angle Painful Side (°)	49 ± 14.3	48.5 ± 9.3	58.3 ± 13.6	0.108
Straight Leg Raise Angle Non Painful Side (°)	69.6 ± 11.7	72.2 ± 10.7	75.5 ± 6.5	0.3
Back Pian Severity (VAS)	6.6 ± 2.8	6 ± 1.9	6 ± 2.4	0.736
Leg Pain Severity (VAS)	7.1 ± 2.4	7.5 ± 1.8	7 ± 2.3	0.809
Owestry Disbility Index	18.3 ± 7.4	20.2 ± 7	16.5 ± 5.7	0.429
Zung Self-Rating Depression Scale	13.9 ± 3.3	13 ± 4.4	14 ± 3.9	0.789
Modified Somatic Perception Questionnaire	6.1 ± 3.2	6.3 ± 3.3	5.0 ± 2.9	0.559
Completion Rate (%)	75	73.3	86.7	

There were no significant differences between the three groups for any of the outcome measures ($p > 0.05$).

Global Rate of Change Scale:

A significant improvement in GRCS (assessed at the end of the treatment or control period) was observed in both intervention groups with no significant difference between the two treatment groups. There was no significant change observed in the control group.

Table 7.2. GRCS recorded following treatment

	Traction only	**Traction plus nerve mobilisation**	**Control**
GRCS	4.73 ± 1.49*	5.64 ± 0.92**	-0.15 ± 2.04

- *p < 0.05, significant differences between Traction Group and control
- **p < 0.05, significant differences between Traction plus nerve mobilisation Group and control
- No significant differences between Traction Group and Traction plus nerve mobilisation Group (p > 0.05).

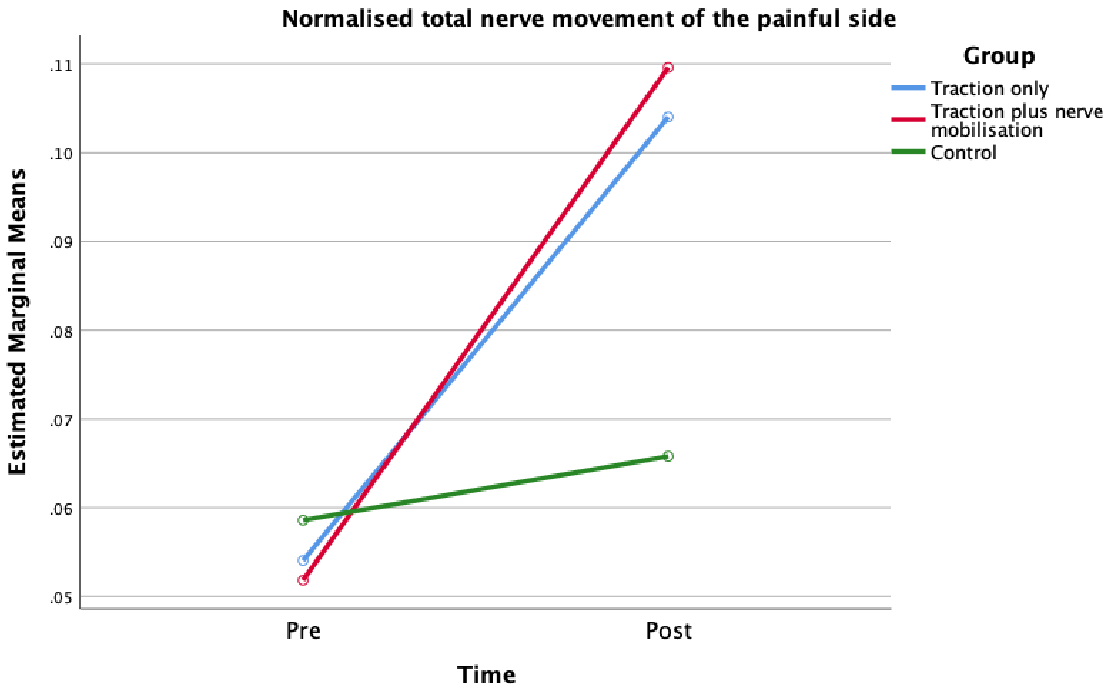
The mean reported GRCS for the traction treatment group was 4.73 (± 1.49) which differed significantly ($p < 0.05$) from the mean score of -0.15 (± 2.04) reported by the control group. The traction plus nerve mobilisation treatment group reported a mean GRCS of 5.64 (± 0.92) which also differed significantly ($p < 0.05$) from the control group reported score. However, there was no significant difference between the reported scores for the two treatment groups.

Tibial nerve movement of the painful side:

There was a significant interaction between time and intervention group observed in the total nerve movement of the painful side ($F(2,36) = 11.474$, $p = 0.000$, effect size = 0.389).

Significant improvement in nerve movement was observed in both the traction group (pre: 0.054 ± 0.011 mm/°; post: 0.104 ± 0.040 mm/°) and traction plus nerve mobilisation group (pre: 0.052 ± 0.009 mm/°; post: 0.110 ± 0.015 mm/°) when compared to the control group (pre: 0.057 ± 0.013 mm/°; post: 0.066 ± 0.015 mm/°). There were no significant differences observed between the traction and traction plus nerve mobilisation group.

Figure 7.1. Normalised total nerve movement (mm/°) of the painful side pre- and post-intervention

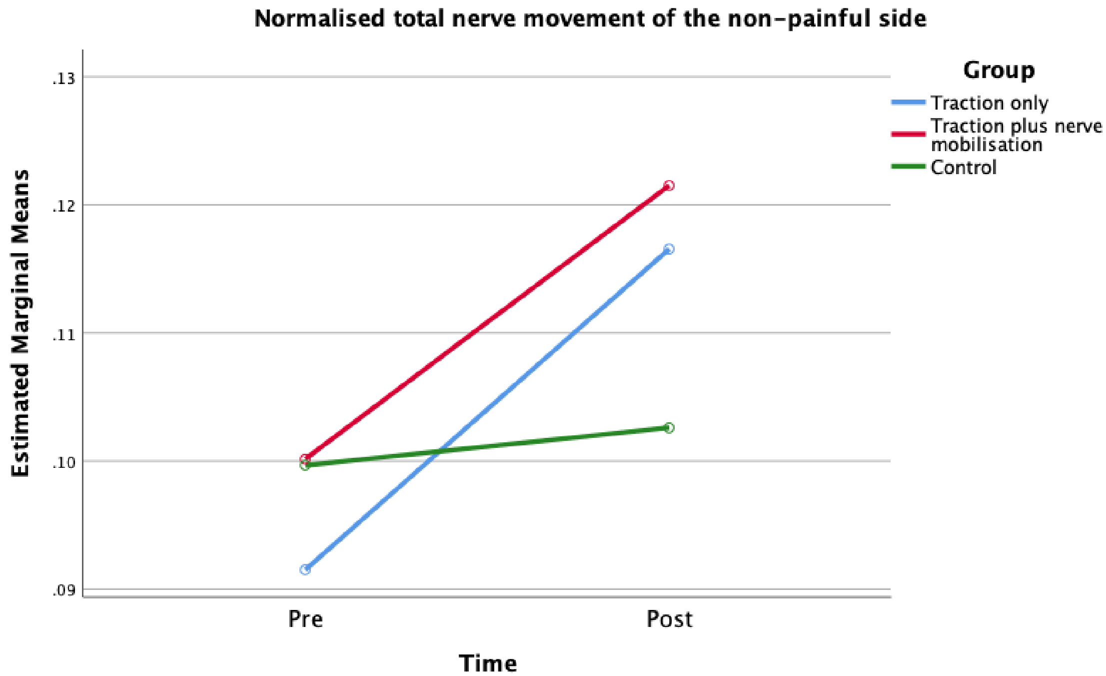


Tibial nerve movement of the non-painful side:

There was no significant interaction between time and intervention group observed in the total nerve movement of the non-painful side (F (2,36) = 1.654, p = 0.205, effect size = 0.084).

No significant improvement in nerve movement was observed between the traction group (pre: 0.092 ± 0.025 mm/°; post: 0.117 ± 0.039 mm/°), traction plus nerve mobilisation group (pre: 0.100 ± 0.019 mm/°; post: 0.122 ± 0.018 mm/°) and control group (pre: 0.099 ± 0.026 mm/°; post: 0.103 ± 0.027 mm/°).

Figure 7.2. Normalised total nerve movement (mm/°) of the non-painful side pre- and post-intervention

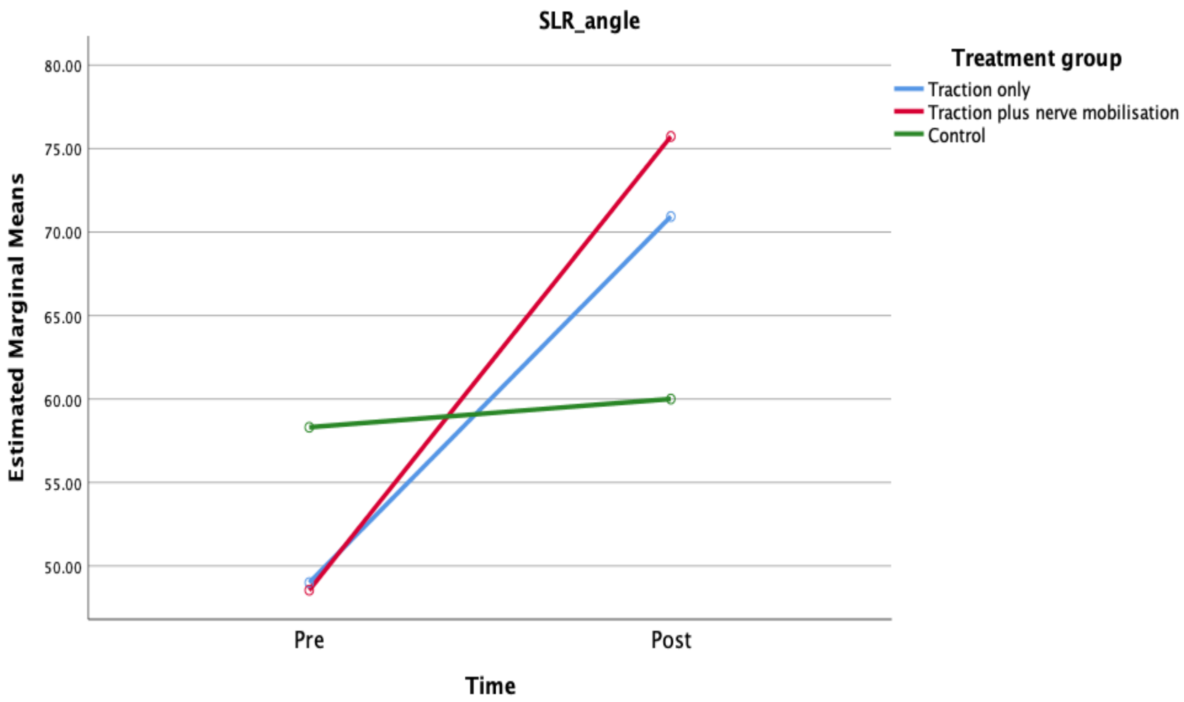


SLR Angle of the painful side:

There was a significant interaction between time and intervention group observed in the straight leg raise angle of the painful side (F (2,36) = 18.768, p = 0.000, effect size = 0.510).

Significant improvement in straight leg raise angle of the painful side was observed in both the traction group (pre: 49.0 ± 14.3°; post: 70.9 ± 5.4°) and traction plus nerve mobilisation group (pre: 48.5 ± 9.3°; post: 75.8 ± 5.0°) when compared to the control group (pre: 58.3 ± 13.6°; post: 60.0 ± 13.5°). There were no significant differences observed between the traction and traction plus nerve mobilisation group.

Figure 7.3. SLR angle (°) of painful side pre- and post-intervention

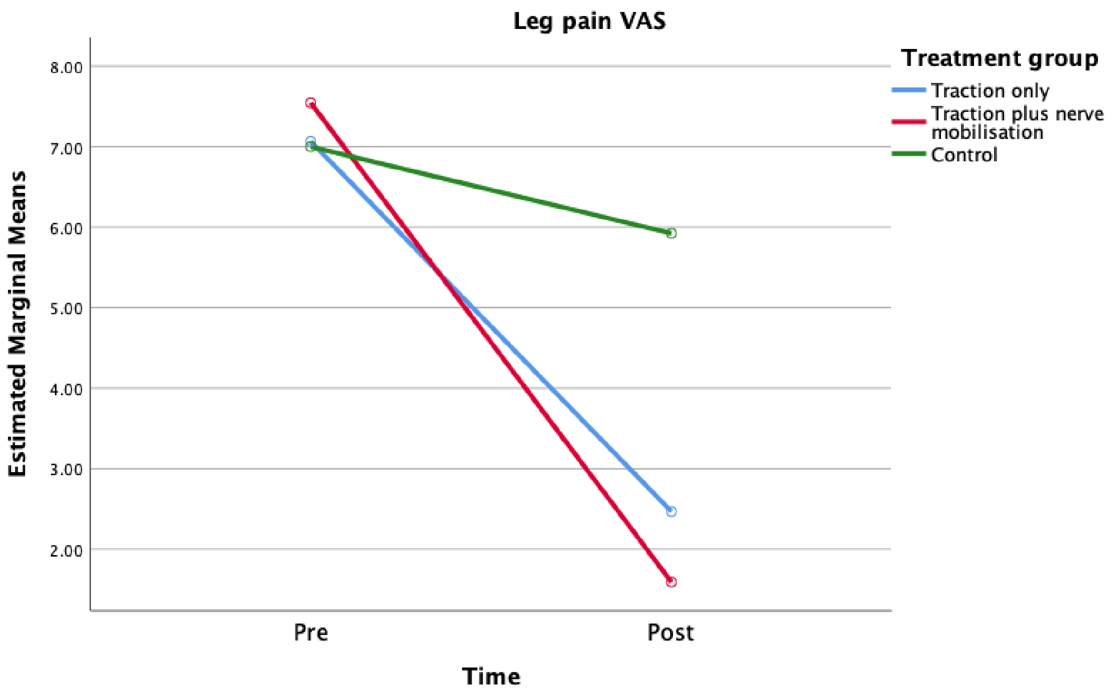


Leg Pain Severity (VAS):

There was a significant interaction between time and intervention group observed in leg pain severity (F (2,36) = 10.719, p = 0.000, effect size = 0.373).

Significant improvement in leg pain severity was observed in both the traction group (pre: 7.1 ± 2.4); post: 2.5 ± 2.8) and traction plus nerve mobilisation group (pre: 7.5 ± 1.8; post: 1.6 ± 2.0) when compared to the control group (pre: 7.0 ± 2.3; post: 5.9 ± 2.8). There were no significant differences observed between the traction and traction plus nerve mobilisation group.

Figure 7.4. Leg Pain Severity (VAS) pre- and post-intervention

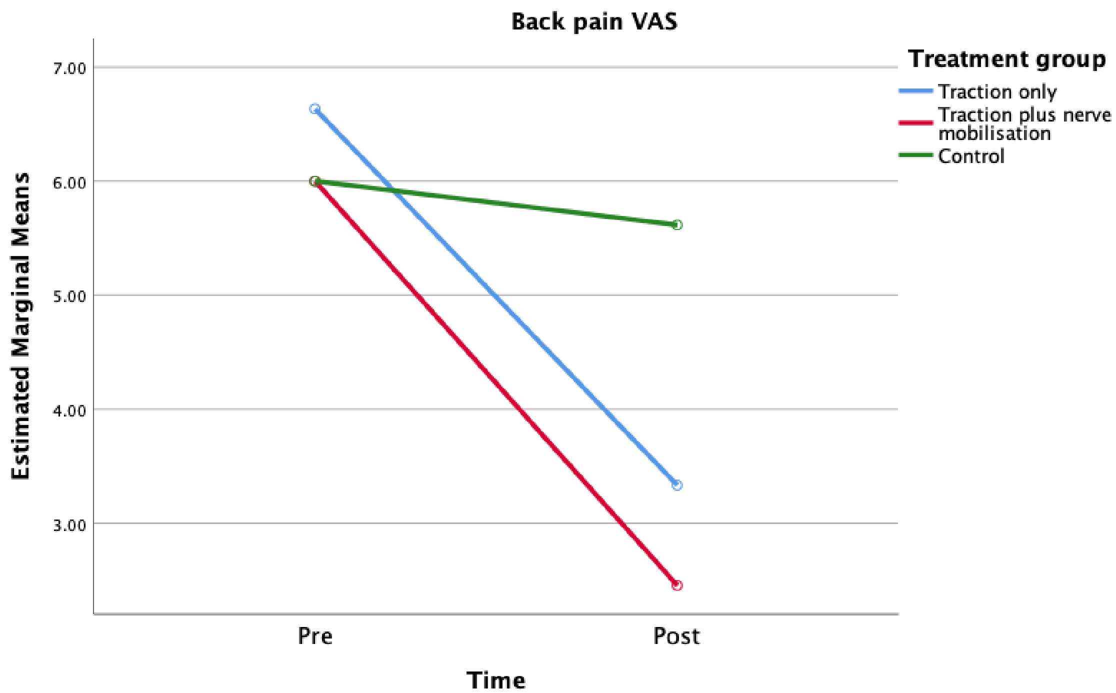


Back Pain Severity (VAS):

There was a significant interaction between time and intervention group observed in back pain severity (F (2,36) = 5.655, p = 0.000, effect size = 0.239).

Significant improvement in back pain severity was observed in both the traction group (pre: 6.6 ± 2.8); post: 3.3 ± 2.4) and traction plus nerve mobilisation group (pre: 6.0 ± 1.9; post: 2.5 ± 2.5) when compared to the control group (pre: 6.0 ± 2.4; post: 5.6 ± 2.9). There were no significant differences observed between the traction and traction plus nerve mobilisation group.

Figure 7.5. Back Pain Severity (VAS) pre- and post-intervention

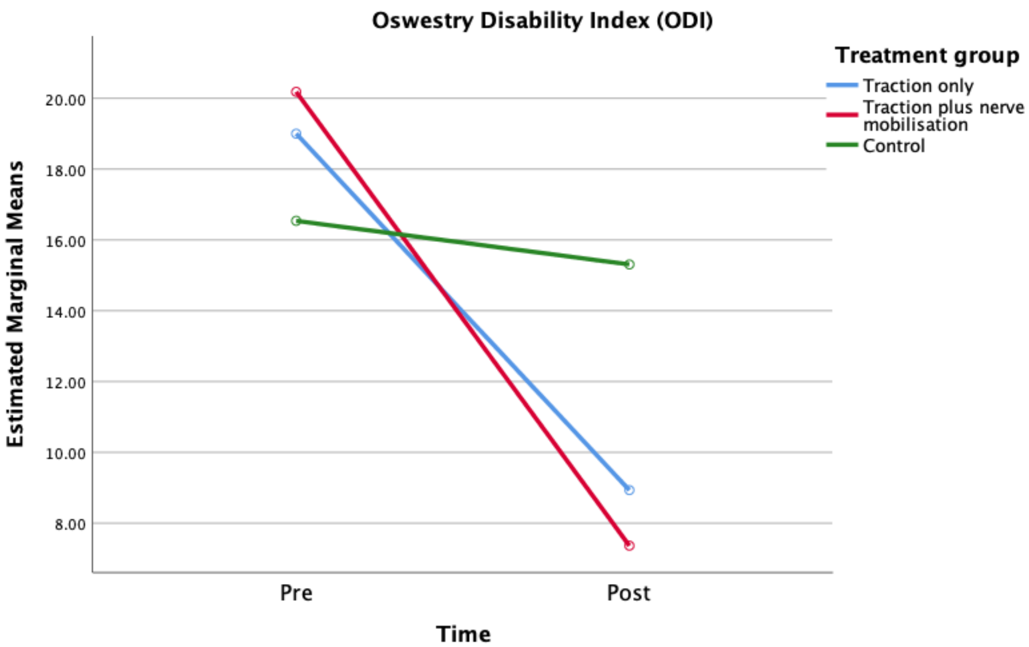


Oswestry Disability Index

There was a significant interaction between time and intervention group observed in ODI (F (2,36) = 8.925, p = 0.001, effect size = 0.331).

Significant improvement in ODI was observed in both the traction group (pre: 18.3 ± 7.4); post: 10.0 ± 8.6) and traction plus nerve mobilisation group (pre: 20.2 ± 6.9; post: 7.4 ± 5.8) when compared to the control group (pre: 16.5 ± 5.7; post: 15.3 ± 5.2). There were no significant differences observed between the traction and traction plus nerve mobilisation group.

Figure 7.6. Oswestry Disability Index pre- and post-intervention



7.6 DISCUSSION

As this was an exploratory study the sample size limits the generalisation of the findings. However, the results of the study suggest that traction is potentially a beneficial intervention for patients with a single-level lumbar disc herniation, as it was shown to reduce leg pain and back pain, as well as increase tibial nerve mobility and SLR angle across both treatment groups. In addition, participants in both treatment groups reported significantly improved GRCS and ODI scores. The changes in the outcome measures observed following treatment were all statistically significant except for tibial nerve mobility of the non-painful leg, for which there was no significant change post intervention for both treatment groups as well as no significant difference between the treatment groups and the control group. There was also a large effect size observed across all the significant variables suggesting that the findings are highly clinically relevant.

In order to evaluate the clinical significance of a study it is important to consider the effect size as well the statistical significance of any findings, both of which should be reported. While evaluating statistical significance determines the presence or absence of an effect, it does not provide any information regarding the size of the effect. Indeed, It has been suggested that effect sizes are the most important outcome of empirical studies as they allow the practical significance of results, in terms of the strength of relationship between the investigated variables, to be determined rather than just the statistical significance (Lakens 2013; Serdar *et al.* 2021; Tomczak and Tomczak 2014). Partial eta squared was used to calculate the effect size of the different variables in the ANOVA calculation. Partial eta squared values range from 0 to 1, with values closer to 1 indicating a higher proportion of variance that can be explained by a specific variable in the ANOVA model after accounting for variance explained by other variables in the model. The effect sizes for mixed ANOVA are small 0.01, medium 0.06 and large 0.14 (Serdar *et al.* 2021).

Generally there was a very large effect size (range 0.239 – 0.510) across the main outcome measures variables which suggests a strong clinical relevance of the observed change in variables observed in both traction groups (Citrome 2014; Serdar *et al.* 2021).

This proof-of-concept randomised study aimed to investigate the effects of mechanical traction on leg pain and tibial nerve mobility in patients with a confirmed diagnosis of a single-level herniated disc in the lumbar spine. However, it is well evidenced that biological, psychological and social factors can all be influential in the development of low back pain (Brunner *et al.* 2013) and it is recognised that psychosocial factors need to be taken into consideration in the management of leg and back pain associated with lumbar radiculopathy (Rogerson *et al.* 2019; Walsh and Hall 2009b). Consequently, the Distress and Risk Assessment Method (DRAM), which has been shown to be an effective tool for identifying patients that will benefit from psychological intervention (Hobby *et al.* 2001), was administered to all study participants to identify any subjects who would be indicated for psychological interventions to address their pain levels rather than a physical intervention such as traction. There were no significant differences identified between the three subject groups in this study in both Zung Self-Rating Depression Scale and Modified Somatic Perception Questionnaire, which are part of DRAM assessment, with the observed results suggesting that the participants in this study were not indicated for any psychological interventions.

There was a significant ($p < 0.05$) difference observed between the patient-reported outcome GRCS between both treatment groups and the control group, with a mean score of 4.73

reported for the traction only group and 5.64 for the traction plus nerve mobilisation group. It is suggested that an increase of 5 or more should be defined as a clinically relevant improvement (Stratford *et al.* 1994), consequently, the observed results can be considered to be relevant to clinical practice, with both traction and traction plus nerve mobilisation, having a positive influence on patient-reported outcome in patients with a lumbar disc herniation.

The ODI showed no significant difference before treatment across all three groups, with a mean score of 18.33 for the traction only group, 20.18 for the traction plus nerve mobilisation group and 16.53 for the control group. However, following treatment there was a significant ($p = 0.000$) change in the ODI for both treatment groups; 10.00 for traction only and 7.36 for traction plus nerve mobilisation. A specific MCID for the ODI has not been agreed in the literature and it is suggested that the clinically relevant value is actually individual to each patient so should not be generalised across all subjects (Schwind *et al.* 2013). However, as the change observed in ODI across both patient groups was statistically significant with a very large effect size, and in addition the change in GRCS in both treatment groups was considered to be clinically relevant, it is suggested that the observed results can be considered to be relevant to clinical practice.

This was one of the first studies regarding mechanical traction that has aimed at establishing a standard protocol for use in future research as well as clinical practice. The protocols and parameters used by previous traction intervention studies were examined and evaluated in terms of their effectiveness at achieving positive outcomes (Apfel *et al.* 2010; Chow *et al.* 2017; Chung *et al.* 2015; Hahne *et al.* 2010; Mitchell *et al.* 2017b; Ozturk *et al.* 2006; Prasad *et al.* 2012). It was identified that continuous mechanical traction appeared to give a more positive outcome than intermittent and that mechanical traction had fewer potential detrimental side effects than inverse traction. In particular Chow et al (2017) demonstrated a significant increase in lumbar intervertebral disc height when a continuous mechanical traction of 42% body weight was applied for 30 minutes as measured by Magnetic Resonance Images which were recorded before and after 30 minutes of horizontal lying and directly after 30 minutes of horizontal traction of 42% body weight.

Standardisation of a traction protocol and parameters, as well as appropriate and specific patient selection, allows for more accurate comparison and critique of research as well as being more applicable to use in a clinical setting. Mechanical traction machines are affordable, standard pieces of therapeutic equipment and the specification of an evidence-based protocol will help to ensure the most beneficial and effective application of this treatment modality in the clinical setting.

Based on the data from this study regarding leg pain severity, with an effect size of 0.373, 90% power and level of significance set at 0.05, a future study would require 24 participants per group, with an equal allocation to each of the three groups, as determined by the G*Power 3 programme (Faul *et al.* 2007). Considering the attrition rate of 25% (traction group) and 26.7% (traction plus nerve mobilisation group) observed in this study, 33 participants per group will need to be recruited in a future study.

7.7 CONCLUSION

This was the first study to our knowledge to investigate the effects of sustained mechanical lumbar traction, with and without a nerve mobilisation exercise, on tibial nerve mobility and leg pain in patients with a confirmed diagnosis of a single-level lumbar disc herniation. Results from this study suggest that sustained mechanical traction can reduce leg pain and increase tibial nerve mobility in patients with a confirmed diagnosis of a single-level lumbar disc herniation. The addition of a nerve mobilisation exercise during traction did not result in any greater benefit than traction alone. The results from this feasibility study support the need for further research in the area in the form of a randomised control trial.

7.7.1 Limitations

A limitation of this study, due to restrictions of time and resources, was a lack of post-study follow-up to assess the longer-term effects of the traction treatment. Consequently, it is unknown if the study participants would have maintained the observed improvements in clinical and biomechanical outcome measures if reassessed over time.

A further limitation of this study was that the assessor was not blinded to the grouping of the participants during the clinical assessments and ultrasound recordings. However, the researcher was blinded to each participant's information and grouping during offline data analysis of the ultrasound nerve mobility data and spinal and hip biomechanical analysis.

There was a relatively high dropout rate of patients, in particular in the traction treatment group. Only two patients reported discomfort during traction as their reason for dropping out, several reported lack of time and most reported that they felt they had sufficiently improved and therefore no longer needed to continue with the treatment. In addition, numerous patients were recruited just before the onset of the Covid-19 pandemic and lockdown restrictions, consequently, their treatment had to be terminated due to lockdown and the research clinic closure. Any future research studies should consider the likelihood of participant dropout and consider the use of more frequent patient follow-up and in-trial communication to try to limit patient dropout. Any patients who do drop out should also be encouraged to complete a final assessment even if not completing the full course of treatment. One of the problems with a treatment trial is that the patient is less motivated to attend further treatment sessions once they start to feel better, especially if the treatment involves a travel commitment and is relatively time-consuming. This study involved the participants having to attend the research clinic twice a week, for 4 weeks, with the traction treatment taking over 45 minutes. Obviously, this is a large commitment in terms of time and also travel costs to attend the research clinic. It is recommended that future studies incorporate a midway assessment, as opposed to just pre and post-intervention assessment, which would be beneficial with respect to data collection as midway data could be used in the results and should ensure there is more available data if participants do drop out. In addition, proposed subject numbers should take into consideration the potential for a high drop-out rate, therefore, ensuring more participants are recruited than would be necessary to satisfy the required number to ensure the study is adequately powered.

7.7.2 Clinical Relevance

The results suggest that eight sessions of sustained mechanical traction can potentially reduce leg pain and improve tibial nerve mobility in patients with a confirmed diagnosis of a single-level lumbar disc herniation. This has strong clinical implications for the management and treatment options for patients with lumbar disc herniation. However, for optimal clinical outcome, it is recommended that a mechanical traction intervention for a single-level lumbar disc herniation adheres to the standard protocol specified in this study:

- Type of Traction: Sustained Mechanical
- Number of Traction Sessions: 8
- Sustained Traction Time: 30 minutes
- Traction Load: 30-45% of patient bodyweight (increasing by 5% each session over 4 sessions)

7.7.3 Future Research

The positive results support the undertaking of a randomised controlled trial (RCT) to further investigate the potential benefits of mechanical traction for patients with a confirmed diagnosis of a single-level lumbar disc herniation. Ideally, this study would involve a longer-term follow-up of such patients to determine if any benefits potentially provided by a course of mechanical traction would be maintained in the longer term. In addition, patient referral to surgery in the longer term could also be investigated. As there was no significant difference identified between the two treatment groups (traction and traction plus nerve mobilisation exercise) it is suggested that only the effects of traction need to be investigated in the future rather than traction plus a nerve mobilisation exercise. Strategies to limit patient dropout should be investigated as the study experienced a relatively high patient dropout rate, despite only two patients reporting discomfort during traction as their reason for dropping out.

CHAPTER EIGHT. DISCUSSION AND CONCLUSIONS

8.1 THE FINANCIAL, SOCIAL AND PERSONAL COSTS OF RADICULOPATHY AND RADICULAR PAIN

Lumbar radiculopathy and radicular pain is a debilitating medical condition that affects many people worldwide and presents a huge challenge and financial cost to patients, healthcare providers and the wider society. There are numerous spinal pathologies that potentially lead to radiculopathy and pain, however, lumbar intervertebral disc disorder is the most commonly diagnosed (Suthar *et al.* 2015) and is reported to be responsible for approximately 90% of spinal pathology cases (Fokter and Yerby 2006). In the UK alone surgery for radicular pain and radiculopathy has been estimated to cost over £100 million per year (Legrand *et al.* 2007) with over 24,000 people undergoing lumbar surgery each year (Weir *et al.* 2017a). Of these patients, it is estimated that between 10 and 40% will continue to experience leg pain and other pre-surgical symptoms despite undergoing technically successful surgery (Eldabe *et al.* 2010); a condition referred to as FBSS, with rates of 35-36.2% reported following lumbar decompression (Cornefjord *et al.* 2000; Fokter and Yerby 2006). These patients experience persistent pain and other pre-surgical symptoms that continue to have a detrimental effect on their daily functions, activities and ability to work. In addition, FBSS has been shown to incur post-surgical healthcare costs over 50% greater than in patients who do not experience post-surgical pain (Weir *et al.* 2017a). Indeed, up to 15% of young, active patients who undergo microdiscectomy surgery will fail to return to work despite technically successful surgery and presenting with no identified re-herniation or lumbar pathology (Dewing *et al.* 2008).

Within the UK, surgical wait times have increased and there has been a significant reduction in new patient surgical referrals, a problem which has been exacerbated by the Covid-19 pandemic (Hampton *et al.* 2021). Consequently, patients with disc herniation and associated radiculopathy may have to wait significant times to be referred for surgery followed by additional waiting time prior to the actual surgery. In addition, some patients may not be appropriate for surgical intervention despite presenting with a lumbar disc herniation. Consequently, it would be beneficial to identify specific interventions that could help relieve radiculopathy and radicular pain associated with intervertebral disc disease for patients pre and post-lumbar surgery. However, there is a lack of evidence regarding interventions that have been shown to improve symptoms associated with radiculopathy as well as many contradictions in terms of recommended treatment options and guidelines.

8.2 FAILED BACK SURGERY SYNDROME – THE START OF THE JOURNEY

The original study for this PhD thesis investigated tibial nerve mobility in two groups of patients post-lumbar surgery; those who had no continuing radicular pain or radiculopathy symptoms following the surgery and those who were still experiencing radicular pain. The research involved assessing and recording excursion of the tibial nerve at the popliteal fossa by an ultra-sound imaging technique that had previously been validated and documented in the literature (Coppieters *et al.* 2009; Shum *et al.* 2013; Shum *et al.* 2011). Following lumbar surgery it is expected that the pre-surgical nerve root compression has been removed and that normal nerve mobility will be resumed. However, despite the patients having undergone technically successful surgery, the results identified decreased tibial nerve mobility in those patients still experiencing pain post-surgery, particularly in the painful leg compared with the non-painful leg. These results suggest that normal nerve mechanics and mobility may not be resumed even though the nerve root compression in the intervertebral canal has been successfully resolved by surgery. Consequently, this initial study identified the potential importance of tibial nerve mobility in both the development and prevention of FBSS. To allow pain-free movement throughout the body peripheral nerves such as the tibial nerve must stretch and glide within the nerve tissue bed to accommodate joint movement whilst still continuing to transmit electrical impulses (Ellis and Hing 2008). Impingement of the nerve root in the intervertebral foramen can potentially inhibit the ability of a peripheral nerve to stretch and glide causing a reduction in nerve excursion, which consequently results in increased neural tension and associated pain (Hunter 1991; Millesi *et al.* 1990). As already mentioned, following technically successful lumbar decompression surgery it is expected that the previously compromised peripheral nerve will return to its full ability to slide and glide, however, our study results suggest that this is not necessarily the case in all patients, and potentially a reason why some patients continue to experience radiculopathy and pain associated with FBSS. Consequently, it is suggested that all patients who undergo lumbar decompression surgery should perform sciatic/tibial nerve mobilisation exercises following surgery.

8.3 TIBIAL NERVE MOBILITY – DOES IT MATTER AND CAN WE CHANGE IT?

The results of the initial study led to the second study documented in this thesis, which aimed to investigate the effectiveness of a nerve mobilisation exercise at improving tibial nerve mobility in post-lumbar surgery patients who were experiencing persistent leg pain. Tibial nerve mobility has been observed by a previously validated ultrasound imaging technique at the popliteal fossa during forward bending in standing, with a mean excursion of 12.2 ± 2.2mm recorded in asymptomatic participants (Shum *et al.* 2013). This significant proximal movement of the tibial nerve during forward bending allows the peripheral nerve tract to accommodate the increase in the nerve bed length induced by lumbar spine flexion (Ellis *et al.* 2008). It was hypothesised that reduced nerve movement could potentially contribute to the persistent leg pain of FBSS and consequently that an increase in tibial nerve mobility could improve the radicular symptoms associated with FBSS. Therefore, the next study investigated the effect of a single ultrasound-guided nerve mobilisation exercise on the SLR angle of patients presenting with FBSS and associated leg pain.

Nerve root compression has been shown to cause peripheral nerve mechanosensitivity which can result in a painful response when the nerve is placed under physical strain during normal movement (Dilley and Bove 2008). A SLR test assesses the mechanosensitivity of the sciatic and tibial peripheral nerves, and following lumbar surgery a positive SLR angle is associated with inferior surgical outcomes (Jönsson and Strömqvist 1999). Significantly reduced SLR angle has been reported in patients with FBSS and associated radicular pain following lumbar decompression surgery compared to a group of non-FBSS patients who underwent the same surgical intervention (Shum *et al.* 2019). In addition, a significantly reduced SLR angle was observed in the painful leg in comparison to the non-painful leg in the FBSS patient group.

Therefore, for the purpose of this research study SLR angle was considered to be an appropriate clinical outcome measure to assess the mechanosensitivity of the tibial nerve in FBSS patients with persistent leg pain. Following a single session of an ultrasound-guided neural mobilisation exercise a 40% improvement in the SLR angle was observed. Consequently, the findings of the study suggested that SLR angle can be increased by performing a single session of tibial nerve mobilisation exercises in a group of patients experiencing FBSS. It was hypothesised that the observed increase in SLR angle was due to an increase in tibial nerve mobility and associated reduction in mechanosensitivity. This suggests that tibial nerve mobility is indeed important and that it can potentially be improved by performing a nerve mobilisation exercise following lumbar decompression surgery. Therefore, it is suggested that tibial nerve 'glide and slide' mobilisation exercises should be included as part of the rehabilitation and recovery programme following lumbar decompression surgery. Further research should focus on establishing a specific protocol regarding the recommended duration and frequency of a nerve mobilisation exercise in post-lumbar decompression surgery patients to facilitate the restoration of optimal nerve mobility and mechanics.

8.4 LUMBAR SURGICAL OUTCOMES – WHAT BIOMECHANICAL AND CLINICAL FACTORS ARE CORRELATED WITH FAVOURABLE PATIENT-REPORTED OUTCOMES?

The second study in this series of investigations suggested that SLR angle and nerve mobility can be influenced in patients with persistent radicular pain post-lumbar decompression surgery by performing a nerve mobilisation exercise. The results of this study demonstrated that a single session of a tibial nerve mobilisation exercise repeated twenty times, produced an immediate improvement in SLR angle. Subsequently, this led to the recommendation that nerve mobilisation exercises should be routinely performed by all patients following lumbar decompression surgery. However, SLR angle is only one variable that is associated with the assessment of lumbar radiculopathy and the next study aimed to identify specific biomechanical factors significantly associated with persistent leg pain in patients post-lumbar decompression surgery. Identifying such variables would have direct clinical implications if these variables could be influenced and improved by specific interventions. Consequently, the third study of the series aimed to investigate biomechanical and clinical variables that are potentially associated with continuing leg pain and patient-reported outcomes in post-operative spinal patients. The main objective of this study was to identify the strength of correlation between both leg pain and GRCS and other specified biomechanical and clinical variables; lumbar flexion, hip flexion, nerve excursion (painful leg), straight leg raise angle (painful leg), back pain (VAS). The results of the study identified that the main biomechanical and clinical variables correlated with leg pain and GRCS in patients following lumbar decompression are lumbar flexion and tibial nerve excursion. In addition, back pain, hip flexion, and straight leg raise angle of the painful leg were also found to be significantly correlated with both leg pain and GRCS. Consequently, it is proposed that interventions to improve lumbar flexion, tibial nerve mobility, back pain and hip flexion could have a beneficial effect on leg pain and GRCS following lumbar decompression surgery. These results have important clinical implications for the management of patients undergoing lumbar surgery and those post-surgical patients experiencing FBSS with associated leg pain as the identified influential variables are all potentially modifiable by specific clinical interventions.

8.5 LUMBAR TRACTION – OLD HAT OR NEW FRONTIER?

Study number four investigated the effect of mechanical traction on tibial nerve excursion in people with a confirmed diagnosis of a lumbar disc herniation. Although traction has been used as an intervention for back pain and spinal pathology for many years (Güevenol *et al.* 2000), the current NICE guidelines for the treatment of low back pain and radicular pain do not recommend the use of traction (National Guideline 2016). However, these recommendations are for generalised radicular pain or sciatica, for which the causes could be multi-factorial, rather than specific to disc pathology. Indeed, numerous studies have identified significant beneficial effects of mechanical traction when used to treat radicular pain caused specifically by disc herniation (Apfel *et al.* 2010; Chow *et al.* 2017; Hahne *et al.* 2010; Mitchell *et al.* 2017b; Ozturk *et al.* 2006; Prasad *et al.* 2012).

Tibial nerve excursion was observed via ultrasound imaging at the popliteal fossa during a nerve mobilisation exercise, before and during sustained mechanical lumbar traction. A lumbar disc herniation can result in an impingement of the sciatic nerve root in the intervertebral foramen which can subsequently cause a reduction in nerve excursion along the distribution of the sciatic nerve (Kobayashi *et al.* 2010). In fact, a reduction in sciatic nerve mobility of up to 66.6% has been observed in people with lumbar intervertebral disc herniation (Rade *et al.* 2017). Nerve mobilisation techniques have been shown to result in improved neural excursion by generating a sliding movement between the neural structures and their surrounding non-neural tissues (Basson *et al.* 2017; Ellis 2012; Nee and Butler 2006). However, in the presence of a lumbar disc herniation, the effectiveness of a nerve mobilisation exercise is reduced, if not completely removed, due to the compression and subsequent restriction of the nerve root in the intervertebral canal. Nerve root compression prevents the peripheral nerve from being able to slide and glide along its length which results in the nerve being placed under increased stretch and strain which is likely to result in an exacerbation of mechanosensitivity and radicular pain (Boyd *et al.* 2012) (Dilley *et al.* 2005). Consequently, for a nerve mobilisation technique to be effective at increasing nerve excursion the nerve root compression must be relieved or adequately reduced.

Although there is conflicting evidence to support its effectiveness, traction has been used as a treatment for LBP for many years (Clarke *et al.* 2007; van der Heijden *et al.* 1995) and was reported to be used as an intervention for LBP by 41% of physiotherapists in the UK (Harte *et al.* 2005). Sustained mechanical traction has been shown to produce an increase in disc height (Chow *et al.* 2017) and also a distraction of the vertebral bodies and associated widening of the intervertebral canal (Kane *et al.* 1985). Consequently, it is hypothesised that mechanical traction could have a positive effect on a disc protrusion or herniation resulting in decreased compression of the affected nerve root. This hypothesis led to the design of study four to investigate the effect of sustained mechanical traction on tibial nerve mobility in patients with a confirmed diagnosis of a lumbar disc herniation. Previous research has demonstrated that nerve mobility can be improved with a nerve mobilisation exercise (Coppieters *et al.* 2015; Coppieters *et al.* 2009; Ellis *et al.* 2021; Shum *et al.* 2013), however, in the presence of a disc herniation and the subsequent compression of the nerve root in the intervertebral foramen, the neural mobility that can be elicited by a nerve mobilisation exercise is likely to be reduced or absent. The study aimed to investigate whether tibial nerve mobility could be improved under mechanical traction, which required the design of an effective traction protocol. An examination of the existing literature identified a dearth of consistent evidence regarding traction type and protocols across previous studies, with a lack of specification and standardisation of traction protocols (Alrwaily *et al.* 2018). In addition, there were very few studies that involved symptomatic patients who had a confirmed diagnosis of intervertebral disc disease. Traction types include mechanical traction and inversion therapy and can be applied as a sustained or intermittent traction force. The applied traction force also varied greatly across the literature, as did treatment duration and frequency. Evaluation of the existing research suggested that sustained mechanical traction of 30 minutes, with a load of 30-45% of patient body weight provided the most beneficial outcome for patients with an intervertebral lumbar disc herniation. The study involved the patient performing a tibial nerve mobilisation exercise following five minutes and thirty minutes of sustained mechanical lumbar traction, with tibial nerve excursion measured via ultrasound imaging at the popliteal fossa, during the nerve mobilisation exercise. Improved tibial nerve mobility was observed following thirty minutes of traction compared with the nerve mobility observed after five minutes of traction. This supported the hypothesis that nerve root compression, and subsequently peripheral nerve mobility, could potentially be improved with sustained mechanical traction.

Significant findings from the first four studies:

- Tibial nerve mobility was decreased in patients with FBSS
- Increased tibial nerve excursion was observed during a nerve mobilisation exercise in patients with FBSS
- SLR angle increased following a nerve mobilisation exercise in patients with FBSS
- Leg pain and patient-reported GRCS are strongly correlated with lumbar flexion and tibial nerve mobility
- Leg pain and patient-reported GRCS are also correlated with back pain, hip flexion, and straight leg raise angle of the painful leg
- Tibial nerve mobility improved during sustained mechanical traction in patients with a confirmed diagnosis of a lumbar disc herniation

These findings have clinical implications for the treatment and management of people with a lumbar intervertebral disc herniation, whether they have received surgical intervention or not. Following the increased nerve mobility observed during traction in study four it was deemed pertinent to further investigate the potential beneficial effects of mechanical lumbar traction in patients with a confirmed diagnosis of a herniated lumbar intervertebral disc. Consequently, the final study undertaken as part of this PhD project was to investigate the effect of a course of eight sustained mechanical traction sessions on people with a confirmed diagnosis of a lumbar disc herniation, both with and without a nerve mobilisation exercise. The study consisted of volunteer participants who had all been diagnosed with a lumbar intervertebral disc herniation, via MRI within the last six months. Participants were randomly allocated to one of three groups: traction, traction with nerve mobilisation or control. This was a feasibility study to determine if a future randomised controlled trial was warranted. The results suggest that traction is an effective intervention to manage lumbar disc herniation. Patients in the treatment groups reported a decrease in both back pain and leg pain, an improved SLR angle in the painful leg and a positive GRCS patient-reported outcome. Increased tibial nerve mobility was also observed in both treatment groups, with no significant difference in nerve mobility observed between the two treatment groups. These results suggest that sustained mechanical traction is a potentially beneficial treatment option for patients with a confirmed diagnosis of lumbar disc herniation and that no additional benefits regarding nerve mobility are achieved by the patient performing a nerve mobilisation exercise during traction. The results support the future undertaking of a randomised controlled trial (RCT) to further investigate the treatment option of mechanical lumbar traction to determine if the beneficial effects of traction are maintained long-term and also if they could potentially reduce the need for surgery in this patient cohort. Currently, there are few evidence-based, effective treatment options available to patients with a lumbar disc herniation and as previously mentioned wait times for surgery are increasing. Consequently, effective treatments that are supported by robust evidence would provide much needed relief to patients and healthcare providers.

A major consideration regarding traction as a potential treatment option is the consideration of patient stratification, which involves the division of a potential patient group into specific subgroups or cohorts. In the past traction has been used as a treatment for generalised low back pain without identifying a specific patient cohort that would be most likely to benefit from the treatment. Low back pain is a commonly occurring condition, for which there are varying causal factors and influences. With respect to traction as a treatment technique, the research suggests that it is not an effective intervention for patients with generalised low back pain (Alrwaily *et al.* 2018; Borman *et al.* 2003; Madson and Hollman 2015; Maher *et al.* 2017; Tanabe *et al.* 2021), however, studies that have reported beneficial outcomes of traction have involved a specific cohort of back pain patients with intervertebral disc disease and disc herniation (Apfel *et al.* 2010; Chow *et al.* 2017; Güevenol *et al.* 2000; Hahne *et al.* 2010; Mitchell *et al.* 2017b; Ozturk *et al.* 2006; Prasad *et al.* 2012). Consequently, the mechanical traction studies undertaken for this PhD only recruited patients with a recently confirmed diagnosis of a lumbar disc herniation. Therefore, the recommendations from these traction research studies only apply to that specific patient cohort with a single-level lumbar disc herniation and cannot be generalised to a wider patient group of people with non-specific low back pain.

8.6 FINAL THOUGHTS AND COMMENTS

The undertaking of this PhD has been a journey involving a large number of patients from varying backgrounds, circumstances and professions. Although the main area of investigation for each of the studies involved in this PhD was tibial nerve pathomechanics and associated nerve movement, the major concern of each patient was the fact that they had continuing radiculopathy and pain associated with their spinal pathology, which in turn had a detrimental effect on their lives and ability to undertake daily activities. I saw many of these patients on a regular basis and, as a consequence, gained an insight into their lives and particularly the detrimental effect that the pain had on their professional and personal lives. Some patients could no longer do their job, some couldn't look after their children, some could no longer drive, some couldn't sit down. Sadly most could no longer do things in their lives that they used to be able to do with ease. Unfortunately, most felt that there were no further treatment options available, other than surgery for the patients that had not already undergone surgery. The patients that had undergone lumbar surgery and developed FBSS were particularly despondent, as obviously they had expected the surgery to relieve their radicular pain and they were left with few remaining treatment options. The common factor across all these patients was that the pain associated with their spinal condition had a huge negative effect on their lives. To be able to offer evidence-based interventions that could potentially reduce radiculopathy and pain in patients with a lumbar disc herniation, or those suffering with FBSS, has been the continuing motivation behind the completion of this thesis and continues to motivate me in my work as a Chartered Physiotherapist. Pain is terribly debilitating for so many people and as responsible, ethical clinicians we must strive to alleviate or control pain by the use of evidence-based clinical practice and interventions. The five studies undertaken for this PhD all present innovative research and techniques that have not been previously investigated. In particular, nerve mobility in patients with a confirmed diagnosis of a lumbar disc herniation or following lumbar decompression surgery has not been previously researched. The research I have undertaken for this PhD adds to the body of evidence regarding tibial nerve pathomechanics and lumbar radiculopathy and will hopefully be beneficial to patients who have the misfortune to experience a lumbar disc herniation or Failed Back Surgery Syndrome.

8.7 RESEARCH LIMITATIONS

The main limitation was the relatively high dropout rate of patients in study five. In particular, we saw a high number of dropouts in the traction treatment group. Only two patients reported discomfort during traction as their reason for dropping out, several reported lack of time and most reported that they felt they had sufficiently improved and therefore no longer needed to continue with the treatment. In addition, numerous patients were recruited just before the onset of the Covid-19 pandemic and lockdown restrictions, consequently, their treatment had to be terminated due to lockdown and the research clinic closure. Any future research studies should consider the likelihood of participant dropout and consider the use of more frequent patient follow-up and in-trial communication to try to limit patient dropout. Any patients who do drop out should also be encouraged to complete a final assessment even if not completing the full course of treatment. One of the problems with a treatment trial is that the patient is less motivated to attend further treatment sessions once they start to feel better, especially if the treatment involves a travel commitment and is relatively time-consuming. Study 5 involved the patients having to attend a university clinic on the outskirts of the city, twice a week, for 4 weeks, with the traction treatment taking 45 minutes. For future similar studies a midway assessment, as opposed to just pre and post-intervention assessment, would be beneficial with respect to data collection as midway data could be used in the results and should ensure there is more available data if patients do drop out. In addition, proposed subject numbers should take into consideration the potential for a high drop-out rate, therefore, ensuring more participants are recruited than would be necessary to satisfy the required number to ensure the study is adequately powered. Indeed, based on the data from study five regarding leg pain severity with an effect size of 0.373, to achieve

90% power with the level of significance set at 0.05, a future study would require 24 participants per group, with an equal allocation on each of the three groups, as determined by the G*Power 3 programme (Faul *et al.* 2007). Considering the attrition rate of 25% (traction group) and 26.7% (traction plus nerve mobilisation group) observed in this study, 33 participants per group will need to be recruited in a future study.

Study five would also have benefited from patient follow-up assessments being completed several months after the patient had completed the study. Unfortunately, this study was interrupted prior to completion by the onset of the Covid-19 pandemic and lockdown restrictions which led to closure of the research clinic.

8.8 CLINICAL IMPLICATIONS

- Tibial nerve 'glide and slide' mobilisation exercises should be included as part of the rehabilitation and recovery programme following lumbar decompression surgery.
- Back pain should be controlled following lumbar decompression surgery.
- Lumbar and hip mobility exercises should be included as part of the rehabilitation and recovery programme following lumbar decompression surgery.
- A course of sustained mechanical lumbar traction should be considered as an intervention to reduce leg pain and improve tibial nerve mobility in patients with a confirmed diagnosis of a single-level lumbar disc herniation.

It is recommended that a mechanical traction intervention for a single-level lumbar disc herniation adheres to the standard protocol specified in this study:

- Type of Traction: Sustained Mechanical
- Number of Traction Sessions: 8
- Sustained Traction Time: 30 minutes
- Traction Load: 30-45% of patient body weight (increasing by 5% each session over 4 sessions)

8.9 FUTURE RESEARCH RECOMMENDATIONS

Results from the statistical analysis reported in paper 3 support the investigation of the effects of reducing back pain, improving lumbar and hip flexion and improving tibial nerve mobility on leg pain in patients experiencing FBSS post-spinal decompression surgery. Future research should aim to determine if FBSS and associated leg pain could be reduced by influencing back pain, lumbar and hip flexion, and tibial nerve mobility in patients following spinal decompression surgery. This would provide further evidence to support treatment options for patients with FBSS and potentially help to reduce the financial and social costs of FBSS currently experienced by healthcare providers and the wider society.

The positive results from the final study support the undertaking of a randomised controlled trial (RCT) to further investigate the potential benefits of mechanical traction for patients with a confirmed diagnosis of a single-level lumbar disc herniation. Ideally, this study would involve a longer-term follow-up of such patients to determine if any benefits potentially provided by a course of mechanical traction would be maintained in the longer term. In addition, patient referral to surgery in the longer term could also be investigated. As study five did not identify any significant differences between the two treatment groups (traction and traction plus nerve mobilisation exercise) it is suggested that only the effects of traction need to be investigated rather than traction plus a nerve mobilisation exercise. Strategies to limit patient drop out should be investigated as study five experienced a relatively high patient dropout rate, despite only two patients reporting discomfort during traction as their reason for dropping out.

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APPENDICES

APPENDIX ONE. Consent Form Template

TITLE OF RESEARCH PROJECT

The effects of pre-operative mechanical traction for patients with a confirmed diagnosis of disc herniation awaiting discectomy on pain and sciatic nerve mechanics.

Name of Researchers: SALLY CINNAMOND (PHD STUDENT), PROFESSOR GARY SHUM, PROFESSOR SAUL BLOXHAM

Version 2: 8 January 2018

I confirm that I have read and understand the participant information sheet dated 28/10/17 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

I understand that my participation is voluntary and that I am free to withdraw at any time without providing a reason.

I understand that data collected during the study may be looked at by individuals from the University of St Mark & St John for regulatory purposes. I give permission for these individuals to have access to my data.

I understand that participation will include lumbar traction.

I understand that the results of the study may be published and / or presented at meetings or conferences and may be provided to research funders. I give my permission for my anonymised data to be disseminated in this way.

I consent to the data being stored and retained for any future research approved by a Research Ethics Committee

I understand that data will be encrypted and stored on a password protected laptop in password protected files using a strong password. Data will also be stored on a password protected ultrasound machine, although no personal information will be recorded and stored on the ultrasound machine.

I agree to take part in the above study

Signed ………………………………………………………………………………. (Research participant)

Print name ……………………………………………………………………… Date ……………………………………………

Signed ……………………………………………………………………………… (Researcher taking consent)

Print name ……………………………………………………………………… Date ……………………………………………

APPENDIX TWO. Participant Information Sheet

Title of study: The effects of pre-operative mechanical traction for patients with a confirmed diagnosis of disc herniation awaiting discectomy on pain and sciatic nerve mechanics.

Version 3: 8 January 2018

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Please ask us if there is anything that is not clear and take time to decide whether or not you wish to take part.

What is the purpose of the study?

People with pain in the leg originating from the back or spine sometimes require spinal surgery to remove a herniated intervertebral disc; this surgical procedure is called a discectomy.

There is some information to suggest that lumbar spine traction can help relieve pain and symptoms of a herniated disc and may even lead to the prevention of surgery.

The primary purpose of the study is to determine the effects of traction on pain associated with a herniated lumbar disc and the influence of traction on the movement of the sciatic nerve in people with a herniated lumbar disc and associated residual leg pain. Traction involves lying on a couch with a harness around your hips which is attached to the traction machine. The machine applies a force which pulls on your pelvis to provide tension to the lumbar spine. This force is maintained for 30 mins. You will feel tension in the back but it should not be painful or uncomfortable. The treatment can be stopped by yourself (by pressing a button) at any time if you feel discomfort or for any other reason. The following photos show a patient receiving traction for a disc herniation:

Why have I been invited?

You have been invited because the study needs to assess a potentially beneficial treatment for people with a herniated lumbar disc and associated residual leg pain. A total of one hundred and twenty participants will be recruited.

Do we have to take part?

No. It is entirely up to you whether or not to take part. If you decide to take part, you may choose to withdraw at any time without giving any reason. If you decide not to take part your usual healthcare will not be affected in any way.

If you decide to take part, you will be asked to sign a consent form. We would, with your permission, send a letter to your GP informing them of your involvement in the study.

What will happen to me if I take part?

If you decide to take part you will be asked to attend for assessment and treatment at the Sports Therapy Clinic, The Sports Centre, Plymouth Marjon University, Derriford Road, Plymouth.

During the assessment you will be asked to answer a few questions about your level of discomfort, type of medications you are taking and whether you have any additional conditions that affect back movement that would prevent you from participating in the study.

You will also be asked to complete 2 questionnaires which will be used to assess your level of distress and function as result of your condition. If you do not feel comfortable answering any of the questions then you are under no obligation to complete the questionnaire and specific questions can be left blank if you prefer.

Patients that are identified as at risk will be excluded from the study and referred to their GP to discuss potential treatment.

It is anticipated that the completion of the questionnaires will take around 10 minutes. All usual medication should be continued.

The assessment will involve the following movements that you will be asked to repeat three times:

- Forward and backward bending in a standing position
- Side bending in a standing position

For each task, you will be asked to move as far as you feel comfortable. During each task we will measure the movement of your back and hips using sensors that will be attached to your back and thighs with Velcro straps.

At the same time, we will measure the movement of your sciatic nerve at the back of your thigh and knee using ultrasound imaging. There are no adverse effects associated with ultrasound imaging and it is completely painless.

Following the assessment, you will be randomly allocated to a treatment group. Some people will receive traction treatment which will last for 30 minutes. Other people will be assessed but receive no traction, however, they will be instructed to continue with any existing physiotherapy treatment that is currently being undertaken. After completion of the assessment, and traction procedure if applicable, we will repeat the measurement of the movement of your sciatic nerve.

The whole process will take about 75 minutes if traction is undertaken or 45 minutes if no traction is undertaken. You can rest during any part of the testing. There is no known risk associated with any of the processes in this study. The assessment of back movement and ultrasound scanning are non-invasive techniques. They do not involve any radiation and there are no known harmful effects. All movements will be performed within a range that does not cause any discomfort.

To summarise if you chose to participate you will be invited to attend an assessment and treatment session at Plymouth Marjon University Sports Therapy Clinic which will consist of:

1. Initial consultation with the treating physiotherapist regarding the history of your condition and current symptoms

2. Completion of questionnaires – questions can be omitted if you do not feel comfortable answering any of them

3. Physiotherapy assessment of lumbar spinal movement and sciatic nerve movement

4. If randomised into the traction treatment group traction will be performed for 30 mins

5. Repeated measurement of sciatic nerve movement

What if there is a problem?

The tests performed are all non-invasive and the movements performed will all be within a pain free range. However, if you do feel any worsening of symptoms after the test procedure, you should initially seek medical advice from your General Practitioner. In the case of an acute, severe increase in pain outside of GP surgery hours you should attend the Accident and Emergency Department of Derriford Hospital. In the event of an increase in pain you should also contact the research team. The research teams contact details are at the bottom of the form.

What are the possible benefits of taking part?

There may be immediate benefit for individuals who take part in this study in terms of pain reduction and improved mobility. The data from this project will provide a foundation for future research and inform clinical trials into the management of herniated disc and associated leg pain.

Will what I say in this study be kept confidential?

All aspects of the study including the results will be strictly confidential and only the research team will have access to information on participants. All data will be stored electronically on a computer at the principal investigator's office. Data will be encrypted and stored on a password protected laptop in password protected files using a strong password that in accordance with the University's in-house advice will be at least 14 characters, using a mix of UPPER and lowercase, numbers and symbols. Access to the laptop will be locked at all times and the laptop will lock automatically if left inactive for one minute. In addition, there will be a clear separation kept between the personal data processed on behalf of the data controller and that processed for the device owner's own purposes. Data will also be stored on a password protected ultrasound machine, although no personal information will be recorded and stored on the ultrasound machine.

Steering group invitation

You are also invited to join a steering group to discuss the feasibility of the study and suggestions for future work and to help develop protocols for future work.

What should I do if I want to take part?

Please contact :

Sally Cinnamond,

Plymouth Marjon University, Derriford Road, Plymouth, PL6 8BH

Tel : 07969 157507

Email: cinnamond.s@pgr.marjon.ac.uk

What will happen to the results of the research study?

A report of the study will be submitted for publication in medical journals, but individual participants will not be identified in such report. A brief report of the study findings will be sent to participants who request it. You will have the right to request access to your own personal data.

Who has funded and reviewed the research?

The study is funded and reviewed by Plymouth Marjon University.

This project has been reviewed and approved by the Marjon Ethics Committee.

Contact for Further Information

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through Marjon Research Office

Tel: 01752 636700 (Ext. 6514)

Email: research@marjon.ac.uk

If you have any further questions or require clarification please feel free to contact:

Sally Cinnamond (Chartered Physiotherapist; MCSP, HCPC, and PhD. Research Scholar)

Tel : 07969 157507

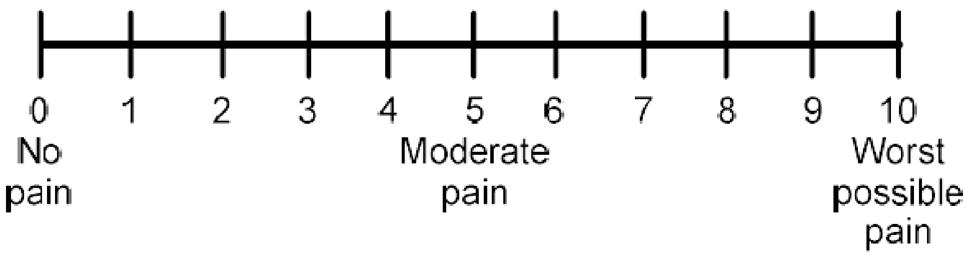
Email : cinnamond.s@pgr.marjon.ac.uk

Thank you for reading this information sheet.

You should be given a copy of this information sheet and a consent form.

APPENDIX THREE. Numeric Pain Rating Scale (VAS)

(From Jensen MP, Karoly P, Braver S. The measurement of clinical pain intensity: a comparison of six methods. *Pain* 1986;27:117-126.)



APPENDIX FOUR. Global Rate of Change Scale

(From Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. *Control Clin Trials* 1989;10:407-415)

Please rate the overall condition of your neck pain and upper limb referred pain and/or paraesthesia from the time that you began treatment until now (check only one):

A very great deal worse (-7)	About the same (0)	A very great deal better (+7)
A great deal worse (-6)		A great deal better (+6)
Quite a bit worse (-5)		Quite a bit better (+5)
Moderately worse (-4)		Moderately better (+4)
Somewhat worse (-3)		Somewhat better (+3)
A little bit worse (-2)		A little bit better (+2)
A tiny bit worse (almost the same (-1)		A tiny bit better (almost the same (+1)

APPENDIX FIVE. Oswestry Disability Index

(From Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine. 2000; 25: 2940-52.)
Please complete this questionnaire. It is designed to give us information as to how your back or leg trouble has affected your ability to manage in every day life. Please answer **every section**. Mark **one box only** in each section that most closely describes you **today.**

Section 1 – Pain intensity in back and/or legs

- ☐ I have no pain at the moment.
- ☐ The pain is very mild at the moment.
- ☐ The pain is moderate at the moment.
- ☐ The pain is fairly severe at the moment.
- ☐ The pain is very severe at the moment.
- ☐ The pain is the worst imaginable at the moment.

Section 2 – Personal care (e.g. washing, dressing)

- ☐ I can look after myself normally without causing extra pain.
- ☐ I can look after myself normally, but it is very painful.
- ☐ It is painful to look after myself, and I am slow and careful.
- ☐ I need some help, but I manage most of my personal care.
- ☐ I need help every day in most aspects of self care.
- ☐ I do not get dressed, I wash with difficulty, I stay in bed.

Section 3 – Lifting:

- ☐ I can lift heavy weights without extra pain.
- ☐ I can lift heavy weights, but it gives me extra pain.
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g., on a table.
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can only lift very light weights.
- ☐ I cannot lift or carry anything at all.

Section 4 – Walking:

- ☐ Pain does not prevent me from walking any distance.
- ☐ Pain prevents me from walking more than 1 mile.
- ☐ Pain prevents me from walking more than ½ of a mile.
- ☐ Pain prevents me from walking more than 100 yards.
- ☐ I can only walk using a stick or crutches.
- ☐ I am in bed most of the time and have to crawl to the toilet.

Section 5 – Sitting:

- ☐ I can sit in any chair for as long as I like.
- ☐ I can sit in my favorite chair for as long as I like.
- ☐ Pain prevents me from sitting more than 1 hour.
- ☐ Pain prevents me from sitting more than ½ an hour.
- ☐ Pain prevents me from sitting more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

Section 6 – Standing:

- ☐ I can stand as long as I want without extra pain.
- ☐ I can stand as long as I want but it gives me extra pain.
- ☐ Pain prevents me from standing for more than 1 hour.
- ☐ Pain prevents me from standing for more than ½ an hour.
- ☐ Pain prevents me from standing for more than 10 minutes.
- ☐ Pain prevents me from standing at all.

Section 7 – Sleeping

- ☐ My sleep is never disturbed by pain.
- ☐ My sleep is occasionally disturbed by pain.
- ☐ Because of pain, I have less than 6 hours of sleep.
- ☐ Because of pain, I have less than 4 hours of sleep.
- ☐ Because of pain, I have less than 2 hours of sleep.
- ☐ Pain prevents me from sleeping at all.

Section 8 – Sex Life (if applicable)

- ☐ My sex life is normal and causes no extra pain.
- ☐ My sex life is normal but causes some extra pain.
- ☐ My sex life is nearly normal but is very painful.
- ☐ My sex life is severely restricted by pain.
- ☐ My sex life is nearly absent because of pain.
- ☐ Pain prevents any sex life at all.

Section 9 – Social Life:

- ☐ My social life is normal and causes me no extra pain.
- ☐ My social life is normal but increases the degree of pain.
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g., sports, etc.
- ☐ Pain has restricted my social life and I do not go out as often.
- ☐ Pain has restricted social life to my home.
- ☐ I have no social life because of pain.

Section 10 – Traveling:

- ☐ I can travel anywhere without pain.
- ☐ I can travel anywhere, but it gives extra pain.
- ☐ Pain is bad, but I manage journeys over two hours.
- ☐ Pain restricts me to journeys less than one hour.
- ☐ Pain restricts me to short necessary journeys less than 30 minutes.
- ☐ Pain prevents me from traveling except to receive treatment.

APPENDIX SIX. Scoring System of the Distress and Risk Assessment Method

Modified Somatic Perception Questionnaire

Please describe how you have felt during the PAST WEEK by marking a check mark (√) in the appropriate box. Please answer all questions. Do not think too long before answering.				
	Not at all	A little, slightly	A great deal, quite a bit	Extremely, could not have been worse
Heart rate increase	0	1	2	3
Feeling hot all over	0	1	2	3
Sweating all over				
Sweating in a particular part of the body				
Pulse in neck				
Pounding in head				
Dizziness	0	1	2	3
Blurring of vision	0	1	2	3
Feeling faint	0	1	2	3
Everything appearing unreal				
Nausea	0	1	2	3
Butterflies in stomach				
Pain or ache in stomach	0	1	2	3
Stomach churning	0	1	2	3
Desire to pass water				
Mouth becoming dry	0	1	2	3
Difficulty swallowing				
Muscles in neck aching	0	1	2	3
Legs feeling weak	0	1	2	3
Muscles twitching or jumping	0	1	2	3
Tense feeling across forehead	0	1	2	3
Tense feeling in jaw muscles				

Modified Zung Depression Index

Please indicate for each of these questions which answer best describes how you have been feeling				
	Rarely or none of the time (less than 1 day per week)	Some or little of the time (1-2 days per week)	A moderate amount of time (3-4days per week)	Most of the time (5-7 days per week)
1. I feel downhearted and sad	0	1	2	3
2. Morning is when I feel best	3	2	1	0
3. I have crying spells or feel like it	0	1	2	3
4. I have trouble getting to sleep at night	0	1	2	3
5. I feel that nobody cares	0	1	2	3
6. I eat as much as I used to	3	2	1	0
7. I still enjoy sex	3	2	1	0
8. I notice I am losing weight	0	1	2	3
9. I have trouble with constipation	0	1	2	3
10. My heart beats faster than usual	0	1	2	3
11. I get tired for no reason	0	1	2	3
12. My mind is as clear as it used to be	3	2	1	0
13. I tend to wake up too early	0	1	2	3
14. I find it easy to do the things I used to	3	2	1	0
15. I am restless and can’t keep still	0	1	2	3
16. I feel hopeful about the future	3	2	1	0
17. I am more irritable than usual	0	1	2	3
18. I find it easy to make a decision	3	2	1	0
19. I feel quite guilty	0	1	2	3
20. I feel that I am useful and needed	3	2	1	0
21. My life is pretty full	3	2	1	0
22.I feel that others would be better off I were dead	0	1	2	3
23. I am still able to enjoy the things I used to	3	2	1	0

Interpretation of scores

The suggested cut-offs:

Normal	modified Zung <17
At Risk	modified Zung 17-33 and MSPQ <12
Distressed Depressive	modified Zung >33
Distressed Somatic MSPQ	modified Zung 17-33 and MSPQ >12

APPENDIX SEVEN. Ultrasound Imaging Analysis.

An illustrated example of ultrasound imaging analysis of the initial (A) and final (B) frame of a typical nerve movement sequence. Five boxes of selected regions of interest were used to measure the axial and longitudinal magnitude of the nerve excursion.