The effectiveness of dry needling versus Flurbiprofen LAT patch in the treatment of myofascial pain syndrome of the upper Trapezius muscle

By

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I, Seerouven Veerasamy, do declare that this dissertation is representative of my own work in both conception and execution (except where acknowledgements indicate the contrary)

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DEDICATION

This work is dedicated to:

My family, my mom, dad and little brother. Thank you all for the support and encouragement over the years.

My family overseas Pati, aunts and uncles thank you all for always remembering me, never forgetting a birthday or special day, your love and support has meant a great deal to me.

And to God, thanks for the chance.

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To: The patients

Without you this research would not have been possible. I cannot thank you all enough for your time, patience and interest in this study.

To: Davisen Veerasamy

Thanks brother your assistance has been instrumental.

To: Tim Kinsman

Buddy thanks for your help, our journey through the years has been eventful to say the least, and hopefully we get some peace and quiet for awhile.

To: Ms. Tonya Esterhuizen

Who assisted me greatly and efficiently with the statistical aspects of the study.

ABSTRACT

Background: Dry needling is known to be effective and efficient in the treatment of myofascial pain syndrome; pragmatically however, patients utilise Flurbiprofen LAT patches as home therapy anticipating similar results. This may not be true and thus, this study aimed to investigate the effectiveness of dry needling versus Flurbiprofen LAT patches in the treatment of myofascial pain syndrome of the upper Trapezius muscle.

Methods: This ethics approved, prospective, randomized, single blinded (blinded assessor), comparative clinical trial required sixty participants, randomly (randomisation table) allocated to two groups. After the completion of informed consent participants received treatment over three consultations with a follow up a week later. Baseline and repeated outcome measures included Numerical Pain Rating Scale, Neck Disability Index Questionnaire, Myofascial Diagnostic Scale, Algometer and Cervical Range of Motion device. The data was analysed using ANOVA tests with the *p*-value set at 0.05.

Results: Baseline demographics and outcome measures showed that only age was significantly different between the groups. This difference was controlled for in the statistical analysis. Dry needling resulted in better treatment outcomes than the Flurbiprofen LAT patches in terms of function (cervical range of motion) (right lateral flexion $p=0.043$) and Myofascial Diagnostic Scale scores ($p<0.001$), whereas the Algometer measures and remaining cervical ranges of motion improved significantly over time in both groups, but not between the groups. Tthe Flurbiprofen LAT patches fared better in terms of the subjective reporting (Numerical Pain Rating Scale), this was not significant.

Conclusion: The interventions were both effective over time, however, the needle group achieved improved functional ability and the Flurbiprofen LAT patches improved the pain outcomes with limited functional ability. Therefore the use of these modalities requires clinical judgement to appropriately administer the treatment option that the patient would best benefit from.

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DEFINITIONS

Active myofascial trigger point (AMFTP):

An AMFTP has an area of tenderness at rest or on palpation, a taut band of muscle, a local twitch response, and spontaneous pain referral which may be aggravated by firm compression and is similar to the participant's pain complaint (Travell and Simons, 1983; Alvarez and Rockwell, 2002).

CROM device:

Cervical range of motion device, this is a device that measures the amount of movement (in degrees) in various directions (Hoving *et al.,* 2005; Lian *et al.,* 2010) of the cervical spine. For this study the CROM will only be utilised to measure lateral flexion of the cervical spine.

Jump Sign:

A jump sign is a pain response where the patient may wince, cry out or move away from the painful stimulus (Travell and Simons, 1999).

Latent myofascial trigger point (LMFTP):

A LMFTP (which occurs more commonly), may display hypersensitivity and exhibit all the characteristics of an AMFTP except that it is not associated with spontaneous pain referral (Simons, 1990; Alvarez and Rockwell, 2002; Lucas, 2007).

Local Action Transcutaneous (LAT) Patch:

LAT medications direct their primary pharmacological action at peripheral sites locally. It does not produce a significant systemic concentration of the anti-inflammatory (Argoff, 2004). In contrast, a transdermal preparation is also topically applied but is an alternative to the oral route, and therefore has systemic effects (Argoff, 2004).

Local twitch response (LTR):

This is an involuntary spinal cord reflex contraction of the muscle fibers in a taut band following palpation or needling of the band that constitutes a MFTP (Travell and Simons, 1983; Hong, 1994; Hong and Torigoe, 1994; Chaitow and DeLany, 2002).

Myofascial pain syndrome (MPS):

Myofascial pain syndrome is a common, painful musculoskeletal disorder characterized by the presence of MFTP's. It is further defined as the sensory, (e.g. referred pain, dysesthesias, and hypesthesias), motor, (e.g. muscle spasm, weakness, loss of coordination and decreased work tolerance and autonomic symptoms, (e.g. abnormal sweating, persistent lacrimation, persistent coryza, excessive salivation, and pilomotor activities) caused by MFTP's (Travell and Simons, 1999; Dommerholt *et al.,* 2006; Wong and Wong, 2012).

Myofascial trigger points (MFTPs):

MFTP's are hyperirritable discrete spots of focal tenderness located within skeletal muscle, and are associated with hypersensitive palpable nodules or taut band; which produces a local twitch in response to snapping or palpation of the taut band in the muscle (Travell and Simons, 1983; Chaitow and DeLany, 2002). The band may cause a local twitch response as well as pain on compression, leading to the characteristic symptoms of referred pain, referred tenderness, motor dysfunction, and autonomic phenomena (Travell and Simons, 1983; Gerwin, 2001; Alvarez and Rockwell, 2002; Cummings and Baldry, 2007).

Needle effect:

The immediate analgesia / pain relief produced by needle insertion into a MFTP (Lewit, 1979; Tough *et al*., 2011).

Non steroidal anti-inflammatory drugs (NSAIDs):

Are a group of drugs that have various degrees of analgesic, anti-inflammatory and antipyretic actions (Neal, 1992).

Spontaneous electrical activity (SEA):

The electromyographic activity that is associated with a MFTP and its associated taut band and is represented by the presence of a negative-positive potential, this activity is termed spontaneous electrical activity (SEA) (Gerwin, 2001).

CHAPTER ONE
Introduction

1.1 Introduction

Myofascial pain syndrome (MPS) is described as regional muscular pain which is a major cause of morbidity; its prevalence is increasing not only with age but in frequency as well (Travell and Simons, 1999; Hou, 2002; Yap, 2007). MPS is characteristically caused by myofascial trigger points (MFTPs) (Han and Harrison, 1997; Cummings and Baldry, 2007; Wong and Wong, 2012) which are described as the hallmark of this syndrome (Rauck, 1997). MFTPs are the most painful and sensitive areas within a taut band of muscle. A taut band is an objective and consistent palpatory finding in muscles with myofascial pain (Yap, 2007).

MFTPs are related to a set standard of clinical characteristics which categorise their clinical presentation depending on the type of MFTP. In a clinical context, there are two types of MFTPs, those which are active and those that are latent (Han and Harrison, 1997; Travell and Simons, 1999). However, MFTPs may also be further classified into primary, secondary or satellite MFTPs dependant on the causative agent of the MFTPs (Han and Harrison, 1997; Travell and Simons, 1999). MFTPs can occur in any muscle group in the body (Han and Harrison, 1997), with the trapezius being the most commonly affected (Gatterman, 1990; Travell and Simons, 1999). These MFTPs are then graded according to prevalence, TP1 (trigger point one) in the upper trapezius muscle being the most frequent, followed by TP2 (trigger point two) (Travell and Simons, 1999).

According to Yap (2007), MPS via MFTPs is extremely common cause of pain accounting for a large incidence within the population, as well as a high prevalence occurring in patients presenting with regional musculoskeletal pain. However, MPS is still under-diagnosed and under-treated (Yap, 2007), even though numerous treatment interventions for MPS exist (Tough and White, 2011; Dagenais and Haldeman, 2012).

There are a great variety of physical therapies employed in the treatment of MPS which include: needling therapies such as dry needling and injection therapies or non-needling therapies such as heat therapy, ultrasound, electrical therapy, medication (such as oral/topical NSAIDs), stretch and spray techniques and exercise therapies (Travell and Simons, 1999; Cummings and Baldry, 2007; Yap, 2007).

The needle effect has been described as distinct from injected substances (Lewit, 1979; Cummings and White, 2001) and a majority of manual and physical therapists adopt the needling technique (e.g. dry needling) which is the most common form of treatment for MPS / MFTPs (Tough and White, 2011). Of almost 9 000 physical therapists in South Africa, more than 75% are estimated to use the technique daily (Dommerholt *et al*., 2006). The needling procedure is described as an invasive procedure where the needle is inserted through the skin into a MFTP (Dommerholt *et al.,* 2006; Hong, 2006). Its therapeutic effect relies in mechanical disruption or direct stimulation of the trigger points, thus producing the needle effect (Han and Harrison, 1997). It has been shown to decrease or even abolish pain of myofascial origin (Han and Harrison, 1997) and has been shown as an effective treatment in clinical practice (Cummings and White, 2001; Dommerholt *et al.,* 2006; Vernon and Schneider, 2009).

Topical NSAIDs (such as Flurbiprofen LAT patches), by contrast, are used by patients as self-home care medication for myofascial pain (Stanos, 2007), and comprises a growing part of the over-the-counter (OTC) analgesic drugs that are used in the treatment of MPS (Stanos, 2007). This may be because topical analgesics seem to provide a safe and effective therapeutic approach for MPS (Stanos, 2007). As a result of the paucity of literature, it is not clear to what extent topical formulations of NSAIDs are clinically effective in reducing myofascial pain (Hsieh *et al.,* 2010). These results vary with application by participants and thus clinical effectiveness has not been as evident with topically applied NSAIDs. Although dry needling and NSAIDs are used in the treatment of MPS, their mechanism of action differs significantly, topical NSAIDs act directly within the area of injury, with limited systemic activity, and reduction of the inflammatory reaction (Galer *et al.,* 2000) whereas, dry needling induces a greater

inflammatory reaction in order to address the MFTPs (due to tissue derangement by the needle) (Travell and Simons, 1999; Vernon and Schneider, 2009).

With a paucity of literature on the effectiveness of Flurbiprofen LAT patches in participants with MPS, this study aimed to compare one of the most effective treatments (dry needling) (Travell and Simons, 1999; Tough and White, 2011), with Flurbiprofen LAT patches in order to determine if there was a difference in the clinical outcomes for the participants.

1.2 Research Aim and Objectives

The aim of the study was to investigate the effectiveness of dry needling versus Flurbiprofen LAT patches in the treatment of myofascial pain syndrome of the upper Trapezius muscle.

The specific objectives were to:

1. Determine the effectiveness of dry needling versus Flurbiprofen LAT patches in terms of the objective findings (i.e.: Myofascial Diagnostic Rating Scale, Algometer and CROM Device).

2. Determine the effectiveness of dry needling versus Flurbiprofen LAT patches in terms of the subjective findings (i.e.: Numerical Pain Rating Scale and Neck Disability Index Questionnaire).

3. Determine if any significant clinical / statistical differences exist between dry needling versus Flurbiprofen LAT patches in terms of the objective and subjective results.

4. Determine the correlation between changes in subjective and objective outcomes from pre to post intervention within the treatment groups.

The null hypothesis linked to the third objective read that there would be no difference between the dry needling and the Flurbiprofen LAT patch interventions.

1.3 Rationale / benefits

Needling therapies are the most common and well tolerated (Dommerholt *et al.,* 2006) form of treatment for MPS / MFTPs (Tough and White, 2011) even though it is invasive (Dommerholt *et al.,* 2006). In particular, dry needling has been shown as an effective treatment for MFTPs (Cummings and White, 2001; Dommerholt *et al.,* 2006; Vernon and Schneider, 2009) and can lead to an immediate relief of the MFTP pain (Han and Harrison, 1997; Hong, 2006).

In South Africa, topical NSAIDs (such as Flurbiprofen LAT patches) are commonly indicated for the symptomatic relief of localised pain and inflammation associated with sprains, strains and muscular conditions (TransAct®, 1994). These topical NSAIDs produce significant improvements in terms of average pain and activities of daily living in patients with MPS (Argoff, 2006). Topical analgesics seem to provide a safe and effective therapeutic approach for MPS (Stanos, 2007), due to the lack of systemic side effects and that they possess a similar efficacy to oral formulations for the treatment of musculoskeletal conditions (Stanos, 2007). Another important characteristic of topical analgesics is the lack of drug-drug interactions, which is important to patients who are concurrently using systemic medications for other conditions (Argoff, 2004).

As such, both topical NSAIDs as well as dry needling (Vernon and Schneider 2009; Cummings and White 2001) may be relatively effective in the treatment of MPS (Stanos, 2007; Jimbo *et al.,* 2008; Karakurum *et al.,* 2001). By investigating these two common intervention methods it may determine which of these modalities delivers the greatest pain relief and therefore effectiveness in the treatment of MPS. This would in turn provide the patient with the more effective and desirable modality in the treatment of MPS.

1.4 Limitations

1.4.1 Subjective Data

The subjective data included the Numerical Pain Rating Scale (NRS) and the Neck Disability Index Questionnaire (NDI). Subjective testing is a process whereby a group of participants are asked to provide their honest opinion or assessment.

In relation to the NRS and NDI:

- It is not possible to account for misunderstandings of either questionnaire by the participants, even in the face of the participants having been informed of their function and interpretation at each measurement point in the study.
- Each participant has a different perception of their pain and thus may record this perception differently.
- Additionally, the research process is required to make the assumption that the participant reflects the reality of their clinical situation clearly and honestly; accurately reflecting their clinical status at the time of the measurements. Any incorrect recording of this reality cannot be determined by the researcher and as such the Letter of Information and Informed Consent Form emphasised the importance of providing reliable and honest data to the researcher.

1.5 Outline of Chapters

Given the outline provided in this chapter to contextualise this research, Chapter Two follows with a review of the pertinent literature and Chapter Three outlines the methodology applied in this study to achieve the objectives. Chapter Four then follows with subsections, each detailing the results, and discussion of the results, before Chapter Five concludes the dissertation and presents the recommendations.

CHAPTER TWO
LITERATURE REVIEW

2.1 Introduction

This chapter reviews the information on MPS and its treatments. Thus the following sections are represented:

- MPS.
- Dry needling for the treatment of MPS.
- Flubiprofen LAT patches a topical NSAID for the treatment of MPS.

2.2 Myofascial Pain Syndrome

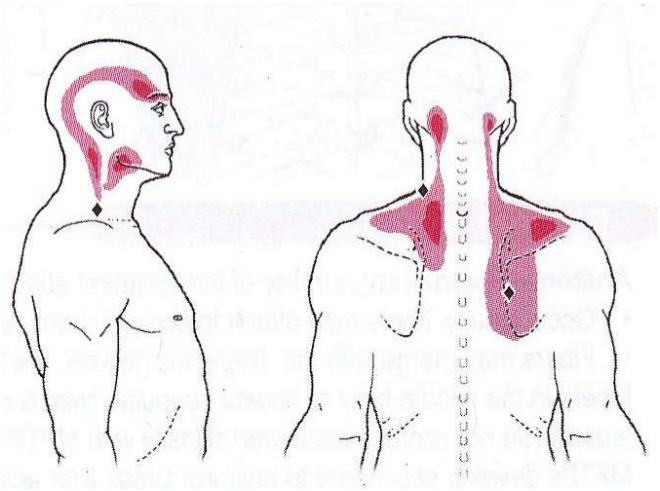
MPS has been loosely used to describe regional muscular pain of any soft tissue origin associated with muscle tenderness, it is more aptly described as, MPS caused by MFTPs (Simons, 1995; Travell and Simons, 1999). Since skeletal muscle is the single largest organ in our human body, it accounts for nearly 50% of our bodyweight (Travell and Simons 1999; Chaitow and DeLany, 2002); and any of these muscles may develop MFTPs, pain and dysfunction (Han and Harrison, 1997; Travell and Simons, 1999; Yap, 2007).

As such MPS is a commonly encountered painful musculoskeletal disorder that is thought to be due to neuronal hypersensitivity and not inflammation, it is characterised by MFTPs (Han and Harrison, 1997; Cummings and Baldry, 2007; Hsieh *et al.,* 2010; Wong and Wong, 2012) and is described as the sensory, motor, and autonomic symptoms caused by MFTPs (Travell, Simons and Simons, 1999; Dommerholt *et al.,* 2006). Nevertheless, it is often unrecognised, misdiagnosed, and mistreated leading to unnecessary pain, suffering, and disability (Auleciems, 1995; Travell and Simons, 1999; Testa *et al.*, 2003; Dommerholt, 2006; Cummings and Baldry, 2007).

MFTPs are usually located, by palpation, within a taut band of contractured muscle fibres. A taut band on palpation feels like a cord of tense muscle fibres (Dommerholt *et al.,* 2006). Along/within the taut band, a nodular area of maximal tenderness usually exists and represents the focal point or MFTP (Travell and Simons, 1999).

MFTPs can be active or latent, which depends on their varied clinical characteristics (Han and Harrison, 1997; Travell and Simons, 1999); however, either of these may cause MPS (Travell and Simons, 1999; Wilks, 2002; Hou, 2002).

- An active MFTP (AMFTP) has an area of tenderness at rest or on palpation, a taut band of muscle, a local twitch response, and spontaneous pain referral (Figure 2.1) which may be aggravated by firm compression and is similar to the participant's pain complaint (Travell and Simons 1999; Alvarez and Rockwell, 2002). It occurs most often in the musculature of the back, neck, shoulders and torso and is a major source of musculoskeletal pain and dysfunction (Travell and Simons 1999).



Key:

♦ AMFTP

Figure 2.1 Upper Trapezius MFTP Referral Adapted from Vizniak (2010)

- A latent MFTP (LMFTP) (which occurs more commonly), may display hypersensitivity and exhibit all the characteristics of an AMFTP (i.e.: motor dysfunction; (stiffness and restricted range of motion due to increased muscle

tension and muscle shortening)) except that it is not associated with spontaneous pain referral (Travell and Simons, 1999; Alvarez and Rockwell, 2002).

Table 2.1: Characteristics of AMFTP and LMFTP

Similarities	
AMFTP	**LMFTP**
Local twitch response	Local twitch response
Muscular stiffness	Muscular stiffness
Restricted range of motion	Restricted range of motion
Reduced muscular stretch	Reduced muscular stretch
Increased muscular tension	Increased muscular tension
Muscle weakness	Muscle weakness
Taut band	Taut band
Differences	
Localized and referred pain on manual compression	Localized pain on manual compression
Spontaneous pain referral	No spontaneous pain referral
Recognition of current pain	Unrecognized, unfamiliar or previous pain

Adapted from Travell and Simons (1999); Chaitow and DeLany (2002) and Wilks (2002)

As such active and latent MFTPs can cause significant motor dysfunction with LMFTPs occurring more commonly than AMFTPs (Travell and Simons, 1999).

Active and latent MFTPs can be further subdivided into primary and satellite MFTPs. A primary trigger point is defined as a MFTP that has been activated directly by acute or chronic overload, or repetitive overuse of the muscle in which it occurs and was not activated as a result of MFTP activity in another muscle (Travell and Simons, 1999). A satellite or secondary trigger point is a MFTP induced mechanically or neurogenically by an active primary trigger point (Travell and Simons, 1999). As such an active MFTP in one muscle can induce an active satellite MFTP in another muscle and vice versa, inactivation of the key MFTP will therefore lead to inactivation of its satellite MFTP without actually treating the satellite MFTP (Travell and Simons, 1999).

2.3 Prevalence

MFTPs are extremely common and become a painful part of nearly everyone's life at one time or another (Travell and Simons, 1999). Thus, it is a major cause of musculoskeletal pain (Travell and Simons, 1999; Yap, 2007), and according to Hou (2002), the prevalence of MPS has been dramatically increasing. According to Dommerholt *et al*., (2006), MFTPs have been identified with nearly every musculoskeletal pain problem.

As such there is a high prevalence of MPS in patients suffering from musculoskeletal regional pain (Yap, 2007) and it is one of the most common causes of back and neck pain (Fernandez de Las Penas *et al*., 2005; Yap, 2007), with the condition being more prevalent in women (Han and Harrison, 1997; Travell and Simons, 1999). According to a number of studies MPS is therefore a common cause of musculoskeletal dysfunction (Fricton *et al*., 1985; Skootsky *et al*., 1989; Schiffman *et al*., 1990; Cummings and White, 2001; Gerwin, 1995; Fernandez de Las Penas *et al*., 2005).

Fricton's *et al*., (1985) study of 164 patients with chronic neck and head pain of at least 6 months duration, found 55% of the patients had a primary diagnosis of MPS. Additionally, Chaiamnuay's *et al*., (1998) study of musculoskeletal disorders found of 431 patients the primary diagnosis in 36% of patients was MPS which agrees with a study in a general medical clinic where 30% of the complaints were due to MPS (Skootsky *et al*., 1989). By contrast a comprehensive pain centre study of 283 patients revealed 85% of patients had a primary diagnosis of MPS (Fishbain *et al*., 1986), which is similar to a further study in another pain centre, which revealed that of their 96 patients, the primary cause of pain in 74% of cases was found to be due to MPS (Gerwin, 1995;).

Thus the incidence of MPS appears to vary between 30% and 85%, with these studies showing that MPS has a high prevalence (Gerwin, 1995; Han and Harrison, 1997;

Rashiq and Galer, 1999; Fernandez de Las Penas *et al*., 2005; Yap, 2007; Lucas, 2009), however it is often under-diagnosed and under-treated (Yap, 2007).

2.4 Aetiology

It appears that the same precipitating factors which are responsible for the development of an active MFTP may cause a latent MFTP (Travell and Simons, 1999).

According to Baldry (1993), Travell and Simons (1999), Chaitow and Delany (2002), Gerwin (2004) and Yap (2007), MFTPs are divided into two categories of causes: mechanical and disease related which in turn, are further classified into primary and secondary causes (Table 2.2).

Table 2.2 Precipitating factors

Mechanical causes		**Disease related causes**	
Primary Causes	Secondary Causes	Primary Causes	Secondary Causes
Ergonomic stresses Forward head posture Hypermobility syndromes Mechanical abuse- this may be through acute, sustained or repetitive muscle overload i.e. prolonged muscle contraction. Sacroiliac joint dysfunction Muscle imbalances (mechanical asymmetries) Somatic (muscle-joint) dysfunction Trauma Nerve root compression	Compensating synergist and antagonist muscles Satellite referral MFTPs	Febrile illness Drug induced myalgia Systemic biochemical imbalances	Infections Allergies Nutritional deficiencies Low oxygenation of tissues

Adapted from Baldry (1993), Travell and Simons (1999), Chaitow and Delany (2002), Gerwin (2004) and Yap (2007)

The most common sites for development of MFTPs are the postural muscles of the back, neck and the rotator muscles of the shoulders (Travell and Simons, 1999;

Chaitow and DeLany, 2002), with the trapezius muscle being the most commonly affected by MFTPs (Travell and Simons, 1999; Gatterman, 1990).

According to Hong (2006), treating the underlying etiological lesion responsible for the MFTP is the most important strategy in MPS therapy as this places a greater emphasis in correct identification of the aetiology as well as the diagnosis of the MFTP. According to Esenyel (2000), the reoccurrence of pain in patients suffering with MPS after treatment is due to perpetuating factors. Therefore, in order to achieve long term pain relief these factors need to be identified and removed (Esenyel, 2000).

Hubbard (1998), Travell and Simons (1999), Chaitow and DeLany (2002), and Yap (2007) have highlighted a number of perpetuating factors:

Table 2.3 Perpetuating factors

1	Mechanical stresses: such as, ergonomically poor furniture, poor posture, prolonged immobility, skeletal anomalies such as a short leg, small hemipelvis or a long second metatarsal bone (Morton's foot).
2	Nutritional inadequacies: such as, decreased levels of vitamins B1, B6, B12, folic acid and iron. Inadequate levels of calcium, potassium, and several trace minerals will result in abnormal muscle functioning.
3	Metabolic and endocrine inadequacies: hypometabolism (hypothyroidism), hyperuricemia and hypoglycemia perpetuate MFTPs.
4	Psychological factors: such as anxiety and depression may delay recovery of MFTPs.
5	Chronic infection: such as viral, bacterial or parasitic.
6	Other factors: physical and emotional stress; strenuous activity and prolonged immobilization can perpetuate MFTPs, impaired sleep, fatigue, cold damp weather, allergy, chronic visceral disease, and radiculopathies
7	LMFTPs: reactivation may lead to perpetuation of symptomatology of MPS. It may also predispose to development of AMFTPs.

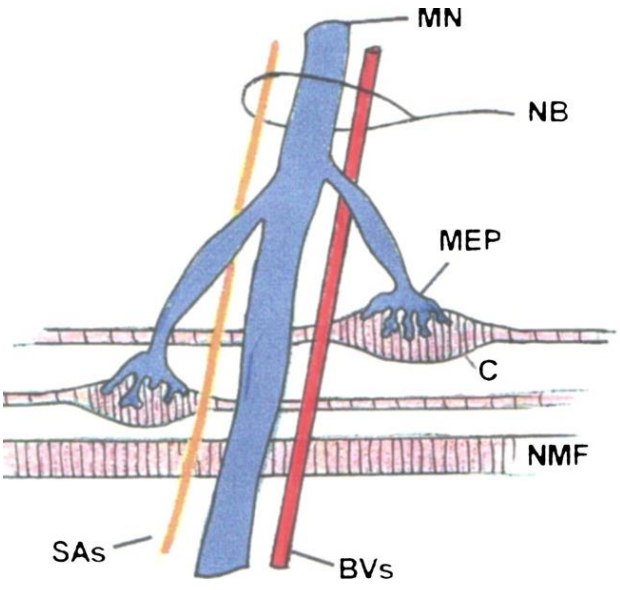
Adapted from Hubbard (1998), Travell and Simons (1999), Chaitow and DeLany (2002), and Yap (2007)

2.5 Pathophysiology

There are a number of clinical features essential in the pathophysiology of MPS/MFTPs (Travell and Simons, 1999; Fernandez de Las Penas *et al*., 2005; Dommerholt *et al*., 2006; Cummings and Baldry, 2007):

- A tender point within a taut band of skeletal muscle.
- A characteristic pattern of spontaneous referred pain (Figure 2.1).
- Recognition of pain on sustained compression over the tender point.
- A local twitch response (LTR) within the band of muscle on palpation.

As described earlier MFTPs are usually located within the taut band of contractured muscle fibres (Figure 2.2) and a local twitch response (LTR) has been described as a characteristic response of MFTPs (Lavelle *et al*., 2007). MFTPs contain a neurovascular bundle, the principal contents being motor nerve endings and nociceptive sensory afferent nerve endings (Figure 2.2) (Mense *et al*., 2001; Baldry, 2001;Cummings and Baldry, 2007).



Key:

MN: Motor nerve

NB: Neurovascular bundle

MEP: Motor end-plates with nerve endings

C: Contractured muscle fibre

NMF: Normal muscle fibre

BVs: Blood vessels

SAs: Nociceptive and sensory afferents

Figure 2.2 Representation of a MFTP Adapted from Cummings and Baldry (2007)

It has been hypothesized by Travell and Simons (1999) that the pathophysiology of MPS and formation of MFTPs usually results from injured or overstressed muscle fibres caused by such precipitating factors described above. According to Travell and Simons (1999) understanding the location of motor end plates is vital for the diagnosis and management of MFTPs. Cummings and Baldry, (2007) state that the key pathophysiological abnormalities associated with MFTPs, principally appear to be located within the centre of the muscle in its motor end-plate zone. This zone is where the motor nerve (Figure 2.2), on entering a muscle divides into a number of branches (Figure 2.2), each of these branches has a terminal claw-like motor end-plate embedded into the surface of a muscle fibre (Figure 2.2) (Cummings and Baldry, 2007). Therefore, it appears that MFTPs appears to be intimately associated with the muscular motor end-plates (Cummings and Baldry, 2007).

As such the precipitating factors (Table 2.2) lead to cell membrane damage, which is the initial event in muscle damage and development of the MFTP and is facilitated by the release of acetylcholine at the motor end-plates (Yap 2007; Ge *et al.,* 2011). More acetylcholine may then be released, perpetuating the cycle of muscular pain and spasm, this increased release of acetylcholine at the motor end-plates produces the spontaneous electrical activity (SEA) (Shah 2005; Ge *et al.,* 2011), within a MFTP (Hubbard and Berkoff, 1993; Simons *et al.,* 2002). In this context, SEA is registered by intramuscular needle electromyography (EMG) when the muscle is at rest (Ge *et al.,* 2011). It is one of the characteristics of MFTPs (Hubbard and Berkoff, 1993; Simons *et al.,* 2002).

Hubbard and Berkoff's (1993) study showed that, SEA was demonstrated at sites in a MFTP, whereas similar activity was not found at adjacent non-tender/non-MFTP sites (Lavelle *et al*., 2007) and according to Cummings and Baldry (2007) the work of Couppe´ *et al*., (2001) was the first blinded study to confirm the presence of SEA at MFTPs.

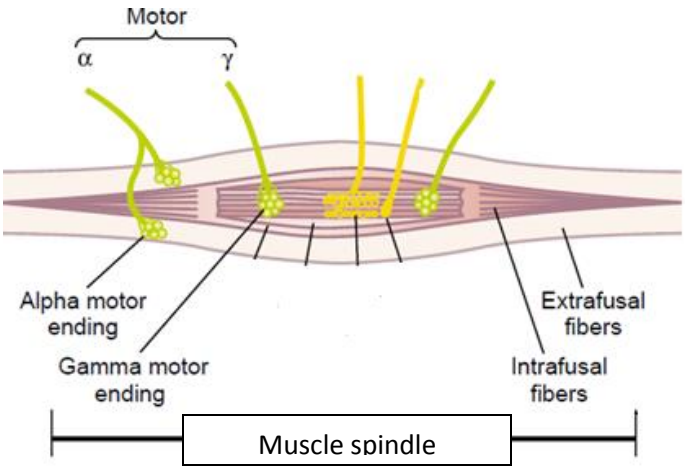


Figure 2.3 Muscle spindle Adapted from Guyton and Hall (2006)

Large extrafusal (alpha motor unit) skeletal muscle fibres (Figure 2.3) are located outside the muscle spindle and the small intrafusal skeletal muscle fibers (gamma motor unit) (Figure 2.3) within the muscle spindle. According to Ge *et al.,* 2011 the spontaneous electrical activity originates from the extrafusal motor end-plate but not from the intrafusal motor endplate. Therefore, in this context, SEA is characterised by dysfunctional extrafusal motor end-plate potentials (Simons *et al.,* 2002) within the muscle fibres which exhibit muscle tissue disruption in the form of a muscle cramp potential (Xu *et al.,* 2010; Ge *et al.,* 2011). It may also contribute to the formation of the taut muscular band in MFTPs, as the SEA is clinically represented by this focal muscle fibre contraction (Ge *et al.,* 2011).

Associated with these localised muscle cramps, are induced intramuscular hypoxia, increased accumulation of algesic substances, direct mechanical stimulation of nociceptors and pain as a result of an inflammatory response (due to tissue degeneration) (Simons and Mense 1998; Laferriere *et al.,* 2008; Ge *et al.,* 2011). Barbara *et al.,* (2012), Cagnie *et al*., (2010) and Flogren *et al*., (2008) indicated changes in the microcirculation during these static low-level muscle contractions in MPS. These studies have demonstrated a decrease in oxygen saturation in the trapezius as well as a decrease in blood flow (Barbara *et al.,* 2012). All of these contribute significantly to the formation of muscle tension and MFTPs (Simons and Mense 1998; Laferriere *et al.,* 2008; Ge *et al.,* 2011).

2.6 Clinical Features

MPS has been described as the great imitator (Yap, 2007). However, there are a number of distinguishing characteristics (Travell and Simons, 1999; Yap, 2007). MPS most commonly presents as regional muscle pain (Travell and Simons, 1999; Yap, 2007; Tough and White, 2011). MFTPs are the hallmark characteristics of MPS, therefore the features of motor, sensory and autonomic dysfunction caused by MFTPs (Table 2.4) characterise MPS (Han and Harrison, 1997; Rauck, 1997; Dommerholt *et al*., 2006; Cummings and Baldry, 2007; Wong and Wong, 2012).

Table 2.4: MPTPs dysfunction

Motor	**Sensory**	**Autonomic**
Taut band	Local tenderness	Vasoconstriction
Muscle pain	Pain referral	Vasodilatation
Spontaneous pain referral- only AMFTPs	Peripheral and central sensitization- allodynia, hyperalgesia	Lacrimation
Local twitch response	Pain on compression	Piloerection
Jump sign		
Restricted range of motion of the affected tissues and loss of coordination		
Muscular fatigue		

Adapted from Travell and Simons, (1999); Fernandez de Las Penas *et al*., (2005); Dommerholt *et al*., (2006)

MFTPs are primarily identified through a number of palpation techniques in which a particular muscle is palpated between the clinician's fingers (Dommerholt *et al*., 2006). Palpating for MFTPs begins with finding and identifying the taut band (Dommerholt *et al*., 2006). The diagnosis of upper Trapezius MFTP's is a clinical one and is confirmed by the presence of all major criteria (Table 2.5) as indicated by Travell and Simons (1999); minor criteria need not be present, but serve to confirm the major criteria.

Table 2.5: Defined / specific criteria for the diagnosis of MFTPs

Major criteria (minimum required)	Minor criteria (confirmatory findings)
Visual or tactile identification of local twitch response. A local twitch of the taut band of muscle when the trigger band is distorted transversely. Pain or altered sensation on compression of the tender nodule Painful limit to full range of motion (active or passive stretch of the opposing muscle). Pain on contraction of the muscle containing the MFTPs Weakness of the muscle containing the MFTPs	A palpable firm area of muscle referred to as the taut band. A localised spot of exquisite tenderness to manual pressure on the MFTP that can be isolated within the taut band. A characteristic pattern of pain in response to sustained pressure on the MFTP within the taut band. This pain is referred in patterns that are specific to individual muscles.

Adapted from Travell and Simons (1983); Travell and Simons (1999)

The diagnosis of MPS is further enhanced by the use of a number of objective and subjective tests:

Table 2.6: Objective and subjective tests

Objective Tests	
Numerical Pain Rating Scale	Neck Disability Index Questionnaire
This scale shows the progression or regression of the participants pain levels, this sensitivity of pain rating scales is the ability to detect change, thereby assisting in quantifying the effectiveness of treatment.	Is used to assess how much the participant's pain had affected their activities of daily life in various tasks as well as any improvement produced by the therapeutic interventions, thereby assisting in quantifying the effectiveness of treatment.
Subjective Tests	
Algometer	Cervical Range of Motion (CROM) device
Used to quantify the sensitivity of MFTPs, by measuring the minimum pressure that induces pain, lower readings indicate decreased tolerance to pain or MFTP pain, and higher results are indicated in normal muscle.	With reference to Prushansky and Dvir (2008) cervical motion is the gold standard for testing head motion and thus, any changes found that depict a deviation from the norm or a return to the norm such as pain related limitations before and after treatment. Cervical motion refers to active rather passive motion and is sub-divided into 6 primary motions: Lateral flexion 1. Left lateral flexion (LLF) 2. Right lateral flexion (RLF) Rotation 3. Right Rotation (RR) 4. Left Rotation (LR) Movement along the sagittal plane 5. Flexion (FLEX) **6.** Extension (EXT)

Myofascial diagnostic scale (MDS)
It is a scale using the signs of a MFTP as an indicator to assess, the extent to which the patient suffers from MPS, MFTPs were assessed on the MDS according to: ➢ soft tissue tenderness ➢ local twitch response, ➢ the presence of a taut band ➢ referred pain Therefore, MDS is a reliable and valid assessment tool for the diagnosis of MPS and allows the clinician to clinically assess for the presence, extent and resolution of MPS/MFTPs.

Adapted from Han and Harrison (1997); Jenson *et al*., (1986); Yeomans (2000); Williamson and Hoggart (2005); Prushansky and Dvir (2008)

2.7 Treatment of MPS

According to Yap (2007), the treatment of MPS in the short term should be to remove the taut band, tender spots and hence the MFTP to reduce pain, and in the long term (due to the chronic nature of MPS) to reduce its recurrence by removing the precipitating and perpetuating factors (Han and Harrison, 1997).

Treatment modalities for MPS include:

Table 2.7: Treatment of MPS

Home care applied therapy	Health care practitioners applied therapy
Massage	Massage
Ischemic compression	Ischemic compression
Exercise	Exercise
Stretch	Post isometric relaxation
Pharmacologic agents (Topical NSAID's)	Stretch and spray technique
	Pharmacologic agents (Oral and Topical NSAIDs)
	Dry needling
	Ultrasound
	Electrical stimulation
	MFTP injection

Adapted from Travell and Simons, (1999); Han and Harrison (1997); Yap (2007) and Haldeman and Dagenais (2012)

According to Han and Harrison (1997), dry needling can decrease or even eliminate MPS, and so the majority of manual and physical therapists adopt this technique (Tough and White, 2011). Other therapists recommend muscle relaxants to self medicate (e.g. topical NSAIDs) (TransAct® 1994; Han and Harrison, 1997).

2.7.1 Dry Needling

Needling therapies are the most common form of treatment for MPS / MFTPs (Cummings and Baldry, 2007; Tough and White, 2011). There are various needling therapies which include wet needling/injection therapy as well as dry needling (Cummings and Baldry, 2007; Tough and White, 2011). According to a systematic review published in 2001 of 23 randomised controlled trials (RCTs), when treating MFTPs with injection therapy, the injected substance and wet needling has no benefit over dry needling (Cummings and White, 2001; Cummings and Baldry, 2007). As such,

it was suggested in the review that the effect derived from these therapies was most likely due to the mechanical effect of the needle (Travell and Simons, 1999; Cummings and White, 2001; Cummings and Baldry, 2007). Therefore, in effect, dry needling has been shown as an effective treatment for MFTPs (Cummings and White, 2001; Dommerholt *et al.,* 2006; Vernon and Schneider 2009) as wet needling/injection therapy (Cummings and White, 2001).

Dry needling is described as an invasive procedure in which an acupuncture needle is inserted into the skin and muscle (Dommerholt *et al.,* 2006), with the needle being directed at the specific MFTP in order to elicit a local twitch response (Hong, 2006). With dry needling, an immediate relief of MFTP pain described as the needle effect, can be achieved if a local twitch response can be elicited during the procedure (Hong, 2006; Tough and White, 2011). Thus, the aim is to mechanically break up the MFTP and associated fibrotic scar tissue; therefore the needle is targeted at the point of maximum tenderness within the taut band in order to achieve the therapeutic effect (Yap, 2007). Needling into the MFTP also induces an bio-electrical effect which causes a local twitch response which relieves the SEA (Szymanski and Voss, 2007). According to Barbara *et al*., (2012), it has been suggested that dry needling may influence the microcirculation of the upper trapezius, (in terms of increasing blood flow to the muscle and inducing a change of the chemical/inflammatory mediators) due to the increase in blood flow to the trigger point region (Shah and Gilliams, 2008; Sandberg *et al*., 2005; Sandberg *et al*., 2003; Sandberg *et al*., 2004; Kubo *et al*., 2010).

Since the SEA is no longer present, the muscle contraction/cramps ceases, which lengthens the contractile element of the muscle and in so doing breaks the negative feedback loop (described as a perpetuating cycle in 2.5) responsible for sustaining the continuous muscle fibre contraction forming the MFTP (Travell and Simons, 1999; Dommerholt, 2006; Szymanski and Voss, 2007). Research has shown that after dry needling and the eliciting of the twitch response, the chemical environment / microcirculation (Jimbo *et al*., 2008) as well as the SEA in the muscle returns to normal (Szymanski and Voss, 2007).

Serotonin is secreted by nuclei that originate in the brain stem and project to many spinal cord areas, which include the dorsal horns of the spinal cord . Serotonin acts as an inhibitor of pain pathways in the spinal cord (Guyton and Hall, 2006). As such, according to Hong (2006) it is also possible that during dry needling of the MFTP, the strong pressure stimulation thus induced (due to insertion of the needle) of the MFTP nociceptors can provide very strong neural impulses to the dorsal horn cells in the spinal cord thus breaking the MFTP perpetuating cycle. This inhibiting effect on the nociceptors, provides pain relief by spinal cord pathway modulation as well as by generalised neuro-humoral stimulation and the release of endorphins (Yap, 2007). Therefore, the strongest analgesic effect is achieved when the most painful spot is precisely reached with a fine needle (Mense and Gerwin, 2010).

In one of the first studies investigating dry needling on MFTPs, it was concluded that dry needling was effective at alleviating MPS (Lewit, 1979). The therapeutic effect of this technique has been studied indicating that dry needling can decrease or even eliminate MPS / MFTPs and is seen as an effective intervention (Mense and Gerwin, 2010; Dagenais and Haldeman, 2012). Based on this, dry needling of MFTPs has been shown as an effective treatment in clinical practice (Cummings and White, 2001; Dommerholt *et al.,* 2006; Vernon and Schneider 2009).

2.7.2 Flubiprofen LAT Patch

In contrast, topical NSAIDs (such as Flurbiprofen LAT patches) are used as self medication for MPS/MFTPs (Stanos, 2007), as it is financially more cost effective than seeing a therapist for dry needling as well as being easily accessible as an over-the-counter pharmaceutical medication. These pharmacological agents are commonly applied home interventions, since topical analgesics seem to provide a safe and effective therapeutic approach for MPS (Stanos, 2007). Topically applied NSAIDs have been shown to have varied clinical effect in the control of pain from acute soft-tissue damage, as well as helping to control articular musculoskeletal pain (Mason *et al.,* 2004; Kao *et al*., 2007). According to Argoff (2006), using topical analgesics (Flurbiprofen LAT

patches) in the treatment of patients with chronic MPS has produced significant improvements in terms of reducing pain and promoting activities of daily living.

The mechanism of action of topical analgesics is exerted within the skin, soft tissues and peripheral nerves (Argoff, 2002) this is an important characteristic of topical analgesics (making them so popular), due to the lack of drug-on-drug interactions and clinically insignificant drug serum levels, which is important to patients who are concurrently using systemic medications for other conditions (Argoff, 2004) (e.g.: blood pressure medication).

Topical NSAIDs have been shown to possess similar efficacy to oral NSAID formulations without the associated systemic side effects for the treatment of musculoskeletal conditions (Stanos 2007). A study done by Martens (1997) found that the Flurbiprofen LAT patch was significantly superior to oral NSAID formulations in terms of its efficacy and tolerability in the treatment of musculoskeletal pain. The only adverse effects of the Flurbiprofen LAT patch were mild skin irritation at the site of application, compared to the gastrointestinal side effects suffered by patients taking the oral NSAID formulations (Oehley, 2002).

Flurbiprofen, a propionic acid derivative, is a highly potent NSAID which inhibits prostaglandin synthesis and leucocyte migration, possesses analgesic, anti-inflammatory and antipyretic properties (TransAct®, 1994; Martens, 1997; Kuehl, 2010). The effects of NSAIDs are mediated through their anti-inflammatory effects, due to the inhibition of cyclo-oxygenase (COX) enzyme. The COX enzyme limits the conversion of arachidonic acid to inflammatory mediators, such as prostaglandins, thromboxanes, and prostacyclins (Gotzsche, 2000; Ong *et al.,* 2007; Hsieh *et al.,* 2010), as well as inhibiting the sensitization of peripheral pain neurons by blocking the production of the same mediators, especially prostaglandin E2 (Funk, 2001; Hsieh *et al.,* 2010). As described in 2.5 MPS results in a inflammatory response and pain (Simons and Mense 1998; Laferriere *et al.,* 2008; Ge *et al.,* 2011). Therefore, topical NSAIDs are administered in

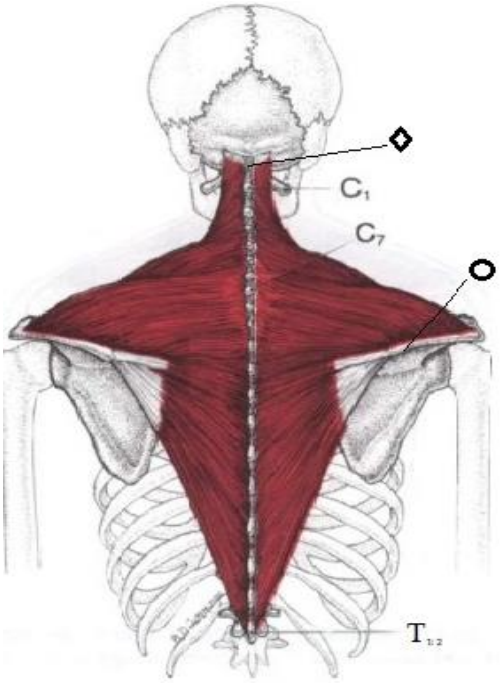
the treatment of conditions involving pain and inflammation, such as those originating from MPS (Hsieh *et al.,* 2010).

In contrast it is not clear to what extent topical formulations of NSAIDs are clinically effective in reducing myofascial pain (which is thought to be due to the neuronal hypersensitivity and not entirely to inflammation/tissue damage) (Hsieh *et al.,* 2010).

To contextualize these two treatment interventions (i.e. dry needling and Flurbiprofen LAT patches) described will be used to assess their relative effectiveness on the upper Trapezius muscle in the treatment of MPS.

2.8 The Trapezius Muscle

The trapezius muscle has been described as a tripartite muscle due to the fibres having different directionality and is therefore considered as having three separate subcomponents, the upper, middle and lower fibers (Travell and Simons, 1999). The trapezius a large diamond shaped muscle which originates at the external occipital protuberance on the medial side of the nuchal line, the nuchal ligament and the spinous processers of C7-T12 (Figure 2.4). It inserts onto the lateral third of the clavicle, acromion and spine of scapula bilaterally (Figure 2.4) (Travell and Simons, 1999; Vizniak, 2010).



Key:

C: Cervical spine

T: Thoracic spine

° Spine of scapula

◊ Nuchal line

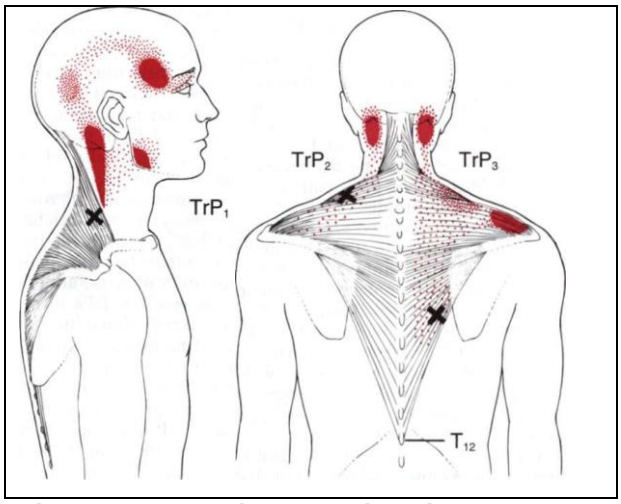
Figure 2.4 Anatomy of the Trapezius muscle Adapted from Travell and Simons (1999)

The trapezius functions to elevate and retract the scapula as well as rotating it upward. Unilaterally it is involved in lateral flexion of the head, bilaterally extension of the head and also acts to stabilize the scapula for arm movements (Vizniak, 2010). To achieve this, the trapezius muscle is innervated by both motor and sensory fibres, the motor

fibres originate from the spinal part of the accessory nerve (cranial nerve XI), whilst the sensory fibres are from the second to the fourth cervical nerves (Vizniak, 2010).

Specifically to the upper trapezius it functions by acting unilaterally, the upper portion of the muscle principally functions in laterally flexing the head and neck toward the same side; it also aids in extreme rotation and extension of the head (Travell and Simons, 1999).

MFTPs most commonly affect the trapezius muscle (Gatterman, 1990; Travell and Simons, 1999). There are six distinctive trigger point regions, two in each subcomponent, with their own characteristic pain patterns (Travell and Simons, 1999). The trigger points are numbered in the order of highest prevalence. Trigger point one (TP1) in the upper trapezius (Figure 2.4) is the most frequently identified MFTP in the body (Travell and Simons, 1999). This TP1 is a centralized trigger point, found in the midportion of the anterior border of the upper trapezius and involves the vertical fibers that attach anteriorly to the clavicle (Travell and Simons, 1999). According to Travell and Simons (1999), trigger points in this area consistently refer pain unilaterally upward along the posterolateral aspect of the neck to the mastoid process and is a major cause of tension headaches (Vizniak, 2010). Trigger points in this TP1 region of the upper trapezius may lead to additional pain by activating satellite trigger points in other muscles (Travell and Simons, 1999).



Key:

TrP1: Trigger point 1

TrP2: Trigger point 2

- Referral pattern

Figure 2.5 Trapezius MFTP locations

Adapted from Travell and Simons (1999)

According to Travell and Simons (1999), the location of TP2 is caudal and slightly lateral to TP1 (Figure 2.5), this region is located in the middle of the more nearly-horizontal fibers of the upper trapezius. Travell and Simons (1999), describe the referred pain pattern of this trigger point as lying slightly posterior to the essential cervical reference zone of TP1, and blends in with its distribution behind the ear.

Table 2.8: Referred pain pattern of TP1 and TP2

TP1	TP2
Side of the head, centering in the temple and back of the orbit.	Suboccipital referred pain
Angle of the jaw	And diffusely over the upper and middle fibers of the trapezius muscle
Occiput	
Lower molar teeth	
Posterolateral aspect of the neck	

Adapted from Travell and Simons, (1999)

According to Travell and Simons (1999) when MFTPs are present in the upper trapezius there is a limitation of head and neck rotation albeit minimally. The most restricted movement is lateral flexion of the head and neck which is side bending of the head away from the involved upper trapezius (Travell and Simons, 1999).

2.9 Summary

MFTPs are extremely common and become a painful part of nearly everyone's life at one time or another it is a major cause of musculoskeletal pain (Travell and Simons, 1999; Yap, 2007) and its prevalence has been dramatically increasing (Hou, 2002). MPS is characterised by MFTPs (Han and Harrison, 1997; Cummings and Baldry, 2007; Wong, 2012), and as a result there are numerous treatment interventions (Tough and White, 2011; Dagenais and Haldeman, 2012).

Needling therapies are the most common form of treatment for MPS / MFTPs (Tough and White, 2011). Dry needling can decrease or even eliminate myofascial pain, as such a majority of manual and physical therapists adopt the needling technique (Han and Harrison, 1997; Tough and White, 2011), whereas topical NSAIDs (such as Flurbiprofen LAT patches) are commonly indicated for the symptomatic relief of localised pain and inflammation associated with sprains, strains and muscular conditions such as MPS (TransAct®, 1994; Hsieh *et al.,* 2010).

Therefore, both topical NSAIDs as well as dry needling may be relatively effective in the treatment of MPS (Stanos 2007, Vernon and Schneider, 2009; Jimbo *et al.,* 2008; Cummings and White, 2001; Karakurum *et al.,* 2001).

By investigating these two common intervention methods it may lead to a determination of which, of these modalities delivers the greatest pain relief and effectiveness in the treatment of MPS. This knowledge may then provide the practitioner with a more effective and desirable modality in the treatment of MPS.

CHAPTER THREE
RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

This chapter outlines the:

- Study design
- The process and procedure involved in data collection
- Material and methods used for data collection
- Statistical procedures for data evaluation

3.2 Study Design:

This study was designed as a prospective, randomized, comparative clinical trial. This was a comparative study of two therapeutic modalities in two groups of participants with upper Trapezius muscle MFTPs.

3.3 Sampling:

Prospective participants were recruited via self selection (Mouton, 1996; Mouton 2001) (viz. their response to the placement of pamphlets (Appendix A), throughout DUT and other places of communal gathering) and advertisements (Appendix A) in local newspapers. Permission was sought for all advertisement placements outside of the DUT premises. Interested participants contacted the researcher telephonically or in person to ascertain if they qualified for the study.

3.4 Telephonic Interview:

Standardised questions were asked in order to ascertain if the prospective participant met the inclusion criteria. Any participants who contacted the researcher were informed

that any information exchanged was confidential, and upon agreement was then asked the following questions:

Table 3.1: Telephonic interview

Question	Response required
May I ask you a few questions?	Yes.
What is your age?	18 – 35 years of age.
Where is your area of pain (exact location)?	Neck, along the shoulders (Localised to the upper trapezius fibers (angle of the neck)).
Does your pain radiate anywhere? (that is down arms or towards your head).	Radiation to the head, neck, angle of the neck, deltoid region (shoulder) and rhomboid regions (upper back) are acceptable for initial inclusion.
Do have decreased neck movement?	Yes
Do you have any areas of tenderness?	Tenderness localised to the angle of the neck.
Have you had previous neck / back injury?	No.
Have you had a previous motor accident?	No.
Do you take any prescribed medication or recreational drugs?	If yes, the prospective participant would require a 3 day washout out period before they would be considered for inclusion.

3.5 Sample size and allocation

Once the participants were recruited, they were then screened for compliance with the inclusion and exclusion criteria and were randomly allocated to one of two groups (utilising a randomisation table). Group A (treatment by Flurbiprofen LAT patch) or Group B (treatment by dry needling).

Thirty participants in each group were sufficient to indicate if any differences were significant (based on an *a priori* analysis using the MCID of the NRS, in which a 2 point difference on a 10 point scale / 20 point difference on a 100 point scale was taken as being the MCID (Jaeshcke *et al*., 1989; Bird *et al*., 2001; Gallagher *et al*., 2001; Bijur *et al*., 2003)). A trend towards an improvement may also be revealed (Hammond, 2011).

3.6 Sampling Characteristics

3.6.1 Inclusion criteria:

- All participants were between 18-35 years, in order to increase sample homogeneity (Mouton, 1996; Mouton, 2001). These parameters were also chosen as people younger than 18 years of age would have needed parental consent. The incidence of degenerative changes to the cervical and thoracic spine would be higher in people older than 35 years (Yochum and Rowe, 2005); in addition to them (people older than 35 years) potentially also being in the stabilization phase of spinal development (Kirkaldy-Willis and Burton, 1992) which changes the biomechanics of these regions (cervical, thoracic spine), which has a potential to negatively affect the musculature (Kendall et al., 2005).
- Active MFTP's of the upper Trapezius muscle (with particular reference to TP1 and TP2), as defined by Travell and Simons (1999).

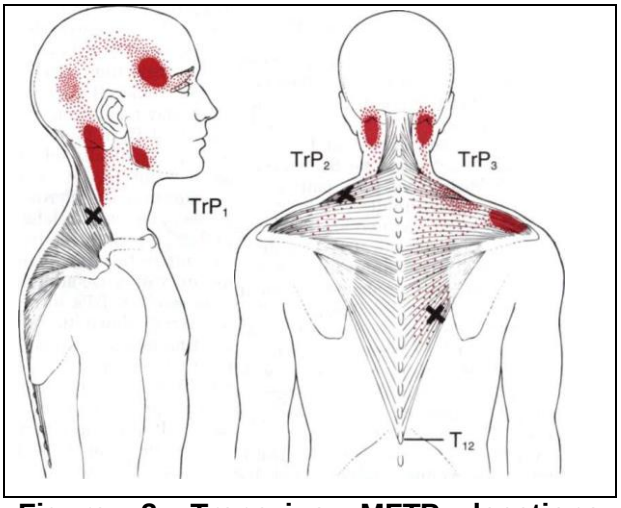


Figure 3 Trapezius MFTP locations
Adapted from Travell and Simons (1999).

For accurate diagnosis of upper Trapezius MFTPs, Travell and Simons (1983) and Travell and Simons (1999) criteria for MFTPs diagnosis will be used. All major criteria were required to be present; minor criteria were not required to be present, but served to confirm the major criteria.

Table 3.2: Specific criteria for the diagnosis of MFTPs:

Major criteria requirements	Minor criteria (confirmatory findings)
Visual or tactile identification of local twitch response. A local twitch of the taut band of muscle when the trigger band is distorted transversely. Pain or altered sensation on compression of the tender nodule Painful limit to full range of motion (active or passive stretch of the opposing muscle). Pain on contraction of the muscle containing the MFTPs Weakness of the muscle containing the MFTPs	A palpable firm area of muscle referred to as the taut band. A localised spot of exquisite tenderness to manual pressure on the MFTP that can be isolated within the taut band. A characteristic pattern of pain in response to sustained pressure on the MFTP within the taut band. This pain is referred in patterns that are specific to individual muscles.

Adapted from Travell and Simons (1983); Travell and Simons (1999)

3.6.2 Exclusion criteria:

- Any potential participant that had received any form of manual therapy for neck or thoracic pain, in the three months preceding this study (Haldeman, 2005).

For all potential participants with particular reference to dry needling

- Any potential participant who had received dry needling treatment in the three months preceding the study (Ferreira, 2006) (in the upper trapezius region).
- Any potential participant had a needle phobia or those prone to convulsions e.g. epilepsy participants (Chaitow and DeLany, 2002; Travell and Simons, 1999).
- Any potential participant who were taking or who had applied a new medication / drug (viz. anti inflammatory drug or muscle relaxant) were required to undergo a three day washout period before being included, otherwise they were excluded (Seth, 1999; Poul *et al*., 1993). Any participant having started a new drug was required to have taken this drug for greater than six weeks prior to the onset of this study (viz. hypertensive medication).
- Any history of trauma and / or surgery to the neck (cervical spine) / back (thoracic spine) (Kendall *et al.*, 2005) resulted in exclusion.
- Pain that could not be reproduced by compression of the MFTPs or that was of an origin not related to MFTPs (Chaitow and DeLany, 2002; Travell and Simons, 1999).

- Participants were screened during the initial examination for any contra-indications for treatment with dry needling (e.g. fever) (Han and Harrison, 1997; Boon and Davidson, 2006).

For all potential participants with particular reference to NSAIDs

- Any potential participant with previous hypersensitivity to Flurbiprofen LAT patches.
- Participants had previously experienced bronchospasm.
- Participants who had had any previous anaphalactoid / anaphylactic reactions.
- Participants who had had any previous angioedema or other hypersensitivity reactions to the use of other NSAIDs.
- Participants who presented with any broken/fragile skin or areas of infection at the site for application, due to the possible systemic absorption of Flubiprofen being compromised or contra-indicated.

NOTE: Even though the exclusion criteria were itemised per group, these criteria were relevant in their entirety to all participants that were evaluated for the purposes of the research.

3.7 Procedure:

1. Advertisements were placed at areas of communal gathering.
2. The researcher was then contacted by the prospective participant. This resulted in an interview that was conducted telephonically or face to face (if the participant presented at the clinic). Questions were asked to determine if the participant met the criteria to join the study (i.e. the inclusion and exclusion criteria). If the inclusion criteria were met then an appointment was made at the Chiropractic Day Clinic, or an appropriate offsite venue.
3. The procedure of the study as well as the research being conducted was then explained to the participant at the initial consultation. If the participant agreed with the outline of the study and time-frame they were then requested to sign a Letter of Information and Informed Consent Form (Appendix B).

4. The participant then received a Letter of Information and Informed Consent Form which they were required to read, after which they had the opportunity ask any questions pertaining to the study. Thereafter, they were asked to sign the Letter of Information and Informed Consent Form (Appendix B). If the participant changed his/her mind they were excluded, if they did not sign a Letter of Information and Informed Consent (Appendix B).
5. The researcher then proceeded to do a thorough case history (Appendix G) and physical examination (Appendix H) which also included a cervical regional examination (Appendix I) to ensure that the participant complied with the inclusion and exclusion criteria.

Two sites were provided for, where the research study was conducted, the first being the Chiropractic Day Clinic and the second an appropriate offsite venue (e.g. sports club as approved by the Durban City Manager (Appendix M). Supervision was provided by the research supervisor at the offsite venues in exactly the same manner as is applicable in the Chiropractic Day Clinic (this is required according to Act 63 of 1982 (as amended)).

Participants were then allocated to their group by a randomisation table (computer generated by the statistician and handed to a neutral third party in order to allocate participants to the groups in a concealed manner) for treatment of the MFTPs. The first group (the Needle group) was treated with dry needling while the second group (the Patch group) was treated with Flubiprofen LAT patches. The research study would take place over two weeks. Each group had three consultations within a week and a follow up within the second week.

3.8 Treatments / Interventions

3.8.1 Treatments

Needle group:

The first group was treated by dry needling which was done under sterile conditions (using appropriate aseptic techniques as well as single needle use (it is noted that the acupuncture needles utilised are made solely for the purpose of single use). The hands of the researcher and area of concern (i.e. upper trapezius muscle) were cleaned using alcohol prior to removal of the needle from its covering and insertion into the MFTP.

The exact site of the MFTP was located. After location, the MFTP was characterised using the Myofascial Diagnostic Scale (Appendix F) (Vaghmaria, 2005; Chettiar, 2001). The participant was then placed in the correct position, which is the prone position or supported seated position (Hong, 2006). The participant was then allowed to relax so that the researcher could expose the area properly. Palpation is the basic method of diagnosis of which there is flat palpation, finger tip palpation, pincer palpation and overlying hand palpation which was used to locate the MFTP (Yap, 2007). The area to be treated was then grasped between the researchers thumb and fingers, with the needle placed over correct area and inserted at that point. The needle tip was expected to encounter the sensitive loci in the MFTP region, which assisted in eliciting a local twitch response (Hong, 2006). The fast-in and fast-out single insertion technique, with a minimum of five fanning strokes (done for 10 seconds) was used for insertion of the dry needle to elicit a twitch response (Hong, 2006). Thereafter, the needle was kept static for one minute so that it could exert its analgesic effects (Hong, 1994). The needle was only used once, before it was then removed and disposed of (in terms of the Health and Safety procedure at the Chiropractic Day Clinic this means disposal into a sharps container).

All students are expected, by the end of their B.Tech: Chiropractic qualification to be able to effectively, efficiently and safely administer dry needling procedures (as

assessed in the B.Tech examinations). Thus, in normal clinic operations, students are expected to be able to administer this intervention without over the shoulder supervision. This would, therefore, apply to the researcher and the context of this research (Korporaal, 2012).

Patch group :

The second group was treated by local action transcutaneous adhesive patches. Flurbiprofen LAT patch is a topical formulation which contains 40mg of flurbiprofen. As a schedule one drug it requires no prescription and can be bought over the counter (TransAct® 1994; Snyman, 2011). The researcher or the participant applied the patch (this was done as per Appendix J).

Flurbiprofen LAT patch are available as a 10cm x 14cm non-woven polyester medicated adhesive patch (TransAct® 1994; Snyman, 2011). The participant was placed in correct position (i.e. prone with the shoulders and back exposed). The correct area (MFTPs located within the upper trapezius muscle) was located (using the Myofascial Diagnostic Scale), and the patch was then placed over the correct area by the researcher, which was stretched to prevent wrinkling. The patch was administered continuously to the skin overlying the painful region. Each patch was applied for a period of 12 hours during the day only, (Galer *et al.,* 2000), with the last patch being applied on the third consultation.

3.8.2 Intervention Frequency

Table 3.3: Treatments / Interventions frequency

		Needle group/Group one	Patch group/Group two
Week One (seven days)	Consultation one	All readings taken for baseline Needling	All readings taken for baseline Application One at visit ,self application daily until next consultation
	Consultation two	Set of readings Needling	Set of readings Daily applications of the patch for the remainder of the week, until next consultation
	Consultation three	Set of readings Needling	Set of readings Application of last patch at this consultation
Week Two	Follow up (Within week two)	Set of readings	Set of readings

During the initial consultation (Table 3.3), readings were taken as a baseline in both groups, and the initial treatment was conducted. Thereafter the next two consultations were scheduled within seven days of the first consultation (Table 3.3). At the second and third consultation, a set of readings was taken before treatment, (Table 3.3) (treatment given, unless participant had complete resolution of MPS) to gauge any changes resulting from the treatments.

The Patch group participants were required to self apply between consultation one and two and between consultation two and three, (Table 3.3) if applicable. For those days that they were not seen by the researcher, each participant was given a box of TransAct® which contained ten Flubiprofen LAT patches. Procedure for self application as per the package insert located in each box (TransAct®, 1994) (Appendix J) applied for the allocated daytime applications of the patch by the participants.

The Needle group participants had a minimum of two days (48 hours) between treatments during the seven day protocol.

The last set of readings was taken at the fourth follow up (within the second week) to confirm the changes, if any. If there was resolution of MPS after the first/second treatment there would be no further application of treatment unless the symptomatology

returned. Due to, improvement of the participant the statistical analysis was done based on the “intention to treat principle”, which indicates that an assumption was made that the participant had achieved optimal outcomes. This implied that the achieved outcomes were maintained over time and therefore no increase or decrease in the clinical outcomes were applicable (viz. the outcomes were maintained at that level) (Hammond, 2011). It was anticipated that very few if any participants would fall into this category.

A blinded assessor (Appendix L) was trained by the researcher / supervisor to record participant improvement outcomes (i.e. measurements/readings). This had been included in order to meet with the PEDro requirements (PEDro, 1999; Maher *et al*., 2003), which define single blinded, based either on patient, therapist or outcomes assessor blinding.

Readings taken, included the Numerical Pain rating Scale (NRS), Neck Disability Index Questionnaire (NDI), Algometer and Cervical Range of Motion (CROM) device for both groups.

After the research study was completed the participant, (if the researcher felt it necessary) was referred to an appropriate health care provider based on continued symptomatology and need for further care, if required.

3.9 Measurements:

3.9.1 Subjective measurements

For this study, the first subjective measurement was the **NRS** which required the participants to estimate their current levels of pain (viz. at the time of the consultation). The NRS is used to determine the severity of pain that patients may be experiencing. The participants were asked to indicate on a line, with a scale of 0-100 what their pain rating was. No pain is indicated by zero and the most extreme pain experienced was

indicated by 100 (Jensen *et al*., 1986). It was chosen due to the ease at which it could be administered and scored and was found to have good reliability, as well as producing data that could be statistically analysed (Williamson and Hoggart, 2005). (Appendix C). The minimal clinically important difference was noted at 20-25mm (Lee et al., 2003; Ostelo and de Vet, 2005).

The **Neck Disability Index Questionnaire** was used to evaluate the cervical spine and associated musculature and was also used to monitor how much the participant's pain had affected their activities of daily life as well as any improvement produced by the therapeutic interventions (Yeomans, 2000). (Appendix D).

3.9.2 Objective measurements

3.9.2.1 Sidedness

The participants left or right side that received treatment was noted so that statistical analysis could determine if there was a difference between treatment outcomes according to sidedness.

3.9.2.2 Myofascial Diagnostic rating Scale (MDS)

The MDS was developed by Chettiar (2001). It is used to assess participants suffering from MPS based on palpation. This instrument has been found to be both a reliable and valid assessment tool for the diagnosis of MPS (Vaghmaria, 2005). According to Fricton (1994), the participant's behavioural reaction to firm palpation is a distinguishing characteristic of myofascial pain and is termed a "jump sign". This reaction may include withdrawal of the head, wrinkling of the face or forehead, or a verbal response such as "That's it" or "Oh yes"", adapted from Vaghmaria (2005). The scale is made up of four grades/indicators. The scale uses numerical grading of the indicators and has been found to be an effective assessment tool when it was positively correlated to the NRS (Vaghmaria, 2005; Myburgh, 2010).

Table 3.4: Myofascial Diagnostic Rating Scale

Grade 0	No tenderness	Score = 0
Grade 1	Tenderness to palpation without grimace or flinch	Score = 1
Grade 2	Tenderness to palpation with grimace and/or flinch	Score = 2
Grade 3	Tenderness with withdrawal	Score = 3
Grade 4	Withdrawal to non-noxious stimuli	Score = 4
The presence of a palpable taut band and a twitch response is indicated by a score each of 4 on the scale. The presence of referred pain is indicated by a score of 5.		

Adapted from Vaghmaria (2005)

According to Vaghmaria (2005), a participant with a rating of greater than or equal to nine on the MDS was found to have MPS. In order to achieve a score of greater than or equal to nine ; two or more criteria on the MDS had to be present (e.g. a participant with a taut band (4) and referred pain (5) would have received a score of greater than or equal to nine according to the scale (Appendix F). This participant in a clinical setting would require treatment (Vaghmaria, 2005). Participants that had less than nine on the MDS did not possess all the major criteria (Table 2.5) for diagnosis of MFTPs and therefore were excluded from participating in the research study.

3.9.2.3 Pressure algometry:

Pressure algometry is a reliable diagnostic tool used to quantitatively document the sensitivity of MFTPs (Hans and Harrison, 1997; Kruze *et al.,* 1992; Maquet *et al.,* 2004; Gold *et al.,* 2006). The algometer is a calibrated force pressure gauge that can be used to assess the pressure pain threshold (PPT) in an individual (Hutchison, 2007). Hutchison (2007) surmised based on a body of evidence (Reeves *et al.,* 1986; Fischer, 1987; Ohrbach and Gale, 1989; Gold *et al.,* 2006; Maquet *et al.,* 2004) that it supports the reliability of pressure gauges (algometers) when used to determine PPTs on bony and muscular landmarks. The reliability of the algometer as an index of MFTP sensitivity has been demonstrated in studies by Reeves *et al*., (1986), Fischer (1987), Maquet *et al.,* (2004) and Gold *et al.,* (2006) who found that it demonstrated both high inter- and intra-examiner reliability in measuring marked MFTPs.

Based on these findings, the algometer was applied manually over MFTPs to measure the minimum pressure that induced pain (Fischer, 1997). The algometer used in this study will be the FDK20 force dial manufactured by Wagner Instruments (Address: P.O. Box 1217 Greenwich, CT, 06836, U.S.A.). The algometer uses kg/cm^2 to show pressure threshold over the MFTP, the more sensitive the MFTP the smaller the reading. Fischer (1987) defines pressure threshold as the minimum pressure that induces pain or discomfort. Correct calibration of the algometer is crucial for achieving reliable readings.

Steps to be taken for algometer reading:

- The dial was set to zero.
- The algometer was placed over the chosen MFTP with the metal rod being perpendicular to the surface of the skin.
- Pressure was applied with an increasing rate of 1kg/second as recommended by Fischer (1987).
- The participant was instructed to express at the point at which the pain was perceived.
- The reading on the algometer was then recorded in kg/cm^2 in Appendix E.

3.9.2.4 CROM Device*:*

The CROM Device was used in testing cervical range of motion (Appendix K) and has been proven to be reliable and a valid tool in cervical range of motion assessment (Hoving *et al.,* 2005). It also compares well against other devices (Lian *et al.,* 2010). For this study the CROM was principally utilised for the measurement of cervical spine lateral flexion (as this is the principle movement of the trapezius muscle), however, other ranges were also recorded and analysed.

3.10 Statistical methodology

Following consultation with a research statistician, statistical analysis was conducted on the data using the latest version of SPSS (manufactured by SPSS Inc., 444N. Michigan Ave, Chicago, Illinois, 60611, USA).

IBM SPSS version 20 was used for the analysis. A *p* value <0.05 was considered as statistically significant (Esterhuizen, 2013).

Independent samples tests were used to compare quantitative baseline and demographic characteristics between the two groups. The data was presented in the form of graphs and tables. Statistical evaluation is aimed at measuring any significant changes occurring between the consultations, as well as between the two groups. Pearson's chi square tests were used when the demographic characteristics were categorical. In order to compare the effectiveness of the two interventions, repeated measures ANOVA was used. Age was use as a covariate in the analysis since the two groups differed significantly in terms of age. A significant time x group interaction effect indicated a significantly different treatment effect in the two groups. The direction and trends of the effects were explored in profile plots. Intra-group correlations between changes in outcomes were achieved using Pearson's correlation coefficient. Correlation coefficients were considered as significant if they were above an absolute value of 0.5 and statistically significant at the 0.05 level (Esterhuizen, 2013).

CHAPTER FOUR

Results

4.1 Introduction

This chapter discusses and compares and contrasts the results. Although it is not the norm to combine the results chapter with the discussion chapter it is done here to facilitate and ease understanding of the results.

4.2 Data sources

The primary sources used to collect data for this study included the:

- NRS (Williamson and Hoggart, 2005; Appendix C)
- NDI (Yeomans, 2000; Appendix D)
- MDS (Chettiar, 2001; Vaghmaria, 2005; Appendix F)
- Algometer (Hans and Harrison, 1997; Kruze *et al.,* 1992; Maquet *et al.,* 2004; Gold *et al.,* 2006; Appendix E)
- CROM (Hoving *et al.,* 2005; Appendix K)
- Cervical spine regional examination (Appendix I)

The secondary sources included:

- Various Books
- Various Journals
- Conferences
- Websites
- Personal communication with a statistician (Esterhuizen, 2013)

4.3 Abbreviations specific to Chapter Four

The following abbreviations occur specifically in Chapter Four:

Alg	Algometer
Df	Differential
EXT	Extension of the cervical spine
F	Refers to the frequency (Swinscow, 1996; Wright, 1998; Hinton, 2001)
FLEX	Flexion of the cervical spine
L	Left
LLF	Left lateral flexion of the cervical spine
LR	Left Rotation of the cervical spine/head
N	Number
p	Indicates the data statistical significance (Swinscow, 1996; Wright, 1998; Hinton, 2001; Campbell and Swinscow, 2009)
R	Right
RLF	Right lateral flexion of the cervical spine
RR	Right rotation of the cervical spine/head
sig	Refers to the significance (Swinscow, 1996; Wright, 1997; Hinton, 2001)
TP	Trigger point
%	Percentage
=	Equals
<	Less than
>	Greater than
≥	Greater or equal to
1	Baseline outcome measures in all graphs
2	The second set of outcome measures prior to visit two
3	The third set of outcome measures prior to visit three
4	The final follow up set of outcome measures

4.4 Patient flow as per the Consort diagram

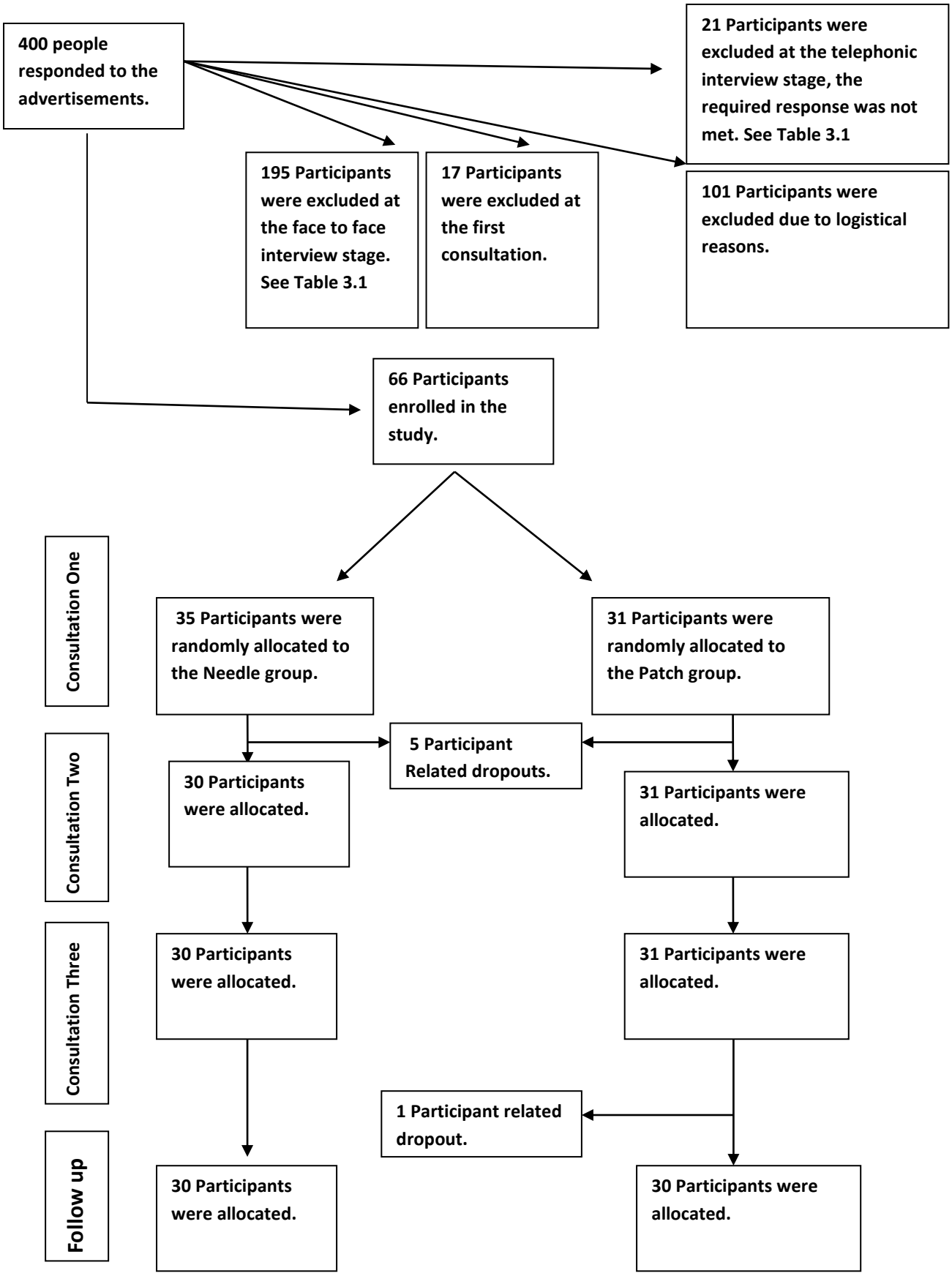


Figure 4.1 Consort diagram outlining the patient flow chart in this study

4.4.1 Discussion of the Consort

CONSORT, is simply defined as a checklist and flow diagram, and is utilized for reporting a randomized controlled trial (RCT) (Moher *et al*., 2001), with the purpose of writing, reviewing and assessing reports of two-group parallel RCTs (Moher *et al*., 2001).According to Moher *et al.,* (2001), and Egger *et al*., (2001), the use of CONSORT helps to improve the quality of reporting of RCTs and as such CONSORT should positively influence the manner in which RCTs are conducted (Moher *et al*., 2001).

According to the CONSORT diagram (Figure 4.1) of the 400 people responding to the advertisements for this study, 101 participants were immediately excluded for logistical reasons (e.g. potential participants indicated their inability to commit to the research schedule). A further 216 participants were excluded initially either through the telephonic interview or through face-to-face interview for not meeting the inclusion criteria or matching one or more of the exclusion criteria. The last 17 potential participants were excluded at the first consultation (after a clinical evaluation revealed that the potential participants did not fully meet the inclusion criteria or presented with one or more exclusion criteria).

As a result of strictly adhering to the inclusion and exclusion criteria meant they were applied in the study and thus allowed for the participants in each group to be equitably compared.

The possibility of bias between the groups, as a result of a greater loss of participants in the Needle group, may have resulted in an unfair clinical picture in terms of clinical improvement (viz. reflecting only those that got better), particularly if all the drop-outs had dropped out for reasons of regression of their clinical symptoms. It is, however, noted that this large group dropped out for reasons of non-compliance in the research protocol and therefore any skewing of the clinical picture was unlikely and comparison between the groups were more equitable.

During the consultation/research process six participants dropped out, five from the Needle group and one from the Patch group. All of these participants dropped out for logistical related reasons (transport, inability to comply with the research protocol).

Thus by implication, this was not due to clinical regression, thus excluding group bias. As such, there was no bias introduced into the study by excluding these participants. This outcome implies that the research was more likely to reflect the effect of the two intervention protocols as opposed to any factor related to the composition of the two treatment groups (Mouton, 1996). It would, therefore, be fair to state that the outcome of this study would be related to either of the two interventions.

4.5 Objectives

Prior to presenting the results of this study, the aims and objectives are briefly outlined here, with the aim having been to investigate the effectiveness of dry needling versus Flurbiprofen LAT patch in the treatment of myofascial pain syndrome of the upper Trapezius muscle.

The specific objectives were to:

1. Determine the effectiveness of dry needling versus Flurbiprofen LAT patches in terms of the objective findings (i.e.: Myofascial Diagnostic Rating Scale, Algometer, and CROM Device).
2. Determine the effectiveness of dry needling versus Flurbiprofen LAT patches in terms of the subjective findings (i.e.: NRS and NDI).
3. Determine if any significant clinical / statistical differences existed between dry needling versus Flurbiprofen LAT patches in terms of the objective and subjective results.
4. Determine the correlation between changes in subjective and objective outcomes from pre to post intervention within the treatment groups.

4.6 Demographic and Baseline Results

4.6.1 Demographics

A total of 60 participants were enrolled into the study and randomised into two equal groups. In order to ensure that randomisation was complete, the two groups were compared in terms of demographic characteristics and baseline outcomes.

4.6.1.1 Age

Table: 4.1a Demographics by group:

	Group				*p* value
	Needle		Patch		
	Mean	Standard Deviation	Mean	Standard Deviation	0.039
Age	27.5	4.0	29.6	3.6	

There was a significant difference in terms of mean age of the two groups (p=0.039). The Patch group was older than the Needle group. Therefore, age had to be adjusted for in analysis of the effect of the intervention.

4.6.1.2 Gender and Ethnicity

Table: 4.1b Demographics by group:

		Group				*p* value
		Needle		Patch		
		Count	Column N %	Count	Column N %	
Gender	Female	9	30.0%	16	53.3%	0.067
	Male	21	70.0%	14	46.7%	
Ethnicity	Black	21	70.0%	19	63.3%	0.790
	Coloured	2	6.7%	1	3.3%	
	Indian	3	10.0%	5	16.7%	
	White	4	13.3%	5	16.7%	

There was no significant difference between the groups in terms of gender or race.

4.6.1.3 Discussion of the Demographics

According to Tables 4.1a and 4.1b, the findings indicate the demographic data of the two groups to be statistically significant different with regards to age (p=0.039) and not statistically significant in regard to gender (p=0.067) and ethnicity (p=0.790).

Participants used in this study were between the ages of 18-35 so as to limit the incidence of degenerative changes to the spine which increases after the age of 35, as well as potentially being in the stabilization phase of spinal development which decreases both movement and pain, thus, affecting the musculature *(*Kirkaldy-Willis and Burton, 1992; Yochum and Rowe, 2005). Additionally, Han and Harrison, (1997) suggested that patients between the ages of 30-49 appear to have the highest prevalence of MFTPs, which decreases thereafter the age of 49. Therefore, in both instances, the group for this study were constituted mainly by the working class. This concurs with Chaiamnuay *et al*., (1998), who indicated an association between the working class and the presentation of MFTPs. The significant age difference (p=0.039) between the two groups resulted in a lack of homogeneity of the groups (Mouton, 1996), which required that age had to be adjusted for in analysis of the effect of the intervention, in order to extract the intervention effect and not the intervention effect as influenced by age.

In regards gender there is a female predominance in terms of the recorded prevalence of MFTPs (Han and Harrison, 1997; Travell and Simons, 1999). In contrast, this study had a majority of male participants, which constituted an inverted presentation when compared to the literature. This may have been as a result of the large proportion of drop-outs/non-participants that were female. This dropout rate seems to have been linked to a reluctance to join the study as a result of various personal constraints (time, transport, home or career responsibilities). Thus, as a result, even though there was a higher predominance of males, this persisted in both groups and therefore there was no significant difference (p=0.067) between the intervention in terms of gender. Therefore, it was concluded that gender had no perceived influence in the clinical outcomes of this study. However, caution is required in terms of the contextualisation of the results in the literature, due to the higher male predominance.

Regarding ethnicity there is a paucity of literature concerning the prevalence of MFTPs within ethnic groups. This limited the ability of the researcher to complete a successful literature based comparison. Nevertheless, within this study there were no significant differences (p=0.790) between the ethnic groups and as such there was no expected influence in the clinical outcomes of this study.

Based on this demographic data, the only significant difference was age, which was adjusted for in the statistical analysis. Furthermore, there were no significant differences between gender and ethnicity. Thus, future studies need to consider stratification for patient ages in order for results to be generalisable to specific population groups and allow for equitable comparison between two interventions without the need for statistical controlling.

4.6.2 Baseline of clinical measures

Table 4.2: Baseline per group:

	Needle		Patch		*p* value
	Mean	Standard Deviation	Mean	Standard Deviation	
Myofascial diagnostic scale					
MDS 1	10.8	1.2	11.3	1.3	0.136
Algometer					
Trapezius TP 1 Alg R 1	5.0	2.3	4.9	1.6	0.889
Trapezius TP 1 Alg L 1	4.8	2.2	4.2	1.2	0.256
Trapezius TP 2 Alg R 1	4.0	2.0	4.4	1.5	0.666
Trapezius TP 2 Alg L 1	3.9	2.4	5.0	1.6	0.267
CROM Range of motion					
LLF 1	30.3	10.2	29.4	8.3	0.710
RLF 1	27.7	9.7	28.1	9.5	0.873
LR 1	53.3	13.8	55.6	12.4	0.506
RR 1	55.5	12.8	57.6	10.7	0.486
FLEX 1	35.8	12.8	36.3	9.5	0.864
EXT 1	50.5	11.8	53.0	10.6	0.385
Numerical pain rating scale					
NRS 1	42.7	16.3	43.9	19.4	0.810
Neck Disability Index					
NDI total % 1	19.6	13.1	24.4	17.6	0.234

There were no significant baseline differences in outcome measurements between the two groups (Table 4.2).

4.6.2.1 Discussion of Baseline

According to the findings stated in Table 4.2 there were no significant baseline differences of the clinical outcomes (objective data and subjective data) (Esterhuizen, 2013). As such, the lack of significance between the Needle and Patch groups indicates that the groups presented with MPS that was clinically similar. It is therefore possible to state that tracking and comparison of the groups over time would allow for an accurate reflection of the effect of the interventions (controlling for age which could be seen as a modifying factor).

4.7 Objective One and Results

Objective one was to determine the effectiveness of dry needling versus Flurbiprofen LAT patches in terms of the objective findings (i.e.: Myofascial Diagnostic Rating Scale, Algometer, and CROM Device).

4.7.1 Objective outcomes

4.7.1.1 Myofascial Diagnostic Scale (MDS)

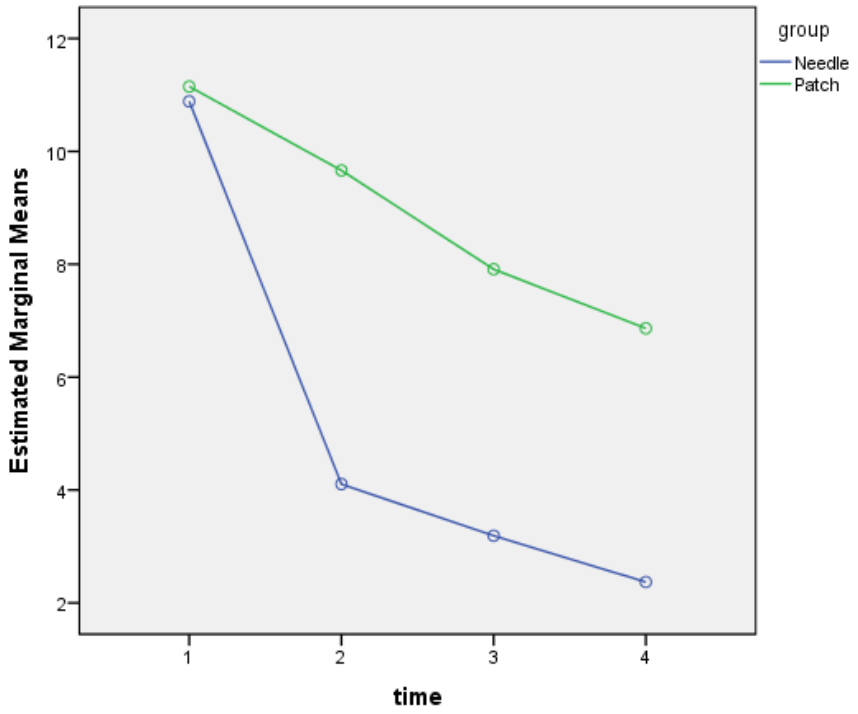
There was a significant difference in MDS values over time between the groups (p<0.001). Figure 4.2 shows that the Needle group experienced a faster rate of decrease in MDS score than the Patch group.

Table 4.3a:Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Pillai's Trace	0.016	0.291[b]	3.000	55.000	0.832
	Wilks' Lambda	0.984	0.291[b]	3.000	55.000	0.832
	Hotelling's Trace	0.016	0.291[b]	3.000	55.000	0.832
	Roy's Largest Root	0.016	0.291[b]	3.000	55.000	0.832
Time * age	Pillai's Trace	0.131	2.760[b]	3.000	55.000	0.051
	Wilks' Lambda	0.869	2.760[b]	3.000	55.000	0.051
	Hotelling's Trace	0.151	2.760[b]	3.000	55.000	0.051
	Roy's Largest Root	0.151	2.760[b]	3.000	55.000	0.051
Time * group	Pillai's Trace	0.442	14.499[b]	3.000	55.000	0.000
	Wilks' Lambda	0.558	14.499[b]	3.000	55.000	0.000
	Hotelling's Trace	0.791	14.499[b]	3.000	55.000	0.000
	Roy's Largest Root	0.791	14.499[b]	3.000	55.000	0.000
a. Design: Intercept + age + group / Within Subjects Design: time						
b. Exact statistic						

Table 4.3b:Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	358.967	1	358.967	19.708	.000
Age	24.319	1	24.319	1.335	.253
Group	787.622	1	787.622	43.243	.000
Error	1038.198	57	18.214		



Covariates appearing in the model are evaluated at the following values: age = 28.57

Figure 4.2 Intergroup MDS changes over time

4.7.1.1.1 Discussion

MDS is described in Section 3.9 (in Chapter Three) as a palpatory scale designed to assess participants suffering from MPS, a score of ≥9 indicates a positive finding of MPS. As such it was reported in Table 4.3 that a significant difference in MDS (see Section 3.5.3 for review of scale) values over time between the groups was seen (p<0.001). Additionally, Figure 4.2 shows that the Needle group experienced a faster rate of decrease in MDS score in contrast to the Patch group.

This implies that the MDS decreased at a faster rate and to a greater extent in the Needle group as compared to the Patch group. There may be a number of possible theoretical constructs that may assist in explaining this outcome in support of the Needle group or the Patch group:

With dry needling being a mechanically invasive procedure, in which an acupuncture needle is inserted into the skin and muscle (Dommerholt *et al.,* 2006), it results in the mechanical disruption of the MFTP and the associated fibrotic scar tissue, therefore, eliminating the taut band (Yap, 2007).

Additionally, the electrical effect within the MFTP (referred to as SEA) has been described as a characteristic of MFTPs (Ge *et al.,* 2011) (Section 2.5 of Chapter Two). This is because the MFTPs are closely associated to motor end-plates. When these motor end-plates are affected adversely by SEA, it usually results in the development of excessive localised muscle contraction (MFTP) (Lavelle *et al*., 2007). Therefore, as seen in Section 2.7.1 of Chapter Two dry needling eliminates the SEA due to its bio-electrical effect (Ge *et al*., 2011). This effect not only changes the ionic charges in the region of the needle, but also increases blood flow to the muscle and induces a change in the level of inflammatory mediators (Barbara *et al*., 2012).

Lastly, the chemical effect: Due to the inflammatory sequelae (described in Section 2.5 of Chapter Two) of MPS, it stands to reason that the Flurbiprofen Lat Patches (Argoff, 2004; Argoff, 2006) would principally affect this domain due to its anti-inflammatory effect. By contrast, the needling effect has no direct effect on MFTPs in terms of chemical changes, other than the indirect

effect of increased blood flow (Barbara *et al*., 2012).

Therefore, the result seems to suggest that since dry needling imparts a direct mechanical, electrical, and an indirect chemical effect on a MFTP, in comparison to the Patch group, which seems to only have a one mechanism of action (i.e. chemical); it would be expected that the Needle group would demonstrate a quicker and steeper rate of MDS score improvement than the Patch group. Therefore, the results related to this outcome measure is consistent with the literature in this domain.

4.7.1.2 Algometer Data

4.7.1.2.1 Trapezius TP1 R

There was no difference in effectiveness between the two interventions (p=0.534). Figure 4.3 shows that both groups experienced an increase in this value (i.e. algometer readings of TP1 R) over time to the same extent (parallel profiles over time).

Table 4.4a: Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Pillai's Trace	0.022	0.346[b]	3.000	46.000	0.792
	Wilks' Lambda	0.978	0.346[b]	3.000	46.000	0.792
	Hotelling's Trace	0.023	0.346[b]	3.000	46.000	0.792
	Roy's Largest Root	0.023	0.346[b]	3.000	46.000	0.792
Time * age	Pillai's Trace	0.044	0.707[b]	3.000	46.000	0.553
	Wilks' Lambda	0.956	0.707[b]	3.000	46.000	0.553
	Hotelling's Trace	0.046	0.707[b]	3.000	46.000	0.553
	Roy's Largest Root	0.046	0.707[b]	3.000	46.000	0.553
Time * group	Pillai's Trace	0.046	0.739[b]	3.000	46.000	0.534
	Wilks' Lambda	0.954	0.739[b]	3.000	46.000	0.534
	Hotelling's Trace	0.048	0.739[b]	3.000	46.000	0.534
	Roy's Largest Root	0.048	0.739[b]	3.000	46.000	0.534
a. Design: Intercept + age + group / Within Subjects Design: time						
b. Exact statistic						

Table 4.4b: Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	Df	Mean Square	F	Sig.
Intercept	1.402	1	1.402	0.134	0.716
age	119.721	1	119.721	11.416	0.001
group	36.153	1	36.153	3.447	0.069
Error	503.395	48	10.487		

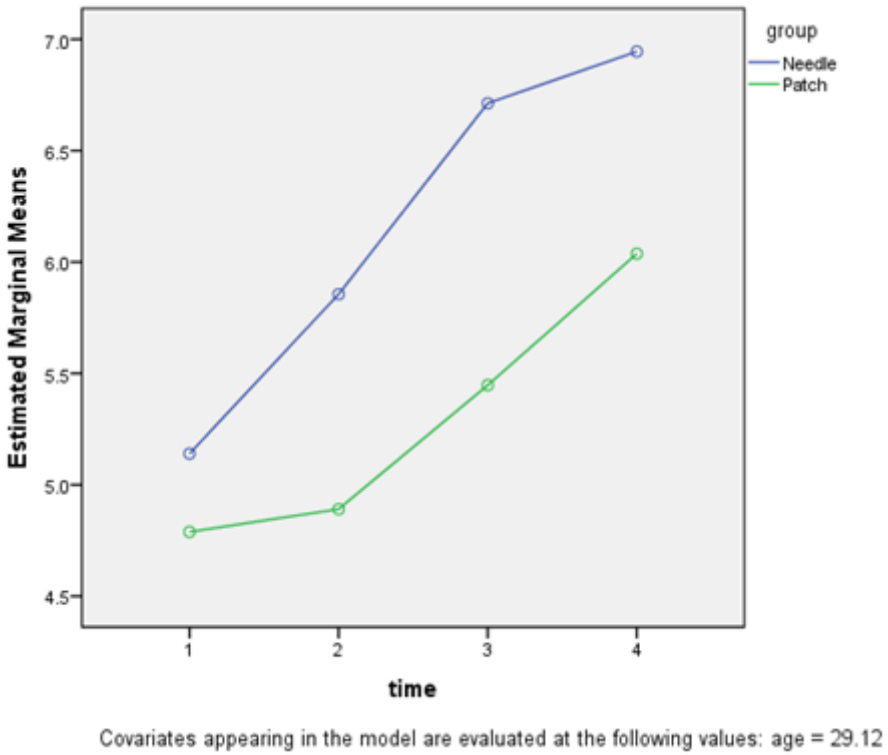


Figure 4.3 Intergroup Algomter TP1 R changes over time

4.7.1.2.2 Trapezius TP1 L

There was no difference in effectiveness between the two interventions (p=0.534). Figure 4.4 shows that both groups experienced an increase in this value (i.e. algometer readings of TP1 L) over time to the same extent (parallel profiles over time).

Table 4.5a: Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	0.009	0.151[b]	3.000	51.000	0.929
	Wilks' Lambda	0.991	0.151[b]	3.000	51.000	0.929
	Hotelling's Trace	0.009	0.151[b]	3.000	51.000	0.929
	Roy's Largest Root	0.009	0.151[b]	3.000	51.000	0.929
time * age	Pillai's Trace	0.007	0.114[b]	3.000	51.000	0.951
	Wilks' Lambda	0.993	0.114[b]	3.000	51.000	0.951
	Hotelling's Trace	0.007	0.114[b]	3.000	51.000	0.951
	Roy's Largest Root	0.007	0.114[b]	3.000	51.000	0.951
time * group	Pillai's Trace	0.038	0.673[b]	3.000	51.000	0.572
	Wilks' Lambda	0.962	0.673[b]	3.000	51.000	0.572
	Hotelling's Trace	0.040	0.673[b]	3.000	51.000	0.572
	Roy's Largest Root	0.040	0.673[b]	3.000	51.000	0.572
a. Design: Intercept + age + group / Within Subjects Design: time						
b. Exact statistic						

Table 4.5b: Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	Df	Mean Square	F	Sig.
Intercept	32.298	1	32.298	2.947	0.092
age	19.919	1	19.919	1.817	0.183
group	47.572	1	47.572	4.340	0.042
Error	580.926	53	10.961		

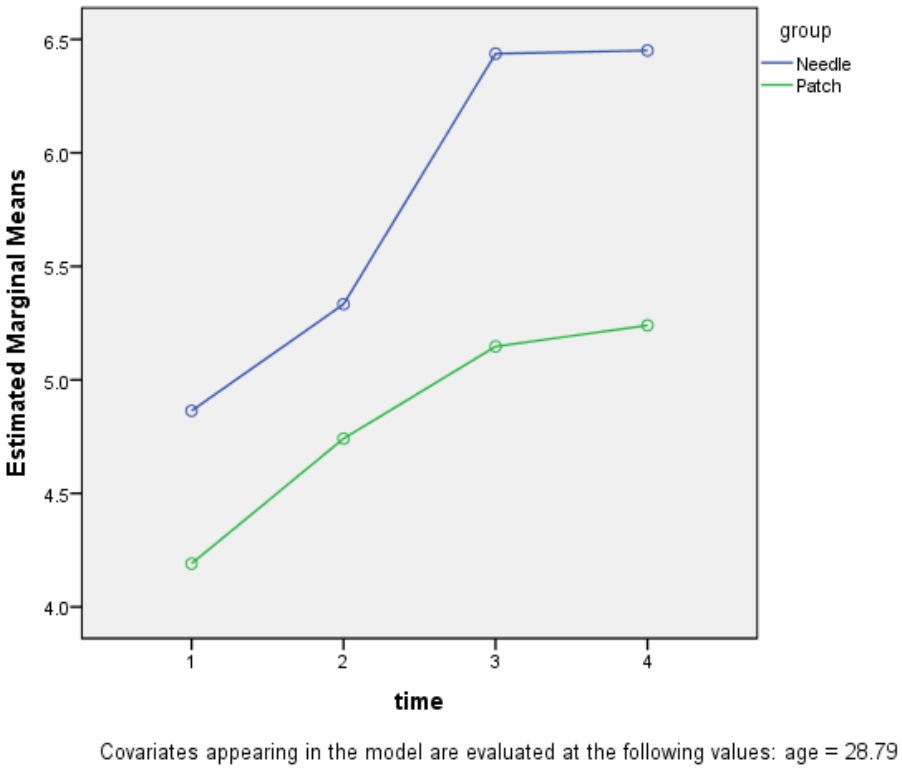


Figure 4.4 Intergroup Algomter TP1 L changes over time

4.7.1.2.3 Trapezius TP2 R

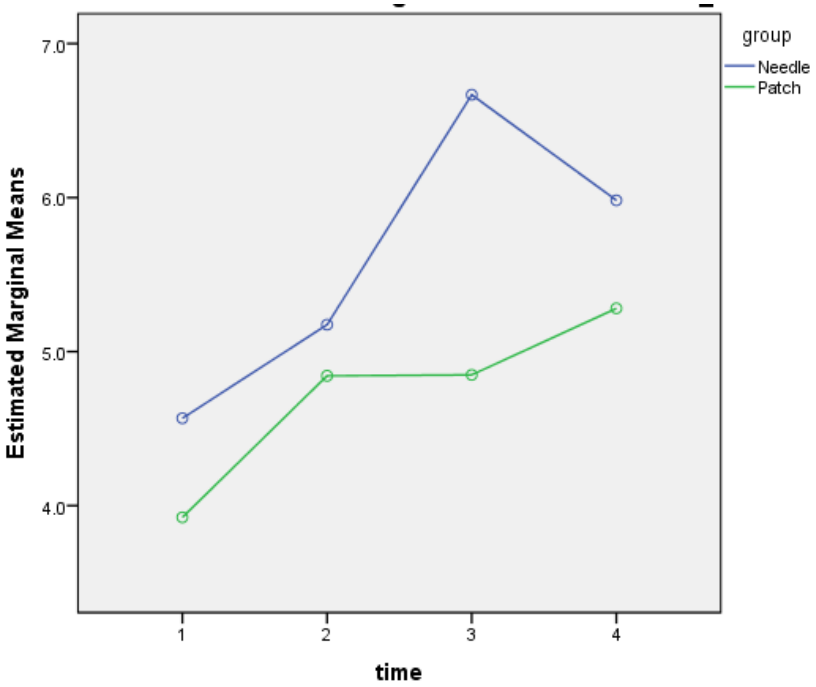
There was no difference in effectiveness between the two interventions (p=0.239). Figure 4.5 shows that both groups experienced an increase in this value (i.e. algometer readings of TP2 R) over time but the profiles were not exactly parallel. The sample size was small for this outcome and thus the power to detect a significant difference was limited.

Table 4.6a: Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	0.301	2.014[b]	3.000	14.000	0.158
	Wilks' Lambda	0.699	2.014[b]	3.000	14.000	0.158
	Hotelling's Trace	0.432	2.014[b]	3.000	14.000	0.158
	Roy's Largest Root	0.432	2.014[b]	3.000	14.000	0.158
time * age	Pillai's Trace	0.286	1.869 k[b]	3.000	14.000	0.181
	Wilks' Lambda	0.714	1.869[b]	3.000	14.000	0.181
	Hotelling's Trace	0.401	1.869[b]	3.000	14.000	0.181
	Roy's Largest Root	0.401	1.869[b]	3.000	14.000	0.181
time * group	Pillai's Trace	0.253	1.577[b]	3.000	14.000	0.239
	Wilks' Lambda	0.747	1.577[b]	3.000	14.000	0.239
	Hotelling's Trace	0.338	1.577[b]	3.000	14.000	0.239
	Roy's Largest Root	0.338	1.577[b]	3.000	14.000	0.239
a. Design: Intercept + age + group / Within Subjects Design: time						
b. Exact statistic						

Table 4.6b: Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	3.298	1	3.298	0.312	0.584
age	19.304	1	19.304	1.827	0.195
group	10.100	1	10.100	0.956	0.343
Error	169.055	16	10.566		



Covariates appearing in the model are evaluated at the following values: age = 26.05

Figure 4.5 Intergroup Algomter TP2 R changes over time

4.7.1.2.4 TrapeziusTP2 L

There was no difference in effectiveness between the two interventions (p=0.834). Figure 4.6 shows that both groups experienced an increase in this value (i.e. algometer readings of TP2 L) over time but the profiles were not exactly parallel. The sample size was small for this outcome and thus the power to detect a significant difference was limited.

Table 4.7a: Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	0.070	0.349[b]	3.000	14.000	0.791
	Wilks' Lambda	0.930	0.349[b]	3.000	14.000	0.791
	Hotelling's Trace	0.075	0.349[b]	3.000	14.000	0.791
	Roy's Largest Root	0.075	0.349[b]	3.000	14.000	0.791
time * age	Pillai's Trace	0.091	0.470[b]	3.000	14.000	0.708
	Wilks' Lambda	0.909	0.470[b]	3.000	14.000	0.708
	Hotelling's Trace	0.101	0.470[b]	3.000	14.000	0.708
	Roy's Largest Root	0.101	0.470[b]	3.000	14.000	0.708
time * group	Pillai's Trace	0.058	0.287[b]	3.000	14.000	0.834
	Wilks' Lambda	0.942	0.287[b]	3.000	14.000	0.834
	Hotelling's Trace	0.062	0.287[b]	3.000	14.000	0.834
	Roy's Largest Root	0.062	0.287[b]	3.000	14.000	0.834
a. Design: Intercept + age + group Within Subjects Design: time						
b. Exact statistic						

Table 4.7b: Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	4.434	1	4.434	0.347	0.564
age	56.769	1	56.769	4.447	0.051
group	13.682	1	13.682	1.072	0.316
Error	204.251	16	12.766		

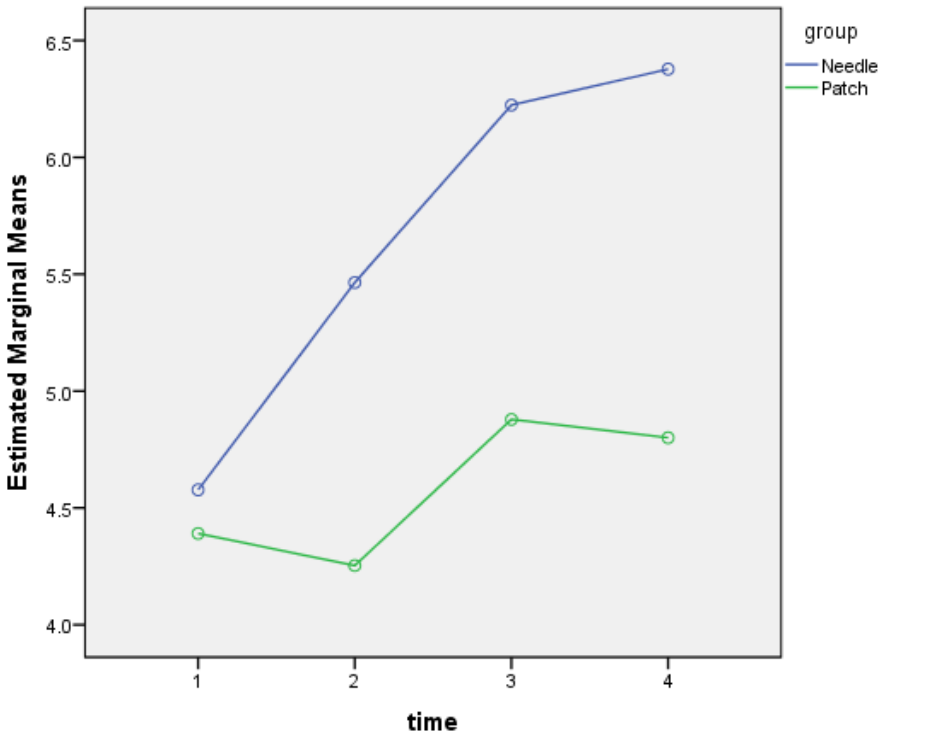


Figure 4.6 Intergroup Algomter TP2 L changes over time

4.7.1.2.5 Discussion

As discussed in Section 3.9.2.3, the algometer is a pressure gauge that is used to assess the pressure pain threshold (PPT) in an individual can tolerate thus the amount of force applied to the MFTP may vary accordingly (Hutchinson, 2007; Reeves *et al*., 1986; Fischer, 1986; Gold *et al*., 2006; Maquet *et al*., 2004).Therefore, the algometer quantifies the sensitivity of MFTPs, by measuring the minimum pressure that induces pain (Reeves *et al*., 1986; Fischer, 1986; Gold *et al*., 2006; Maquet *et al*., 2004). Lower readings indicate decreased tolerance to MFTP pain, and higher results indicate an increase in pain tolerance resulting from decreased MFTP sensitivity (Han and Harrison, 1997).

Recorded means for TP1 R and TP1 L (Figures 4.3 and 4.4) indicated a far steeper slope of incline in measurements for the Needle group than the Patch group over the course time. It was noted that both groups showed an increase in algometer measurements over time. As such, according to the results obtained for TP1R and TP1L there was no statistical difference in terms of degree (p=0.534) in increase between the two interventions. Clinically, this implies that the two MFTPs clinically improved to the same extent (as measured by tenderness), implying that there were

parallel improvements in any oedema (brought on by the inflammatory response see 2.5) (Simons and Mense, 1998; Laferriere *et al*., 2008) associated with the MFTPs and / or in the degree of sensitivity (Han and Harrison, 1997) of the two MFTPs as precipitated through either the inflammatory process or stimulation of the nociceptive fibers due to a build up of noxious stimuli (Guyton and Hall, 2000) that are not taken away from the hyper-metabolic area associated with the MFTP (Simons and Mense, 1998; Laferriere *et al*., 2008; Ge *et al*., 2011). The steeper rate of improvement of the Needle group would concur with the findings of the MDS, where the Needle group was seen to improve to a greater extent (when compared by gradient). Therefore, these results agree with each other.

Secondly and according to the algometer results obtained there was no difference in effectiveness over time between the two interventions, as they related to TP2 R (p=0.239) and TP2 L (p=0.834). Figure 4.5 and Figure 4.6 show that both groups experienced an increase in this value over time but the profiles were not exactly parallel (as compared to the right and left TP1). This would suggest a deviation from the discussion around the resolution of TP1 as well as the MDS.

The reason(s) for this deviation, can only be speculated because of the small sample size of the group (therefore, a question that needs to be asked is, was it a factor within the group that led to this outcome – e.g. and outlier reading?). Additionally, the amount of time given for interventions and readings may have affected the outcome as well (viz. it would be necessary for further follow up readings to be taken in order to ensure that the trend noted continues and whether or not it is significant).

From a clinical perspective it would be necessary to consider the functions of the muscle components of the trapezius in which the TP1 and the TP2 are located (Travell and Simons, 1999; Vizniak, 2010). These functions may assist in determining the difference in the clinical outcome of the algometer readings (an example of this would be hand dominance, which would place a different stressor on the trapezius fibers associated with the specific MFTPs). In a similar manner, participant activity may have influenced this outcome by placing particular stress on certain parts of the trapezius muscle resulting in particular fibers being affected more than others – thereby affecting the clinical picture of the groups, making them less comparable.

In this vein it is also prudent to consider the possibility that the needle effect may have resulted in particular changes within the musculoskeletal system / biomechanics of the region, which may place undue strain on particular parts of the musculoskeletal system - particularly on the dominant side (Norkin and Levangie, 1992; Sahrmann, 2000).

In terms of a minimal important clinical difference, the literature notes that a 15% (Paungmali *et al*., 2003; Potter *et al*., 2006 and O'Leary *et al*., 2007) or a 1.77kg/cm^2 change from the baseline (Chesterton, 2007), should be considered as significant. For the change in algometer readings this is found only for the readings measured at the TP1 on the R and the L, indicating that the interventions are clinically effective a reducing the tenderness/inflammation and increasing the pressure threshold of the patients at this specified MFTP.

4.7.1.3 CROM Data

4.7.1.3.1 Left Lateral Flexion (LLF)

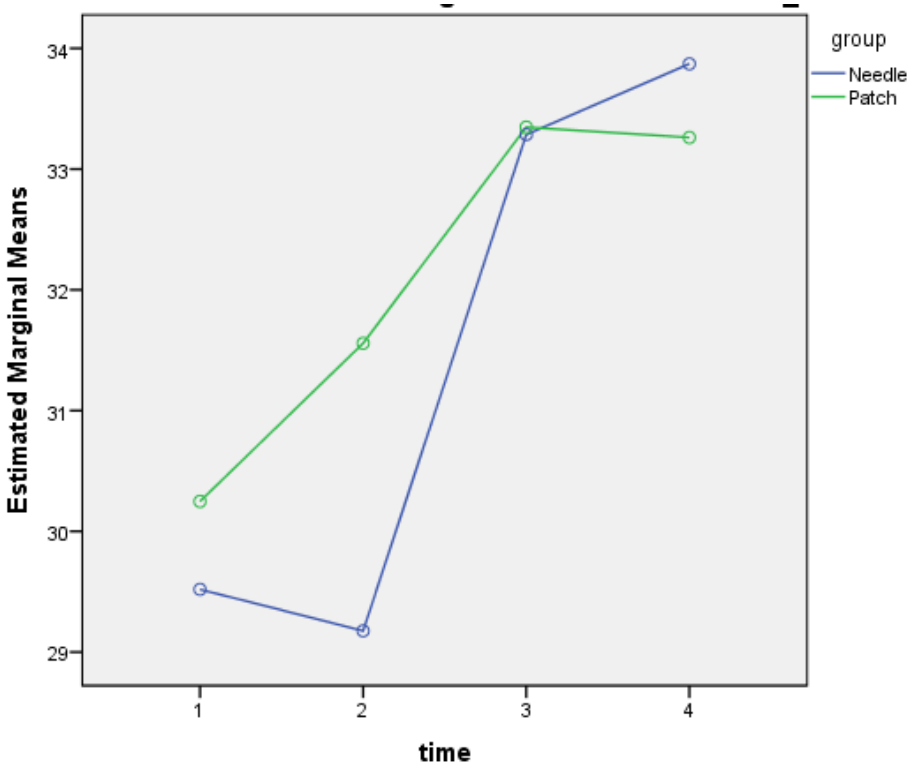
There was no difference in effectiveness between the two interventions (p=0.338). Figure 4.7 shows that both groups experienced an increase in the LLF score over time but the profiles were not exactly parallel. There was a trend towards the Needle group showing a greater rate of increase, but this could have happened by chance and cannot be confirmed statistically.

Table 4.8a: Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	0.010	0.183[b]	3.000	55.000	0.907
	Wilks' Lambda	0.990	0.183[b]	3.000	55.000	0.907
	Hotelling's Trace	0.010	0.183[b]	3.000	55.000	0.907
	Roy's Largest Root	0.010	0.183[b]	3.000	55.000	0.907
time * age	Pillai's Trace	0.022	0.410[b]	3.000	55.000	0.746
	Wilks' Lambda	0.978	0.410[b]	3.000	55.000	0.746
	Hotelling's Trace	0.022	0.410[b]	3.000	55.000	0.746
	Roy's Largest Root	0.022	0.410[b]	3.000	55.000	0.746
time * group	Pillai's Trace	0.059	1.148[b]	3.000	55.000	0.338
	Wilks' Lambda	0.941	1.148[b]	3.000	55.000	0.338
	Hotelling's Trace	0.063	1.148[b]	3.000	55.000	0.338
	Roy's Largest Root	0.063	1.148[b]	3.000	55.000	0.338
a. Design: Intercept + age + group Within Subjects Design: time						
b. Exact statistic						

Table 4.8b: Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	11504.384	1	11504.384	52.206	0.000
age	1932.152	1	1932.152	8.768	0.004
group	22.873	1	22.873	0.104	0.748
Error	12560.815	57	220.365		



Covariates appearing in the model are evaluated at the following values: age = 28.57

Figure 4.7 Intergroup CROM LLF changes over time

4.7.1.3.2 Right Lateral Flexion (RLF)

There was a significant difference in RLF values over time between the groups (p=0.043). Figure 4.8 shows that the Needle group experienced a faster rate of increase in RLF score than the Patch group.

Table 4.9a: Multivariate Tests[a]

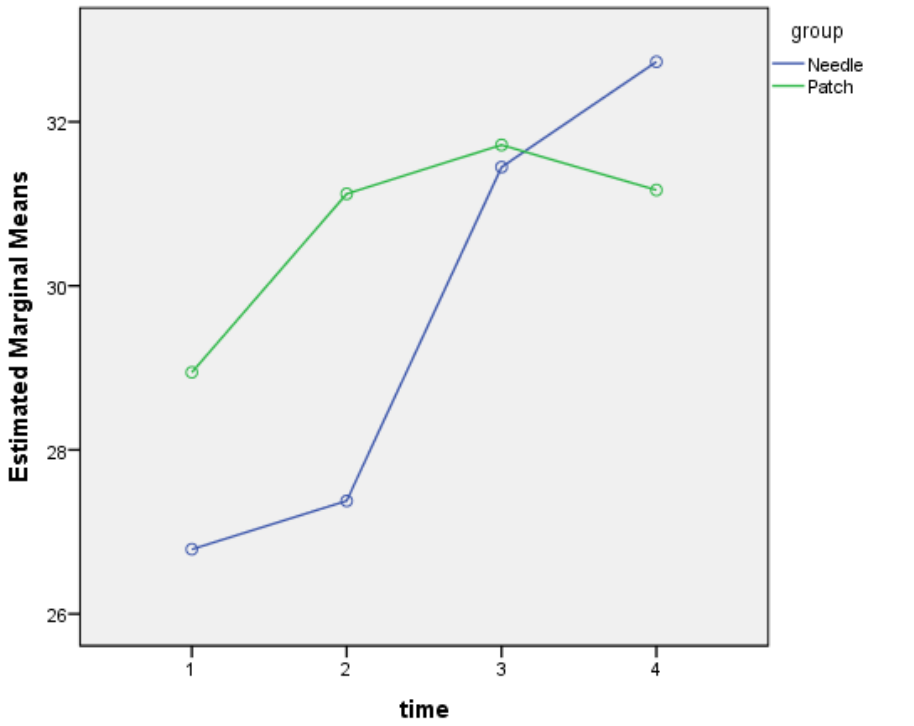
Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	0.015	0.287[b]	3.000	55.000	0.835
	Wilks' Lambda	0.985	0.287[b]	3.000	55.000	0.835
	Hotelling's Trace	0.016	0.287[b]	3.000	55.000	0.835
	Roy's Largest Root	0.016	0.287[b]	3.000	55.000	0.835
time * age	Pillai's Trace	0.009	0.170[b]	3.000	55.000	0.916
	Wilks' Lambda	0.991	0.170[b]	3.000	55.000	0.916
	Hotelling's Trace	0.009	0.170[b]	3.000	55.000	0.916
	Roy's Largest Root	0.009	0.170[b]	3.000	55.000	0.916
time * group	Pillai's Trace	0.137	2.900[b]	3.000	55.000	0.043
	Wilks' Lambda	0.863	2.900[b]	3.000	55.000	0.043
	Hotelling's Trace	0.158	2.900[b]	3.000	55.000	0.043
	Roy's Largest Root	0.158	2.900[b]	3.000	55.000	0.043

a. Design: Intercept + age + group
Within Subjects Design: time

b. Exact statistic

Table 4.9b: Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	11318.232	1	11318.232	47.858	0.000
age	2148.513	1	2148.513	9.085	0.004
group	73.878	1	73.878	0.312	0.578
Error	13480.395	57	236.498		



Covariates appearing in the model are evaluated at the following values: age = 28.57

Figure 4.8 Intergroup CROM RLF changes over time

4.7.1.3.3 Left Rotation (LR)

There was no difference in effectiveness between the two interventions (p=0.168). Figure 4.9 shows that both groups experienced an increase in the LR score over time but the profiles were not exactly parallel. Again the trend was for greater increase in the Needle group.

Table 4.10a: Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	0.061	1.189[b]	3.000	55.000	0.322
	Wilks' Lambda	0.939	1.189[b]	3.000	55.000	0.322
	Hotelling's Trace	0.065	1.189[b]	3.000	55.000	0.322
	Roy's Largest Root	0.065	1.189[b]	3.000	55.000	0.322
time * age	Pillai's Trace	0.025	0.462[b]	3.000	55.000	0.710
	Wilks' Lambda	0.975	0.462[b]	3.000	55.000	0.710
	Hotelling's Trace	0.025	0.462[b]	3.000	55.000	0.710
	Roy's Largest Root	0.025	0.462[b]	3.000	55.000	0.710
time * group	Pillai's Trace	0.087	1.745[b]	3.000	55.000	0.168
	Wilks' Lambda	0.913	1.745[b]	3.000	55.000	0.168
	Hotelling's Trace	0.095	1.745[b]	3.000	55.000	0.168
	Roy's Largest Root	0.095	1.745[b]	3.000	55.000	0.168
a. Design: Intercept + age + group Within Subjects Design: time						
b. Exact statistic						

Table 4.10b: Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	22232.516	1	22232.516	56.201	0.000
age	915.916	1	915.916	2.315	0.134
group	0.244	1	0.244	0.001	0.980
Error	22548.634	57	395.590		

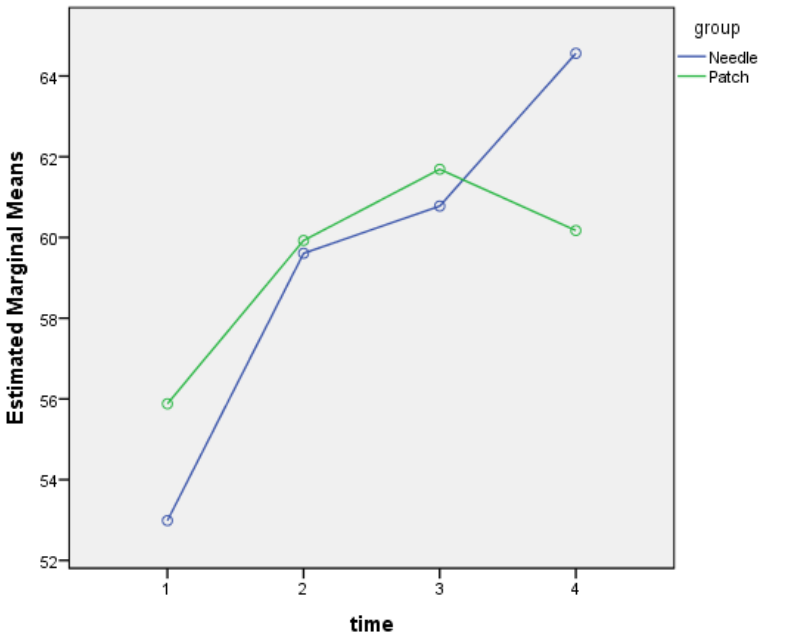


Figure 4.9 Intergroup CROM LR changes over time

4.7.1.3.4 Right Rotation (RR)

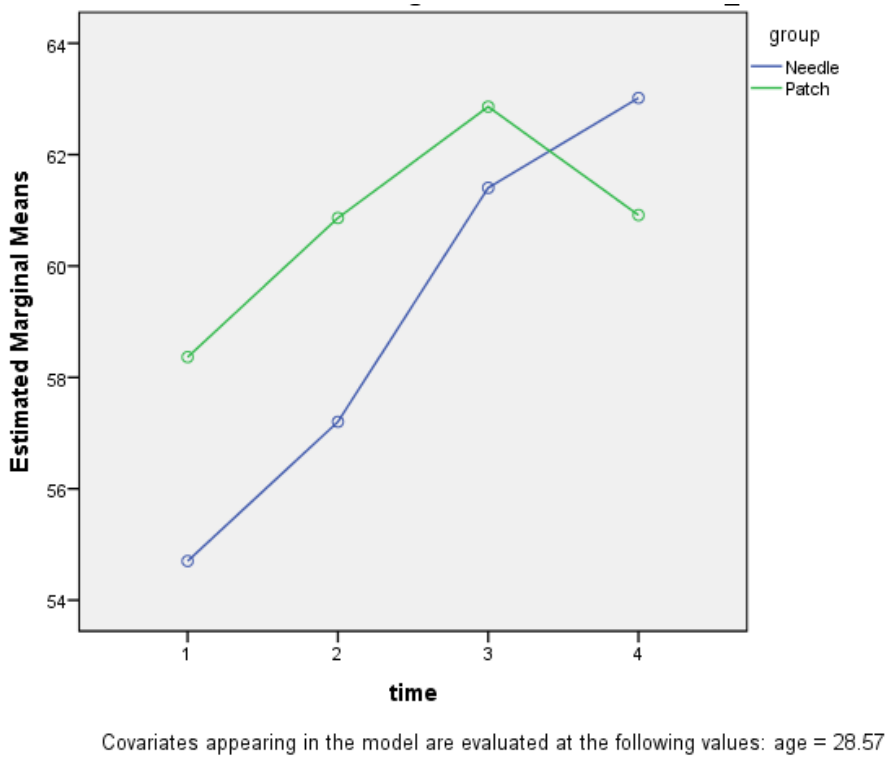
There was no difference in effectiveness in terms of RR between the two interventions (*p*=0.200). Figure 4.10 shows that both groups experienced an increase in the RR score over time but the profiles were not exactly parallel. Again the trend was for greater increase in the Needle group, specifically between the 3rd and 4th time point.

Table 4.11a: Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	0.052	1.003[b]	3.000	55.000	0.398
	Wilks' Lambda	0.948	1.003[b]	3.000	55.000	0.398
	Hotelling's Trace	0.055	1.003[b]	3.000	55.000	0.398
	Roy's Largest Root	0.055	1.003[b]	3.000	55.000	0.398
time * age	Pillai's Trace	0.040	0.772[b]	3.000	55.000	0.515
	Wilks' Lambda	0.960	0.772[b]	3.000	55.000	0.515
	Hotelling's Trace	0.042	0.772[b]	3.000	55.000	0.515
	Roy's Largest Root	0.042	0.772[b]	3.000	55.000	0.515
time * group	Pillai's Trace	0.080	1.600[b]	3.000	55.000	0.200
	Wilks' Lambda	0.920	1.600[b]	3.000	55.000	0.200
	Hotelling's Trace	0.087	1.600[b]	3.000	55.000	0.200
	Roy's Largest Root	0.087	1.600[b]	3.000	55.000	0.200
a. Design: Intercept + age + group Within Subjects Design: time						
b. Exact statistic						

Table 4.11b: Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	29827.323	1	29827.323	113.350	0.000
age	2821.874	1	2821.874	10.724	0.002
group	155.182	1	155.182	0.590	0.446
Error	14999.193	57	263.144		



Covariates appearing in the model are evaluated at the following values: age = 28.57

Figure 4.10 Intergroup CROM RR changes over time

4.7.1.3.5 Flexion (FLEX)

There was no difference in effectiveness for flexion between the two interventions (p=0.420). Figure 4.11 shows that both groups experienced an increase in the FLEX score over time but the profiles were not exactly parallel. Again, the trend was for greater increase in the Needle group.

Table 4.12a: Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	0.148	3.177[b]	3.000	55.000	0.031
	Wilks' Lambda	0.852	3.177[b]	3.000	55.000	0.031
	Hotelling's Trace	0.173	3.177[b]	3.000	55.000	0.031
	Roy's Largest Root	0.173	3.177[b]	3.000	55.000	0.031
time * age	Pillai's Trace	0.119	2.472[b]	3.000	55.000	0.071
	Wilks' Lambda	0.881	2.472[b]	3.000	55.000	0.071
	Hotelling's Trace	0.135	2.472[b]	3.000	55.000	0.071
	Roy's Largest Root	0.135	2.472[b]	3.000	55.000	0.071
time * group	Pillai's Trace	0.050	0.956[b]	3.000	55.000	0.420
	Wilks' Lambda	0.950	0.956[b]	3.000	55.000	0.420
	Hotelling's Trace	0.052	0.956[b]	3.000	55.000	0.420
	Roy's Largest Root	0.052	0.956[b]	3.000	55.000	0.420
a. Design: Intercept + age + group Within Subjects Design: time						
b. Exact statistic						

Table 4.12b: Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	26236.703	1	26236.703	67.078	0.000
age	6865.558	1	6865.558	17.553	0.000
group	1.538	1	1.538	0.004	0.950
Error	22294.858	57	391.138		

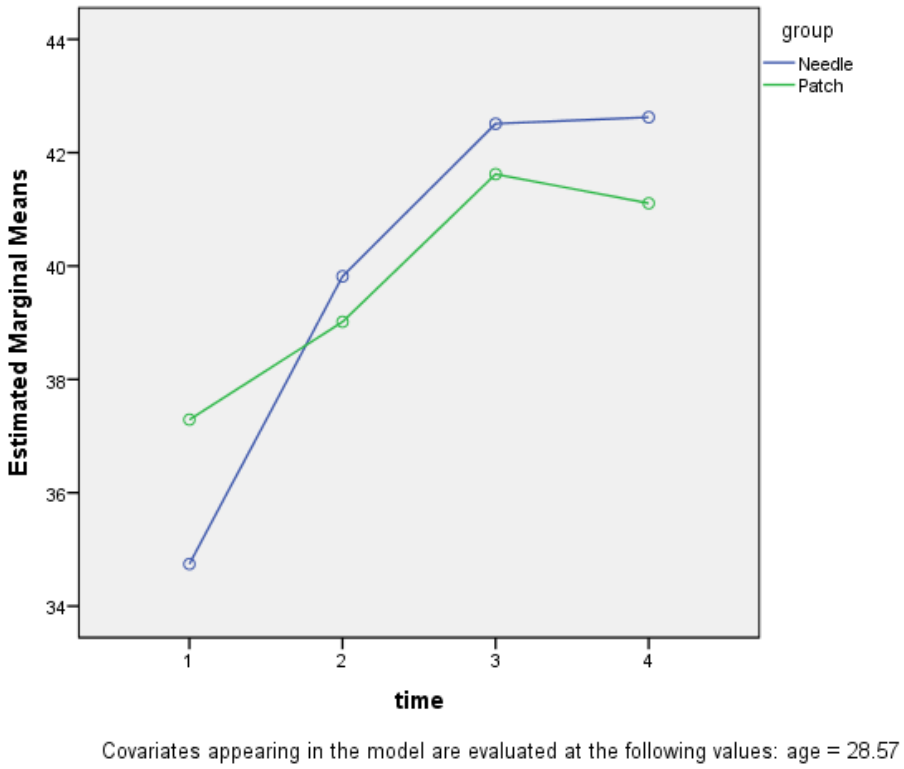


Figure 4.11 Intergroup CROM FLEX changes over time

4.7.1.3.6 Extension (EXT)

There was no significant difference in effectiveness for extension between the two interventions (p=0.107). However, Figure 4.12 shows that the two groups experienced different rates of change over time. While the Patch group decreased, the Needle group increased. It is possible that the sample size was not sufficient to adequately power this study to detect this difference as statistically significant.

Table 4.13a: Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	0.063	1.235[b]	3.000	55.000	0.306
	Wilks' Lambda	0.937	1.235[b]	3.000	55.000	0.306
	Hotelling's Trace	0.067	1.235[b]	3.000	55.000	0.306
	Roy's Largest Root	0.067	1.235[b]	3.000	55.000	0.306
time * age	Pillai's Trace	0.055	1.071[b]	3.000	55.000	0.369
	Wilks' Lambda	0.945	1.071[b]	3.000	55.000	0.369
	Hotelling's Trace	0.058	1.071[b]	3.000	55.000	0.369
	Roy's Largest Root	0.058	1.071[b]	3.000	55.000	0.369
time * group	Pillai's Trace	0.104	2.125[b]	3.000	55.000	0.107
	Wilks' Lambda	0.896	2.125[b]	3.000	55.000	0.107
	Hotelling's Trace	0.116	2.125[b]	3.000	55.000	0.107
	Roy's Largest Root	0.116	2.125[b]	3.000	55.000	0.107
a. Design: Intercept + age + group / Within Subjects Design: time						
b. Exact statistic						

Table 4.13b: Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	15068.535	1	15068.535	35.823	0.000
age	369.082	1	369.082	0.877	0.353
group	79.609	1	79.609	0.189	0.665
Error	23976.535	57	420.641		

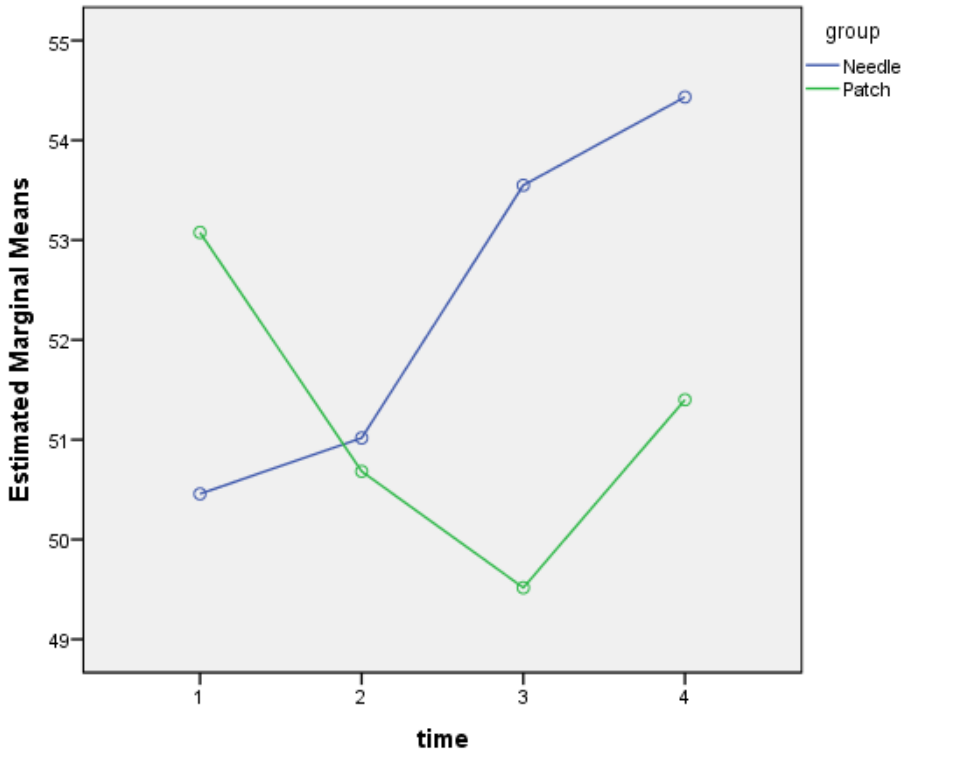


Figure 4.12 Intergroup CROM EXT changes over time

4.7.1.3.7 Discussion

As discussed in Table 2.6 (Chapter Two) cervical motion is the gold standard for testing head motion (Prushansky and Dvir, 2008) and thus, any variations will highlight a change in norm such as those due to pain related limitations of cervical motion. Taking this into account the CROM device was used due to its proven reliability and validity as a tool in assessing cervical range of motion (Hoving *et al.,* 2005).

The principal movement pertaining to this study of the upper trapezius was lateral flexion as described in Section 2.8. MFTPs present in the upper trapezius were expected to limit lateral flexion movement principally (Travell and Simons, 1999; Vizniak, 2010). The upper trapezius also aids in extension and rotation of the head and since cervical motion consists of six primary movements (Standring, 2008), the other ranges where also recorded and analysed.

Lateral flexion:

In both left and right lateral flexion measurements there was a trend towards the Needle group showing a greater rate of increase, however of the two measurements LLF was not significantly different in statistical terms (p=0.338).

LLF: Since there was no difference in effectiveness between the two interventions (p=0.338), it indicates that the interventions had similar effects on the participants. However, in terms of the trends, the Needle group shows an initial decline in the LLF movement, which may be as a result of an initial increase in the oedema of the MFTP due to the mechanical disruption associated with the needle (Yap, 2007) and its sequelae, as compared to the Patch group which did not have this decline.

Additionally, considering the outcomes of the algometer on the R TP2, it is of interest to note that LLF increases to an equal extent in both groups. This suggests that the needling effect allows for extensibility without a concomitant decrease in the algometer readings. This may be related to needle induced oedema (Yap, 2007), which allows extensibility but does not alter the algometer readings substantively.

RLF: Due to the significant difference in RLF values over time between the groups (p=0.043), it was determined that the Needle group experienced a faster rate of increase in RLF score than the Patch group. This would concur with the suggested physiological changes in the muscle as described under the LLF, where the muscle functionality is returned to the muscle (viz. muscle contraction is eliminated by the needle effect), but that oedema maintains the sensitivity without affecting the muscle stretch or contraction.

In this context, the results suggests that the Needle group had a faster rate of increase in right and left lateral flexion.

Other movements tested:

For these other movements it was noted that they were not part of the set objectives at the outset of the study, particularly as the movements of the head and neck do not directly link the trapezius muscle to these movements (Standring, 2008). These recordings were however taken in order to determine if any change was associated with the needling of the TP1 and TP2 of the trapezius muscle.

It was also expected that the rate of improvement would not necessarily show a significant change over time or potentially between the groups as the small effects of the pathology would not have allowed for a large change (and therefore significant possibilities).

Rotation:

LR:

For left rotation there was no difference in effectiveness between the two interventions (p=0.168). Figure 4.9 shows that both groups experienced an increase in this value over time but the profiles were not exactly parallel. Again the trend was for greater increase in the Needle group.

RR:

For right rotation there was no difference in effectiveness between the two interventions (p=0.200). Figure 4.10 shows that both groups experienced an increase in this value over time but the profiles were not exactly parallel. Again the trend was for greater increase in the Needle group, specifically between the 3rd and 4th time point.

In this context the results suggests that there was no statistical significance in effectiveness between the two interventions even though the Needle group demonstrated a faster rate of increase in rotation.

Flexion:

There was no difference in effectiveness for flexion between the two interventions (p=0.420). Figure 4.11 shows that both groups experienced an increase in this value over time but the profiles were not exactly parallel. Again, the trend was for greater increase in the Needle group.

In this context the results suggests that there was no statistical significance in effectiveness between the two interventions even though the Needle group demonstrated a faster rate of increase in flexion.

Extension:

There was no significant difference in effectiveness for extension between the two interventions (p=0.107). Figure 4.12 shows that the two groups experienced different rates of change over time. While the EXT score in the Patch group decreased, the Needle group increased. It is possible that the sample size was not sufficient to adequately power this study to detect this difference as statistically significant.

Again the results suggest that there was no statistical significance in effectiveness between the two interventions even though the Needle group demonstrated a faster rate of increase in extension and the Patch group declined.

4.8 Objective Two and Results

Objective Two: To determine the effectiveness of dry needling versus Flurbiprofen LAT patches in terms of the subjective findings (i.e.: Numerical Pain Rating Scale (NRS) and Neck Disability Index Questionnaire (NDI)).

4.8.1 Subjective outcomes

4.8.1.1 Numerical Pain Rating Scale

NRS did not show a significant difference in effectiveness between the two interventions (p=0.125). Figure 4.13 shows that both groups experienced a decrease in pain over time and the profiles were more or less parallel. One could argue for a slightly faster rate of pain reduction in the Needle group.

Table 4.14a: Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	0.051	0.991[b]	3.000	55.000	0.404
	Wilks' Lambda	0.949	0.991[b]	3.000	55.000	0.404
	Hotelling's Trace	0.054	0.991[b]	3.000	55.000	0.404
	Roy's Largest Root	0.054	0.991[b]	3.000	55.000	0.404
time * age	Pillai's Trace	0.009	0.165[b]	3.000	55.000	0.919
	Wilks' Lambda	0.991	0.165[b]	3.000	55.000	0.919
	Hotelling's Trace	0.009	0.165[b]	3.000	55.000	0.919
	Roy's Largest Root	0.009	0.165[b]	3.000	55.000	0.919
time * group	Pillai's Trace	0.098	1.998[b]	3.000	55.000	0.125
	Wilks' Lambda	0.902	1.998[b]	3.000	55.000	0.125
	Hotelling's Trace	0.109	1.998[b]	3.000	55.000	0.125
	Roy's Largest Root	0.109	1.998[b]	3.000	55.000	0.125
a. Design: Intercept + age + group Within Subjects Design: time						
b. Exact statistic						

Table 4.14b: Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	8009.704	1	8009.704	10.038	0.002
age	1817.081	1	1817.081	2.277	0.137
group	3456.399	1	3456.399	4.332	0.042
Error	45481.719	57	797.925		

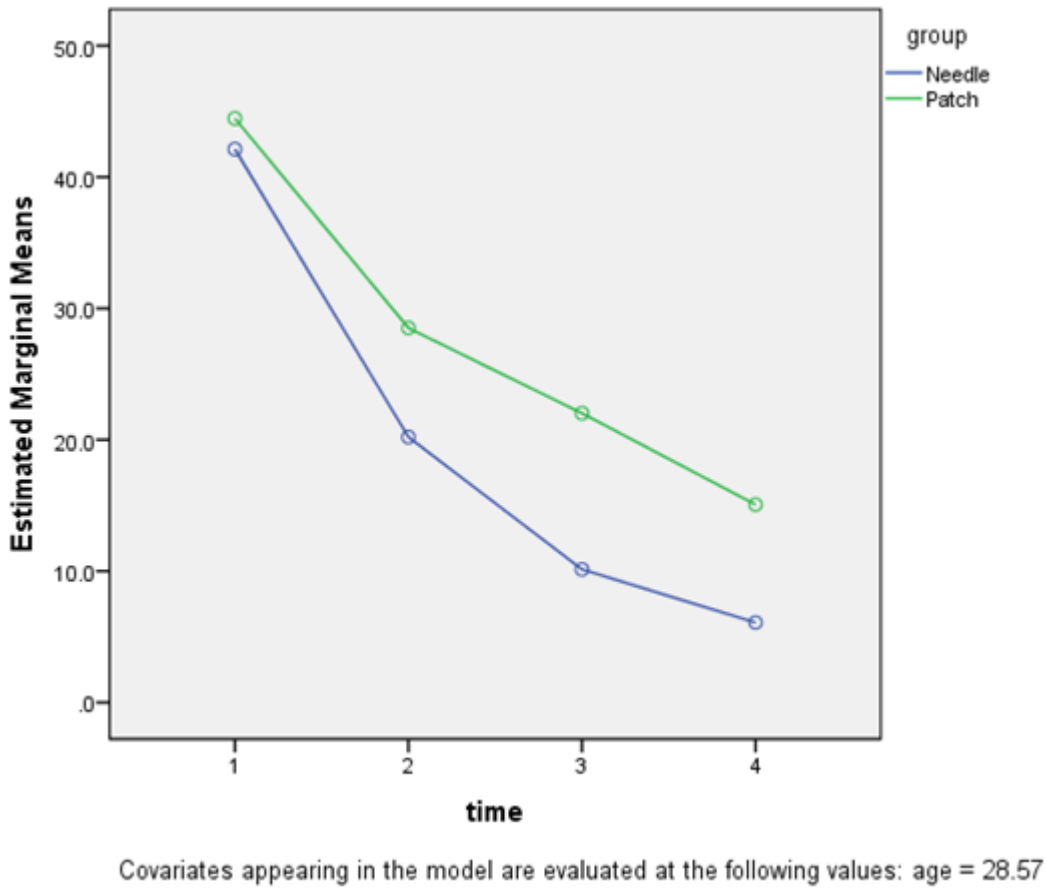


Figure 4.13 Intergroup NRS changes over time

4.8.1.1.1 Discussion

As described in 3.9.1 of Chapter Three and Table 2.6 of Chapter Two the NRS is used to monitor the pain perception and levels experienced by patients (Williamson and Hoggart, 2005). An elevation in the mean score indicates an increase in the pain experienced and vice versa (Jensen, Karoly and Braver, 1986). However, since both of the interventions in this study are indicated for MPS, a trend towards a decrease in pain was expected. In the Patch group, the anti-inflammatory effects of the Flurbiprofen LAT patches resulted in an immediate decrease, even though there was an expectation for the Needle group to show a slight rise between consultation one and two. This latter phenomenon would be in congruence with the suggested needle disruption effect and the sequelae of inflammation associated with it.

Over the entire treatment period, the NRS did not show a significant difference in effectiveness between the two interventions (p=0.125) as Figure 4.13 showed that both groups experienced a decrease in pain over time where the profiles were more or less parallel. However one could argue for a slightly faster rate of pain reduction in

the Needle group (particularly since the improvement was only noted from reading two) due to the greater mean reduction in relation to time when looking at Figure 4.13.

According to Lee *et al.,* (2003); Ostelo and de Vet (2005), the minimal clinical important difference, is a 20-25mm change on a 100 point scale. Therefore, the outcomes of this study suggest that the two interventions both achieved a clinically significant change in the NRS.

4.8.1.2 Neck Disability Index Questionnaire (NDI) scale

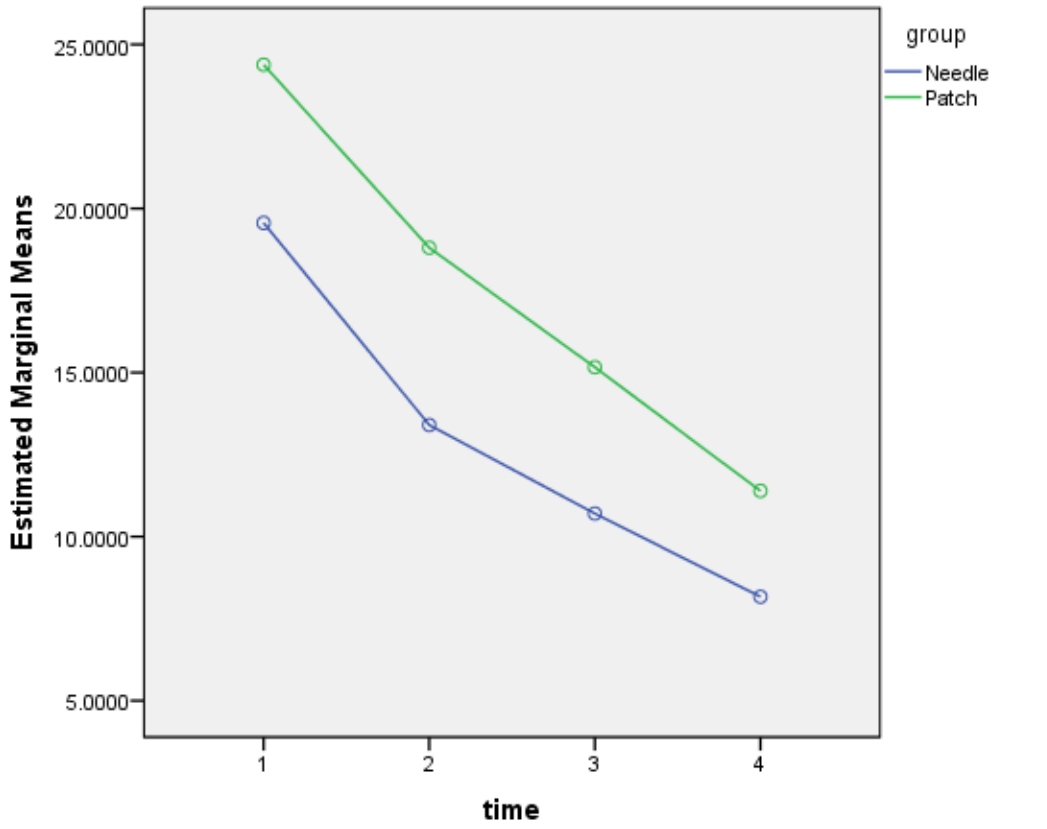
There was no difference in effectiveness for NDI scale between the two interventions (p=0.857). Figure 4.14 shows that both groups experienced a decrease in disability over time and profiles were more or less parallel.

Table 4.15a: Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	0.018	0.341[b]	3.000	55.000	0.796
	Wilks' Lambda	0.982	0.341[b]	3.000	55.000	0.796
	Hotelling's Trace	0.019	0.341[b]	3.000	55.000	0.796
	Roy's Largest Root	0.019	0.341[b]	3.000	55.000	0.796
time * age	Pillai's Trace	0.012	0.230[b]	3.000	55.000	0.875
	Wilks' Lambda	0.988	0.230[b]	3.000	55.000	0.875
	Hotelling's Trace	0.013	0.230[b]	3.000	55.000	0.875
	Roy's Largest Root	0.013	0.230[b]	3.000	55.000	0.875
time * group	Pillai's Trace	0.014	0.255[b]	3.000	55.000	0.857
	Wilks' Lambda	0.986	0.255[b]	3.000	55.000	0.857
	Hotelling's Trace	0.014	0.255[b]	3.000	55.000	0.857
	Roy's Largest Root	0.014	0.255[b]	3.000	55.000	0.857
a. Design: Intercept + age + group Within Subjects Design: time						
b. Exact statistic						

Table 4.15b: Tests of Between-Subjects Effects

Measure: MEASURE_1 Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	964.168	1	964.168	1.596	0.212
age	0.374	1	0.374	0.001	0.980
group	1115.998	1	1115.998	1.847	0.179
Error	34432.841	57	604.085		



Covariates appearing in the model are evaluated at the following values: age = 28.57

Figure 4.14 Intergroup NDI changes over time

4.8.1.2.1 Discussion

In terms of the NDI, it was noted that there was no statistically significant difference between the groups (p=0.857) in this context, Figure 4.14 shows that both groups experienced a decrease in disability (noted as a perceived change over time with respect to both function and pain) (Hoving *et al.,* 2005; Yeomans, 2000) over time and the profiles were more or less parallel.

According to Yeomans (2000), disability is precipitated by the perception of pain, thus pain would limit a patient's ability to complete activities of daily living. As such, it is not by chance that the patients reported a decrease in the NDI in accordance with the NRS outcomes. The outcomes are similar to the NRS (Section 4.8.1.1), which indicates that the participants reported a decrease in pain. A change in function would be consistent with the improvements of the ranges of motion over time. It is, however, significant that the significant difference between the groups in terms of the RLF did not negatively impact on the NDI. This correlation would require further investigation to determine the impact of the differences in the range of motion and how they result in or are related to the NDI. The lack of consistency between these outcomes seems to suggest that sample size or treatment duration may have had an impact. Therefore, correlation tables were drawn to determine possible correlations with the limited sample. Future research may need to expand this.

4.9 Objective Four and Results

Objective Four: To determine the correlation between changes in subjective and objective outcomes from pre to post intervention within the treatment groups.

4.9.1 Intra-group correlations

4.9.1.1 Needle group

Significant negative and positive correlations are highlighted.

Table 4.16: Needle Group Correlations[a]

		Change in MDS	Change in Trapezius TP1 R	Change in Trapezius TP1 L	Change in Trapezius TP2 R	Change in Trapezius TP2 L	Change in LLF	Change in RLF	Change in LR	Change in RR	Change in flexion	Change in extension	Change in NRS	Change in NDI scale
Change in MDS	Pearson Correlation	1	-0.363	-0.205	-0.261	0.146	0.158	0.136	0.093	-0.020	0.028	0.424*	-0.035	0.234
	Sig. (2-tailed)		0.074	0.305	0.498	0.707	0.405	0.475	0.625	0.916	0.881	0.020	0.856	0.213
	N	30	25	27	9	9	30	30	30	30	30	30	30	30
Change in Trapezius TP1 R	Pearson Correlation	-0.363	1	0.430*	0.976*	0.806	-0.232	-0.067	-0.150	0.142	0.026	-0.324	-0.100	-0.042
	Sig. (2-tailed)	0.074		0.032	0.024	0.053	0.265	0.752	0.473	0.498	0.901	0.115	0.635	0.842
	N	25	25	25	4	6	25	25	25	25	25	25	25	25
Change in Trapezius TP1 L	Pearson Correlation	-0.205	0.430*	1	0.747	0.899*	-0.204	0.039	0.054	0.207	0.078	-0.219	0.081	0.002
	Sig. (2-tailed)	0.305	0.032		0.088	0.015	0.307	0.845	0.789	0.299	0.699	0.272	0.687	0.994
	N	27	25	27	6	6	27	27	27	27	27	27	27	27
Change in Trapezius TP2 R	Pearson Correlation	-0.261	0.976*	0.747	1	0.883*	-0.255	0.148	0.407	0.793*	0.427	0.323	-0.449	0.107
	Sig. (2-tailed)	0.498	0.024	0.088		0.020	0.508	0.704	0.276	0.011	0.251	0.397	0.225	0.785
	N	9	4	6	9	6	9	9	9	9	9	9	9	9
Change in Trapezius TP2 L	Pearson Correlation	0.146	0.806	0.899*	0.883*	1	-0.278	0.549	0.767*	0.871**	0.608	0.631	-0.299	-0.076
	Sig. (2-tailed)	0.707	0.053	0.015	0.020		0.469	0.126	0.016	0.002	0.082	0.068	0.434	0.846
	N	9	6	6	6	9	9	9	9	9	9	9	9	9
Change in LLF	Pearson Correlation	0.158	-0.232	-0.204	-0.255	-0.278	1	0.483**	0.170	0.053	0.038	0.086	-0.155	0.002
	Sig. (2-tailed)	0.405	0.265	0.307	0.508	0.469		.007	0.368	0.780	0.843	0.650	0.412	0.992

Table 4.16: Needle Group Correlations[a]

	N	30	25	27	9	9	30	30	30	30	30	30	30	30
Change in RLF	Pearson Correlation	0.136	-0.067	0.039	0.148	0.549	0.483**	1	0.302	0.299	0.319	0.394*	0.048	-0.092
	Sig. (2-tailed)	0.475	0.752	0.845	0.704	0.126	0.007		0.104	0.108	0.085	0.031	0.802	0.629
	N	30	25	27	9	9	30	30	30	30	30	30	30	30
Change in LR	Pearson Correlation	0.093	-0.150	0.054	0.407	0.767*	0.170	0.302	1	0.518**	0.725**	0.171	0.034	0.018
	Sig. (2-tailed)	0.625	0.473	0.789	0.276	0.016	0.368	0.104		0.003	0.000	0.367	0.859	0.924
	N	30	25	27	9	9	30	30	30	30	30	30	30	30
Change in RR	Pearson Correlation	-0.020	0.142	0.207	0.793*	0.871**	0.053	0.299	0.518**	1	0.482**	0.246	-0.058	-0.050
	Sig. (2-tailed)	0.916	0.498	0.299	0.011	0.002	0.780	0.108	0.003		0.007	0.191	0.761	0.795
	N	30	25	27	9	9	30	30	30	30	30	30	30	30
Change in flexion	Pearson Correlation	0.028	0.026	0.078	0.427	0.608	0.038	0.319	0.725**	0.482**	1	0.146	0.151	-0.049
	Sig. (2-tailed)	0.881	0.901	0.699	0.251	0.082	0.843	0.085	0.000	0.007		0.440	0.427	0.798
	N	30	25	27	9	9	30	30	30	30	30	30	30	30
Change in extension	Pearson Correlation	0.424*	-0.324	-0.219	0.323	0.631	0.086	0.394*	0.171	0.246	0.146	1	-0.187	-0.081
	Sig. (2-tailed)	0.020	0.115	0.272	0.397	0.068	0.650	0.031	0.367	0.191	0.440		0.322	0.670
	N	30	25	27	9	9	30	30	30	30	30	30	30	30
Change in NRS	Pearson Correlation	-0.035	-0.100	0.081	-0.449	-0.299	-0.155	0.048	0.034	-0.058	0.151	-0.187	1	0.301
	Sig. (2-tailed)	0.856	0.635	0.687	0.225	0.434	0.412	0.802	0.859	0.761	0.427	0.322		0.106
	N	30	25	27	9	9	30	30	30	30	30	30	30	30
Change in NDI scale	Pearson Correlation	0.234	-0.042	0.002	0.107	-0.076	0.002	-0.092	0.018	-0.050	-0.049	-0.081	0.301	1
	Sig. (2-tailed)	0.213	0.842	0.994	0.785	0.846	0.992	0.629	0.924	0.795	0.798	0.670	0.106	
	N	30	25	27	9	9	30	30	30	30	30	30	30	30

*. Correlation is significant at the 0.05 level (2-tailed).

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

a. group = Needle

4.9.1.1.1 Discussion of Intra-group correlations within the Needle group

According to findings indicated in Table 4.16, the following summary of the significant and strongly correlated findings within the Needle group are as follows:

To effectively discuss the correlation tables, the findings have been ranked according to the Pearson's correlation statistic which have a strong and weak value/correlation.

The strong correlations indicate the following:

- Change in TP1 R is related to a change in TP2 R (p = 0.24) with a correlation of 0.976.
- Change in TP1 L is related to a change in TP2 L (p = 0.15) with a correlation of 0.899.
- Change in TP2 R is related to a change in TP2 L (p = 0.20) with correlation of 0.883.

From this subset it can be seen that TP1 and TP2 on the same side are correlated with one another, which was expected yet it is significant as these MFTPs fall within each other's pain referral pattern (Chapter Two Section 2.8) and it is suggested by Travell and Simons (1999), Chaitow and DeLany (2002) that they tend to occur together.

Additionally, the correlation between the right and the left TP2 is clinically and functionally significant as these TPs are closely approximated on either side of the spinous processes to which they attach (Moore and Dalley, 2006; Standring, 2008). Therefore, they are reciprocally related (Travell and Simons, 1999; Chaitow and DeLany, 2002; Sahrmann, 2010) so these findings bear out this significance in the Needle group.

These strong correlations bear witness to the improved functional ability of the muscle and therefore the improvement in the algometer readings. It is however important to note that there is no relationship of these outcomes to the NRS, which indicates that although there was functional improvement, it was not mirror in terms of the pain reported by the patient,

- Change in TP2 L is related to a change in RR (p = 0.02) with correlation of 0.871.
- Change in TP2 R is related to a change in RR (p = 0.11) with correlation of 0.793.
- Change in TP2 L is related to a change in LR (p = 0.16) with correlation of 0.767.

This above correlations bear further testament to the improved function and the relationship between the function and the algometer readings as they changed over time (viz. as the algometer increased so too did the range of motion measures).

- Change in LR is related to a change in FLEX (p = 0.00) with correlation of 0.725.
- Change in LR is related to a change in RR (p = 0.03) with correlation of 0.518.

The above correlations support the functional improvement further indicating that there are significant correlations between the improvements in the various range of motion parameters measured.

The weaker, but significant correlations indicate the following:

- Change in LLF is related to a change in RLF (p = 0.07) with correlation of 0.483.
- Change in RR is related to a change in EXT (p = 0.07) with correlation of 0.482.
- Change in TP1 R is related to a change in TP1 L (p = 0.32) with a correlation of 0.430.
- Change in MDS is related to a change in extension (p = 0.20) with a correlation of 0.424.
- Change in RLF is related to a change in EXT (p = 0.31) with correlation of 0.394.

These correlations again suggest that there are changes within these dynamics that support a relationship between the function and the reduction in pain.

Of interest in the Needle group, however, is the lack of correlations between the subjective and the objective findings which go to support the assertions made in those Sections (4.7.1 and 4.8.1) that discuss the changes in the various measures over time and between the groups, where it was suggested (when the results were contextualised in the literature) that there is a disjuncture between the improvement in those measures reported by the participants and those that are measured by the blinded assessor.

4.9.1.2 Patch group

Table 4.17: Patch Group Correlations[a]

		Change in MDS	Change in Trapezius TP1 R	Change in Trapezius TP1 L	Change in Trapezius TP2 R	Change in Trapezius TP2 L	Change in LLF	Change in RLF	Change in LR	Change in RR	Change in flexion	Change in extension	Change in NRS	Change in NDI scale
Change in MDS	Pearson Correlation	1	-0.489*	-0.511**	-0.326	-0.536	-0.019	-0.071	-0.287	-0.159	-0.165	-0.225	0.440*	0.296
	Sig. (2-tailed)		0.011	0.005	0.358	0.110	0.922	0.710	0.124	0.402	0.383	0.231	0.015	0.113
	N	30	26	29	10	10	30	30	30	30	30	30	30	30
Change in Trapezius TP1 R	Pearson Correlation	-0.489*	1	0.754**	0.754	0.876**	-0.092	0.009	0.212	-0.043	-0.316	-0.281	-0.286	-0.541**
	Sig. (2-tailed)	0.011		0.000	0.050	0.002	0.654	0.966	0.297	0.836	0.116	0.164	0.157	0.004
	N	26	26	25	7	9	26	26	26	26	26	26	26	26
Change in Trapezius TP1 L	Pearson Correlation	-0.511**	0.754**	1	0.697*	0.703*	0.064	0.120	0.215	0.177	-0.090	-0.051	-0.495**	-0.704**
	Sig. (2-tailed)	0.005	0.000		0.025	0.035	0.742	0.534	0.263	0.358	0.643	0.791	0.006	0.000
	N	29	25	29	10	9	29	29	29	29	29	29	29	29
Change in Trapezius TP2 R	Pearson Correlation	-0.326	0.754	0.697*	1	0.846	-0.026	0.112	0.190	0.190	-0.010	0.227	-0.649*	-0.590
	Sig. (2-tailed)	0.358	0.050	0.025		0.154	0.944	0.758	0.598	0.599	0.977	0.529	0.042	0.072
	N	10	7	10	10	4	10	10	10	10	10	10	10	10
Change in Trapezius TP2 L	Pearson Correlation	-0.536	0.876**	0.703*	0.846	1	0.076	0.261	0.097	0.170	-0.238	0.040	-0.667*	-0.503
	Sig. (2-tailed)	0.110	0.002	0.035	0.154		0.835	0.466	0.791	0.639	0.507	0.913	0.035	0.139
	N	10	9	9	4	10	10	10	10	10	10	10	10	10
Change in LLF	Pearson Correlation	-0.019	-0.092	0.064	-0.026	0.076	1	0.623**	0.034	0.106	0.036	0.115	-0.326	-0.121
	Sig. (2-tailed)	0.922	0.654	0.742	0.944	0.835		0.000	0.857	0.577	0.852	0.546	0.079	0.525
	N	30	26	29	10	10	30	30	30	30	30	30	30	30
Change in RLF	Pearson Correlation	-0.071	0.009	0.120	0.112	0.261	0.623**	1	0.027	-0.084	-0.049	-0.050	-0.196	0.050
	Sig. (2-tailed)	0.710	0.966	0.534	0.758	0.466	0.000		0.888	0.659	0.799	0.791	0.300	0.792
	N	30	26	29	10	10	30	30	30	30	30	30	30	30
Change in LR	Pearson Correlation	-0.287	0.212	0.215	0.190	0.097	0.034	0.027	1	0.700**	0.133	0.455*	-0.424*	-0.285
	Sig. (2-tailed)	0.124	0.297	0.263	0.598	0.791	0.857	0.888		0.000	0.485	0.012	0.020	0.126
	N	30	26	29	10	10	30	30	30	30	30	30	30	30
Change in RR	Pearson Correlation	-0.159	-0.043	0.177	0.190	0.170	0.106	-0.084	0.700**	1	0.258	0.420*	-0.278	-0.302
	Sig. (2-tailed)	0.402	0.836	0.358	0.599	0.639	0.577	0.659	0.000		0.168	0.021	0.138	0.105

Table 4.17: Patch Group Correlations[a]

	N	30	26	29	10	10	30	30	30	30	30	30	30	30
Change in flexion	Pearson Correlation	-0.165	-0.316	-0.090	-0.010	-0.238	0.036	-0.049	0.133	0.258	1	0.604**	-0.108	0.183
	Sig. (2-tailed)	0.383	0.116	0.643	0.977	0.507	0.852	0.799	0.485	0.168		0.000	0.570	0.333
	N	30	26	29	10	10	30	30	30	30	30	30	30	30
Change in extension	Pearson Correlation	-0.225	-0.281	-0.051	0.227	0.040	0.115	-0.050	0.455*	0.420*	0.604**	1	-0.257	-0.068
	Sig. (2-tailed)	0.231	0.164	0.791	0.529	0.913	0.546	0.791	0.012	0.021	0.000		0.171	0.720
	N	30	26	29	10	10	30	30	30	30	30	30	30	30
Change in NRS	Pearson Correlation	0.440*	-0.286	-0.495**	-0.649*	-0.667*	-0.326	-0.196	-0.424*	-0.278	-0.108	-0.257	1	0.497**
	Sig. (2-tailed)	0.015	0.157	0.006	0.042	0.035	0.079	0.300	0.020	0.138	0.570	0.171		0.005
	N	30	26	29	10	10	30	30	30	30	30	30	30	30
Change in NDI scale	Pearson Correlation	0.296	-0.541**	-0.704**	-0.590	-0.503	-0.121	0.050	-0.285	-0.302	0.183	-0.068	0.497**	1
	Sig. (2-tailed)	0.113	0.004	0.000	0.072	0.139	0.525	0.792	0.126	0.105	0.333	0.720	0.005	
	N	30	26	29	10	10	30	30	30	30	30	30	30	30

*. Correlation is significant at the 0.05 level (2-tailed).

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

a. group = Patch

4.9.1.2.1 Discussion of Intra-group correlations within the Needle group

According to the findings indicated in Table 4.17, the following summary of the significant and strongly correlated findings within the Patch group are as follows:

To effectively discuss the correlation tables, the findings have been ranked according to the Pearson's correlation statistic which have a strong and weak value/correlation.

The strong correlations indicate the following:

- Change in TP1 R is related to a change in TP2 L (p = 0.02) with correlation of 0.876.
- Change in TP1 R is related to a change in TP1 L (p = 0.00) with correlation of 0.754.
- Change in TP1 R is related to a change in TP2 R (p = 0.50) with correlation of 0.754.
- Change in TP1 L is related to a change in TP2 L (p = 0.35) with correlation of 0.703.
- Change in TP1 L is related to a change in TP2 R (p = 0.25) with correlation of 0.697.

From the correlations that are outlined, it is seen that the MFTPs are related in much the same manner as the MFTPs were in the Needle group.

- Change in LR is related to a change in RR (p = 0.00) with correlation of 0.700.
- Change in LLF is related to a change in RLF (p = 0.00) with correlation of 0.623.
- Change in FLEX is related to a change in EXT (p = 0.00) with correlation of 0.604.

Similarly, the ranges of motion are related to each other in much the same way as evidenced by the Needle group in Table 4.16.

- Change in NRS is related to a change in NDS (p = 0.05) with correlation of 0.497.

- Change in LR is related to a change in EXT (p = 0.12) with correlation of 0.455.
- Change in MDS is related to a change in NRS (p = 0.15) with correlation of 0.440.
- Change in RR is related to a change in EXT (p = 0.21) with correlation of 0.420.

The weak correlations indicate the following:

- Change in LR is related to a change in NRS (p = 0.20) with correlation of -0.424.
- Change in TP1 L is related to a change in NRS (p = 0.06) with correlation of -0.495.
- Change in TP2 L is related to a change in NRS (p = 0.35) with correlation of -0.667.
- Change in TP2 R is related to a change in NRS (p = 0.42) with correlation of -0.649.
- Change in MDS is related to a change in TP1 L (p = 0.05) with correlation of -0.511.
- Change in TP1 R is related to a change in NDS (p = 0.04) with correlation of -0.541.
- Change in TP1 L is related to a change in NDS (p = 0.00) with correlation of -0.704.

The weak and strong correlations reveal another side to the Patch group, which was not evident in the Needle group and that is the presence of correlations between the functional outcome measures and the perceived pain measures. This seems to indicate that the participants reporting of decreased pain ratings was more related to the improved function in the Patch group, than when compared to the Needle group. This may be because the only agreement between objective outcomes were that it was not related to the participants perception of pain. This re-enforces and underscores the suggestion that the mechanisms of action between the groups is inherently different and therefore results in different outcomes for the participants. It is suggested that future research look at defining those population groups that would best respond to these individual therapies – e.g. the clinical prediction rules (Fritz and Hebert, 2012).

4.10 Review of the objectives and hypotheses

The objectives as noted in Chapter One were as follows:

Objective One:

Determine the effectiveness of dry needling versus Flurbiprofen LAT patches in terms of the objective findings (i.e.: MDS, Algometer and CROM Device).

Objective Two:

Determine the effectiveness of dry needling versus Flurbiprofen LAT patches in terms of the subjective findings (i.e.: NRS and NDI).

Objective Three

Determine if any significant clinical / statistical differences exist between dry needling versus Flurbiprofen LAT patches in terms of the objective and subjective results.

Based on these objectives the null hypothesis linked to the third objective read that there would be no difference between the dry needling and the Flurbiprofen LAT patch interventions in terms of subjective and objective findings in this study.

In terms of the statistical outcomes of this study the null hypothesis ***was rejected*** for the MDS and CROM (RLF) measures and ***not rejected*** for the NDI, NRS, algometer and CROM (LLF, RR, LR, EXT and FLEX) outcomes.

4.11 Conclusion

This chapter has thus outlined the findings/results of this study, outlining both the statistical and clinical significance of the findings and contextualised these within the literature. The following chapter now presents the conclusions and recommendations.

CHAPTER 5
Conclusion and Recommendations

5.1 Introduction

This chapter contextualises the findings of this study and outlines recommendations for future studies.

5.2 Conclusion

At the onset of this study it was known that dry needling is effective and efficient in the treatment of myofascial pain syndromes. By contrast, it was also known that Flurbiprofen LAT patches are used pragmatically by patients for their self-medication when they experience myofascial pain syndromes. There is controversy as to the effectiveness of the Flurbiprofen LAT patch use in this context, therefore this study aimed to investigate the effectiveness of dry needling versus Flurbiprofen LAT patch in the treatment of MPS of the upper Trapezius muscle.

This thesis presented an investigation that was achieved through a randomised clinical control trial that was approved through the ethical review board structures of the Durban University of Technology. This approval granted the recruitment of sixty participants for a period of two weeks, in which the participants underwent three treatments followed by a follow up consultation. This allowed for participants have their syndromes measured (Numerical Pain Rating Scale, Neck Disability Index Questionnaire, Myofascial Diagnostic Scale, Algometer and Cervical Range of Motion Device) at the baseline, at consultation three and the final follow up. Data was recorded and then analysed using the SPSS (IBM), using the ANOVA testing as well as the controlling analyses for data skewing (age), in order to determine the effectiveness of the treatments over time and between each other.

The results indicated that over the two week time period (short term), that the interventions improved the myofascial pain syndrome significantly in terms of their individual effects over time. When compared the interventions they were not statistically significantly different over time with the exception of the MDS and right lateral flexion range of motion. When scrutinising the results, the trends suggested that the two groups improved their clinical symptomatology by two different mechanisms, with the tendency to favour the Needle group in terms of overall effect. Notwithstanding this, the Needle group did show some regression in the clinical symptoms before the participants improved. Thus although, the Needle group may have initial disadvantages to the participant it achieves better long term results.

It is suggested that this study be repeated with a significantly larger population in order to ensure that the lack of a large sample has not incorrectly reflected the trends that would be applicable to the general patient population. In addition, it is also suggested that longer periods of follow up after the completion of the study would allow for more accurate descriptions of the changes that these interventions introduce and how they change over time.

5.3 Recommendations

Methodologically, it is important to consider increasing the sample size as the aggregated mean of an increased sample size would more adequately represent the patient population and therefore allow for increased approximation of clinical practice.

Similarly, increasing the sample homogeneity by stratification of age, activity, occupation and related factors (hand dominance) may allow for more concrete conclusions in terms of the effectiveness of the intervention (viz. when these variables are controlled, it would result in a greater likelihood that the clinical measures only reflect clinical improvement and not lifestyle changes).

It would also be suggested that future studies look at a double blinded strategy for patient intervention and assessment to improve the reliability and the validity of the outcome measures within this type of clinical context.

Future studies would also need to consider enabling an equitable gender distribution between the groups under study, as this has been known to affect the clinical outcomes, particularly in terms of a participant's perception (Yeomans, 2000) which would impact on the results obtained in the study.

Although language was not a problem in this study, it is an outcome measure as interventions need to be tested for concurrent and content validity (Bernard, 2000). This would enable participants to respond in a familiar language and improve the credibility of the clinical data.

For future studies the use of diagnostic ultrasound measures for scar tissue may yield some surprising results, particularly as this study suggested that the TP2R had some unique features (particularly in the Needle group), which may only be measured accurately once tissue consistency has been established. This mechanism may also be useful in determining a set of specific inclusion criteria.

Additionally, future studies should look at developing clinical prediction rules (Hebert and Fritz, 2012) for those patients that are likely to respond better to dry needling than those who may respond better to the Flurbiprofen LAT patches, as it would seem their mechanisms may achieve different clinical outcomes. These outcomes may be directly related to specific groups of patients and their perceived clinical or psychological need.

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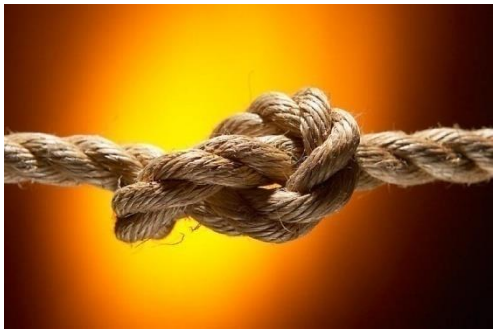
APPENDIX A:

Are you between the ages of 18 – 35 and suffering from:

Neck or Shoulder pain



At your Desk\Computer all Day?

Does it feel like you have a Knots Along your shoulder muscles?

Are you tired of the Gnawing Pain?

Research is currently being carried out at the

Durban University of Technology: Chiropractic Day Clinic

FREE TREATMENT

For those who take part in this study

CONTACT Jason Veerasamy on 0718482335 or 031 373 2205/2512 FOR MORE INFORMATION

APPENDIX B:
Information& Informed Consent

Dear Participant

Welcome to my study!

Title of Research:	The effectiveness of dry needling versus Flurbiprofen LAT patch in the treatment of myofascial pain syndrome of the upper Trapezius muscle	
Researcher:	Jason Veerasamy	031 3732205
Supervisor:	Dr. Charmaine Korporaal	031 3732611
Co-supervisor	Ms.Yasmeen Thandar	031 373 2402

Purpose of Research
With a lack of literature on the relative effectiveness of Flurbiprofen LAT patches in patients with MPS, this study aims to compare the gold standard treatment of dry needling with Flurbiprofen LAT patches in order to determine which treatment modality is more effective as a single therapeutic modality.

Please read the following regarding the research topic:

What is Dry Needling?
It is described as a procedure in which an acupuncture needle is inserted into the skin and muscle.The needle is 0.25 mm in diameter. It delivers a sensation which is not usually painful, and is considers safe when used by a trained professional.

What is A Flurbiprofen LAT Patch?
It is a topical preparation which is used in the treatment of localised musculoskeletal pain and inflammation.

Outline of procedure
At the initial consultation you will undergo a history, physical, and a regional examination, after which you will be accepted, providing you fit the necessary criteria for the research.If you are accepted into the study and you have agreed to partake in this study you will then be placed into one of two groups for treatment of the MPS. First group will have a treatment of dry needling while the second group will undergo the treatment with Flurbiprofen LAT patches (a commercially available product).Please note that you will not have a choice in terms of the group to which you are allocated. Group allocation is determined by someone who has nothing to do with this research study and therefore you may have a 50% chance of being in either group. You will receive your first treatment on the day of the first consultation followed by two more visits for treatments which will occur within seven days. In the last day of the second week, the final readings will be taken at the fourth visit. Readings will include algometer, numerical pain scale, neck disability index, myofascial diagnostic scale and the inclinometer. Thus, the duration of the study is 14 days.

Should you however not meet the inclusion criteria, you will be referred to an intern at the Chiropractic Day Clinic for your condition or we will gladly write a letter of referral to your nearest general practitioner / chiropractor for further care.

Possible risks and discomforts
If you are included in the dry needling group, you may experience slight discomfort during the treatment procedure and/or after treatment. It is possible that stiffness or post needling soreness of the treated muscle may be felt after treatment. If you are in the group receiving Flurbiprofen LAT patches you may experience skin irritation and itchiness associated with

the patch however this is rare. Should the discomfort worsen or you experience skin irritation from the Flurbiprofen LAT patches; you will be referred to the appropriate provider for further care.

Benefits of the research for you
All treatment will be free of charge. The study will determine which treatment modality works best in a clinical setting. This will benefit future patients with similar conditions. The treatment, regardless of which group you are placed in, should be of benefit to you.

You may withdraw
It is your prerogative as to whether you wish to complete, or withdraw from the study at any time.

Reason/s why the Subject May Be Withdrawn from the Study:
You may not take any form of medication that will influence the results of the study or undergo any other treatment during the duration of the study [i.e. any analgesics, muscle relaxants, non-steroidal anti-inflammatories, steroids or manual therapy (such as massage, soft tissue manipulation and physiotherapy to the area of investigation)].

Confidentiality
All information supplied by you throughout the study will be regarded as confidential.

Remuneration and costs for study
No financial award will be awarded to you. Also, no financial fees will be charged for the consumables (patches and needles) as well as for the services provided by the researcher.

Persons to contact for any queries

Researcher:	Jason Veerasamy	071 848 2335
Supervisor:	Dr. Charmaine Korporaal	031 373 2094
Co-supervisor**:**	Ms.Yasmeen Thandar	031 373 2402
IREC Research Administrator		031 3732900

Statement of agreement

I, …….(print name) of ID number

……. hereby acknowledge that I have read

this document and understand the research procedure. Any queries have been fully explained to me by the **Jason / Seerouven Veerasamy** (researcher). I also understand that I may withdraw from the research at any time without any consequences. I hereby voluntarily agree to participate in this study.

Full name of participant: _____

Signature of participant: _____

Date: _____

Signature of researcher: _____

Date: _____

Signature of witness: _____

Date: _____

APPENDIX C:

Numerical Pain Rating Scale- 101

Date:_____ **File number:**_____ **Visit number:**_____

Patient name:_____

Please indicate on the line below, the number between 0 and 100 that best describes the painyou experience **when it is at its worst**. A zero (0) would mean “no pain at all”, and one hundred (100) would mean,”pain as bad as it could be”.

Please write only one number.

0_____100

Please indicate on the line below, the number between 0 and 100 that best describes the painyou experience **when it is at its least**. A zero (0) would mean “no pain at all”, and onehundred (100) would mean “pain as bad as it could be”.

Please write only one number.

0_____100

APPENDIX D:

FORM C–10. NECK DISABILITY INDEX QUESTIONNAIRE (NDI)

PLEASE READ: This questionnaire is designed to enable us to understand how much your neck pain has affected your ability to manage your everyday activities. Please answer each section by circling the **ONE CHOICE** that most applies to you. We realize that you may feel that more than one statement may relate to you, but **PLEASE JUST CIRCLE THE ONE CHOICE WHICH MOST CLOSELY DESCRIBES YOUR PROBLEM RIGHT NOW.**

SECTION 1—Pain Intensity
- A I have no pain at the moment.
- B The pain is very mild at the moment.
- C The pain is moderate at the moment.
- D The pain is fairly severe at the moment.
- E The pain is very severe at the moment.
- F The pain is the worst imaginable at the moment.

SECTION 2—Personal Care (Washing, Dressing, etc.)
- A I can look after myself normally without causing extra pain.
- B I can look after myself normally, but it causes extra pain.
- C It is painful to look after myself and I am slow and careful.
- D I need some help, but manage most of my personal care.
- E I need help every day in most aspects of self care.
- F I do not get dressed, I wash with difficulty and stay in bed.

SECTION 3—Lifting
- A I can lift heavy weights without extra pain.
- B I can lift heavy weights, but it gives extra pain.
- C Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, for example, on a table.
- D Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- E I can lift very light weights.
- F I cannot lift or carry anything at all.

SECTION 4—Reading
- A I can read as much as I want to with no pain in my neck.
- B I can read as much as I want to with slight pain in my neck.
- C I can read as much as I want to with moderate pain in my neck.
- D I cannot read as much as I want because of moderate pain in my neck.
- E I cannot read as much as I want because of severe pain in my neck.
- F I cannot read at all.

SECTION 5—Headaches
- A I have no headaches at all.
- B I have slight headaches which come infrequently.
- C I have moderate headaches which come infrequently.
- D I have moderate headaches which come frequently.
- E I have severe headaches which come frequently.
- F I have headaches almost all the time.

SECTION 6—Concentration
- A I can concentrate fully when I want to with no difficulty.
- B I can concentrate fully when I want to with slight difficulty.
- C I have a fair degree of difficulty in concentrating when I want to.
- D I have a lot of difficulty in concentrating when I want to.
- E I have a great deal of difficulty in concentrating when I want to.
- F I cannot concentrate at all.

SECTION 7—Work
- A I can do as much work as I want to.
- B I can only do my usual work, but no more.
- C I can do most of my usual work, but no more.
- D I cannot do my usual work.
- E I can hardly do any work at all.
- F I cannot do any work at all.

SECTION 8—Driving
- A I can drive my car without any neck pain.
- B I can drive my car as long as I want with slight pain in my neck.
- C I can drive my car as long as I want with moderate pain in my neck.
- D I cannot drive my car as long as I want because of moderate pain in my neck.
- E I can hardly drive at all because of severe pain in my neck.
- F I cannot drive my car at all.

(continued)

SECTION 9—Sleeping
- A I have no trouble sleeping.
- B My sleep is slightly disturbed (less than 1 hour sleepless).
- C My sleep is mildly disturbed (1–2 hours sleepless).
- D My sleep is moderately disturbed (2–3 hours sleepless).
- E My sleep is greatly disturbed (3–5 hours sleepless).
- F My sleep is completely disturbed (5–7 hours sleepless).

SECTION 10—Recreation
- A I am able to engage in all of my recreational activities with no neck pain at all.
- B I am able to engage in all of my recreational activities with some pain in my neck.
- C I am able to engage in most, but not all of my recreational activities because of pain in my neck.
- D I am able to engage in a few of my recreational activities because of pain in my neck.
- E I can hardly do any recreational activities because of pain in my neck.
- F I cannot do any recreational activities at all.

COMMENTS:_____

_____

Name_____ Age_____ Date_____ Score_____

From Vernon H, Mior S. The Neck Disability Index: A study of reliability and validity. *J Manipulative Physiol Ther* 1991;14:409–415.

APPENDIX E:

ALGOMETER DATA

Date:_____ File number:_____

Patient name:_____

DATE	VISIT NO.	ALGOMETER (R)	ALGOMETER (L)
	1		
	3		
	4		

APPENDIX F:

Myofascial Diagnostic Scale (MDS)

GRADE	CLASSIFICATION	
Grade 0-	no tenderness	score= 0
Grade 1-	tenderness to palpation without grimace or flinch	score= 1
Grade 2-	tenderness to palpation with grimace and/or flinch	score= 2
Grade 3-	tenderness with withdrawal	score= 3
Grade 4-	withdrawal to non-noxious stimuli	score= 4
The presence of a palpable taut band is indicated by a score of 4 on the scale and the LRT. The presence of referred pain is indicated by a score of 5.		

Date_____File no._____

Patient name_____

DATE	VISIT NUMBER	MDS SCORE
	1	
	2	
	3	
	4	

APPENDIX G:

DURBAN UNIVERSITY OF TECHNOLOGY
CHIROPRACTIC DAY CLINIC
CASE HISTORY

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

Intern : _____ Signature _____

FOR CLINICIANS USE ONLY:
Initial visit
Clinician: Signature :

Case History:

Examination:

Previous:
Current:

X-Ray Studies:

Previous:
Current:

Clinical Path.lab:

Previous:
Current:

CASE STATUS:

PTT:	Signature:	Date:

CONDITIONAL:
Reason for Conditional:
Signature: Date:

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

Case Summary signed off: Date:

Intern's Case History:

1. **Source of History:**
2. **Chief Complaint: (patient's own words):**

3. **Present Illness:**

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

4. **Other Complaints:**

5. **Past Medical History:**

< General Health Status
< Childhood Illnesses
< Adult Illnesses
< Psychiatric Illnesses
< Accidents/Injuries
< Surgery
< Hospitalizations

6. **Current health status and life-style:**

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

7. Immediate Family Medical History:

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

8. Psychosocial history:

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

9. Review of Systems:

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

APPENDIX H:

Durban University of Technology

PHYSICAL EXAMINATION: SENIOR

Patient Name : _____ **File no :** _____ **Date :** _____

Student : **Signature :**

VITALS:				
Pulse rate:			Respiratory rate:	
Blood pressure:	R	L	Medication if hypertensive:	
Temperature:			Height:	
Weight:	Any recent change? Y / N	If Yes: How much gain/loss		Over what period

GENERAL EXAMINATION:		
General Impression		
Skin		
Jaundice		
Pallor		
Clubbing		
Cyanosis (Central/Peripheral)		
Oedema		
Lymph nodes	Head and neck	
	Axillary	
	Epitrochlear	
	Inguinal	
Pulses		
Urinalysis		

SYSTEM SPECIFIC EXAMINATION:

CARDIOVASCULAR EXAMINATION

RESPIRATORY EXAMINATION

ABDOMINAL EXAMINATION

NEUROLOGICAL EXAMINATION

COMMENTS

Clinician: **Signature :**

APPENDIX I:

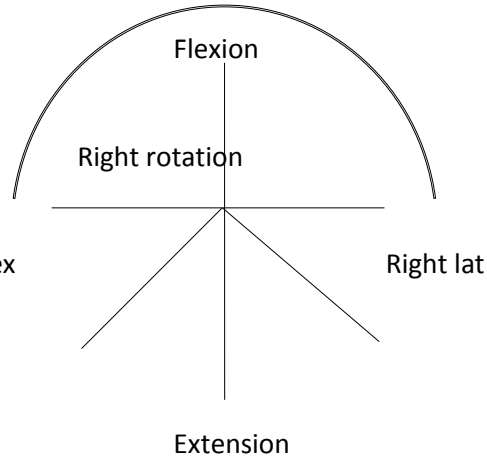
DURBAN UNIVERSITY OF TECHNOLOGY
REGIONAL EXAMINATION - CERVICAL SPINE

Patient: ..... File No: .....
Date: ..... Student: .....
Clinician: ..... Sign: .....

OBSERVATION:
Posture
Swellings
Scars, discolouration
Hair line
Body and soft tissue contours

Shoulder position
Left :
Right :
Shoulder dominance (hand):
Facial expression:

RANGE OF MOTION:
Extension (70º):
L/R Rotation (70º):
L/R Lat flex (45º):
flex
Flexion (45º):



PALPATION:
Lymph nodes Thyroid Gland Trachea

ORTHOPAEDIC EXAMINATION:

Tenderness		Right	Left
Trigger Points:	SCM		
	Scalenii		
	Post Cervicals		
	Trapezius		
	Lev scapular		

	Right	Left		Right	Left
Doorbell sign			Cervical compression		
Kemp's test			Lateral compression		
Cervical distraction			Adson's test		
Halstead's test			Costoclavicular test		
Hyper-abduction test			Eden's test		
Shoulder abduction test			Shoulder compression test		
Dizziness rotation test			Lhermitte's sign		
Brachial plexus test					

NEUROLOGICAL EXAMINATION:

Dermatones	**Left**	**Right**	**Myotomes**	**Left**	**Right**	**Reflexes**	**Left**	**Right**
C2			C1			C5		
C3			C2			C6		
C4			C3			C7		
C5			C4					
C6			C5					
C7			C6					
C8			C7					
T1			C8					
			T1					
Cerebellar tests:		Left		Right				
Disdiadochokinesis								

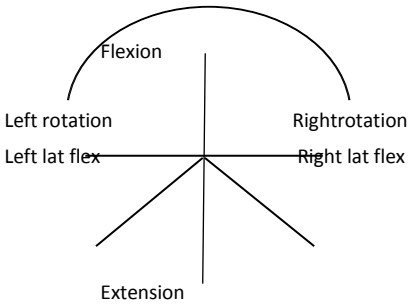
VASCULAR:	**Left**	**Right**		**Left**	**Right**
Blood pressure			Subclavian arts.		
Carotid arts.			Wallenberg's test		

MOTION PALPATION & JOINT PLAY:
Left: Motion Palpation:
Joint Play:
Right: Motion Palpation:
Joint Play:

BASIC EXAM: SHOULDER:
Case History:

ROM: Active:
Passive:
RIM:
Orthopaedic:
Neuro:
Vascular:

BASIC EXAM: THORACIC SPINE:
Case History:
ROM:



Motion Palpation:	
Orthopaedic:	
Neuro:	
Vascular:	
Observ/Palpation:	
Joint Play:	

APPENDIX J:

Things to remember about anti-inflammatories:

- **Make sure it is suitable** for you to use TransAct - see inside
- **Use as directed** on the label of your medicine or by your doctor or pharmacist.
- **TransAct sometimes causes problems.** You can find these listed inside this leaflet.
- **Keep this product away from children.** TransAct should not be used by children younger than 12 years of age.

What's in your medicine?

TransAct patches are white, polyester based with a menthol - type aroma and contain 40 mg flurbiprofen. Other ingredients include : peppermint oil, isopropyl myristate, glycerol, titanium dioxide, carboxymethylcellulose sodium, heavy kaolin, tartaric acid, polysorbate 80, sorbitan sesquioleate, water and sodium polyacrylate.

Indications

The name of your medicine is TransAct. Its active ingredient is flurbiprofen. TransAct is indicated for the symptomatic relief of localised pain and inflammation associated with sprains, strains and muscular or arthritic conditions.

Before you apply your medicine
You must consult your doctor or pharmacist before using TransAct if:

You are pregnant, planning to become pregnant or breast feeding
You suffer from liver, kidney or heart disease
You suffer from asthma or have had an allergic reaction or wheezing after taking aspirin or other arthritis medicines
You are taking any of the following medicines:
- Aspirin or other drugs used to treat arthritis

You are on medicines for thrombosis (e.g. warfarin), blood pressure or water tablets
You have previously shown allergic reaction to the active ingredient, flurbiprofen
You have a history of non-allergic asthma
You have a history of stomach or duodenal ulcers, internal bleeding of the stomach or intestines, a chronic disease affecting the colon (large bowel), heart failure or high blood pressure.
You have a potential for abnormal bleeding.

If the answer is yes to any of these questions, tell your doctor or pharmacist

Warnings:

This product should not be applied to broken skin, fragile skin or skin affected by irritation or infection. Systemic absorption (dosage of the product absorbed) is increased if this product is applied to damaged skin.

Keep out of reach of children.

This product should not be used in children younger than 12 years of age.

Do not use continuously for more than 4 weeks.

If you are taking other medicines on a regular basis, concomitant use of these medicines may cause undesirable interactions. Please consult your doctor or pharmacist

How to apply your medicine

TransAct is for external use only. Follow the directions below about when and where to apply your medication. Your pharmacist will also help you if you are not sure. Use only one patch at a time on your skin and replace every 12 hours.

1. Wipe the affected area clean.

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

3. First rub the corner of the patch between the thumb and fingers to peel off the backing and apply the adhesive side to the skin.

4. When applying stretch the patch gently to prevent the surface of the patch wrinkling. When first applied this product may feel cool.

5. Where a joint is affected slightly bend the joint before applying.

6. You may find it helpful to use a bandage to keep the patch in place on joints like a knee or elbow.

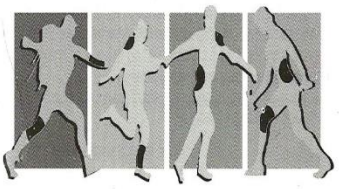
It is recommended that bathing or showering should be arranged to coincide with routine changing of the patch. Do not get the patch wet - remove before bathing.

PASIËNT INFORMASIE VOUBILJET

S1 Z/0.14/288

TransAct®

Verligting van spier- en gewrigspyn



Flurbiprofeen 40 mg

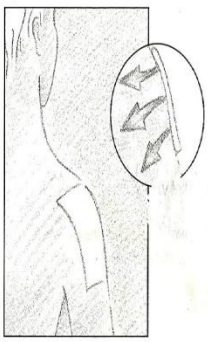
per plakker

Wat u behoort te weet omtrent TransAct.

Lees asseblief die blaadjie aandagtig deur voordat u die produk gebruik.

Die blaadjie bevat 'n opsomming van beskikbare inligting rakende u behandeling. Indien u enige vrae het of onseker is omtrent enige aspek, raadpleeg u geneesheer of apteker.

Die naam van die produk wat u gekoop het is TransAct wat flurbiprofeen bevat. Dit is een van die groep medisyne wat bekend staan as anti-inflammatoriese pynstillers.



APPENDIX K:

CERVICAL RANGE OF MOTION (CROM) DATA

Date:_____ **File number:**_____

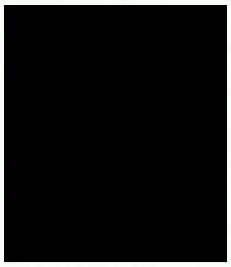
Patient name:_____

Visit	LEFT LATERAL FLEXION SCORE
1	
2	
3	
4	

APPENDIX L:

4 March 2012

I, Tim Graham Kinsman, I.D 8506275161089, agree to be a blinded assessor in the research project done by Jason Veerasamy. I have understood the research project in it's entirety and also fully understand the application of all the tools utilised in this study.

Signature 

APPENDIX M:

LETTER OF PERMISSION
To Whom It May Concern:

My name is Jason Veerasamy; I am currently doing my Masters Degree in Chiropractic at the Durban University of Technology,

The title of my research project is: The effectiveness of dry needling versus Flurbiprofen LAT patch in the treatment of myofascial pain syndrome of the upper Trapezius muscle.

Name of supervisor:	Dr. C. Korporaal (031-2042094) M.Tech: Chiropractic, CCSP, CCFC, ICSSD, FICS
Name of Research Student:	Jason Veerasamy (0718482335) (Email – searover76@gmail.com)
Name of Institution:	Durban University of Technology

The purpose of the study:
This study will involve research on participants between the ages of 18-35 years of age with myofacial trigger points in the greater Durban area (which are commonly found in sportsmen and women as well desk bound individuals) to determine the effectiveness of dry needling vs flurbiprofen LAT patches (EG: Transac patches) in the treatment of myofascial trigger points.

Procedures:
The participants will be required to undergo a non-invasive screening, degree of myofascial pain as well as location of the myofascial trigger point will be determined. The average time for participants to complete the screening process will approximately take an hour.

Benefits:
All treatment will be free of charge. The study will determine which treatment modality works best in a clinical setting. This will benefit future patients with similar conditions. The treatment, regardless of which group participants are placed in, should be of benefit to them.

Cost:
There is no cost involved from your participation in the study.

Based on the above-mentioned study, I am required to seek permission at those venues where i will be able to have access to these individuals Eg: sportsclubs, SARS offices. Therefore I would like to request your permission to utilize any of these's aforementioned municipal venue's within the confines of the greater Durban Area.

Yours in anticipation,

Jason Veerasamy (Chiropractic Intern)

Dr. C. Korporaal (Supervisor)

_____

I (name) _____ hereby give (Jason) S N Veerasamy consent to conduct the above-mentioned research at Municipal venue's.

Signature: _____ Date: _____