Reliability of deep cervical fascia and sternocleidomastoid thickness measurements using ultrasound imaging

Jude James Harley
Declaration

Name of candidate: Jude Harley

This thesis entitled: *Reliability of deep cervical fascia and sternocleidomastoid thickness measurements using ultrasound imaging* is submitted in partial fulfilment for the requirements for the Unitec degree of Master of Osteopathy.

Candidate’s declaration

I confirm that:

- This thesis represents my own work;
- The contribution of supervisors and others to this work was consistent with the Unitec Regulations and Policies.
- Research for this work has been conducted in accordance with the Unitec Research Ethics Committee Policy and Procedures, and has fulfilled any requirements set for this project by the Unitec Research Ethics Committee.

Research Ethics Committee Approval Number: 2014-1111

Candidate Signature: ……………………………………Date: 03/02/2016

Student number: 1385753
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Reliability of deep cervical fascia and sternocleidomastoid muscle thickness measurements using ultrasound imaging

Abstract

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Abbreviations

CV – Coefficient of variation
DF – Deep fascia
EME – Extraction measurement error (manuscript only)
HA – Hyaluronic acid
ICC – Intraclass correlation coefficient
LCT - Loose connective tissue
MDC – Minimal detectable change
MPS – Myofascial pain syndrome
MRI – Magnetic resonance imaging
MTrPs – Myofascial trigger points
QAREL – Quality appraisal of diagnostic reliability
RCT – Randomised controlled trial
RTUS – Real-time ultrasound
SCM - Sternocleidomastoid muscle
SDF – Superficial deep fascia (manuscript only)
SEM – Standard error of measurement
TLF – Thoracolumbar fascia
USI – Ultrasound imaging
Introduction to thesis

Musculoskeletal pain is associated with substantial socioeconomic burden and is the most common cause of incapacity to work (Bevan et al., 2009). Of all non-communicable diseases, those of musculoskeletal origin have the greatest association with poor quality of life (Sprangers et al., 2000), and musculoskeletal neck pain is second only to low back pain in terms of prevalence by body region (Eurobarometer, 2007). Myofascial pain syndrome (MPS) has been described as a musculoskeletal pain condition, with a reported prevalence of 37% in men and 65% in women (Drewes & Jennum, 1995). This syndrome is characterised by hyperirritable areas within taut bands of skeletal muscle and fascia, which are referred to as ‘myofascial trigger points’ (MTrPs) (Giamberardino, Affaitati, Fabrizio, & Costantini, 2011). Despite extensive research conducted on MPS to date (Dommerholt, Grieve, Hooks, & Layton, 2015), debate remains over the validity of this syndrome as a diagnostic entity (Quintner, Bove, & Cohen, 2015). This debate is largely due to the absence of objective evidence supporting the pathophysiology of MPS, and poor reliability for the clinical identification of MTrPs (Lucas, Macaskill, Irwig, Moran, & Bogduk, 2009).

Although the term ‘myofascial pain’ implies involvement of fasciae, research investigating MPS has focused almost entirely on skeletal muscle tissue (Stecco, Macchi, Porzionato, Duparc, & De Caro, 2011). However, recent literature reports findings that may help elucidate the role of fascia within MPS. As mechanically-induced strain on soft tissue has been postulated as an aetiological factor associated with MPS (Bron & Dommerholt, 2012), research has investigated how fascia responds to tensile loading. Schliep et al., observed in vitro thickening of murine fascia in response to strain, characterised by an increase in tissue fluid during the post-strain ‘rest phase’ (Schliep et al., 2012). Schliep et al., proposed that the observed fascia thickening was responsible for the reported ‘strain-hardening’ phenomena (Haut & Haut, 1997; Yahia, Pigeon, & DesRosiers, 1993), defined as an increase in tissue stiffness induced by stretch. This proposed fluid-induced causation for strain hardening contrasts previously purported mechanisms of myofibroblast contraction (Schleip et al., 2012; Schleip, Klingler, & Lehmann-Horn, 2005; Yahia et al., 1993). Stecco et al., termed this thickening ‘densification’, and using ultrasound imaging (USI) derived measurements of deep cervical fascia enveloping sternocleidomastoid muscle (SCM), demonstrated a significant difference in fascia thickness between participants with chronic neck pain and controls (Stecco, Meneghini, Stern, Stecco, & Imamura, 2014). As the fascia thickening was observed within the loose connective tissue (LCT) layer of fascia that has been demonstrated to contain aqueous hyaluronic acid (HA) (Stecco, 2011), the reported findings appeared to support the fluid-induced thickening described by Schliep et al. (2012). The fascia enveloping the SCM muscle is referred to as the investing layer of cervical fascia, and the observed thickening in this muscle tissue is particularly relevant, given that dysfunction of SCM has been correlated with chronic neck pain (O'Leary, Falla, & Jull, 2011).
Stecco et al. (2014) postulate that fascia densification is involved in the pathophysiology of chronic neck pain, and report that patients with cervical fascia thickness greater than 0.15cm can be considered to have ‘myofascial disease’. The densification phenomena described by Stecco et al., and the reported diagnostic cervical fascia thickness threshold to infer a fascia-specific diagnosis (0.15cm), is of particular interest within this thesis.

**Fascia research summary**

Prior to the research conducted by Stecco et al. (2014), no normative data for USI measurements of cervical fascia had been reported, nor reliability research conducted. Currently, a limited number of studies have reported investigations into reliability of USI-obtained fasciae measurement, most of which focus on the plantar fascia (Crofts, Angin, Mickle, Hill, & Nester, 2014; Rathleff, Moelgaard, & Lykkegaard Olesen, 2011). Whilst plantar fascia measurements utilising USI have demonstrated acceptable reliability, this fascia is a comparatively thick dense connective tissue, in contrast to thin LCT of the SCM deep fascia.

The preliminary research conducted by Stecco et al., concerning the densification phenomenon is probably best considered to be exploratory in nature, but does provide findings of future clinical interest that warrant further investigation. Given that much of the evidence supporting the densification hypothesis derives from cervical fascia thickness measurements utilising USI, investigating the reliability of these measurements is necessary. Therefore, the primary aim of the study reported in this thesis was to establish the *intra*-operator and *inter*-operator reliability of cervical fasciae measurement utilising a standardised USI measurement protocol. A secondary aim was to establish the *intra*-operator and *inter*-operator reliability of SCM muscle thickness measurement, given the increasing use of this measurement within chronic neck pain populations (Goo, Kim, & Jun, 2015; Jesus-Moraleida, Ferreira, Pereira, Vasconcelos, & Ferreira, 2011).
SECTION I: Literature review
1.1 Literature review: Overview

The intention of this literature review is to provide relevant background information pertaining to this research. In order to comprehend the reasoning and purpose for this reliability research, it is necessary to understand the underlying mechanisms of myofascial pain, specifically, the role fascia may play within this condition. The relevant anatomy and physiology will primarily be reviewed in the context of the cervical spine, given that this was the body region investigated by Stecco et al., in research that is significant to the aim of this thesis (Stecco et al., 2014). This will be followed by a review of fascia function, allowing for a more comprehensive understanding of the possible implications associated with the structural alteration of this tissue. Reviewing the functional capacity of fasciae, and the known pathophysiology of fasciae dysfunction, also gives context to the densification phenomena described by Stecco et al. (2014), an hypothesis which explores the role of fascia within MPS. Given the primary aim of this research is to establish the intra-operator and inter-operator reliability of USI-obtained fascia thickness measurements overlying SCM, the second part of this review outlines USI application within manual therapy. In accordance with the aim of this research study, this section outlines the use of USI on fascia tissue and cervical musculature, primarily with a methodological and reliability focus. A review and appraisal of the use of ultrasound methodology for both the measurement of fascia tissue and blinding procedures used within reliability research, provides justification for the methodology undertaken within this thesis.

1.2 Anatomy of sternocleidomastoid muscle and cervical fascia

1.2.1 Sternocleidomastoid

Sternocleidomastoid is a superficial neck muscle, which attaches from the mastoid process and superior nuchal line of the cranium, to the manubrium and medial aspect of the clavicle via two separate heads (Hasan, 2011). It is innervated by the spinal accessory nerve (CNXI) and also receives proprioceptive fibres from the cervical plexus (Standring, 2015). Bilaterally, SCM is a powerful neck and head flexor, whilst unilaterally it functions to provides ipsilateral side-bending and contralateral rotation.

Hasan et al. (2011) conducted a review of SCM anatomical variation. This review reported anatomical variation of the clavicular portion of SCM is common, with numerous variations in thickness and morphology cited. These included the lack of fusion between the clavicular and sternal heads, resulting in a separate cleidoocciput muscle, and fusion of the SCM muscle with the trapezius muscle. Anatomical variations at the occiput and temporal bone insertions were cited as being rare.
1.2.2  Fascia definition

Tozzi et al. (2014) discussed how fascia has traditionally been described from the perspective of the ‘dissector’. Consequently, fascia has not been viewed as a body-wide connective tissue network, but rather named by its regional anatomy. This point is illustrated well by descriptions such as ‘thoracolumbar fascia’, ‘crural fascia’, and ‘antebrachial fascia’. Although these regional fascia labels provide insight into fascia location, they do not acknowledge the body-wide functional role of fascia (Natale et al., 2014; Tozzi, 2014). Schliep et al., discussed the need for a broader definition that portrays fascia as an interconnected tensional network (Schleip, Jäger, Klingler, 2012).

Fascia is defined by the Fascia Research Congress ¹ (2012) as a soft tissue component of the connective tissue system that permeates the human body. Fascia researchers have adopted this broad definition that incorporates all fibrous connective tissue, including ligaments, retinaculum, tendons, periosteum, intermuscular septums and muscular casings (Findley & Schleip, 2007; Stecco et al., 2014). Whilst this definition illustrates well the functional interplay between body-wide connective tissues, this broad definition can create confusion for specific research purposes, particularly given the extensive research already conducted on tendons and ligaments (Benjamin, 2009). Considering the differences in tissue composition between a ligament and muscular casings, there is a need for more specific descriptions concerning the type of fascia being investigated. This review acknowledges the definition of fascia set out by the Fascia Research Congress, but for the sake of clarity, is specifically investigating muscular casing external to the epimysium; commonly referred to as deep fascia (DF) (Stecco et al., 2011).

1.2.3  Fascia types

The fascia structures relevant within this thesis include:

1.2.3.1  Superficial fascia

Whilst the reliability of measures of cervical superficial fascia thickness/dimensions is not being investigated within this thesis study, as discussed later within this review, superficial fascia is often observed to be adjacent to deep fascia, and is therefore relevant to this research. The superficial fascia is formed from interwoven collagen fibres, loosely packed and mixed with abundant elastic fibres (Benjamin, 2009). This fascial layer is located in the subcutaneous space, and divides this space into superficial and deep adipose tissue (Natale et al., 2015; Stecco et al., 2011). The presence of superficial fascia continuity throughout the body has been demonstrated by numerous authors (Abu-

¹ The Fascia Research Congress was founded by a committee of scientific researchers and practicing health care professionals whose various multidisciplinary fields are interested in the human body’s soft connective tissue matrix.
Hijleh, Roshier, Al-Shboul, Dharap, & Harris, 2006; Lancerotto et al., 2011), and is observed on USI as a well-defined thin hyper-echoic band (Bradley & O'Donnell, 2002).

### 1.2.3.2 Deep Fasciae

Deep fasciae is classified as a continuous dense connective tissue (Benjamin, 2009). Histological analysis has demonstrated that collagen accounts for 18% of total volume, with elastin accounting for <1% (Benetazzo et al., 2011), although ratios may vary depending on location. As observed within ligaments and tendons, Type I collagen fibres are dominant (Casanova, Trindade, & Trindade, 2009). The DF encasing muscle can consist of two or three dense connective tissue layers each separated by LCT abundant in HA (Stecco et al., 2011). The presence of HA has also been demonstrated between deep fascia and epimysium surfaces, and within the muscular belly itself (Laurent, Johnson-Wells, Hellstrom, Engstrom-Laurent, & Wells, 1991; Stecco et al., 2011). The LCT layers rich in HA are hypothesised to allow for sliding between individual fascia layers, and fascia-to-muscle surfaces (Stecco et al., 2011).

### 1.2.3.3 Epimysium

The epimysium acts as an external sleeve, encasing the contractile muscle tissue. It is thicker than the perimysium and endomysium, and primarily consists of large diameter type I collagen fibres (Turrina, Martinez-Gonzalez, Stecco, 2013). The epimysium is continuous with muscle tendon via thickened collagen fibres merging with the paratenon (Benjamin, 2009), providing resistance when the tension parallels the collagen fibre orientation (Purslow, 2010). The fundamental functions of epimysium are to limit the expansion of muscle tissue during concentric contractions, transmit forces from tension via the tendon and aponeurotic expansions, and allow for sliding with adjacent structures (Purslow, 2010; Stecco et al., 2011).

### 1.2.4 Cervical fascia

The deep cervical fascia is traditionally described as having four distinct parts (Standring, 2015):

1. The investing layer: The most superficial deep fascia layers which encase the entire neck
2. The carotid sheath: An extension of deep cervical fascia which encloses the common carotid artery, internal jugular vein, vagus nerve and deep cervical lymph nodes
3. The pretracheal fascia: Encloses the viscera of the neck
4. The prevertebral fascia: Encloses the vertebral segments of the neck
1.2.5  Cervical fascia: Contentious anatomical classification

The cervical investing layer of fascia encloses the superficial and deep aspects of SCM anteriorly and trapezius posteriorly (Standring, 2015). It is therefore a component of the cervical investing fascia which has been measured within this thesis study, both on the superficial and deep surfaces of the SCM muscle. Common anatomical textbook descriptions portray the investing fascia enveloping the whole neck like an external sleeve; providing extensions which contribute to the formation of the carotid sheath (Standring, 2015). In this way, the traditional perspective is that carotid sheath and the investing layer of fascia communicate. However, anatomical research challenges these traditional textbook descriptions of cervical fascia, reporting the absence of the investing fascia in the anterior and posterior cervical triangles (Nash, Nicholson, & Zhang, 2005; Zhang & Lee, 2002), and proposing that the carotid sheath is formed with exclusive input from the pretracheal fascia (Hayashi, 2007).

Anatomical descriptions of cervical fascia vary between authors, and have been described as taking different shapes according to the observer (Nash, Nicholson, & Zhang, 2005). Nash et al. (2005) discussed complications associated with studying the configuration of cervical connective tissue within a cadaver, particularly, the difficulty in distinguishing between the fibrous components of subcutaneous tissue, deep fascia and epimysium. This difficulty is believed to have contributed to conflicting cervical fascia descriptions (Natale et al., 2014).

Natale et al. (2015) recently completed a literature review to establish a more comprehensive anatomical classification for cervical fascia. This review recognised three different types of fascia; the superficial fascia, within the subcutaneous space enveloping platysma muscle; the deep muscular fascia, the external layer enclosing SCM and trapezius muscle; and the visceral fasciae, that which envelops organs of the neck. Natale et al., concluded that despite research demonstrating the absence of investing fascia within the anterior and posterior cervical triangles (Nash et al., 2005; Zhang & Lee, 2002), there is currently insufficient evidence to apply these findings to the general population. This is illustrated well by the fact that the 40th edition of Gray’s Anatomy, cited the research by these authors, but did not change their description of investing fascia.

1.2.6  Cervical fascia anatomy: Relevance within this thesis

The study undertaken in this thesis requires the ability to distinguish the DF that encompasses SCM muscle (investing fascia) from adjacent connective tissue. Consensus surrounding cervical fascia anatomy is therefore of critical importance, to allow for accurate tissue boundary classification.
Boundary misclassification may occur when the DF is adjacent to structures of a similar composition, making it difficult to distinguish with USI.² If the cervical superficial fascia is located in the deep aspect of the subcutaneous space, it could be seen as an additional layer of the DF, particularly considering the reported occurrence of LCT between fascia layers on USI (Stecco et al., 2014). Therefore, USI guidelines for DF measurement overlying SCM must ensure the superficial fascia is not included within measurement values. This can be achieved by visualising the superficial fascia as a separate structure before measurement, as this tissue should always be visible, given its body-wide continuity (Abu-Hijleh et al., 2006). An operator should therefore be able to match the USI layers with histological descriptions, to ensure validity of measurement.

The carotid sheath has been described in two parts, the thin sheath which encompasses both the internal carotid artery and internal jugular vein within one circular ring, and the laminar adventitia, a thicker membrane (>1mm) which encases both of these vessels separately within two rings (Hayashi, 2007). The carotid sheath is demarcated by adjacent portions of the deep cervical investing layer of fascia (Standring, 2015), with a separation of 0.2mm to 0.5mm at the midpoint of SCM reported (Hayashi, 2007). When SCM muscle is visualised using USI, the carotid sheath appears adjacent to the DF underlying SCM. Whilst the carotid sheath is traditionally described as loose connective tissue (Standring, 2015), it has also been demonstrated to be of fibrous composition at higher magnification (Hayashi, 2007), potentially complicating tissue differentiation with USI. Furthermore, transducer pressure may approximate the DF and carotid sheath, as demonstrated in research where a patent jugular vein has been used to measure the extent of transducer-induced tissue distortion (Kuo, Jian, Wang, & Wang, 2013). To ensure validity of measurement, and avoid including the carotid sheath within the DF tissue boundary classification, the measurement protocol should assess the thickness of the carotid sheath separately, before measuring the DF. The USI operator should visualise the sheath with the transducer transverse to SCM, so the sheath can be observed continuing medial from the deep aspect of the muscle belly to allow for distinction with DF. Additionally, all USI-obtained measurements of fascia encompassing SCM should take place with a patent jugular vein, to limit transducer-induced tissue distortion.

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² Examples of this include the cervical superficial fascia, which during USI pilot testing appeared to have a highly variable position within the subcutaneous space, and was often observed adjacent to the deep fascia overlaying SCM.
1.3 Myofascial Pain Syndrome

1.3.1 Differentiating myofascial pain and MPS
The densification phenomena described by Stecco et al., proposes a ‘dysfunctional cascade’ of how fasciae may be involved in myofascial pain (Pavan, Stecco, Stern, & Stecco, 2014; Stecco et al., 2011; Stecco et al., 2014). As such, it is important to clarify that myofascial pain can refer to any noxious stimulus arising from muscle or fascia tissue, whilst MPS is a particular myofascial affliction involving MTrPs. This review acknowledges that these terms are not synonymous, however the vast majority of literature investigating pain from a myofascial origin is conducted utilising the MPS framework. Therefore, a review of MPS is necessary to provide insight into the current understanding of how myofascial tissue causes pain. This review allows the densification phenomena proposed by Stecco et al. (2014) to be considered in an appropriate context.

1.3.2 Myofascial neck pain
The entity of MPS is considered by some authors as a sub-classification of musculoskeletal pain, with a reported prevalence of 37% in men and 65% in women (Drewes & Jennum, 1995). Musculoskeletal neck pain is second only to low back pain in terms of prevalence by body region (Eurobarometer, 2007), and is associated with significant financial burden (Borghouts, Koes, Vondeling, & Bouter, 1999). Myofascial neck pain is responsible for a large proportion of musculoskeletal neck pain, and is reported to have a high recurrence rate (Gerwin, 2001; Simons, Travell, & Simons, 1999). As with MPS itself, myofascial neck pain is characterised by hyperirritable areas within taut bands of skeletal muscle and fascia, which are referred to as MTrPs (Giamberardino et al., 2011). Typical signs and symptoms of myofascial neck pain include neck tenderness, pain referral, postural, and emotional contributing factors (Fricton, Kroening, Haley, & Siegert, 1985).

1.3.3 Myofascial pain syndrome: Pathogenesis and aetiology
The proposed biological process associated with the formation of MTrPs involves abnormal acetylcholine release at neural endplates (Mense, Simons, & Russell, 2001). It is postulated that muscular microtrauma caused by acute or chronic overload, further increases the saturation of acetylcholine perpetuating endplate motor activity. This results in sustained muscular fibre depolarisation and an imbalance of calcium ions, potentiating sarcomere shortening. Chronic exposure to this vicious cycle is thought to result in tissue hypoxia, causing a release of vasoactive substances which are responsible for local nociceptor sensitisation. Bron & Dommerholt (2012) conducted a review of literature relating to MPS aetiology, and concluded that sustained low level, eccentric and submaximal concentric muscle contractions were likely responsible for the development
of MTrPs. These contractions and the related MTrP cascade may occur as a result of recreational, occupation or other activities where muscular use exceeds the functional capacity of muscular recovery (Bron & Dommerholt, 2012).

1.3.4 Objective analysis of myofascial trigger points

Despite extensive research conducted on MPS to date, contention remains over the validity of this syndrome as a diagnostic entity (Quintner, Bove, & Cohen, 2015). This is largely due to the absence of objective evidence supporting the pathophysiology of MPS, and poor reliability for the clinical identification of MTrPs (Lucas et al., 2009). To better comprehend the validity of MPS as a diagnostic entity, what follows is a review of literature that investigates the objective properties of MTrPs.

Ballyns et al., set out to investigate objective differences between active MTrPs, latent MTrPs and normal muscle tissue within a population of people with neck pain (n=44) (Ballyns et al., 2011). Sonoelastography was utilised to assess muscular stiffness, and Doppler imaging to assess the local vascular environment of MTrPs. A total of 4 predetermined sites on the upper trapezius muscle were used for imaging purposes. Within this study, muscle stiffness as quantified by elastography was an effective parameter for distinguishing between different MTrP classifications and normal tissue. This allowed for accurate identification of active MTrPs (mean ± SD, 0.57 ± 0.20 cm$^2$), latent MTrPs (0.36 ± 0.16 cm$^2$), and normal tissue (0.17 ± 0.22 cm$^2$), achieved by analysis of stiffness area. However, considering that all participants within this study had neck pain and at least one MTrP on a small surface area such as the upper trapezius muscle, the classification of a ‘normal tissue’ subgroup is questionable.

In a similar study, Turo et al., evaluated whether USI elastography could differentiate between symptomatic MTrPs and normal muscle tissue (Turo et al., 2013). A sample of 14 people with chronic neck pain (>3 months pain) and palpable MTrPs were recruited and matched with healthy controls (absence of MTrPs). The upper trapezius muscle was again the site where vibration elastography was performed. The results suggested that active MTrPs have more of a homogeneous texture when compared with normal muscle tissue. Turo et al., proposed that this homogeneity may be a consequence of low-level muscle contractures, supporting the earlier described aetiology and pathogenesis for MPS (Mense et al., 2001; Bron & Dommerholt 2012). Within this study, a combined calculation of entropy analysis and vibration elastography demonstrated a sensitivity of 69% and specificity of 81% in differentiating active MTrPs from normal muscular tissue. Given the main diagnostic criteria for MPS is the presence of MTrPs, the ability to objectively demonstrate their
presence with accuracy would be clinically useful. Whilst a sensitivity of 69% has no real clinical utility for ‘ruling out’ MPS, a specificity of 81% could inform diagnostic reasoning processes and assist in confirmation of diagnosis.

An earlier pilot study explored the validity of magnetic resonance elastography in the identification of MTrPs (Chen, Bensamoun, Basford, Thompson, & An, 2007). The sample consisted of two participants with a history of MPS and palpable upper trapezius MTrPs, and an asymptomatic control. The findings of this study suggested that the MTrPs can be quantitatively measured utilising magnetic resonance elastography, and that stiffness in a MTrP is 50% greater than that of adjacent muscular tissue. The use of just two participants in this study limit the applicability of these findings.

Shah et al. evaluated the biochemical environment of MTrPs, compared with normal muscle tissue (Shah et al., 2008). Microanalytic techniques were utilised to assay small molecules (neuropeptides, inflammatory mediators, and catecholamines) within the trapezius muscle MTrPs, and the results where compared against samples taken from the ‘normal’ (absence of MTrPs) trapezius and gastrocnemius muscle tissues. These small molecules are known to be implicated in nociception and sensitisation processes, and specifically included bradykinin, substance P, and tumor necrosis factor alpha. Shah et al., reported that all measured substances where found in significantly higher quantities in active MTrPs compared with normal tissue (P<.05), supporting the idea that MTrPs are a genuine source of pain and may be prone to sensitisation processes.

1.3.5 Limitations of research
The use of elastography and biochemical analysis to objectively demonstrate how the physical and biochemical properties of MTrPs differ from normal muscle tissue, supports the pathophysiology of MPS. However, there are a number of limitations within this reviewed research. Firstly, the trapezius muscle was the centre of all investigations, with no MTrPs in other muscles reviewed, limiting the applicability of findings. Secondly, palpation was used to identify the MTrPs, despite research demonstrating poor reliability of this method (Lucas et al., 2009). Thirdly, whilst elastography has been demonstrated to be a valid diagnostic tool for viscera (Beckebaum et al., 2010; Friedrich–Rust et al., 2008), its ability to characterise muscle tissue is comparatively unknown. Finally, all of the research was conducted using small sample sizes; underpowered to make inferences concerning differences between MTrPs and normal muscle tissue. The scarcity of literature which objectively characterise MTrP properties and the underlying pathological processes appears disproportionate to the international adoption of the MPS framework within manual therapy. Additionally, the vast majority of research has focused on a muscular origin, with comparatively little research conducted on
the role of fascial within MPS (Stecco., 2011). Further high quality research is required to clarify the pathogenesis of MPS.

1.3.6 The role of fascia within MPS
Although the term ‘myofascial pain’ implies involvement of fasciae, research has focused almost entirely on skeletal muscle tissue (Stecco et al., 2011). The role of fascia within MPS is seldomly reported in literature. However, the functional perspective that fascia is a body-wide connective network that has been adopted by the Fascia Research Congress (2015), as opposed to a closed-chain regional muscular casing, has ignited a new-found interest in this connective tissue.³ Recent literature reports findings that may help elucidate the role of fascia within MPS, by outlining a proposed fascia-specific structural alteration termed ‘densification’ (Schleip et al., 2012; Stecco et al., 2014). However, to better understand the implications of fascial dysfunction, it is necessary to comprehend the diverse functional capacity this connective tissue fulfils within the human body.

1.4 Fascia: functional capacity

1.4.1 Traditional perspective of fascia function
The primary role of fascia has been traditionally described as compartmentalising muscular tissue (Benjamin, 2009; Klingler, Velders, Hoppe, Pedro, & Schleip, 2014). The presence of HA in the LCT layer of fascia functions to allow contractile muscular tissue and fascia to slide effectively over one another during movement (Stecco et al., 2011). Whilst these functions are important roles of fascia, this limited functional appraisal is in keeping with the more traditional regional-based anatomical classification, without an appreciation of fascia as a body-wide network. A number of additional important functions of fascia have been described.

1.4.2 Force transmission and protective capacity
Turrina et al. (2013) explored the interaction between connective tissue and muscle. Specifically, this review focused on the muscular force transmission system, examining the functional interplay between muscles and connective tissue in the generation of force. Turrina et al., concluded that due to the inseparable anatomical relationship between muscle and connective tissues, muscular tissue should not be studied in isolation. Whilst traditional views of movement generation involve force

³ This is illustrated well by the increase in volume of published fascia-related literature as reported on PubMed
transmission from muscular contraction to tendinous junction on bone, studies have demonstrated that 30-40% of the force generation from muscle contraction is transferred to connection tissue outside the muscle as opposed to through the enthesis (Huijing & Jaspers, 2005; Huijing, 1999; Turrina et al., 2013). It is clear that force generated by muscular contraction on the connective tissue network provides a mechanical platform for the human body to perform functional movement (Lindsay, 2008).

Other force-related functional properties have been described concerning fascia, including myofibroblast contraction (Benjamin, 2009; Schleip, Klingler, Lehmann-Horn, 2005). This contraction is facilitated through the production of actin stress fibres and the development of gap junctions between cells (Benjamin, 2009). The role of myofibroblast’s in closing the edges within wound healing cascades is well documented (Gabbiani, 2003). However, beyond this capacity, observed resistance of lumbodorsal fascia under isometric load was proposed by Yahia et al. (1993) as being a result of fascia-specific myofibroblast contraction. This phenomena suggests resistance properties of fascia which function beyond the passive fibrous structure of this tissue.

Bouch and Johnson (2007) discussed a force dissipation role of fascia within medical tibial stress syndrome. The fascial attachment to the medial tibial ridge was proposed as a pathomechanical reasoning for this condition, where eccentric contraction of plantarflexors over-stresses the deep fascia insertion. Therefore, this syndrome suggests a force dissipation capacity of fascia, which in this particular instance has been overstressed. Further protective functions of fascia are demonstrated through thickenings over neurovascular structures. An example of this is the bic iptial aponeurosis, which provides protection to neurovascular structures within the cubital fossa (Athwal, Steinmann, & Rispoli, 2007).

### 1.4.3 Proprioception

Histochemical analysis of the thoracolumbar fascia (TLF) was conducted by Yahia et al. (1992), revealing an abundance of mechanoreceptors and free nerve endings. Specifically, large pacini corpuscles were identified, receptors known to respond to vibration and rapid changes in pressure. Yahia et al., concluded that thoracolumbar fascia may fulfil a neurosensory role within the lumbar spine. Given that the identified receptors within the TLF also contribute to proprioceptive afferent feedback, Schleip et al., proposes that fascia is involved in proprioception, informing efferent motor recruitment patterns (Schleip, 2003). Indeed, mechanoreceptors have been demonstrated in abundance within connective tissue such as joint capsules and ligaments, with the proprioceptive capacity of these tissues well established (Burke, Gandevia, & Macefield, 1988; Proske & Gandevia,
Further research is required to establish the extent to which fascia contributes to proprioception and motor control.

1.4.4 Venous and lymphatic return
In addition to providing a tensional network which assists movement, the deep fascia muscular casing has important implications on haemodynamics, particularly in the periphery (Benjamin, 2009). During musculature contraction, the muscle pushes against the deep fascia encasing it, increasing intra-compartment pressure. This increased pressure results in the venous and lymphatic structures being compressed, facilitating fluid return to the heart through unidirectional valves.

1.5 Structural alterations of fascia
Two structural alterations of fascia tissue have been described; damage to the fibrous network of fascia and impairment of the loose connective tissue layer of fascia. These two alterations have been described as fibrosis and densification processes respectively.

1.5.1 Fascia fibrosis
When fascia is damaged by trauma or surgery, the classically described healing responses ensue: hemostasis, inflammation, proliferation and remodelling (Tomasek, Gabbiani, Hinz, Chaponnier, & Brown, 2002). The latter phases are regeneration focused, and their failure can result in formation of excessive scar tissue. This is when the post-injury connective tissue matrix heals, but does not closely resemble the preinjury structural or functional capacity of the tissue. In this sense, body-wide connective tissue either heals by regeneration, scar-tissue fibrosis or a combination of these two processes.

During the regeneration phase, deposition of collagen occurs. The optimal orientation of collagen distribution is necessary to promote high levels of post-trauma functionality (Nahar et al., 2013). Many existing biological models have been proposed to explain how connective tissue architecture responds to mechanical stress. Wolff’s law highlights the relationship between mechanical load and bone architecture, in that bone deposition is regulated in part by loading patterns (Frost, 2004). Similarly during regeneration phases following injury, ligaments and tendon fibroblasts respond to mechanical forces to organise placement of the collagen fibre matrix (Grodzinsky, Levenston, Jin, & Frank, 2000; Tomasek et al., 2002). It is in consideration of this biological process that rehabilitation of tendon and ligament injury promotes the use of controlled stress vectors throughout the
regeneration phase (Cao, Hicks, & Standley, 2013; Meltzer et al., 2010). Named conditions such as Duypuytren’s disease and plantar fasciitis are examples of fascia fibrosis processes, however, their aetiology is more complicated than connective tissue trauma or chronic overload.

1.5.1.1 Duypuytren’s Disease

Duypuytren’s disease is classified as a benign contractile disorder of the hand, where a thickening and contracture of the palmer fascia occurs (Worrell, 2012). This disease is a chronic process that typically effects the medial palmer surface and the 4th and 5th digits. The prevalence of Duypuytren’s disease has been reported to be highly variable, ranging from 0.2% to 56% dependent on population groups, age, and methods of data collection (Hindocha, McGrouther, & Bayat, 2009). The pathophysiology involves abnormal increases in myofibroblasts and subsequent fibroproliferation, however the aetiology underlying the increase in myofibroblasts remains unknown (Hindocha et al., 2009; Khashan, Smitham, Khan, & Goddard, 2011; Picardo & Khan, 2012). Microvessels within the Duypuytren’s disease population have been shown to be considerably narrowed, raising the possibility of tissue hypoxia being involved in the pathogenesis (Al-Qattan, 2006). Epidemiological associations with Duypuytren’s disease including increasing age, diabetes, alcohol abuse and cigarette smoking support the hypoxia-causation hypothesis given that these factors are all associated with microvessel narrowing (Hindocha et al., 2009).

1.5.1.2 Plantar Fasciitis

Plantar fasciitis is among the most common causes of heel pain (Goff & Crawford, 2011), however the pathophysiology and aetiological factors associated with this condition remain poorly understood. USI has demonstrated increased plantar fascia thickness in patients with plantar fasciitis, compared to controls (Sconfienza et al., 2013). Histological analysis has demonstrated degenerative changes within the plantar fascia in those affected by plantar fasciitis (Lemont, Ammirati, & Usen, 2003). Commonly cited aetiological factors such as limited dorsiflexion, obesity, posterior calf muscle tightness and excessive foot pronation, are all factors increasing the strain on the plantar fasciitis and predisposing to repetitive microtrauma injuries (Goff & Crawford, 2011). It is likely that plantar fascia overload causes degenerative changes histologically similar to those observed in tendinosis, where type III collagen fibres do not mature into more structurally robust type I fibres (Silva, Glazebrook, Campos, & Vasconcelos, 2011). This degenerative cascade has been shown to occur in the absence of inflammation (Lemont et al., 2003), prompting a discussion around whether a more suitable name should be adopted that does not imply an inflammatory process, such as ‘fasciosis’ or ‘fasciopathy’ (Fabrikant & Park, 2011).
In summary, fascia fibrosis is often associated with trauma and/or abnormal loading that results in tissue damage. Instead of successful regeneration where the healing process allows fascia to return to a structural and functional preinjury capacity, fibrosis ensues, characterised by the deposition of collagen fibres in an unorganised orientation (Pavan et al., 2014). Both Duyputren’s disease and plantar fasciitis are established named conditions, and demonstrate the negative implications on regional tissue compliance that can result from fibrosis.

1.5.2 Densification
Fascia ‘densification’ is a term recently proposed by Stecco et al., and refers to an increase in thickness and viscosity of the LCT layer of fascia (Stecco et al., 2014; Pavan et al., 2014). Research has demonstrated that HA, a normally aqueous substance which is proposed to facilitate sliding of fascia and adjacent surfaces, is the main component of the LCT (Stecco et al., 2011). This acid is theorised to be produced in larger quantities under mechanical load, or when the local environment pH decreases (Gatej, Popa, & Rinaudo, 2005; Matteini et al., 2009; Scott & Heatley, 2002). Biochemical analysis of HA has demonstrated that the greater the concentration of this substance, the more viscous it becomes; the result of interaction between large straight chain polymers (Matteini et al., 2009). Stecco et al., postulated that the increased viscosity of HA, alters the dynamic properties of from an aqueous solution to a ‘thick gel’, compromising fascia’s primary lubrication function and reducing tissue compliancy (Pavan et al., 2014; Stecco et al., 2011; Stecco et al., 2014).

The increase in LCT thickness proposed by Stecco, is supported by research conducted by Schleip et al. (2012) who observed in vitro thickening of fascia in response to strain, characterised by an increase in tissue fluid during the post-strain ‘rest phase’. Schleip et al., proposed that the observed fascia thickening was responsible for the reported ‘strain-hardening’ phenomena (Haut & Haut, 1997; Yahia et al., 1993), defined as an increase in tissue stiffness induced by stretch (Schleip et al., 2012). This was in contrast to the previously proposed mechanisms for strain hardening, believed to be a facilitated by myofibroblast contraction (Schleip et al., 2012; Schleip et al., 2005; Yahia et al., 1993). Stecco et al. demonstrated increased LCT thickness within neck pain patients compared to controls (Stecco et al., 2014). The greater thickness in LCT was proposed to be a result of fluid retention previously described by Schliep et al. (2012), which Stecco et al. referred to as ‘fascia densification’.

Relating to clinical dysfunction, Stecco et al., postulates that this may be perceived by patients as an increase in fascial stiffness (Pavan et al., 2014; Stecco et al., 2014). This hypothesis is supported by research the same author conducted, reporting a ‘statistical difference’ (P <0.05) in neck range of
motion between chronic neck pain patients with thicker cervical fascia and controls (Stecco et al., 2014). Stecco et al., stated that “connective tissue inside the fasciae may play a significant role in the pathogenesis of CNP”, reporting that patients with cervical fascia thickness greater than 0.15cm can be considered to have myofascial disease (Stecco et al., 2014).

The densification phenomena and associated pathophysiological process described by Stecco et al. (2014) is based on limited research, and is not widely accepted. However, the emphasis on the LCT, and the demonstrated association with neck pain and stiffness, warrants further investigation. Therefore, it is necessary to review the key components of the densification phenomena and critique the supporting research conducted by Stecco et al.

1.5.3 Hyaluronic acid structure and function
The earlier described HA is a large straight-chain carbohydrate polymer and has a diverse functional capacity including supporting normal homeostasis, suppressing cell proliferation, migration, angiogenesis, tissue inflammation, immunogenicity (Day & Sheehan, 2001; Delmage, Powars, Jaynes, & Allerton, 1986; Feinberg & Beebe, 1983; Stecco et al., 2011). The HA substance is a normal component of extracellular fluid, and has long been understood to afford viscoelastic properties to fluid within muscles and synovial joints (Laurent et al., 1991; Ogston & Stanier, 1953). Research investigating HA has focused on how differing local environments effect the physical properties of this solution. Under increased physical loading or specific changes in pH, short HA chains have a propensity to self-associate (Gatej et al., 2005; Matteini et al., 2009; Scott & Heatley, 2002), increasing the viscosity from a liquid to a gel-like substance. Stecco et al., demonstrated that HA is the primary component of the loose connective tissue layers of fascia (Stecco et al., 2011), and postulates that this alteration may have negative implications on the primary lubrication function of HA.

1.5.4 Fascia innervation: A source of pain?
According to postulates described by Bogduk et al., in order for a tissue to be confirmed as a source of pain, several criteria must be met (Bogduk, 2005). These postulates are outlined in Table 1 as they apply to fascia, along with a descriptive summary of existing research pertaining to each postulate. Further indepth discussion of the reviewed research follows.
Table 1. Bogduk’s postulates for a tissue to be considered a genuine source of pain with existing fascia research

<table>
<thead>
<tr>
<th>Bogduk’s postulates (Bogduk, 2005)</th>
<th>Existing research overview</th>
<th>Postulate satisfied?</th>
<th>Key references</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The structure must have a nerve supply</td>
<td>Research from multiple sources demonstrating innervation of fascia.</td>
<td>Yes</td>
<td>Stecco et al., 2007; Yahia et al., 1992</td>
</tr>
<tr>
<td>2. The structure should be capable of causing pain similar to what is clinically observed (e.g., when provoked in normal volunteers)</td>
<td>Only preliminary research exists with limited investigations in normal healthy populations.</td>
<td>Further research required to satisfy postulate.</td>
<td>Taguchi et al., 2008; Schilder et al., 2012</td>
</tr>
<tr>
<td>3. The structure should be susceptible to painful disease or injury; such disorders should be detectable by clinical imaging, biomechanical, or post-mortem tests.</td>
<td>Only preliminary research exists showing microinjuries and other structural changes within fascia that could induce pain. However, existing evidence exists for other connective tissues that have similar structural composition that strongly support the notion that fascia is susceptible to overload-related damage.</td>
<td>Yes</td>
<td>Lemont et al., 2003; Langevin et al., 2011</td>
</tr>
<tr>
<td>4. The structure should be shown to be a source of pain in actual patients using reliable and valid diagnostic tests</td>
<td>No existing research in this area.</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

1.5.4.1 Postulate 1: The structure must have a nerve supply

The first postulate stipulates that in order for a tissue to be considered a source of pain, it must be innervated. Several studies have demonstrated that fascia is richly innervated with free and encapsulated nerve endings, both in the trunk and extremities (Sanchis-Alfonso & Rosello-Sastre, 2000; Stecco et al., 2007; Yahia et al., 1992). Tesarz et al. (2011) reported that the outer layer of the thoracolumbar fascia (TLF) is densely innervated with sensory fibres, with the presence of substance P positive nerve endings cited. Stecco et al. (2007) reported that the upper extremity deep muscular fascia is highly innervated, with both free nerve endings and encapsulated receptors observed.
1.5.4.2 Postulate 2: The structure should be capable of causing pain similar to what is clinically observed

The second postulate states that it is desirable that the tissue under investigation has been shown to cause pain experimentally. Limited research has been conducted involving in vivo stimulation of fascia, with the vast majority of high quality studies conducted on the TLF. Kulich et al. (1991) investigated the effect of mechanical stimulation on both the TLF and nerve root within patients undergoing disc-related surgery. Whilst nerve root irritation evoked strong radiating LBP, this did not occur when the same stimulus was applied to the TLF. However, similar exploration by Pedersen et al. (1956) and Taguchi et al. (2008) reported findings in contrast to this. Taguchi et al. (2008) explored the reaction of TLF to mechanical stimulation and hypertonic saline separately, and observed dorsal horn neural activity from type IV afferents, suggesting a nociceptive function of TLF. More recently, Schiødt et al. (2014) showed that hypertonic saline injected into the TLF induced pain within healthy participants. Interestingly, following hypertonic saline injection, the TLF was more painful than the other tissues tested, including lumbar erector spinae or subcutis. This is consistent with research conducted on tendons and crural fascia, where higher pain scores and larger pain referral patterns where found in connective tissue structures compared to muscle tissue (Gibson, Arendt-Nielsen, & Graven-Nielsen, 2006; Gibson, Arendt-Nielsen, Taguchi, Mizumura, & Graven-Nielsen, 2009).

1.5.4.3 Postulate 3: The structure should be susceptible to painful disease or injury

The third postulate states that the structure must be shown to be affected by a lesion which could induce nociception. Bednar et al., demonstrated microinjuries of TFL in patients with chronic mechanical low back pain suggestive of ischemia or inflammation processes (Bednar, Orr, & Simon, 1995). Whilst no normative investigations have been completed on TLF within healthy volunteers to better understand the significance of these findings, degenerative changes consistent with connective tissue overload have been well described in those with plantar fasciitis (Lemont et al., 2003). The notion of microinjuries is supported by research conducted by Langevin et al. (2011) which showed a 20% reduction in TLF shear strain capacity in patients with LBP (n=71) compared to healthy controls (n=50), potentially a consequence of connective tissue pathology. Other forms of connective tissue with similar structural composition include tendons, ligaments and retinaculum, where microinjury in response to strain is well established (Hayashi, 2010; Maganaris, Narici, Almekinders, & Maffulli, 2004).
1.5.4.4 Postulate 4: The structure should be shown to be a source of pain using reliable and valid diagnostic tests

The fourth postulate states that the structure under investigation should be objectively demonstrated as a source of pain in actual patients. To date, no research has been conducted that definitely demonstrates fascia to be a source of existing pain within patients. Although further research is needed to demonstrate that fascia is a source of pain in certain patients, one must also appreciate the methodological difficulties associated with meeting this postulate. Diagnostic anaesthetic blocks are frequently utilised to confirm a source of pain, despite reports of high false positive rates associated with this method (Rupert, Lee, Manchikanti, Datta, & Cohen, 2009). This high false positive rate may be a by-product of inaccurate injection, where anaesthetic does not remain in the tissue being investigated (Hildebrandt, 2001). This has been reported in instances where anaesthetic blocks have been utilised to assess pain arising from the sacroiliac and zygapophyseal joints (Bogduk, 2010; Gupta et al., 2012), structures that compared with fasciae, both have the advantage of being compartmentalised. When applying such a technique to fascia, it would likely be difficult to identify and isolate the region of interest, particularly considering the thin enveloping nature of fascia.

1.5.4.5 Fascia: Source of pain summary

Fascia appears to be a highly innervated tissue, and research continues to grow which supports its involvement as a source of pain. However, limited in vivo research exists demonstrating that fascia reliably induces pain in response to mechanical and chemical stimulus. The vast majority of research conducted in this area has focused on the TLF and plantar fascia, limiting inferences to other deep muscular fascia. Whilst degenerative changes in fascia composition have been demonstrated within TLF, the importance of these results are difficult to interpret in the absence of normative data from healthy individuals. Although research investigating disease-specific characteristics in patients with plantar fasciitis have demonstrated alterations from normal, including in plantar fascia thickness, histology, echogenicity and stiffness, it remains unknown whether these changes are responsible for the pain experienced within this condition (Abul, Ozer, Sakizlioglu, Buyuk, & Kaygusuz, 2015; Gadalla et al., 2014; Rios-Diaz et al., 2015; Sconfienza et al., 2013). Further research is required to better understand the role fascia plays as a source of pain.

1.5.5 Densification phenomenon and neck pain

The research conducted by Stecco and colleagues (2014) is the main study from which this thesis investigation is based. Stecco et al., completed a randomised clinical trial (RCT) which aimed to establish the importance of fascia within chronic nonspecific neck pain (Stecco et al., 2014). The main clinical study correlated fascia LCT thickness with the visual analogue scale during the course of numerous interventions. The chronic neck pain participants (n=28) were assigned to one of two
intervention groups; either MEL (massage, electrotherapy, LASER) or FM (fascial manipulation). During the course of treatment, the thickness of cervical DF was measured utilising USI. This study reported a significant correlation (Spearman’s: \( r=0.44 \)) between chronic neck pain and LCT thickening (>0.05cm). A thickness value of 0.15cm associated with SCM fascia was stipulated by the authors to distinguish clinically the presence of fascial disease (Stecco et al., 2014). As part of the ‘pre-clinical study’, both fascia thickness overlying SCM utilising USI, and cervical range of motion using goniometers, were measured in healthy controls (\( n=25 \)) and chronic neck pain participants (\( n=28 \)). The measures were compared between groups, and the fascia thickness was found to be significantly larger within people with chronic neck pain, compared to controls. This difference was pertaining to the DF overlying SCM on both the right (Mann-Whitney test: \( P=0.035 \)) and left (Mann-Whitney test: \( P=0.025 \)) sides. This increased thickness was not attributed to the dense connective tissue of the fascia, but the LCT matrix that comprises largely of HA. The preclinical study also reported that patients with chronic neck pain have greater neck stiffness.

1.5.6 Stecco et al. 2014: Study appraisal and limitations

Standardised scales exist which allow consistent appraisal of a study’s quality, and are useful to contextualise research findings. The PEDro scale is a reliable and valid tool to assess the quality of RCTs (de Morton, 2009; Maher, Sherrington, Herbert, Moseley, & Elkins, 2003). Utilising the PEDro methodological quality criteria, the RCT conducted by Stecco et al. (2014) scored 5/10 as reported on the online PEDro resource, appraised to be of “fair” quality (“PEDro score,” 2016). Points were lost primarily due to inconsistent blinding of subjects and the therapist within the study methodology.

Whilst this appraisal provides useful information pertaining to the general quality of this RCT, the correlation of fascia thickness and neck dysfunction were classified as pre-clinical study finding and are therefore not directly critiqued within the PEDro appraisal.

Several limitations within the preclinical study are apparent. Firstly, the small sample of participants and controls limits inferences pertaining to normative thickness values. Whilst observable differences in layer characteristics were reported between groups, the correlation between LCT thickness and chronic neck pain appears underpowered to set clinical guidelines relating to the diagnosis of “fascia disease”. Secondly, the study cites a correlation between neck stiffness (decrease in ROM), increases in deep fasciae thickness and chronic neck pain. Whilst the clinical trial shows through raw data that participants with chronic neck pain had reduced cervical range of motion, no correlation coefficient was actually reported. The authors also suggest that the stiffness is related to an increase in LCT thickening. However, again this research did not correlate LCT thickening and neck stiffness.
independently, therefore the reported data does not support this relationship. As such the result may be due to the chronic neck pain itself, or another factor causing the neck pain. Finally, the USI protocol is scant of detail, with no information pertaining to how the fascia layers were visualised (depth/zoom), or the experience of the ultrasonographer who performed the measurements. In addition to the unknown expertise of the USI operator, no reliability data currently exists for cervical fascia measurements, with very limited research conducted in other body regions. To date, no fascia measurement reliability research conducted has focused on the ability of USI to appraise LCT of fascia, which requires accurate boundary classification of the adjacent dense connective tissue. Given that the limits of validity for a clinical measure are constrained by its reliability (Zumbo, 2007), further research is required to establish the reliability of cervical fascia measurements.
2 Ultrasound: Musculoskeletal application

2.1 Ultrasound review purpose

Within manual therapy, USI is frequently used to determine the thickness of soft tissue such as muscles, fascia, and tendons. Within the research conducted by Stecco et al., that is of primary interest to this thesis, USI was utilised to obtain the cervical fascia thickness values that were reported to be significantly thicker (left, $P = 0.025$ right: $P = 0.035$) within people with chronic neck pain. As establishing the reliability of USI cervical fascia measurements is the primary aim of this thesis, the purpose of this section is to provide an overview of the relevant research and information that was reviewed to assemble the utilised ultrasound methodology. This will include a general review of research utilising USI to measure fascia thickness, with more attention given to research where reliability of fascia measurement was investigated. This section will also discuss the importance of SCM and use of real-time ultrasound imaging (RTUS) within the field of chronic neck pain. This review of SCM provides insight into why the fascia enveloping this muscle is of interest. Initially, however, it is necessary to clarify the use of USI as an imaging modality within manual therapy.

2.2 USI overview

Ultrasound imaging is considered a safe and cost-effective method of medical imaging (Chiou, Chou, Chiou, Liu, & Chang, 2003; Ellis, 2011; Hashimoto, Kramer, & Wiitala, 1999; Whittaker et al., 2007). Whilst magnetic resonance imaging (MRI) has demonstrated superior results in the identification and appraisal of many soft-tissue conditions, the availability and high operating costs result in MRI being utilised only when absolutely necessary (Jacobson, 2005; Nazarian, 2008). In many instances, USI is a viable alternative to MRI, and has the advantage of providing real-time in vivo feedback.

Within the musculoskeletal system, USI has been used for diagnostic, therapeutic, and exploratory applications (Van Holsbeeck & Introcaso, 2001). For many common musculoskeletal conditions, USI has been demonstrated to be a valid imaging modality, including the assessment of muscular tears, tendinopathy and many rheumatological pathologies (McNally, 2014). The use of post-imaging analysis such as speckle tracking has allowed for analysis of muscular contraction during movement. This has furthered understanding of muscular recruitment patterns, specifically, interaction between agonist, synergist and antagonist muscle groups (Peolsson, Löfstedt, Trygg, & Peolsson, 2012). Thickness measurements obtained through the use of USI have demonstrated associations with musculoskeletal dysfunction/pain, allowing the development of new therapeutic management.
strategies (Jun & Kim, 2013). Recently, the use of elastography technique to provide quantitative information of tissue quality has also been reported (Rios-Diaz et al., 2015; Sconfienza et al., 2013).

2.3 Ultrasound imaging adverse effects

Ultrasound is generally considered to be a safe form of imaging, as it does not involve any exposure to ionising radiation. It has been historically difficult to ascertain whether exposure to USI may have adverse effects at a biological level. This is largely been due to the difficulty in measuring the effect on cells because of insensitive assays, and in vitro testing methods (ter Haar, 2015). Additionally, many exposure levels utilised in research to determine the effect of ultrasound are at levels not reflective of normal clinical practice. Whilst high exposure may allow for a greater effect size that is consequently easier to detect, it is not generalisable to clinical practice settings. The exposure associated with diagnostic ultrasound is widely accepted as being safe (Houston, Odibo, & Macones, 2009).

2.4 Fascia measurements utilising ultrasound

Ultrasound imaging has been frequently utilised to determine the thickness of fascia, in various regions of the body (Gyaran, Spiezia, Hudson, & Maffulli, 2011; Stecco et al., 2014; Welk, Haun, Clark, & Kettner, 2015). Fascia is seen on ultrasound images as thin linear hyperechoic lines with boundaries which are often easily identifiable, due to the adjacent hypoechoic band of muscular tissue (Stecco et al., 2014). Table 2 shows a spectrum of relevant studies utilising USI on fascia tissue in different body regions.
Table 2. Overview of research where USI was used to appraise fascia

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Fascia Site</th>
<th>Description</th>
<th>Outcome Measures</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gadella et al. (2014)</td>
<td>Plantar fascia</td>
<td>Normative data within a healthy population (n=31)</td>
<td>Plantar fascia: thickness, vascularity, calcifications, fluid, echogenicity</td>
<td>A thickness &gt;4 mm and hypoechoicogenticity are common in the plantar fascia</td>
</tr>
<tr>
<td>Rios-Diaz et al. (2015)</td>
<td>Plantar fascia</td>
<td>Elastography evaluation of plantar in asymptomatic (n=23) and patients with plantar fasciitis (n=21)</td>
<td>Plantar fascia: thickness and echotexture (elastography)</td>
<td>Sonoelastography useful for objectively evaluating plantar fascia</td>
</tr>
<tr>
<td>Welk et al. (2015)</td>
<td>Plantar fascia</td>
<td>Pre and post exercise – plantar fascia evaluation in walkers (n=36) and runners (n=25)</td>
<td>Plantar fascia thickness</td>
<td>No significant change in plantar fascia following exercise</td>
</tr>
<tr>
<td>Langevin et al. (2011)</td>
<td>Thoracolumbar fascia</td>
<td>TLF shear strain differences between healthy (n=50) and patients with chronic low back pain (n=71)</td>
<td>TLF: tissue displacement and thickness</td>
<td>Reduced TLF shear strain (20% less) in patients within chronic low back pain</td>
</tr>
<tr>
<td>Deising et al. (2012)</td>
<td>Thoracolumbar fascia</td>
<td>USI guided nerve growth factor injection into TLF (n=14)</td>
<td>Pain hypersensitivity</td>
<td>Fascia nociceptors prone to hypersensitivity</td>
</tr>
<tr>
<td>Schilder et al. (2014)</td>
<td>Thoracolumbar fascia</td>
<td>USI guided hypertonic saline injection into TLF, lumbar erector spinae and adjacent subcutis (n=12)</td>
<td>Pain: intensity, quality and distribution. Fascia thickness</td>
<td>Fascia most pain-sensitive tissue</td>
</tr>
<tr>
<td>Gyaran et al. (2011)</td>
<td>Iliotibial band</td>
<td>ITB thickness normative data (n=38)</td>
<td>ITB thickness association with age, weight, sex, dominant limb</td>
<td>No association was reported</td>
</tr>
<tr>
<td>Hyun-sook et al. (2012)</td>
<td>Iliotibial band</td>
<td>ITB thickness resting and during numerous stretches</td>
<td>Change in ITB thickness during different stretches</td>
<td>Most effective ITB stretch standing position</td>
</tr>
<tr>
<td>Goh et al. (2003)</td>
<td>Iliotibial band</td>
<td>ITB thickness normative data (n=31)</td>
<td>ITB Thickness association with age, weight, height</td>
<td>Negative correlation ITB thickness and patient age</td>
</tr>
<tr>
<td>Tozzi et al. (2011)</td>
<td>Cervical fascia</td>
<td>Ultrasound observation of cervical fascial sliding pre and post myofascial manipulation (n=60)</td>
<td>Fascia sliding observation classification</td>
<td>Myofascial treatment is effective on fascia restrictions</td>
</tr>
</tbody>
</table>
2.4.1 Ultrasound methodology: Cervical fascia measurements

To date, it appears that only two studies have been conducted utilising ultrasound imaging to investigate cervical fascia (Stecco et al., 2014; Tozzi et al., 2011). The research conducted by Stecco et al. was discussed earlier in this review (see Section 1.5.5). Here, this section focuses on the ultrasound methodology of each of these studies, to inform the USI protocol within this research.

2.4.1.1 Study 1: Stecco et al. (2014) ultrasonography in myofascial neck pain

Stecco et al. (2014) completed a randomised controlled trial of fascial manipulation which involved thickness measurements of fascia enveloping SCM in healthy participants (n=25) and people with chronic neck pain (n=28). Utilising B-mode, a 38mm linear array transducer (5-10 MHz) was used to carry out the measures. With the patient supine, and exercising quiet breathing, the transducer was placed lateral to the cricoid cartilage for the measurement of SCM muscle. Transducer movements in a coronal plane were allowed for the USI operator to establish the thickest point of the SCM muscle belly. Here, three measurements were taken at the distal, middle and proximal aspects of the transducer for each tissue structure. Specifically, the tissues measured included the SCM muscle and related deep fascia; on the superficial and deep aspects of this muscle. This fascia is often referred to as the cervical investing fascia, and was reported to be easily visualised in the majority of instances within this research. An average of the three measurements per tissue structure was used for data analysis.

2.4.1.2 Study 2: Tozzi et al. (2011) fascial release effects on non-specific neck pain

Tozzi et al., utilised dynamic ultrasound topographic anatomy evaluation to assess the effect myofascial therapy has on the sliding of cervical layers (Tozzi, Bongiorno, & Vitturini, 2011). Utilising B-mode USI, a 7.5-13 MHz linear probe was placed on the antero-lateral surface of the neck between the SCM muscle and adjacent neurovascular bundle. This position allows for observation of both qualitative and quantitative changes in fascial mobility pertaining to the pretrachael and retropharangeal fascia. Measurements were taken before and after myofascial treatment, during quiet breathing, maximum inspiration-expiration, and swallowing. The imaging was carried out by medical doctor with 15 years of experience in USI who was blinded to patient specific information. Evaluation of the changes in fascial mobility were conducted by two independent investigators (both medical doctors), who were requested to categorise mobility changes as ‘none’, ‘discrete’ or ‘radical’.
The research conducted by Stecco et al. (2014) and Tozzi et al. (2011) provide useful methodological insight into the investigation of cervical fascia utilising USI. Of particular relevance, is the research conducted by Stecco et al, given its association with the densification phenomena described earlier within this review. Where possible, the USI protocol within the research reported in this thesis will emulate that conducted by Stecco et al. (2014). However, there will be several important differences to enhance validity of measurement. These differences are elaborated on below.

- Details of ultrasound settings used for visualisation of fascia tissue is not reported by Stecco et al. (2014). It is not clear whether zoom function was utilised to better visualise fascia, or whether measurements were obtained from the same depth used for SCM muscle. Given the large differences in tissue thickness between muscle and fascia, it seems logical to adjust the depth setting for these measurements accordingly. Considering this, write zoom should be utilised to better visualise fascia tissue boundaries.

- Stecco et al., (2014) utilised a 38 mm linear array transducer, commonly used for musculoskeletal applications. However, given the superficial nature of SCM and the requirement to visualise thin hyperechoic fascial bands, the hockey stick transducer is superior when available. This transducer is used specifically for superficial application, and its compact light design helps limit tissue distortion.

- It is also unclear within the research conducted by Stecco et al., (2014) the level of experience of the USI operator conducting the thickness measurements. Reporting the extent of operator training and experience is important in determining generalisability. In the study within this research thesis, atleast two ultrasound operators should be used. The two operators could include an experienced musculoskeletal USI operator, and a novice operator with limited USI exposure. The justification for the novice operator will be discussed later in this review (see Section 2.5.4).

2.4.2 Ultrasound of fascia: Reliability
The investigation of reliability is common within quantitative research, and denotes replicability of research results using the same methodology. Davidson et al. (2014) discusses how reliability demonstrates stability of repeated measurements, indicating the ‘noise’ or error within any given measurement. In this way, the limits of validity for a clinical measure are constrained by its reliability (Zumbo, 2007). Reliability is often subcategorised into three different types described by Kirk et al. (1986) as being (1) the degree to which measurement remains the same when repeated; (2) how stable
a particular measurement is over time; and (3) the likeness of measurements within a particular time period (Bashir, Afzal, & Azeem, 2008). An understanding of measurement reliability is critical for appropriate interpretation of study results. Interpretation of reliability coefficients is aided by associated statistics such as the minimal detectable change (MDC), which derived from reliability intraclass correlation coefficients (along with the Standard Error of Measurement), and represents the minimum value that can be considered true change independent of measurement variability (Wu, Chuang, Lin, Lee, & Hong, 2011).

The Quality Appraisal of Reliability checklist (QAREL) provides a valid and reliable means to assess the quality of reliability research through appraisal of methodological rigor (Lucas et al., 2013; Lucas, Macaskill, Irwig, & Bogduk, 2010). The quality of any given study is appraised by assessing compliance with a standardised methodological checklist. In the next section, the QAREL checklist is used to appraise three reliability studies conducted on fascia utilising USI, followed by further indepth analysis of the methodology used within this research.
Table 3

QAREL evaluation of reliability research conducted on fascia utilising USI.

<table>
<thead>
<tr>
<th>QAREL item</th>
<th>Representative participants</th>
<th>Representative raters</th>
<th>Inter-rater blinding</th>
<th>Blind to prior findings</th>
<th>Blind to reference standard</th>
<th>Blind clinical information</th>
<th>Blind to additional cues</th>
<th>Varied order examination</th>
<th>Time interval</th>
<th>Test application and interpretation</th>
<th>Appropriate statistics</th>
<th>Total Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rathleff et al. (2011)</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>9/10</td>
</tr>
</tbody>
</table>

Notes: Abreviations: N = No, Y = Yes, NA = Not applicable, ? = Unclear

QAREL checklist item Lucas et al., 2010

1. Was the test evaluated in a sample of subjects who were representative of those to whom the authors intended the results to be applied?
2. Was the test performed by raters who were representative of those to whom the authors intended the results to be applied?
3. Were raters blinded to the findings of other raters during the study?
4. Were raters blinded to their own prior findings of the test under evaluation?
5. Were raters blinded to the results of the reference standard for the target disorder?
6. Were raters blinded to clinical information that was not intended to be provided as part of the testing procedure or study design?
7. Were raters blinded to additional cues that were not part of the test?
8. Was the order of examination varied?
9. Was the time interval between repeated measurements compatible with the stability (or theoretical stability) of the variable being measured?
10. Was the test applied correctly and interpreted appropriately?
11. Were appropriate statistical measures of agreement used?
Rathleff et al. (2011) investigated the reliability of plantar fascia measurements utilising USI, where 20 healthy subjects with no current or history of prior foot pain participated. Two ultrasound operators, each with 2-5 years musculoskeletal experience, used recommendations set out by the European Society of Musculoskeletal Radiology to complete plantar fascia measurements. The operators were each given a maximum of four sessions before data collection to familiarise themselves with the USI machine and measurement protocol. Subjects were positioned prone, with the talocrural joint positioned neutral (0 degree), and the toes flexed. The transducer was placed on the plantar surface of the foot to optimise visualisation of the plantar fascia insertion into the calcaneus. Thickness measurements of the plantar fascia were conducted on both feet, using a 13 MHz linear transducer with a scan depth of 2cm. On each participant, the operator order and side that would be scanned first was randomised. Each operator completed a measurement three times, each time removing the transducer before repositioning for the next measurement. This allows for analysis of single measure and an average of three measures for intra and inter-rater reliability. The measurement process was repeated 60 minutes apart to limit biological tissue change, and during this time subjects were requested to reframe from physical activity. Intra-rater reliability using a single measurement was ICC 0.50 and 0.52, and improved to 0.77 when using the mean of three measures. Inter-rater reliability for one measurement was ICC 0.62, but also improved to 0.82 when using the mean of three measures. The higher reliability associated with the mean of three measures is consistent with reliability values reported by Croft et al. (2014) and Cheng et al. (2012) where similar methodology was used.

Gyaran et al. (2011) investigated the reliability of iliotibial band thickness measurement, obtained from USI as part of a larger assessment for iliotibial band syndrome. For the reliability component of the study, a total of 11 subjects aged between 15-25 years were recruited. With the patient supine, the operator marked a location on the iliotibial band on each participant’s knee 2cm superior to the lateral joint line. Using a high resolution 3–12 MHz transducer, the operator completed a single measurement on each of the participant’s knees. The same operator completed this measurement process on the same participant over three sessions to establish inter-session reliability. The intraclass correlation coefficient was 0.75 and 0.71 for the right and left iliotibial band measurements respectively. The thickness range of the iliotibial band was 0.8 to 1.4 mm.

2.4.3 Fascia measurement reliability: Summary
Limited research has been conducted which investigates the reliability of fascia measurement utilising USI, with no research to date investigating the reliability of cervical fascia measurement. Whilst fascia measurement reliability research conducted within the plantar fascia and iliotibial band have
demonstrated acceptable reliability, the absence of LCT layer within the fasciae measured in these studies limits inference to other body region where fascia has been demonstrated to have a more complex multi-layer structure (Stecco et al., 2014). Therefore, reliability research should be conducted in the cervical spine to help validate measurement data within previous and future literature.

Research investigating the reliability of fascia measurement utilising USI should consider the methodology used within previous literature, specifically relating to the USI measurement protocols, and reliability blinding guidelines. The study completed by Rathleff et al. (2011) which investigated plantar fascia reliability, was discussed earlier within this review (section 2.4.2) and appraised through the QAREL criteria. Rathleff et al., complied with 9 of the 10 applicable criteria stipulated within the QAREL framework (Table 3), demonstrating the high methodological rigor within this study. Rathleff et al. (2011) clearly outline the methodology used for USI operator and participant blinding, operator educational training, learning effect of operators, fascia measurement protocols, and other relevant information which should inform the methodology used within this thesis study.

2.5 Real-time ultrasound imaging

The title ‘real-time ultrasound’ indicates the advantage USI has over many other imaging modalities, that is, an ability to observe anatomy in real-time. This ability has been extensively used within medicine to review organs and other various tissues (Giggins, Persson, & Caulfield, 2013; Hides, Richardson, & Jull, 1998). However, its widespread application within the musculoskeletal system, often for rehabilitation purposes, is more recent (Jedrzejczak & Chipchase, 2008). The use of RTUS allows a USI operator real-time observation of muscle activity, determined through changes in shape characteristics of the observed tissue. Potter et al., reported that 81% of physiotherapists who practice RTUS predominantly do so for biofeedback rehabilitation purposes (Potter, Cairns, & Stokes, 2012). The validity of this usage is supported by research showing improved ability to contract abdominal (Teyhen et al., 2005), pelvic floor (Dietz, Wilson, & Clarke, 2001) and multifidi muscles (Van, Hides, & Richardson, 2006) when facilitated through RTUS biofeedback (Giggins et al., 2013). Each of these muscle groups are associated with regional pain and dysfunction, and are therefore therapeutic targets for rehabilitation.

2.5.1 Real-time ultrasound imaging within chronic neck pain
Chronic neck pain is common, with a lifetime prevalence of approximately 70% (Cote, Cassidy, & Carroll, 1998), and is second only to low back pain in terms of prevalence of musculoskeletal pain by body region (Eurobarometer, 2007). Research into the validity and reliability of RTUS, and its possible role within clinical management of chronic neck pain is ongoing. Javanshir et al. (2010) reviewed literature pertaining to RTUS evaluation of cervical muscles. In total, 16 studies were reviewed, the majority focusing on posterior cervical muscles (12 of 16 studies). The review aimed to investigate the validity of RTUS on cervical spine musculature. The studies reviewed included RTUS evaluation of sternocleidomastoid, splenius capitis, trapezius, longus colli, deep cervical flexors, deep posterior muscles, rectus capitis posterior, and oblique capitis superior. Javanshir et al., concluded that preliminary findings suggest that RTUS is a reliable and valid method for muscle assessment, although this author stressed the need for further research in this area. This was largely due to general methodological inconsistencies between studies, including differing anatomical landmarks, transducer placement and participant set-up, making inter-study analysis difficult. Considering this, both USI measurement protocols and reliability methodology should be standardised and reported in sufficient detail for reproducibility purposes. Improving methodological homogeneity will improve the ability to compare findings between studies and combine analysis of between-study results.

2.5.2 Deep cervical flexors and sternocleidomastoid
Reduced activation of deep cervical flexor muscles has been associated with chronic neck pain (Falla, Jull, & Hodges, 2004; Jun & Kim, 2013), as such, targeted strengthening programs have been utilised to improve clinical outcomes in this population (Iqbal, Rajan, Khan, & Alghadir, 2013). USI has been proposed as a means of identifying cervical flexor dysfunction, through the assessment of contraction ratios between deep cervical flexors and SCM during the craniocervical flexion test (Goo et al., 2015; Jesus-Moraleida et al., 2011). Assessing muscular contraction with USI is achieved through observing dynamic changes in muscle thickness, a process which has been investigated within deep cervical flexors (Javanshir, Mohseni-Bandpei, Rezasoltani, Amiri, & Rahgozar, 2011; Jesus-Moraleida et al., 2011).

Abbaspour et al., aimed to establish the reliability of longus colli (a deep cervical flexor muscle) cross-sectional measurements in healthy participants (n=21), and patients with a cervicogenic headache (n=13) (Abbaspour, Amiri, Javanshir, & Karimlo, 2012). Two measurements were taken on the same day, separated by a 60-minute interval, and a final measurement obtained two days later for the purpose of inter-day reliability analysis. The results indicated that ultrasonography could be a reliable tool to measure the cross-sectional area of longus colli muscle in healthy subjects (ICC min-max range: 0.83-0.92) and patients with cervicogenic headache (ICC min-max range: 0.90-0.98). These findings complemented earlier research by Javanshir et al., with similar methodology, which also
concluded that USI was a reliable means to establish cross sectional area of longus colli (Javanshir et al., 2011). Given that cross sectional area is calculated from muscle lateral and anterior-posterior thickness values, high cross sectional area reliability should also imply high reliability associated with less-complex thickness measurements.

### 2.5.3 Reliability of sternocleidomastoid muscle measurement

Whilst 8 of the 16 studies reviewed by Javanshir et al., involved a component of USI measurement reliability, only one reported reliability data relating to SCM muscle (Emshoff, Bertram, & Strobl, 1999). Emshoff et al., evaluated the intra-rater reliability of USI to determine the local cross-sectional area of SCM. Measurement was conducted halfway between SCM origin and insertion on a total of 46 participants within temporomandibular disorders. SCM was easily observed utilising USI, with measurements obtained during two sessions separated by a 5 minute interval, to allow for *intra*-rater analysis. This study demonstrated high reliability for USI-guided SCM measurements, with an ICC of 0.86 (CI = not reported) reported (Emshoff et al., 1999). More recently, Jesus et al. (2011) investigated the reliability of ultrasound-obtained SCM thickness measurements during the craniocervical flexion test. In 10 participants, 5 measurements were obtained throughout incremental increases in resistance during the craniocervical flexion test, of SCM muscle thickness at each of these points. This study demonstrated high reliability of SCM measurement utilising USI during different intensities of muscle contraction (ICC min-max range: 0.75-0.94. CI not reported).

Whilst reliability of SCM measurement has been demonstrated to be high in both the aforementioned studies (Emshoff, Bertram, & Strobl, 1999; Jesus-Moraleida et al., 2011), SCM reliability was an adjunct component of each study and not the primary aim. As such, operator and participant blinding criteria among other important methodological details, are not reported in sufficient detail to appraise each study’s quality in accordance with QAREL. Additionally, it appears that no research has reported inter-operator reliability for SCM thickness measurements. The confirmation of high intra-operator and inter-operator reliability for USI thickness measurements of SCM, would in turn support the reliability of USI protocols which aim to establish SCM and deep cervical flexor recruitments ratios utilising these very measurements (Goo et al., 2015).

### 2.5.4 Representative experience within ultrasound operators

Whilst referral for *diagnostic* USI within physiotherapy is common, the use of imaging is often practiced by physiotherapists themselves. Potter et al., completed a study to better understand the skills and training of physiotherapists who use RTUS within the United Kingdom (Potter, Cairns, &
Stokes, 2012). A total of 46 respondents who practiced RTUS within clinical practice participated. A total of 23 communicated having received some form of training relating to ultrasound use, with 21 having received no formal training. Of the participants who had received no formal training, 60% had received <2 hours of training experience. These results indicate that within this study sample 1 in 4 physiotherapists who practice RTUS have received <2 hours of training. The authors of this study acknowledged that as convenience sampling methods were used, and the sample was small, the results are not necessarily indicative of physiotherapists who utilise RTUS within the UK, however, similar findings have been reported in relation to a sample of South Australian physiotherapists (Jedrzejczak & Chipchase, 2008). Jedrzejczak and Chipchase. (2008) used a cross-sectional survey, with an RTUS questionnaire sent out to all physiotherapists registered by the Physiotherapy Board of South Australia (n = 1328). A total of 664 physiotherapists completed and returned usable questionnaires. Of all respondents, 11.6% utilised RTUS within clinical practice. Of these practitioners, 35.1% had received less than half a day of supervised practical training.

Limited research exists investigating the use of RTUS by physiotherapists. The research appraised indicates that physiotherapists who practice RTUS have often received no formal training, and minimal hours of total training (formal and informal). The use of RTUS may increase, as further studies highlight the use of this technique and define its role within musculoskeletal manual therapy. However, the use of RTUS requires the practitioner to be able to locate and differentiate tissue types, identify specific muscles, measure thickness values, adjust settings to optimize visibility, and ensure patient safety. It is currently unknown whether the limited training physiotherapists receive related to RTUS is sufficient to reliably assess patients in clinical practice. Additionally, in accordance with the QAREL checklist, reliability research should use raters who are representative of those the results are intended to be applied (Table 3, item 2). It is in consideration of the high USI use by manual therapists with limited training that prompted involvement of a novice operator within the manuscript reported in this thesis.
2.6 Research purpose

The preliminary research conducted by Stecco et al. (2014) concerning the densification phenomena is exploratory in nature, but provides findings of possible clinical interest that warrant further investigation. Whilst the research conducted by Stecco et al. investigated the densification phenomena within the neck, if validated, it is possible that this phenomena could be relevant to other body regions considering the continuity of fascia. However, there is currently very limited research that has been conducted on fascia utilising USI, beyond named conditions such as Plantar Fasciitis and iliotibial band syndrome. There is even less research investigating fascia within the neck, with this review only identifying two studies investigating cervical fascia utilising USI. Given that much of the evidence supporting the densification hypothesis derives from cervical fascia thickness measurements utilising USI, investigating the reliability of these measurements is necessary.

The thicker cervical fascia observed within people with chronic neck pain Stecco et al. (2014) was attributed to fascia overlaying the SCM muscle, a muscle which has historically been implicated in neck pain (Bae, 2014; Lee et al., 2013). Most recently, the role of SCM within deep cervical flexor weakness has been investigated, with contraction ratios between these cervical flexors proposed as a means to diagnose deep cervical flexor dysfunction (Goo et al., 2015). Confirming muscular contraction ratios utilising USI involves establishing thickness measurements of the muscle in question. To date, limited high quality research exists investigating the reliability of SCM thickness measurement through USI. Given the use of RTUS by manual therapists with limited training, reliability research which represents the spectrum of operator experience, will improve external validity and provide useful insight into the use of this imaging modality by inexperienced operators.

Considering the above, the research reported in Section 2 of this thesis has three objectives:

1. Establish the intra-operator and inter-operator reliability of cervical fasciae measurement utilising a standardised USI measurement protocol.
2. Establish the intra-operator and inter-operator reliability of SCM muscle thickness measurement utilising a standardised USI measurement protocol.
3. Provide insight, through preliminary data, on the reliability of a novice operator for the measurement of cervical musculature and fascia.
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SECTION II – Manuscript

Note to reader:

The manuscript presented in this section follows the Instruction to Authors for *Surgical and Radiological Anatomy* available for viewing here: [http://goo.gl/tnxfVL](http://goo.gl/tnxfVL). To facilitate thesis marking the referencing style in this version is author-date, however, the Vancouver format will be used for journal submission.
Reliability of deep cervical fascia and sternocleidomastoid muscle thickness measurements using ultrasound imaging

Author:
Jude J Harley

Author affiliation:
Department of Community and Health Sciences, Unitec Institute of Technology

Correspondence address:
Department of Community and Health Sciences
Unitec Institute of Technology
Private Bag 92025
Auckland Mail Centre
Auckland 1142, NZ

Tel: +64 9 8154321 x8642
Email: judeharley01@gmail.com
Abstract

Reliability of deep cervical fascia and sternocleidomastoid thickness measurements using ultrasound imaging

**Background:** Recent literature has provided a hypothetical framework for the possible role of fascia within myofascial pain. This hypothesis involves structural alteration of deep cervical fascia within the loose connective tissue layer, as observed through ultrasound imaging (USI). This structural alteration has been termed ‘densification’, and has been associated with increased fascia thickness and reduced tissue compliance. Whilst increased cervical fascia thickness has been reported in one study to be significantly thicker within people with chronic neck pain compared to controls, a study assessing the reliability of cervical fascia measurements has not been conducted to date.

**Objective:** To investigate the reliability of deep cervical fascia and sternocleidomastoid thickness measurements utilising USI.

**Methods:** High-resolution, B-mode ultrasound was utilised to execute a standardised protocol for repeated thickness measurements of deep cervical fascia enveloping SCM muscle, and the SCM muscle itself. A convenience sample of 10 participants (5 males, 5 females, mean ± SD age = 26.2 ± 5.8 years, height 172.9 ± 13.2 cm, body mass 76.4 ± 16.6 kg, and median NDI score was 7% (range: 0 to 34 %) attended a single session. *Intra* -operator and *inter* -operator reliability was calculated for all thickness measurements obtained by a novice and an experienced USI operator.

**Results:** Both operators demonstrated ‘very high’ *intra*-operator and *inter*-operator reliability for SCM muscle thickness measurements (all ICCs >0.7). The experienced operator demonstrated ‘moderate’ reliability (ICC = 0.312; 95%CI 0.357 - 0.770) to ‘very high’ (ICC = 0.821; 95%CI 0.434 - 0.952) *intra*-operator reliability for cervical fascia measurements. The level of *intra*-operator reliability for the novice operator was inconsistent for both the SDF and DF measurements, ranging from ‘very low’ to ‘very high’. *Inter*-operator reliability for all fascia thickness measurements was ‘low’ (ICC = 0.033; 95%CI 0.581 - 0.623) to ‘moderate’ (ICC = 0.428; 95%CI 0.235 - 0.819).

**Conclusion:** Within this study, the experienced operator demonstrated acceptable reliability for cervical fascia measurement with USI, whilst the novice operator was not reliable. Both the novice and experienced operators demonstrated high *intra*-operator and *inter*-operator reliability for SCM muscle thickness measurements.

**MeSH Keywords:** Fascia; Muscle, Neck; Ultrasound Imaging; Reliability, Test-Retest
Introduction

Musculoskeletal pain is associated with substantial socioeconomic burden and is the most common cause of incapacity to work (Bevan et al., 2009). Of all non-communicable disease, those of musculoskeletal origin have the greatest association with poor quality of life (Sprangers et al., 2000). Musculoskeletal neck pain is second only to low back pain in terms of prevalence by body region (Eurobarometer, 2007). Myofascial pain syndrome (MPS) is considered by some as a sub-classification of musculoskeletal pain, with a reported prevalence of 37% in men and 65% in women (Drewes & Jennum, 1995). This syndrome is characterised by hyperirritable areas within taut bands of skeletal muscle and fascia, which are referred to as myofascial trigger points (Giamberardino, Affaitati, Fabrizio, & Constantini, 2011). Despite extensive research conducted on MPS to date (Dommerholt, Grieve, Hooks, & Layton, 2015), contention remains over the validity of this syndrome as a diagnostic entity (Quintner, Bove, & Cohen, 2015). This is largely due to the absence of objective evidence supporting the pathophysiology of MPS, and poor reliability for the clinical identification of trigger points (Lucas, Macaskill, Irwig, Moran, & Bogduk, 2009).

Although the term ‘myofascial pain’ implies involvement of fasciae, research has focused almost entirely on skeletal muscle tissue (Stecco, Macchi, Porzionato, Duparc, & De Caro, 2011). However, recent literature reports findings that may help elucidate the role of fascia within MPS. Schliep et al. (2012) observed in vitro thickening of fascia in response to strain, characterised by an increase in tissue fluid during the post-strain ‘rest phase’. Stecco et al., termed this thickening ‘densification’, and using ultrasound imaging (USI) derived measurements of deep cervical fascia enveloping sternocleidomastoid muscle (SCM), demonstrated a positive correlation between fascia loose connective tissue (LCT) densification and chronic neck pain ($r = 0.44$) (Stecco, Meneghini, Stern, Stecco, & Imamura, 2014). Increased electromyographic activity of SCM during the craniocervical flexion test, has also been demonstrated to have a ‘modest’ correlation with chronic neck pain (O’Leary, Falla, & Jull, 2011), validating why superficial neck structures are of interest. Stecco et al. (2014) postulate that the fascia densification phenomena is involved in the pathophysiology of chronic neck pain, and reported that patients with cervical fascia thickness greater than 0.15cm can be considered to have ‘myofascial disease’.

Prior to the research conducted by Stecco et al (2014), it appears that no normative data for USI measurements of cervical fascia had been reported, nor reliability research conducted. Currently, limited research exists investigating the reliability of USI for measurement of fascia thickness, most of which focuses on the plantar fascia (Croft’s, Angin, Mickle, Hill, & Nester, 2014; Rathleff, Moelgaard, & Lykkegaard Olesen, 2011). Whilst USI guided plantar fascia measurements have
demonstrated acceptable reliability, plantar fascia is a comparatively thick dense connective tissue, in contrast to thin LCT of the SCM fasciae.

The preliminary research conducted by Stecco et al. (2014) concerning the densification phenomena is probably best considered exploratory in nature, but provides findings of possible clinical interest that warrant further investigation. Given that much of the evidence supporting the densification hypothesis derives from cervical fascia thickness measurements utilising USI, investigating the reliability of these measurements appears necessary. Therefore, the primary aim of this study was to establish the *intra*-operator and *inter*-operator reliability of cervical fasciae measurement utilising a standardised USI measurement protocol.
Methods

Design and ethics
A repeated measures test-retest design was used to investigate the *intra*-operator and *inter*-operator reliability of USI measurements for thickness of SCM muscle, and the adjacent investing layers of deep fascia (superficial and deep). Measures were undertaken in a single session. A novice and an experienced USI operator each independently completed an established measurement protocol. Written informed consent was provided by all subjects and the study was approved by the institutional ethics committee (UREC 2014-1111). The study design was informed by the Quality Appraisal of Reliability Studies checklist to reduce bias (Lucas, Macaskill, Irwig, & Bogduk, 2010).

Participants

Subjects
A convenience sample of subjects was recruited using posters and word-of-mouth. Inclusion criteria were purposefully broad, open to all people able to provide informed consent and aged ≥ 18 years. The only exclusion criterion was a current, or previous history of neck pathology. Each subject was required to complete the neck disability index to characterise neck disability (Vernon & Mior, 1991).

Operators
The novice USI operator (J.H.) was a final year postgraduate student of osteopathy with no previous experience or formal training in sonography. The experienced operator was a registered sonographer (S.A.) with a special interest in musculoskeletal USI and 20 years of clinical sonography experience.

Procedures
All images were acquired using a 2013 Philips iU22 ultrasound scanner in B-mode (Philips, Medical Systems Company, Eindhoven, Netherlands). A 17-5 MHz ‘hockey stick’ transducer was used to maximise superficial resolution and minimise tissue distortion. Each operator used a pre-piloted, standardised imaging protocol for all measurements. The experienced operator was involved in the development of the imaging protocol, which was developed during four sessions over a 6-week period prior to the study (see Appendix A). The protocol was informed by previously published methods for measurement of SCM muscle and fascia thickness (Emshoff, Bertram, & Strobl, 1999; Stecco., 2014; Bongiorno, & Vitturini, 2011). The novice operator received 4 hours of practical training including direct supervision (90 mins) during pre-study pilot sessions, representing a comparable level of training to manual therapists who practice real-time ultrasound (Jedrzejczak & Chipchase, 2008).
Measurement protocol

All measurements took place in the presence of a research assistant whose role was to ensure that both operators complied with the imaging protocol. Additionally, the research assistant made sure that only one operator was in the USI clinic whilst the protocol was being conducted and that blinding between operators was maintained. Neither operator was privy to patient-specific characteristics (age, weight, height) or NDI scores. Each subject was instructed by the operator to assume a supine position, with one cervical pillow on a standard adjustable examination plinth (Metron Medical: Aster plinth). The operator ensured the subject’s neck was in a neutral position, with subtle adjustments to the angle of the table allowed to ensure the SCM muscle was parallel to the plane of the floor. The subject was requested not to talk during the protocol, keeping their mouth closed during scanning and exercising quiet breathing. Each operator used a clear plastic ruler to bisect the SCM muscle, establishing the midpoint between the ipsilateral mastoid process and clavicular head. The transducer was placed horizontally at the SCM midpoint. Subtle movements of the transducer in the frontal plane were allowed to visualise the thickest aspect of the SCM muscle. The transducer was then rotated to run parallel with the SCM muscle and the thickness of three structures were measured: the SCM muscle, the superficial layer of deep fascia overlying the SCM muscle (SDF); and the deep fascia underlying the SCM muscle (DF) (Fig 1, Panel A). Each operator took three measurements of each structure, beginning at the transducer’s longitudinal centre point, and then 1 cm right and left of this centre point (Fig 1, Panel B). All images were captured and saved for later offline analysis. The assistant ensured that each operator was blinded to all measurement values displayed on the USI screen, which were masked by an opaque paper shield. Write zoom function was used to improve visualisation of fascial layers. Focus and gain settings were adjusted at each operator’s own discretion. Upon completion of the three measurements of the right SCM and associated fasciae, the process was repeated on the left. Once the measurements on the left side were complete, the assistant requested that the participant stood up, and a 2-minute interval was observed before the protocol was repeated by the same operator, on the same subject. An interval of 2 minutes was selected to limit the possibility of thickness changes relating to the LCT layer of fascia, as biological change in the LCT has been observed following manipulation (Schleip et al., 2012; Stecco et al., 2014). Once the operator had completed the protocol twice on the same subject, the alternate operator completed the same process. The order in which operators undertook the protocol on each participant was randomised by coin toss.
Panel A: Shows all layers, SDF, SCM and DF in one image. The red double-sided arrows demonstrate the approximate orientation of these respective layers. SDF and DF are visualised as hyperechoic bands, whilst the SCM muscle between these layers is hypoechoic. The clear difference in echogenicity between the muscle and fascial layers allows for accurate boundary identification. Write zoom was utilised to enhance visualisation of the structure being measured.

Panel B: Centre, right and left measurements (1cm apart) on superior border of SCM muscle (inferior border not shown). The red double-sided arrows represent the SDF layer, as all three thickness measurements were obtained from the superior leading edge to inferior leading edge of each structure (SDF, SCM, DF).

Figure 1: Description of tissue layers and calliper placement

**Extraction measurement error**

Extraction measurement error (EME) was operationally defined as the variance attributable to operator positioning of digital callipers to measure thickness values. EME is independent of transducer placement, or change in the true measurement value of the structure, allowing for identification of error beyond these variables. EME can be estimated by comparing the measurements obtained by both operators on the same USI image. Therefore, to assess EME, one image of each tissue structure (SCM, SDF, DF) was selected from each subject. This selection process produced a total of 30 images, with 10 images pertaining to each tissue structure. The 30 images were duplicated to allow for additional *intra*-operator analysis for EME. With the file name of each image masked and the order of presentation randomised, the novice and experienced operator independently completed the measurements utilising digital imaging editing software (ImageJ, v1.49) (Schneider, Rasband, & Eliceiri, 2012). To allow for conversion of pixels to millimetres, the pixel to distance...
ratio was calculated for each image, using image scale markings as the known reference distance. The 60 measurements completed by each operator were used to calculate intra-operator and inter-operator reliability relating to EME.

**Follow-up session**

Of the 10 subjects within this study, five had a thin hyperechoic band close enough to the SDF to complicate tissue boundary classification. In an attempt to clarify the origin of the adjacent hyperechoic band, we recalled three of these subjects for additional scanning, to undertake further exploration of whether this structure was continuous towards the proximal attachment of SCM. Thickness measurements, consistent with those previously described, were obtained for the thin hyperechoic band and SDF. This involved both individual and combined measurements of these structures, both at the midpoint of SCM and above the angle of the mandible towards the proximal attachment (Figure 3).

**Data analysis**

Each of the three structures (SCM, SDF, DF) was measured twice on the left, and twice on the right side by each operator. A single measurement value per structure was used for data analysis, but was calculated by averaging the three measurements obtained per image (centre, right and left calliper values). A comparison of the repeated protocol measurement values, obtained by each operator, was used to establish intra-operator reliability. An average of the repeated protocol measurement values was calculated for each operator, allowing for inter-operator reliability analysis. Intraclass correlation coefficients (ICCs) were calculated with 95% confidence intervals using two-way random model ANOVA (ICC 2,1). To estimate operator reliability for each structure (SCM, SDF, DF) independent of side, a combined analysis was completed, including all measurement values (left and right) for each structure by each operator. Separate analysis was conducted to calculate side-specific reliability (left and right). In addition to ICCs, the standard error of measurement (SEM) was calculated using the formula $SEM = SD_{pooled} \times \sqrt{(1-ICC)}$. Minimal detectable change ($MDC_{95}$) was calculated based on the 95% confidence interval ($z = 1.96$) and represents the smallest change necessary for objective detection (Donoghue & Stokes, 2009). $MDC_{95}$ was calculated as $MDC_{95} = 1.96 \times SEM \times \sqrt{2}$ (Wu, Chuang, Lin, Lee, & Hong, 2011). Coefficient of variation (CV) was calculated to clarify the significance of standard deviation within this study, and allow for proportion-based comparison with existing USI fasciae measurement data. CV was calculated as $CV\% = (SD/mean)\times100$. All statistical analysis was conducted using SPSS version 22 (IBM SPSS, Armonk, NY., IBM Corp). Qualitative descriptors for interpreting the magnitude of reliability coefficients were based on Hopkins et al. (2009).
Results

Measurement protocol reliability

Ten adults (5 males, 5 females) participated in this study. Their mean age was 26.2 years (SD ± 5.8), height was 172.9 cm (SD ± 13.2), body mass was 76.4 kg (SD ± 16.6), and median NDI score was 7% (range: 0-34%). The mean thickness and range of SDF, DF and SCM structures are reported in Table 2. Intra-operator and inter-operator reliability ICCs, SEM, CV and MDC are shown for all tissue structures in Table 1. Both operator’s demonstrated ‘very high’ intra-operator and inter-operator reliability for SCM muscle thickness measurements. The experienced operator showed ‘moderate’ to ‘very high’ intra-operator reliability for all tissue structures measured. The intra-operator reliability for the novice operator was inconsistent for both the SDF and DF measurements, ranging from ‘very low’ to ‘very high’. Inter-operator reliability for all fascia thickness measurements was ‘low’ to ‘moderate’. Anatomical variation of the SDF at the midpoint of SCM (Figure 2), including the observation of intra-fascial vascular structures, complicated tissue boundary identification.

Extraction measurement error reliability

Intra-operator reliability for EME was ‘near perfect’ for all tissue structures measured (all ICC’s > 0.965). Inter-operator reliability for extraction error measurement was near perfect for SCM muscle measurements (ICC = 0.997; 95%CI: 0.986 to 0.999), ‘high’ for SDF measurements (ICC = 0.628; 95%CI: 0.042 to 0.893), and ‘very high’ for DF measurements (ICC = 0.764; 95%CI: 0.3 to 0.936). Excluding one outlier where difference in boundary classification occurred, the EME reliability for SDF improved to ICC 0.989 (CI: 0.951 to 0.997).

Follow-up session

The observed thin hyperechoic band adjacent to the SDF was not visualised in 3 of 6 of the images (3 participants, 6 sides) above the angle of the mandible (Figure 3). The combined measurement of the SDF and thin hyperechoic band was observed to be thicker at the level of the SCM mid-point, compared to above the angle of the mandible.
Table 1. The results of *intra*-operator and *inter*-operator reliability for SCM muscle and related fascia thickness measurements utilising USI

<table>
<thead>
<tr>
<th>Operator</th>
<th>SCM</th>
<th>DF</th>
<th>SDF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ICC (95%CI)</td>
<td>SEM CV% MDC95</td>
<td>ICC (95%CI)</td>
</tr>
<tr>
<td>Novice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Side</td>
<td>0.822 (0.596, 0.969)</td>
<td>0.77 22.5 2.13</td>
<td>0.484 (-0.166, 0.841)</td>
</tr>
<tr>
<td>Left Side</td>
<td>0.708 (0.184, 0.918)</td>
<td>1.29 23.6 3.58</td>
<td>-0.418 (-0.815, 0.246)</td>
</tr>
<tr>
<td>Combined</td>
<td>0.780 (0.523, 0.906)</td>
<td>1.06 22.8 2.94</td>
<td>0.116 (-0.334, 0.522)</td>
</tr>
<tr>
<td>Experienced</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Side</td>
<td>0.917 (0.704, 0.979)</td>
<td>0.61 26.6 1.70</td>
<td>0.706 (0.181, 0.918)</td>
</tr>
<tr>
<td>Left Side</td>
<td>0.969 (0.883, 0.992)</td>
<td>0.45 30.6 1.26</td>
<td>0.821 (0.434, 0.952)</td>
</tr>
<tr>
<td>Combined</td>
<td>0.949 (0.876, 0.979)</td>
<td>0.52 28.6 1.45</td>
<td>0.781 (0.526, 0.907)</td>
</tr>
<tr>
<td></td>
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</table>

**INTER**

<table>
<thead>
<tr>
<th>Novice v Experienced</th>
<th>SCM</th>
<th>DF</th>
<th>SDF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Side</td>
<td>0.888 (0.614, 0.971)</td>
<td>0.79 NR 2.18</td>
<td>0.203 (-0.455, 0.717)</td>
</tr>
<tr>
<td>Left Side</td>
<td>0.848 (0.502, 0.960)</td>
<td>0.99 NR 2.70</td>
<td>0.033 (-0.581, 0.623)</td>
</tr>
</tbody>
</table>

Notes: SCM = sternocleidomastoid muscle; DF = deep fascia underlying SCM muscle; SDF, deep fascia overlying SCM muscle (most superficial layer); ICC = intraclass correlation coefficient; CI = confidence interval; SEM = standard error of measurement (units = millimetres); CV = Coefficient of variation; MDC95 = minimum detectable change (units = millimetres); NR = not reported
<table>
<thead>
<tr>
<th></th>
<th>Right Side</th>
<th>Left Side</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Range (min – max)</td>
</tr>
<tr>
<td>DF</td>
<td>0.660 ± 0.178</td>
<td>0.433 – 1.007</td>
</tr>
<tr>
<td>SDF</td>
<td>0.486 ± 0.166</td>
<td>0.260 – 0.793</td>
</tr>
</tbody>
</table>

All measurement in millimetres (mm)
Panel A: Intrafascial vein (V) observed within the SDF (X), complicating standardisation of calliper placement and therefore measurement consistency.

Panel B: The thin hyperechoic band (*) observed parallel to the SDF (X) of SCM muscle. Operators were unsure whether to include this layer in the SDF measurement.

Panel C: The thin hyperechoic band (*) is observed higher in the subcutaneous space. Its position appears highly variable.

Figure 2: Measurement of SDF overlying SCM - variations at the mid-point of SCM.
Panel A: Measurement at the mid-point of SCM. A separate measurement was obtained for the thin hyperechoic band (small callipers), and a combined measurement of SDF and the hyperechoic band (large callipers). The combined measurement value was similar to the mean thickness observed in earlier research by Stecco et al. (2014)

Panel B: Measurement slightly inferior to the angle of the mandible. The external jugular vein (V) was observed in all participants at this point. Here, the hyperechoic line appears to merge with the SDF (X)- superior to the external jugular vein

Panel C: Measurement superior to the angle of the mandible. No hyperechoic layer was observed in 50% of images obtained. This layer is likely to have merged with the SDF at this point of interest

Figure 3: Measurement of SDF and the thin hyperechoic band at different aspects of SCM
Discussion

The first aim of this study was to investigate the reliability of USI-obtained measurements for the investing layer of deep fascia encasing SCM. The results show that an experienced sonographer can measure cervical fascia with ‘moderate’ to ‘high’ reliability. However, inter-operator reliability of fasciae measurements was generally low (3 of 4 measurement ICCs <0.3), which may be a consequence of the inconsistent intra-operator reliability demonstrated by the novice operator.

To our knowledge, this is the first study to report the reliability of cervical fascia thickness measurements utilising USI, however, reliability studies have been conducted on other myofascial structures. Gyaran (2011), demonstrated very high intra-operator reliability of iliotibial band thickness measurement using USI (ICC right = 0.75; ICC left = 0.71). Rathleff et al. (2011) investigated the reliability of plantar fascia measurements utilising USI. Using the mean of three measurements, the intra-rater and inter-rater reliability was 0.77 and 0.82 respectively. These findings are consistent with other research investigating the reliability of USI obtained plantar fascia measurements (Cheng, Tsai, Yu, & Huang, 2012; Crofts et al., 2014). Within our study, the intra-operator reliability of the experienced USI operator for the measurement of the investing layer of deep fascia encasing SCM was ‘moderate’ to ‘high’ (range: ICC = 0.312 to 0.821). This reliability is comparable, but generally lower than reliability research conducted on the ITB and plantar fascia. The difference in mean fascia thickness, between the cervical fascia measured within this study (0.553mm), and the ITB (1.1mm) and plantar fascia (3.05mm) reported in previous literature (Crofts et al., 2014; Gyaran et al., 2011), may have contributed to the lower reliability within our study. This is supported by the differences obtained when calculating the CV for the different body regions. Expressed as a percentage, the CV for DF (CV = 31.7%) and SDF (CV = 29.4%) as calculated using the experienced operator measurements, is near double that calculated for the ITB (CV = 18.2%) (Gyaran, Spiezia, Hudson, & Maffulli, 2011), or plantar fascia (CV = 17.2%) (Crofts et al., 2014). The higher CV associated with cervical fascia measurements may be a consequence of greater difficulty in visualising cervical fascia, and the larger impact measurement error has on reliability when measuring smaller structures.

Relevance of fascia measurement reliability

Our results guide interpretation of research conducted by Stecco et al., who also reported measures of fascia adjacent to SCM, and found a ‘moderate’ correlation between cervical deep fascia loose connective tissue (LCT) thickness (≥0.05cm) and chronic neck pain (Spearman’s: r = 0.44) (Stecco et al., 2014). The LCT thickening reported, supports the previously hypothesised fascia dysfunction
described as ‘densification’ (Pavan, Stecco, Stern & Stecco, 2014; Stecco et al., 2011). Stecco et al. purports that ‘densification’ may be associated with myofascial pain (Stecco et al., 2013), citing that patients with cervical fascia thickness >0.15cm can be considered to have ‘fascia disease’ (Stecco et al., 2014). However, preceding this research conducted by Stecco et al., the reliability of cervical fascia measurements utilising USI had not been investigated, nor had any normative data values of this tissue been reported. This becomes pertinent when considering that the mean fascia thickness values reported by Stecco et al., within healthy controls (SDF = 1.10mm; DF = 1.15mm) were more than twice that observed within this study (SDF = 0.45mm; DF = 0.55mm). The absence of normative data for the thickness of fascia enveloping SCM, does not allow for comparison against a set standard. Additionally, the small sample size of each study (Stecco et al. n = 25) limits inferences surrounding a normative mean cervical fascia thickness range. However, further analysis of the potential sources of error that may have been responsible for this between-study cervical fascia thickness disparity, will help future research progress. Numerous sources of error need to be considered, these include: extraction measurement error, presence of intra-fascial vascular structures, tissue boundary classification, and differences in transducer placement.

Identification of error

Extraction measurement error
Extraction measurement error (EME) associated with USI measurement of cervical fascia was investigated to identify the reliability of measurement, independent to transducer placement. The high intra-operator and inter-operator reliability that both operators achieved when measuring the same image (EME reliability), suggest that variation in transducer placement and orientation, may be primarily responsible for the difference in measurement values observed. Considering the high ICCs associated with EME analysis, measurement bias is unlikely to be a significant factor. However, an outlier was identified during analysis where large differences existed in the fascia measurements obtained by the experienced and novice operators. This difference was due to boundary misclassification of SDF, which was primarily responsible for the lower EME inter-operator reliability associated with this tissue (ICC = 0.628). This is supported by a higher ICC of 0.989 (CI: 0.951 to 0.997), calculated without the measurement data from this image.

Tissue boundary misclassification
Both operators communicated difficulty in visualising cervical fascia tissue boundaries. Specifically, identifying the SDF superficial tissue margin was problematic. This was due to the commonly observed LCT layer of fascia, which makes establishing the anatomical boundaries between the
adjacent linear dense connective tissue, seen on ultrasound as hyperechoic bands, difficult to define. Figure 2 (Panel B) illustrates the difficulty in establishing whether the most superficial thin hyperechoic band is an additional layer of deep cervical fascia (SDF), or related to superficial fascia within the subcutaneous tissue. This exemplifies the tissue boundary misclassification that occurred within EME, where operators differed on the inclusion of this thin hyperechoic band as an addition layer of SDF. This situation is further complicated by platysma muscle, a uniquely superficial anterior neck muscle. Considering its attachments, it is likely that platysma is present at the USI scanning site used within our research. Whilst the platysma muscle is enclosed by the superficial fascia suspended in subcutaneous tissue (Natale et al., 2015), histological investigation has demonstrated that it has an aponeurotic continuation which forms a potential space superficial and parallel with the SDF of SCM (Nash, Nicholson, & Zhang, 2005), which has been reported to mimic the SDF (Standring et al., 2015). Given this histology and similar dense connective tissue composition, it is unlikely that these tissues would be independently distinguishable using USI.

Given that superficial fascia has been demonstrated to be continuous throughout the body (Abu-Hijleh et al., 2006; Lancerotto et al., 2011), and platysma is not normally present above the angle of the mandible (de Castro, 1980), we hypothesised that if this layer was superficial fascia or platysma-related connective tissue, it would be present and thinner towards the proximal attachment of SCM. However, the thin hyperechoic band was absent in 3 of the 6 images taken above the angle of the mandible, and no apparent thickness differences were observed in the thin hyperechoic band superior to the platysma muscle. The absence of the superficial layer may have been due to superficial fascia approximation with the SDF closer to the SCM proximal attachment, at a level where platysma muscle (and related connective tissue) is not present. This transition, from two to one layers, appeared to occur superior to the external jugular vein (Figure 3, Panel B). In those images where a distinct layer was observed (3 of 6), this may represent the continuity of the superficial fascia that did not merge with the SDF. Alternatively, this hyperechoic band may be an additional layer of SDF, as described by Stecco et al (2014). The thickness values obtained when including this layer in our measurements (Fig 3, Panel A) were similar to those reported by Stecco et al (2014). However, its presence in other subjects situated higher within the subcutaneous tissue as a distinct separate layer makes this unlikely. By definition, our USI review of this layer was exploratory in nature. Further research is required to align USI visualisation with histological findings within the superficial layers of the neck. Difficulty identifying tissue boundaries from USI measurement of superficial fascia when attempting to quantify SDF thickness could inflate the SDF thickness measurement values.
Transducer application

The site of measurement was standardised by identifying the halfway point between the proximal (mastoid process) and distal attachment (clavicular head) of SCM muscle. After establishing the mid-point, the operators were not allowed to mark the skin to avoid the presence of cues that operators could use as reference points, and to reflect a more realistic clinical setting in which surface anatomy is utilised. Differences in surface landmark identification may have contributed to differences between operators in transducer placement on the external surface of the neck.

Intra-fascial vascular structures

The presence of veins, and lymph nodes within the LCT layer of cervical fascia (Fig 2, Panel A) produced separation of the dense connective tissue. The regular occurrence of these structures, arguably more prevalent in the well vascularised neck region, complicates measurement. Therefore, future research undertaking cervical fascia measurements should develop clear measurement ‘rules’ for measuring fascia thickness when intra-fascial vessels are encountered.

Error summary

As the USI methods reported by Stecco et al., were not reported in sufficient detail to allow comparison with our study, it is difficult to accurately account for mean cervical fascia thickness differences between studies (Stecco et al., 2014). However, based on EME analysis, observation of measurement differences between operators, and appraisal of relevant histological literature, we propose that the differences observed may be a consequence of fasciae boundary misclassification and different transducer placement.

SCM muscle thickness reliability

The second aim of this study was to establish the reliability of SCM muscle thickness measurements utilising USI. Here, we observed high intra-operator and inter-operator reliability for both the novice and experienced operators for SCM thickness. USI measurements of SCM thickness have been reported in several studies (Jun & Kim, 2013; Stecco et al., 2014), although only two studies have reported intra-operator reliability (Emshoff et al., 1999; Jesus-Moraleida, Ferreria, Pereria, Vasconcelos, & Ferreria, 2011). Jesus et al., investigated changes in SCM and deep cervical flexor muscles during the cranio-cervical flexion test in chronic neck pain participants (n=31) and asymptomatic controls (n=31), before and after a cervical mobilisation technique. As a preliminary component to this study, the intra-operator reliability of longus colli and SCM was investigated in 10 people with chronic neck pain over two sessions (1 week interval). The transducer was placed in line
with the trachea, approximately 5 cm from its midline. Thickness measurements were taken during five established stages of the cranio-cervical flexion test with comparisons of each stage allowing for separate ICC analysis. Jesus et al., demonstrated ‘excellent’ intra-operator reliability, with ICCs which ranged from 0.75 to 0.94 (no CI reported) for SCM, and 0.77 to 0.91 (no CI reported) for longus colli. Similarly, Emshoff et al., used USI to measure cross sectional dimensions of numerous muscles in the cervical and cranial regions, in a sample of 46 people with temporomandibular disorders. Due to its possible mechanical influence on the temporomandibular joint, SCM muscle was included in the measurement protocol. Intra-operator reliability was calculated by analysing two measurements from the same operator, with a 5-minute time interval observed between measures. SCM was scanned half way between the muscle origin and insertion, similar to the protocol in our study. The results of this study showed ‘acceptable’ reliability for SCM (ICC = 0.86; no CI reported). Neither of these study designs (Emshoff et al., 1999; Jesus-Moraleida et al., 2011) allowed for inter-operator reliability analysis, a primary component of our study. The SCM thickness values reported here (table 2) are consistent with those obtained within previous research where a similar measurement protocol was utilised (Emshoff et al., 1999; Stecco et al., 2014).

The high reliability observed for SCM measurement within this study is consistent with other USI reliability research on cervical musculature (Javanshir, Mohseni-Bandpei, Rezasoltani, Amiri, & Rahgozar, 2011). Abbaspour et al., demonstrated ‘very high’ reliability (ICC range: 0.77- 0.90. no CI reported) for longus colli measurements in both symptomatic (n=10) and asymptomatic participants (n=15) (Abbaspour, Amiri, Javanshir, & Karimlo, 2012). Lin et al., assessed the intra-operator reliability of USI thickness measurements for dorsal neck muscle (splenius capitis, multifidus muscles) and demonstrated ‘very high’ to ‘nearly perfect’ reliability for muscle thickness measurements (ICC range: at rest = 0.87-0.99, 50% contraction = 0.90-0.98) (Lin, Chai, & Wang, 2009). Similar results have been reported by Lee et al. (2007) for the reliability of cervical multifidus thickness measurements (CV=7.22%. CI: 4.55–9.88%).

Chronic neck pain is common, with a lifetime prevalence of approximately 70% (Cote, Cassidy, & Carrol, 1998). Reduced activation of deep cervical flexors has been associated with chronic neck pain (Falla, Jull, & Hodges, 2004; Jun & Kim, 2013), as such, targeted strengthening programs are utilised to improve clinical outcomes in this population (Iqbal, Rajan, Khan, & Alghadir, 2013). USI has been proposed as a means to identify cervical flexor dysfunction, through the assessment of contraction ratios between deep cervical flexors and SCM during the craniocervical flexion test (Goo, Kim, & Jun, 2015; Jesus-Moraleida et al., 2011). Assessing muscular contraction utilising USI is achieved through changes in muscle thickness, a process which has been demonstrated to be reliable within the deep cervical flexors (Javanshir, 2011). The high reliability of SCM thickness measurements within this study, provides further evidence that SCM thickness can be measured reliably.
The rationale for inclusion of a novice operator within this research, was based on reports of high clinical use of real-time USI by operators with minimal training (Jedrzejczak & Chipchase, 2008). We purposefully included a novice operator and provided limited training of a duration comparable to survey data of manual therapists who practice real-time USI. Although the novice operator demonstrated ‘high’ reliability for SCM thickness measurements, the reliability of fascia measurement by the novice operator was poor and suggests that greater skill is required to visualise and measure the cervical fascia than might be achieved within the training and experience arranged here.

**Limitations and further research**

The limitations of this study include the small sample size (n=10), which in combination with the high variation associated with fascia measurement, contributed to the wide confidence intervals observed with this tissue. Also, considering the range of NDI scores in this sample, which indicated mild neck disability, the sample was not typical of people with chronic neck related complaints. A larger sample including higher levels of neck related disability (NDI scores > 30%), would improve clinical representativeness (Macdermid et al., 2009). Further research should utilise a standardised USI protocol with multiple experienced operators taking measurements over >2 sessions (inter-session reliability). As transducer placement and orientation was identified as a source of measurement error within this research, we recommend using USI-visualised anatomical landmarks as opposed to external landmarks.

**Conclusion**

Within this study, the experienced operator demonstrated acceptable reliability for cervical fascia measurement with USI, whilst the novice operator was not reliable. Both the novice and experienced operators demonstrated high *intra*-operator and *inter*-operator reliability for SCM muscle thickness measurements.
References


SECTION III - Appendices
Appendix A: Ultrasound protocol

Ultrasound Protocol

For the measurement of sternocleidomastoid (SCM) muscle and related fascia thickness values
USI Machine

2013 Philips IU22 Ultrasound Machine

(utilised when assembling the following protocol)

USI Settings

Preset: Small parts thyroid

Transducer: 17-5 MHz ‘hockey stick’

Depth:

- SCM: Depth is set to the full thickness of the muscle
- Fascia: write zoom to focus on the image with increased resolution

Focus: A single focal zone at the maximum depth of the muscle and fascia measures

Participant Positioning

The participant should be positioned in supine, with one (flat) head pillow. This will ensure the cervical spine is not unnecessarily flexed. The cervical spine should be in a neutral position, neither flexed nor extended, to avoid changes in length of the SCM muscle and related fascia. The head position should be neutral, and can be checked by ensuring the face is level as demonstrated below (Figure I). The participant should be advised not to speak during measurements, and to breathe normally.

Figure I. Participant positioning. The horizontal lines indicate the plane of the face is parallel to the plane of the examination table.
Transducer placement and measurements

1. Begin with the measurement of SCM and related Fascia on the participant’s right side
2. Locate both the inferior aspect of the mastoid process and the superior aspect of the clavicle head (the proximal and distal attachments of SCM muscle). Use a ruler to establish the mid-point between these landmarks.
3. At this point place the transducer transverse (Figure II) across the anterior neck surface. Identify the relevant structures including:
   a) Superficial fascia
   b) Deep fascia overlying SCM
   c) SCM muscle
   d) Deep fascia underlying SCM muscle
   e) Carotid sheath (moving medially from muscle)

4. Once all the structures have been identified, rotate the transducer (centre of rotation being SCM) so the SCM muscle can be viewed longitudinally. Align the transducer with the perimysium direction of the SCM muscle. See Figure III with SCM muscle highlighted. Readjust transducer pressure so jugular vein is patent (Figure IV).

Figure II. Transducer initially transverse

Figure III. Longitudinal view of SCM muscle

Figure IV. Patent jugular vein – inferior hypoechoic area
5. Viewing the SCM muscle longitudinally, identify the thickest region of this muscle within this view. Very slight transducer movement in a frontal plane to identify the thickest area of SCM is warranted. Once identified, utilise write zoom function to focus on the full muscle thickness when taking the measurement value. See image V for guidance on borders for measurement relating to SCM. Take three measurements:

1) Centre measurement (thickest aspect of viewable SCM)
2) 1cm superior from centre measurement (use callipers to measure 1cm distance)
3) 1cm inferior from centre measurement

Figure V. The final thickness value will be an average of these three measurements.

**Fascia Thickness Measurement**

1. Adjust the write zoom to focus on the fascia layer deep to SCM initially, then superficial fascia afterwards.
2. Fascia thickness includes the dense connective tissue layers and loose connective tissue layers. Measurement should include all layers, as demonstrated by Figure V. In some participants the loose connective layer may not be visible. Care should be taken to identify the cutaneous and subcutaneous loose connective layers before measurement is taken.
3. Take three measurements for both the superficial aspect and deep aspect of SCM deep fascia as demonstrated in Figure V.
   
   a) Centre measurement (thickest aspect of viewable SCM)
   b) 1cm right from centre measurement
   c) 1cm left from centre measurement

Note: The final thickness value will be an average of these three measurements. The grey layers represent the dense connective tissue layers of fascia. The white layer represents the loose connective tissue layer of fascia, a layer which is not always visible during ultrasound.

4. Repeat process on the contralateral side for both the SCM and fascia measurements.
Appendix B: Quality Appraisal of Diagnostic Reliability (QAREL) Checklist

Table 1: Quality Appraisal of Diagnostic Reliability (QAREL) Checklist

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the test evaluated in a sample of subjects who were representative of those to whom the authors intended the results to be applied? (DEF: 3, 4, 5, 7, 8, 9)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Was the test performed by raters who were representative of those to whom the authors intended the results to be applied? (DEF 3, 4, 6, 7, 8, 9)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Were raters blinded to the findings of other raters during the study? (DEF 10)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Were raters blinded to their own prior findings of the test under evaluation? (DEF 11)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. Were raters blinded to the results of the reference standard for the target disorder (or variable) being evaluated? (DEF 12)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. Were raters blinded to clinical information that was not intended to be provided as part of the testing procedure or study design? (DEF 13)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7. Were raters blinded to additional cues that were not part of the test? (DEF 14)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8. Was the order of examination varied? (DEF 15, 16)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9. Was the time interval between repeated measurements compatible with the stability (or theoretical stability) of the variable being measured? (DEF 17)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10. Was the test applied correctly and interpreted appropriately? (DEF 18)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>11. Were appropriate statistical measures of agreement used? (DEF 19, 20, 21)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*DEF numbers relate to items on the QAREL Data Extraction Form*

Appendix C: Ethics approval

Jude Harley
68 Woodward Rd
Mt Albert
Auckland

18.2.15

Dear Jude,

Your file number for this application: 2014-1111

Title: Reliability of ultrasound imaging measures of cervical deep fascia and sternocleidomastoid muscle thickness

Your application for ethics approval has been reviewed by the Unitec Research Ethics Committee (UREC) and has been approved for the following period:

Start date: 24.12.14
Finish date: 24.12.15

Please note that:

1. The above dates must be referred to on the information AND consent forms given to all participants.

2. You must inform UREC, in advance, of any ethically-relevant deviation in the project. This may require additional approval.

You may now commence your research according to the protocols approved by UREC.

We wish you every success with your project.

Yours sincerely,

Sara Donaghey
Deputy Chair, UREC

cc: Rob Moran
Cynthia Almeida
Appendix D: Participant information sheet

Participant Information Sheet

The reliability of ultrasound imaging for cervical deep fascia and sternocleidomastoid muscle thickness measurements

About this research

You are invited to participate in a research project that is investigating the reliability of ultrasound imaging to measure neck muscle (sternocleidomastoid) and connective tissue (fascia) thickness. This study will also provide preliminary data on the relationship between neck disability and connective tissue thickness and may contribute to better understanding neck pain and disability. At this point we are collecting measures from a wide range of people who may, or may not have neck pain and disability.

If you choose to participate you will need to undertake the following:

1. Brief telephone conversation with the researcher to confirm eligibility for the project. A full explanation of the study will be provided at this stage (10min)
2. An information pack will be sent to you by email, including a general information sheet to be completed (full name, age, height details etc.) All information collected during this study is stored securely, and kept strictly confidential.
3. You will receive a follow-up call to:
   - Discuss any questions you have relating to the study
   - Confirm your interest in participating and arrange a date to visit the ultrasound laboratory
4. You will need to sign the consent form before participation in the study can commence
5. You will be required to attend a single data collection session taking approximately 60 minutes

The data collection session involves:

1. Completing a Neck Disability Index Questionnaire. This Questionnaire is designed to assess each person’s level of neck disability (if any).
2. You will receive a neck ultrasound by two different operators with different levels of ultrasound experience (beginner and expert). Each operator will conduct the same ultrasound protocol, but you will have contact with only one operator at a time. The ultrasound protocol involves the operator placing a pre-warmed gel over the side of your neck; this helps with the ultrasound image quality. The gel is simply wiped off after the images are recorded. An ultrasound probe will be placed on both sides of your neck for measurements to
be taken.

3. The total commitment of time will be 60 minutes. This includes:
   - 20 minutes to confirm all necessary documents have been completed, and answer any final questions you may have
   - A 40 minute ultrasound session

4. Following completion of the session, refreshments will be provided.

Questions & Answers

Is there risk associated with having an ultrasound?

Unlike X-ray, ultrasound imaging does not involve any exposure to ionising radiation, instead ultrasound uses sound wave feedback to create images. The level of ultrasound needed to cause harm is extremely high, but in this study only low levels will be used. The exposure used within this study is well within the health safety standards stipulated by ISO 2012 framework 14971. Ultrasound imaging is widely accepted as a safe form of imaging.

Can I have access to the data collected on me?

Yes. We will ask whether you would like access to the ultrasound data taken on your neck. If you would like this information, it will be emailed to your preferred email address. This information will be in the form of thickness values obtained by each operator. After completion of the study we can also provide you with a plain language summary of the main findings if you wish.

Can I receive further information on the progress of the study and results?

Yes. We will ask whether you would like to receive further correspondence regarding study progress, and if you wish we will send a short email update on the progress of the study.

Will the data be used for anything other than the outlined research?

No. The ultrasound scans obtained from this study are for research purposes only.

Is the ultrasound imaging in this study a diagnostic procedure?

No. The ultrasound protocol within this study is not for diagnostic purposes. The ultrasound scans are for research purposes only.

Can I withdraw from the study after being scanned?

After having the neck muscle measurement recorded, you can withdraw your data from this research project until three days following the data collection session. To withdraw your data you don’t need to give a reason, and you can notify us by email or phone (contact details are at the bottom of this sheet).
Is the information taken during this study confidential?

Yes. We will ensure that the information you have given is kept confidential. Raw data collected during the study will be anonymised (identified by an ID code) and will be stored securely so that only the researcher and supervisors have access. Raw copies of the data will be stored for five years following the study and will then be destroyed.

Who can I contact if I have any further concerns or queries?

Jude Harley (Researcher)  Rob Moran (Supervisor)
Tel: 022 097 3829  Tel: 021 073 9984
judeharley01@gmail.com  rmoran@unitec.ac.nz

Consent

All of this information will be reviewed with you in person and if you wish to participate we will ask you to complete a written consent form. Before giving consent there will be an opportunity for you to clarify and have answered any questions you may have.

Thank you for your interest in participating. If you have questions at any time during the course of the study or following the completion of the study, please don’t hesitate to contact Jude Harley (022 0973 829) or the study supervisor Rob Moran (021 073 9984).

UREC REGISTRATION NUMBER: 2014-1111
This study has been approved by the Unitec Research Ethics Committee from 24 December 2014 to 24 December 2015. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 7248). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Participant Consent Form

The reliability of ultrasound imaging for cervical deep fascia and sternocleidomastoid muscle thickness measurements

This research project is investigating the reliability of ultrasound imaging for cervical deep fascia (connective tissue) and sternocleidomastoid muscle thickness measurements. This research is being undertaken by Jude Harley from Unitec New Zealand, and will be supervised by Robert Moran.

Name of Participant: ______________________________________________________

I have been given a copy of the Participant Information Sheet for people taking part in the study ‘The reliability of ultrasound imaging for cervical deep fascia and sternocleidomastoid muscle thickness measurement’.

I have had the opportunity to read the contents of the information sheet and to discuss the project with the researcher and I am satisfied with the explanations I have been given. I understand that taking part in this project is voluntary and that I may withdraw my data up until three days after the data collection session, and this will in no way affect my access to the services provided by Unitec Institute of Technology or any other support service.

I understand that my participation in this study is confidential and that no data or information gained could breach this confidentiality.

I understand the responsibilities associated with volunteering in this study.

I have had enough time to consider whether I want to take part.

I know whom to contact if I have any questions or concerns about the project.

The principal researcher for this project is Jude Harley:
Tel: 022 097 3829 Email: judeharley01@gmail.com

The project is supervised by Rob Moran:
Tel: 021 073 9984 Email: rmoran@unitec.ac.nz

Participant Signature _____________________________ Date: ______________

Project explained by: ____________________________

Signature ___________________________________________ Date: ______________

UREC REGISTRATION NUMBER: 2014-1111
This study has been approved by the Unitec Research Ethics Committee from 24 December 2014 to 24 December 2015 If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 7248). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Participant Information Sheet
Ultrasound Operator

The reliability of ultrasound imaging for cervical deep fascia and sternocleidomastoid muscle thickness measurements

About this research

You are invited to participate in a research project that is investigating the reliability of ultrasound imaging to measure neck muscle (sternocleidomastoid) and connective tissue (fascia) thickness. This study will also provide preliminary data on the relationship between neck disability and connective tissue thickness and may contribute to better understanding neck pain and disability.

We require the participation of two ultrasound operators with varying experience; novice, moderate and expert levels of ultrasound competence.

You are invited to participate in this research as a ____________ ultrasound operator.

If you choose to participate you will need to undertake the following:

6. Brief telephone conversation with the researcher to confirm eligibility for the project. A full explanation of the study will be provided at this stage (15min).
7. An information pack will be sent to you by email, including a general information sheet to be completed (full name, age, relevant qualifications etc.) All information collected during this study is stored securely, and kept strictly confidential.
8. You will receive a follow-up call to:
   - Discuss any questions you have relating to the study
   - Confirm your interest in participating and arrange a training session for the ultrasound protocol.
9. You will be required to perform an ultrasound protocol on a minimum of 20 participants. You will receive full training on the ultrasound protocol, and will receive a written hardcopy of the protocol. An expert ultrasound operator will answer any questions you have relating to the protocol.
10. The total time commitment for each ultrasound operator within this study is approximately 25 hours. This includes:
    o 14 hours participating in data collection (ultrasound sessions). Note: each operator will spend a total of 7 hours (approximately) performing the ultrasound protocol themselves. However, you will be required to be present for the entire data collection session. This allows for each ultrasound operator to perform the protocol on each participant
    o Attend two, two hour training sessions (four hours total)
    o One hour of additional communication (phone, email, completing required information)
11. As we appreciate that 19 hours is a significant time commitment, we aim to organise the ultrasound data collection sessions at a time and date that best suits all the operators. The duration and number of data sessions is yet to be confirmed, but will be scheduled considering the availability of the ultrasound operators. This may be one of the following:
    o 3 x full day data sessions
    o 6 x half day data sessions
    o A combination of the above
Questions & Answers

Can I receive further information on the progress of the study and results?
Yes. We will ask whether you would like to receive further correspondence regarding study progress, and if you wish we will send a short email update on the progress of the study.

Will the data be used for anything other than the outlined research?
No. The ultrasound scans obtained from this study are for research purposes only.

Is the ultrasound imaging in this study a diagnostic procedure?
No. The ultrasound protocol within this study is not for diagnostic purposes. The ultrasound scans are for research purposes only.

How do I know that my ultrasound experience corresponds with the requirements for this study (novice, moderate, expert)?
Your eligibility as an ultrasound operator will be confirmed during a preliminary telephone conversation (point 1).

Can I withdraw from the study?
We aim to provide you with adequate information to make an informed decision surrounding your involvement in this study. We ask that you consider carefully the study requirements before committing to participation. However, if circumstances are such that you need to withdraw from the study, you can do so at any time without consequence.

What happens if I cannot attend a scheduled data collection session?
Please inform the primary researcher (Jude Harley) as soon as possible.

Is the information taken during this study confidential?
Yes. We will ensure that the information you have given is kept confidential. Raw data collected during the study will be anonymised (identified by an ID code) and will be stored securely so that only the researcher and supervisors have access. Raw copies of the data will be stored for five years following the study and will then be destroyed.

Who can I contact if I have any further concerns or queries?
Jude Harley (Researcher)  Rob Moran (Supervisor)
Tel: 022 097 3829  Tel: 021 073 9984
judeharley01@gmail.com  rmoran@unitec.ac.nz

Consent
All of this information will be reviewed with you in person and if you wish to participate we will ask you to complete a written consent form. Before giving consent there will be an opportunity for you to clarify and have answered any questions you may have.

Thank you for your interest in participating. If you have questions at any time during the course of the study or following the completion of the study, please don’t hesitate to contact Jude Harley (022 0973 829) or the study supervisor Rob Moran (021 073 9984).

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Ultrasound Operator
Participant Consent Form

The reliability of ultrasound imaging for cervical deep fascia and sternocleidomastoid muscle thickness measurements

This research project is investigating the reliability of ultrasound imaging (USI) for cervical deep fascia (connective tissue) and sternocleidomastoid muscle thickness measurements. This research is being undertaken by Jude Harley from Unitec New Zealand, and will be supervised by Robert Moran.

Name of USI Operator: _______________________________________________________

I have attended a meeting with the primary researcher, in which my involvement in the study was explained in full. I was given an opportunity to ask any questions relating to the study, and I am satisfied with my understanding of this project.

I understand that taking part in this project is voluntary and that I may withdraw at any time, and this will in no way affect my access to the services provided by Unitec Institute of Technology or any other support service.

I understand that my participation in this study is confidential and that no data or information gained could breach this confidentiality.

I understand the responsibilities associated with volunteering in this study.

I have had enough time to consider whether I want to take part.

I know whom to contact if I have any questions or concerns about the project.

The principal researcher for this project is Jude Harley:
Tel: 022 097 3829 Email: judeharley01@gmail.com

The project is supervised by Rob Moran:
Tel: 021 073 9984 Email: rmoran@unitec.ac.nz

USI Operator Signature _________________________________ Date: _____________

Project explained by: _________________________________

Signature __________________________________________ Date: _____________

UREC REGISTRATION NUMBER: 2014-1111
This study has been approved by the Unitec Research Ethics Committee from 24 December 2014 to 24 December 2015. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 7248). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Full name of author: [Name]

Full title of thesis/dissertation/research project: Reliability of dual neural tissue and subocular-dermatomal thinness measurement testing (OTT) shaving

Department of: [Department]

Degree: [Degree] Year of presentation: [Year]

EITHER:

(1) I agree to my thesis/dissertation/research project being lodged in the Unitec Library (including being available for inter-library loan), provided that due acknowledgement of its use is made. I consent to copies being made in accordance with the Copyright Act 1994.

and

I agree that a digital copy may be kept by the Library and uploaded to the institutional repository and be viewable worldwide.

OR:

(2) I wish to apply for my thesis/dissertation/research project to be embargoed for a limited period as per Academic Policy 12 Conduct of Student Research, Guideline 12/8.

Reason for embargo: .............................................................................................................

Supervisor Approval: .............................................................................................................

Dean, Research Approval: .....................................................................................................

Embargo Time Period: .........................................................................................................

Signature of author: [Signature]

Date: [Date]