1-1-2017

Dry Needling of Myofascial Trigger Points: Quantification of the Biomechanical Response Using a Myotonometer.

Joseph P. Kelly
Nova Southeastern University

Dry Needling of Myofascial Trigger Points: Quantification of the Biomechanical Response Using a Myotonometer.

by

Joseph P. Kelly, PT, MSPT, OCS

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy

Nova Southeastern University
College of Health Care Sciences
Physical Therapy Department

2017

Approval/Signature Page

We hereby certify that this dissertation, submitted by Joseph P. Kelly, conforms to acceptable standard and is fully adequate in scope and quality to fulfill the dissertation requirement for the degree of Doctor of Philosophy

_____ _____

Joshua A. Cleland, DPT, Ph.D., OCS, FAAOMPT — Date
Chairperson, Dissertation Committee

_____ _____

Morey J. Kolber, PT, Ph.D., OCS — Date
Dissertation Committee Member

_____ _____

Shane Koppenhaver, PT, Ph.D., OCS, FAAOMPT — Date
Dissertation Committee Member

Approved:

_____ _____

M. Samuel Cheng, PT, MS, ScD — Date
Director, Physical Therapy PhD Program

_____ _____

Shari Rone-Adams, PT, MHSA, DBA — Date
Chair, Department of Physical Therapy

_____ _____

Stanely Wilson, Ed.D., PT, CEAS — Date
Dean, College of Health Care Sciences

Nova Southeastern University
College of Health Care Sciences
Physical Therapy Department

2017

Dry Needling of Myofascial Trigger Points: Quantification of the Biomechanical Response Using a Myotonometer.

by

Joseph P. Kelly, PT, MSPT, OCS

2017

Background: Biomechanical stiffness has been linked to risk of injury and found to be a measureable characteristic in musculoskeletal disorders. Specific identification of stiffness may clarify who is most likely to benefit from the trigger point dry needling (TDN). The purpose of this study is to investigate the reliability and concurrent validity of the MyotonPRO® to the criterion of shear wave ultrasound elastography for the measurement of biomechanical stiffness in the infraspinatus, erector spinae, and gastrocnemius of healthy subjects over increasing muscle contraction. Second purpose is to investigate the biomechanical effects of TDN to latent myofascial trigger points (MTrPs) in the infraspinatus, erector spinae, or gastrocnemius. **Research Design and Method:** The first phase of the study investigated 30 subjects who completed three levels of muscle contraction in standardized test positions for the infraspinatus, erector spinae and gastrocnemius. Biomechanical stiffness measures were collected using shear wave elastography and MyotonPRO®. The second phase of the study investigated 60 new subjects who were categorized into infraspinatus, erector spinae, or gastrocnemius group based on an identified latent MTrP. These subjects underwent TDN while monitoring biomechanical stiffness at baseline, immediately post TDN, and 24 hours later. **Analysis:** Discriminate ability, reliability, and correlations were calculated for measured stiffness variable across the three conditions of contraction in the first phase of the study. Differences between stiffness at baseline and after TDN were calculated in the second phase of the study. **Results:** Correlation of the two measurement methods in the three muscle regions was significant and strongest in the gastrocnemius. MyotonPRO reliability was excellent, and demonstrated ability to discriminate between the three levels of muscle contraction. In the second phase, immediate decreased stiffness was observed in the MTrP following TDN treatment. Significant decreased stiffness was found in in the erector spinae and gastrocnemius group who also demonstrated a localized twitch response during TDN. Stiffness returned to near baseline values after 24 hours. **Discussion:** The MyotonPRO® stiffness measurement was found to be reliable and discriminate across predefined muscle contraction intensities. TDN may cause an immediate change in stiffness but this change was not observed at 24 hours. It is not known whether these effects are present in a symptomatic population or related to improvements in other clinical outcomes. Future studies are necessary to determine if a decrease in biomechanical stiffness is an indication of patient improvement in pain and function.

ACKNOWLEDGEMENTS

I would like to begin by thanking my committee members, Drs. Joshua Cleland, Shane Koppenhaver, and Morey Kolber for their contributions to the successful completion of this dissertation project.

I would like to thank Drs. Shane Koppenhaver, Lori Michener, and Joshua Cleland, for the mentorship, support and countless email correspondence to encourage me. Thank you for the opportunity to collaborate and learn from you as research role models.

I would like to thank Dr. Shane Koppenhaver, Laurel Proulx, and Francis Bisagni for their assistance in navigating the grant submission process, providing resources to conduct research and specific laboratory set up on my dissertation project. Laurel and Francis were instrumental in recruiting subjects and helping to carry out data collection.

Finally, and most importantly, I would like to thank my wife, Keri, who is my best friend, mother of my three smart ladies, and the best physical therapist that I know. Thank you for allowing me the freedom to pursue a vocation that makes me happy and fulfilled.

Table of Contents

LIST OF TABLES

LIST OF FIGURES

Dry Needling of Myofascial Trigger Points: Quantification of the Biomechanical Response Using a Myotonometer.

CHAPTER 1: INTRODUCTION

BACKGROUND

Structural changes in skeletal muscle can occur with injury and chronic pain causing abnormal function.[1-3] Muscle that undergoes structural change may lead to altered elasticity and increased risk of injury.[4] Research has identified structural and neurologic changes in the multifidus muscle as a result of chronic pain.[1-3] Musculoskeletal injury and disorders are the leading cause of chronic pain in the U.S.[5] The chronic pain epidemic in the U.S. costs in excess of $560 billion annually in healthcare expenses, and lost productivity.[5] This epidemic is punctuated by escalating use of opioids leading to a reported 22.6 million addicted users.[6] The costs associated with chronic pain disability continue to rise.[7] The increased cost and decreased quality of living create a significant societal impact.[1-3] Preliminary observations suggest that muscular injuries have unique stiffness properties that can be characterized with novel measurement techniques.[8-11] Measurement of tissue stiffness affords an opportunity to progress the understanding of muscle structural deficits that may be related to injury.[12,13] Researching improved strategies of musculoskeletal diagnosis and patient matched intervention is a priority.

Trigger point dry needling (TDN) is becoming more common in clinical practice. Incorporating research based treatment management strategies in clinic practice is especially challenging when the evidence is incomplete.[14-16] A body of TDN intervention research is also beginning to take shape. Sound scientific investigations examining the

effects of TDN is necessary to understand its utility in patient management. The first chapter discusses the problem and outlines the foundation to investigate the clinical effects of biomechanical stiffness following TDN in subjects with myofascial trigger points (MTrPs).

STATEMENT OF THE PROBLEM

There is a paucity of quality randomized control trials examining the effectiveness of TDN. A recent systematic review suggests the positive short-term benefit of TDN for upper quarter myofascial pain.[17,18] Conclusions were based on best available evidence that included 12 randomized control trials (RCT).[18,19] Another systematic review found some evidence, 3 randomized control trials, to suggest tentative support for TDN in treatment of cervicogenic and tension-type headaches.[5,20] The limited number of high quality control trials investigating the treatment effects of TDN overshadows the preliminary support for its inclusion in current practice guidelines.[18,21,22] Specific identification of TDN outcomes such as biomechanical stiffness may clarify which patients are most likely to benefit from the intervention.

New, novel approaches measuring biomechanical properties are currently available.[14-16] Myotonometry and shear wave elastography (SWE) are two measurement techniques to objectively quantify the biomechanical stiffness of muscle. The objective measurement of stiffness may serve as a useful outcome tool to understand the role of TDN intervention in clinical practice. The measurements of biomechanical properties may also assist future investigations into the mechanism of action of TDN.

SPECIFIC AIMS

The purpose of this study was to first investigate the reliability and concurrent validity of the MyotonPro to the criterion of SWE over increasing muscular contractions. The second specific aim of this study was to investigate the biomechanical effects of TDN to MTrPs using the MyotonPRO to measure stiffness.

RESEARCH QUESTIONS

The research questions for this investigation were:

1. What is the concurrent validity of the MyotonPro as compared to the criterion of SWE in the measurement of biomechanical stiffness in the infraspinatus, erector spinae, and gastrocnemius of healthy subjects over increasing muscle contraction?
2. What is the instrument test-retest reliability of the MyotonPRO measurement?
3. What is the biomechanical response of a latent MTrP to TDN in the infraspinatus, erector spinae, or gastrocnemius measured using the MyotonPro?

RELEVANCE AND SIGNIFICANCE

MTrPs have been reported to contribute to chronic pain.[23,24] These taut, painful fibers were also identified in subjects with cervical pain using sonoelastography.[17,18] MTrPs are characterized as hyperalgesic taut fibers of skeletal muscle. These taut fibers within the muscle create palpable bands or nodules that may cause local pain, and refer pain elsewhere with soft tissue examination.[18,19] Identification by palpation has been described as a ropiness or nodularity felt by the examiner.[19]

MTrPs are sensitive to direct or indirect compression and are thought to be a peripheral source of nociception and may contribute to central sensitization of the nervous system.[25] Clinical studies report an abnormal increase in the electric activity around the motor endplate.[26] The increased motor endplate noise or spontaneous electrical activity (SEA) creates an involuntary muscle contraction that is palpable with physical exam.[27] MTrPs may also give rise to motor dysfunction due to increased tissue stiffness and restricted range of motion as a result of increased motor unit activity and muscle fiber contraction. The palpable taut band of a MTrP has been analyzed using magnetic resonance elastography (MRE).[28] The MTrPs is distinguished from the surrounding tissue by a shear modulus or biomechanical stiffness that was 50% greater than the surrounding tissue as measured by MRE.[28]

The presence of MTrPs in muscle may give rise to increased tissue stiffness as a result of the contracted fibers.[28] Stiffness is a biomechanical property that varies in contractile and non-contractile tissue. Stiffness is the amount of force divided by deformation or the slope of force vs. deformation.[29] Stiffness is dependent on the muscle structure (length and cross-sectional area), forces applied, and material property of elasticity.[29] Elasticity is an intrinsic biomechanical property of muscle based on the material composition.[30] Elasticity represents the ability of a material to return to its previous shape following deformation. Material elasticity is independent of the structural geometry and is established through Young's modulus.[31] Material that is highly resistant to deformation will also have a higher Young's modulus. Highly elastic characteristics translates to increased structural stiffness.[29,31,32]

MTrPs may represent a temporary heterogeneous variation of the soft tissue elasticity. In theory, with MTrPs representing a contracted portion of muscle, the resultant stiffness measured would be greater than surrounding, non-contracted tissue. The application of the load perpendicular to the underlying soft tissue constitutes an assumption that the stiffness measured represents or approximates the deformation oriented parallel to the fiber direction. The material stiffness of MTrPs may represent a magnitude that is greater than the variable viscoelastic properties of the local soft tissue surrounding it. This has been confirmed by magnetic resonance elastography.[33]The accurate and precise measurement of this material property may serve to be a useful biomarker for clinical intervention research. Emerging technologies, such as the MyotonPro (Myoton AS, Tallinn, Estonia) and ultrasonic SWE (Aixplorer; SuperSonic Imagine, Aix-en-Provence, France), will enable noninvasive quantification of localized properties (stiffness, and shear modulus) of resting and active muscle non-invasively.[34-36]

SWE is a unique non-invasive ultrasound imaging technique that quantifies the Young's modulus of soft tissue. The device is available for clinical use and has been used primarily to measure and diagnose soft tissue tumors.[8,18] Despite SWE availability, the device is not readily accessible for broad clinical research and cost inhibitory (> $100,000) for use in a physical therapy setting. An alternative measurement tool is available. The MyotonPro® (Myoton AS, Talinn, Estonia) is a handheld device that measures superficial tissue stiffness at a clinically affordable cost of entry.[14,35,37] The device measures the material property stiffness using a perpendicular approach causing compression under a small probe. A criterion reference of SWE will help gauge the MyotonPro® measurement for future clinical investigations. Biomechanical

characterization of stiffness using a myotonometer could potentially serve as a valid concurrent outcome measure to the criterion of SWE. These devices may prove useful to the diagnosis of MTrPs and quantifying patient response to TDN intervention beyond subjective reports of pain.

Recently, the quantification of MTrPs biomechanical stiffness and the change following TDN has been reported using a SWE.[18,20,35] Maher et al reported the shear modulus of a MTrP in the upper trapezius (MTrP) decreased 29.5% immediately following one TDN application.[35] Clinical techniques focused at treating MTrPs include stretching, massage, acupressure, ultrasound, transcutaneous electrical stimulation, heat, and TDN. All methods have demonstrated varying levels of utility in small clinical trials, leaving questions in regards to clinical effectiveness. Two recent systematic reviews have recommended the use of TDN for immediate pain relief related to MTrPs found in the upper quarter.[18,20] TDN of MTrPs is a neurophysiological intervention technique performed by physical therapists.[38] The intervention is performed using a thin filiform needle inserted through the skin, underlying soft tissue, and into muscle to stimulate the MTrPs. The needle insertion may elicit a localized twitch response (LTR). The LTR is a phenomenon of involuntary contraction of the muscle fibers within and around the MTrP and is thought to correlate with needling effectiveness.[34]

SCOPE OF THE INVESTIGATION

Objective in vivo measurement of the biomechanical structural properties of muscle is a complimentary approach to current clinical assessment. This investigation will use the MyotonPro® to characterize the biomechanical stiffness of MTrPs pre and post TDN

intervention. Current available evidence from a recent systematic review suggests TDN treatment effectiveness compared to placebo in decreasing pain in the short term (<4 weeks).[18] This pragmatic and novel approach may identify a clinically relevant biomarker for trigger point identification and response of clinical TDN intervention. Concurrent validity and reliability of the MyotonPro® and SWE measurement may assist data collection in future clinical investigations such as a multi-site randomized control trial.

The proposed investigation required two major resources for completion. The first major resource was access to SWE. The second major resource needed was two separate groups of subjects: asymptomatic individuals to examine the concurrent validity of two measurement devices; and a second group of subjects with MTrPs in the infraspinatus, erector spinae, and gastrocnemius for TDN intervention. LTC Shane Koppenhaver, PT, PhD, FAAOMPT, OCS (U.S. Army-Baylor University Doctoral Program in Physical Therapy) provided access to a SWE device, access to asymptomatic subjects at Fort Sam Houston, and grant support through the Army Medical Department, Advanced Medical Technology Initiative. The Department of Physical Therapy at Bradley University (Peoria, IL) provided access to a MyotonPRO® device.

DEFINITION OF TERMS

Elasticity[29] – The property of a material to resist deformation from a force and to quickly return to its normal shape. The mechanical measure of a material's elasticity is stiffness.

Stiffness[29] – The measure of a material's elasticity. It is an inherent biomechanical property of muscle that represents the amount of strain per unit stress. It is the

deformation of material per unit stress/force. Most commonly quantified as the slope of a strain-stress curve (Young's modulus). This material property is dependent on the resting viscoelastic structure and the contracted active state.

Myofascial Trigger Point[19] – Taut fibers of skeletal muscle that are sensitive to direct or indirect compression and are thought to be a component of musculoskeletal pain. They create palpable bands or nodules that may cause local pain, and refer pain elsewhere with soft tissue examination.

Dry Needling[34,39] – Treatment for MTrPs, where a needle is inserted into muscle to target the MTrPs. Needle insertion is typically followed by 2-3 seconds of a small rhythmic pistoning to elicit a localized twitch response.

Localized twitch response[34] – Involuntary muscle contraction of the MTrP and surrounding fibers following TDN.

Myotonometry – Measurement of biomechanical properties of superficial muscle using the MyotonPro® device (Myoton AS, Tallinn, Estonia).

Shear wave elastography – Ultrasound imaging measurement of the biomechanical properties of superficial and deep musculature using the Aixplorer device (SuperSonic Imagine, Aix-en-Provence, France).

Summary

TDN has been found to cause a significant decrease in stiffness of MTrPs in a small subject sample.[35] Current TDN treatment of MTrPs is applied broadly without regard to who may be more likely to benefit. There is some available evidence to support TDN but there are too few RCTs to make definitive recommendations.[18,20] The identification of abnormal stiffness and change in that stiffness after TDN may provide direction for its most appropriate clinical application and future research of an underlying mechanism. Also, establishing reliability and validity of a more feasible technology in the MyotonPRO® may facilitate this line of investigation and clinical utilization of such technology. Objective measurement of the immediate and short-term biomechanical effects of TDN on MTrPs remains to be elucidated and requires further investigation.

CHAPTER 2: REVIEW OF THE LITERATURE

INTRODUCTION

Trigger point dry needling is an emerging technique in physical therapy practice but has roots dating back to the 1940's and 50's.[40-42] Recent professional visibility is expanding as evidence from increasing continuing education course offerings. While trigger point dry needling (TDN) origins date back several decades, research focus is relatively new with most randomized control trials occurring in the last ten to fifteen years.[43] The purpose of this chapter is to provide a detailed review of research literature related to myofascial trigger points (MTrPs), the effectiveness of TDN, and measurement of biomechanical stiffness.

ETIOLOGY OF TRIGGER POINT DRY NEEDLING

TDN is an intervention technique performed by qualified, licensed physical therapists.[38,44] The professions of medicine, dentistry, chiropractic, and acupuncture also utilize TDN. TDN involves the insertion of a solid filament needle into the muscles of the body to treat painful musculoskeletal conditions. The "dry" description of needling practice originates from a confluence of early injection therapy research and later exposure to acupuncture type needles. The history of TDN in the United States grew from investigations of injection therapy to treat musculoskeletal pain in the 1940's and '50's.[43] Researchers studied the effects of injecting local anesthetics to treat musculoskeletal pain in comparison to the absence of substance as a research control.[40,41] The absence of injection substance gave rise to the term "dry" needle. Later, the

technique of TDN transitioned to solid filament needles like those used in acupuncture instead of the hollow hypodermic needle.

The origins of TDN can be traced to the published account of pain relief caused by insertion of a needle without injectable substance in 1941.[40] Brav and Sigmond recruited 62 subjects with low back pain (LBP) or sciatica who were then divided into 3 treatment groups. All subjects were treated with needling into the erector spinae musculature. Twenty-eight subjects received 1% novocaine injection, 17 subjects received a salt solution, and the final 17 subjects where treated with an empty hypodermic needle to serve as a control. The novocaine group received the best outcome with 16 of 28 (57%) subjects reporting temporary or permanent relief of pain. In the group that received normal saline solution, 9 of 17 (53%) reported some relief of pain. Finally, the control group was described as a "startling" result with 10 of 17 (59%) subjects reporting some relief of symptoms. The authors concluded that the needle itself was the common variable for success in relieving symptoms and not the injectable substance.

Paulett's paper, published in 1947 in the Lancet, is recognized as the earliest mention of the term "dry needling" as an intervention used to treat LBP.[41,43] The author takes a fragmentary approach to reporting 25 subjects diagnosed with "non-organic low back pain." Paulett refers to attempts to eliminate pain by injection into the tender lumbar points. It is difficult to link specific treatment to subject, but the author does mention TDN tender muscle to successfully treat LBP. The author makes two specific mentions that relief could be obtained not only from injection of procaine or saline and but even

intramuscular TDN. The author emphasizes the treatment location as intramuscular and not cutaneous/subcutaneous thus differentiating TDN from acupuncture.

Early medical science publications established a foundation for the use of TDN and were followed by growing interest in the application of Chinese acupuncture.[43] In 1976, Ghia et al published an investigation considered the first to compare traditional Chinese acupuncture to TDN.[45] Thirty-eight subjects with a wide variety of lower quarter pain (>6mos) were included in this study. Diagnoses ranged from low back pain, individuals post surgical spine surgery, recurrent thrombophlebitis, and herpetic neuralgia. Two outcome instruments were administered at baseline to assess pain (Global Pain Estimate) and function (North Carolina Pain Clinic Performance Profile). The Global Pain Estimate requires the subject to rate pain on a scale of 1-100 and the North Carolina Pain Clinic Performance Profile is a Likert type scale designed to asses deficits in 8 functional items such as work, sleep, and daily activities. Subjects were randomly assigned to receive either traditional acupuncture or needling to tender musculoskeletal areas. Intervention was provided once a day for seven days with a two-day break between the 5th and 6th treatment. The reported results included 9 subjects out of 38 that experienced greater than 70% improvement in pain and function lasting 2 months or greater. A remaining 7 subjects reported at least 50% improvement lasting at least 2 weeks. Interestingly, no significant differences were found between the two needling approaches. In this study, location of needling did not demonstrate a difference in effectiveness.

The paper by Lewit, published in 1979, reports the clinical experience of TDN in 241 patients.[46] The author purposefully chose TDN over the common practice of

anesthetic injection based on the observation that effect of anesthesia is similar regardless of type, quantity, and concentration of solution. The author points out that the locally injected anesthesia lasts only a few hours yet the therapeutic effect lasts much longer. The identified common denominator is the needle itself.[46]

The author describes the inclusion of TDN into the subjects' usual medical care. The author reported immediate analgesic effects in 271 out of 312 painful structures.[46] This response to treatment is loosely correlated to the authors description of "pronounced and irrepressible pain reaction" when the tender area is needled.[46] The author comments that the overall effectiveness of TDN may be related to the intensity of the pain caused when the needle is correctly inserted.[46] The dosage and frequency of treatment was unreported. TDN was performed using both hypodermic needles and acupuncture needles.

Traditional Chinese acupuncture is one of the oldest approaches to health care in human history. The classic definition of acupuncture procedure is the insertion of needles into specific points along meridians to interact with the life force or energy call Qi, within a dynamic system of yin-yang.[47] Practitioners of the traditional theory propose that this will rebalance energy flow in the body.[47] This nebulous definition is not consistent with a scientific foundation and evidence based medicine.[48] The identity of traditional acupuncture is limited to an untestable theory, but modern acupuncture has since been expanded to include neuroanatomical and physiological rationale.[48,49]

The convergence of two distinct needling approaches, TDN and acupuncture, to treating pain could be viewed as a circular argument.[50] Professional efforts to claim jurisdiction over the practice of TDN are ever present, especially between acupuncturists

and physical therapists.[44,51,52] There are similarities between TDN and acupuncture. The use of solid filament needles in TDN and acupuncture is the clear consistent variable between the two practices. The primary difference between the two interventions is the theoretical approach. TDN focuses on the skeletal muscle and associated with trigger point theory while acupuncture follows a more philosophical concept of Yin and Yang forces within the body. Modern or medical acupuncture evolved by adopting a scientific rationale following western medical research.[53,54] Western acupuncture splits the difference between TDN and traditional acupuncture. The consistent overlap in scope of practice will fuel continued efforts to diverge acupuncture from TDN or vice versa. However, TDN theory originates from scientific medical research dating back to the 1940's and 50's.[40-42] The best available evidence for clinical effectiveness of TDN will be introduced later.

ETIOLOGY OF MYOFASCIAL TRIGGER POINT THEORY

MTrPs are characterized as hyperalgesiac taut fibers of skeletal muscle.[19,55] The taut fibers within the muscle create palpable bands or nodules that may cause local pain, and refer pain elsewhere with soft tissue examination.[19] Early publications of clinical observation and treatment gave rise to the MTrPs theory and TDN practice.[40-42,45,56,57] The following studies serve as a theoretical foundation for this proposed research.

The first published paper to restrict the term "trigger point" to tender points in muscle was published by Travell, Rinzler, and Herman.[56] The authors reported on 58 subjects treated with intramuscular injections of procaine hydrochloride. Subjects were treated for pain in the upper quarter near the shoulder. Duration of symptoms ranged

from “less than two months to a year or longer.”[56] Treatment was directed at trigger points found primarily in the upper trapezius and infraspinatus. The authors reported 62% of the subjects experienced complete relief of symptoms after an average of 3.5 treatments. This early clinical description of care set the stage for future investigations of MTrPs and TDN intervention.

Travell and Rinzler expanded the concept of MTrPs further in 1952.[57] This paper reported the clinical findings of referred pain caused by trigger points within muscle. Detailed mapping of the referral area was provided. The authors report the data was drawn from 1000 patients with pain and identified trigger points. In doing so, Travell and Rinzler proposed a trigger point generated afferent stimulus resulting in local and referred pain patterns. These symptoms and referral areas were relieved or abolished following treatment, which included procaine injection, TDN, sustained trigger point pressure, or ethyl chloride spraying of overlying skin.

MYOFASCIAL TRIGGER POINT TYPES

MTrPs can be further categorized theoretically as either latent or active by their clinical presentation.[58] Latent MTrPs are described as trigger points that are present within skeletal muscle that is otherwise pain free.[58] The latent MTrP becomes symptomatic once compressed during manual examination.[58] An active MTrP spontaneously reproduces pain symptoms locally or in a referred pattern.[59] Upon compression of both active and latent MTrPs, local tenderness is reproduced with and without referred pain. It is hypothesized that a latent MTrP could potentially progress or transition to an active MTrP due to repetitive overuse, micro or macro-trauma, and

psychological stress.[60] Clinically these active MTrPs may then regress back to latent MTrPs following the passage of time or direct intervention.[60]

CLINICAL DIAGNOSIS OF MYOFASCIAL TRIGGER POINTS

The clinical diagnosis of a MTrP relies heavily on the manual skill of palpatory examination. Distinct accuracy and reliability of trigger point identification in clinical examination is essential to matched prescription of treatment. Intervention outcomes and judgment of intervention effectiveness relies on the accurate diagnosis and measurement of baseline characteristics. Two separate systematic reviews investigated the available literature to provide a synthesis on the reliability of identifying trigger points through manual palpation. [61,62]

The classical definition of MTrP is a "hyperirritable spot in a taut band of skeletal muscle that is painful on compression, stretch, overload or contraction of the tissue which usually responds with a referred pain that is perceived distinct from the spot."[63] This characterization of MTrPs provides two commonly used variables that can be quantified: pain and palpable nodule in a taut band of muscle. However, this expert definition is not well defined and measureable beyond subjective reports of symptoms and reliance on skilled palpation. A systematic review of the criteria used to diagnose MTrPs in published research exposed inconsistencies in the MTrP diagnostic process.[64] Variability in criteria used in diagnosing MTrPs highlights a limited consensus between clinicians and researchers. The six most commonly reported criteria are: tender spot (or nodule) in a taut band; patient pain recognition on tend spot palpation; predicted pain referral pattern; local twitch response on muscle palpation; limited range of movement; and tender spot (without taut band).[64]

The diagnostic accuracy and reproducibility of palpation reported in the literature is difficult to assess. Primarily, investigations of trigger point palpation suffer poor quality in methodology and varying criteria for diagnosis.[61,62] Myburgh et al identified six studies investigating reliability of trigger point palpation following a search strategy that excluded studies that failed to report statistics. A quality analysis based on the Standards for the Reporting of Diagnostic Accuracy guidelines was employed by the authors to identify three of the remaining six studies that demonstrated medium to high quality. However, it was noted by the authors that broad methodological problems left each study vulnerable to bias and error.[61] These vulnerabilities included: multiple muscle site analysis which could result in patient recall bias; sample heterogeneity and unclear diagnostic criteria; and inconsistent training of examiners and non-standardization of palpation pressures.[61]

Lucas et al identified eight studies while using a broader search strategy that included an additional year of publications (2008 vs. 2007).[62] Five of the studies identified overlapped with the previous systematic review. The authors also used a checklist to grade the quality based on both the Standards for the Reporting of Diagnostic Accuracy and the Quality Assessment of Diagnostic Accuracy Studies appraisal tools. A parallel conclusion on quality assessment was provided. Current publications suffer significant problems with methodology which threatened the statistical integrity of the study.[62] The authors were most concerned about the research focus on isolated individual signs versus a composite of the recommended criteria to diagnose a trigger point. Lucas et al called for future research to include interrater reliability of composite criteria as well

as reliability of identifying location within the muscle.[62] Neither of these important reliability components was reported as of 2008.

A composite of both systematic reviews concluded the limited number of studies provided the possibility of moderate evidence for reproducible diagnosis of trigger points based on individual criteria.[61,62] The variables of local tenderness ($\boldsymbol{\kappa}$ ***range***, 0.15-1.0) and pain reproduction ($\boldsymbol{\kappa}$ ***range***, 0.29-1.0) achieved acceptable reliability in most of the investigations but included a wide range.[61,62] While subjective reports of tenderness and pain reproduction achieve acceptable reliability, they are not sufficient to accurately diagnose a trigger point or rule out other systemic involvement in isolation.

The addition of another objective sign such as a taut band would assist in the diagnosis of a trigger point and is proposed as an essential criterion. Reported reliability estimates for a taut band across all studies ranged from $\boldsymbol{\kappa}$ = -0.08 to 1.0.[61,62] Both systematic reviews called for higher quality investigations of a more global, but well defined assessment that included the taut band and subjective report of tenderness to palpation or pain reproduction.

The authors Myburgh et al followed their systematic review with a more recent investigation of interexaminer reliability of trigger point palpation in the upper trapezius and the influence of clinical experience.[65] A global assessment of trigger point diagnosis was used based on four criteria proposed by Tough et al: a taut band in skeletal muscle; local tenderness; patient pain recognition; and patient pain referral. [64,65] The existence of a taut band was considered to be essential for a trigger point diagnosis in this study while the remaining criteria factored into an overall global assessment.[65] Two experienced and two inexperienced examiners completed examination training that included psychomotor

skills to standardize pressure and rate of pressure application.[65] The experienced clinicians averaged 5.75 years in chiropractic practice while the inexperienced clinicians were represented by student chiropractors.[65]

The sample size of 81 participants consisted of symptomatic neck subjects (n=67) and asymptomatic subjects (n=14).[65] The authors reported trigger point diagnosis reliability between experienced clinicians was good $\boldsymbol{\kappa}$ = 0.63 (0.37, 0.80) but poor $\boldsymbol{\kappa}$ = 0.22 (-0.01, 0.44) amongst inexperienced clinicians.[65] The authors note that pooling the data into a global assessment may unfairly bias results based on experience.[65,66] However, this approach towards trigger point diagnosis may be more reasonable given the high variability of criteria signaled out and used in previous studies. Global assessment may also be more representative of clinical practice.

A more recent study by Barbero et al investigated the intratester reliability of trigger point identification in the upper trapezius.[66] What is interesting is the authors' focus on the exact physical location of a trigger point and not just the trigger point existence. A blindfolded examiner identified and located trigger points on the upper trapezius of 24 subjects using an anatomical landmark system. X and Y coordinates were established in reference to a line drawn from the acromial angle to the C7 spinous process. The analysis of intratester reliability demonstrated high correlation for Y coordinates ($ICC_{(1,1)}$=0.81) and moderate correlation for x coordinates ($ICC_{(1,1)}$=0.62).[63,66]

INTEGRATED HYPOTHESIS OF MYOFASCIAL TRIGGER POINTS

The integrated hypothesis of MTrPs is the most prominent theory for the etiology and mechanism of MTrPs.[63,67-69] Since its introduction, the original theory has been updated with advancing scientific support.[67-70] While the theory is evolving and based on a small number of studies, the best available evidence supports the integrated hypothesis. The integrated hypothesis proposes the origin of MTrPs may occur following biomechanical overload of the muscle structure.[67,70]

MTrPs are postulated to occur following biomechanical stress of the muscle which precipitates the development of a taut band.[67] Gerwin et al proposed that submaximal repetitive muscle contractions, sustained postures, and acute maximal overload could lead to the evolvement of the MTrP.[67,68] Biomechanical overload results in an energy crisis with persistent small muscle fiber contraction around the motor endplate. The taut band is theorized to continue due to motor end plate dysfunction following muscle fiber injury.[68,71,72]

Normally the central nervous system initiates a muscle contraction by releasing acetylcholine (ACh) at the motor endplate. ACh is released at the interface between the alpha motor neuron and the muscle fiber. ACh then binds to post synaptic nicotinic ACh receptors (AChR) in the muscle cell allowing the movement of sodium & potassium ions across the muscle cell membrane. This action leads to a slight depolarization of the muscle cell identified as a miniature end plate potential (MEPP). The summation of multiple MEPPs activates sarcomere contraction. Remaining ACh is deactivated in the synaptic cleft by acetylcholinesterase (AChE) following the action potential. The

integrated hypothesis proposes the biomechanical overload results in dysregulation of this process.

Biomechanical overload in the muscle fiber following a contraction might theoretically result in either micro or macro-traumatic stress.[67] The deleterious muscle activity induces a cascade of events that contribute to the development and maintenance of MTrPs.[67] Key events such as localized ischemia, and release of noxious biochemical substances result in dysfunctional motor endplates.[67] Endplate dysfunction characterizes a vicious cycle of sustained spontaneous electrical activity resulting in depolarization of post-synaptic membrane of the motor endplate.[71-73]

The integrated hypothesis proposes the localized environment is the result of continued depolarization of the motor endplate resulting in an energy crisis and biochemical imbalance. Continued small fiber muscular contraction increases the local intramuscular pressure. The change in pressure gradient impedes capillary blood flow and produces ischemic hypoxia associated with MTrPs. This restriction limits the resupply of oxygen and ATP creating the proposed energy crisis.

Local oxygen saturation at a MTrP has been reported to be less than 5% of normal.[70,73-75] The lack of oxygen and ATP may allow sarcomeres to stay contracted and cause altered biochemical concentrations through the acidic pH levels found in active MTrPs.[70,74,75] Elevated biochemical such as calcium gene related peptide (CGRP), substance P, and bradykinin are found in significantly higher concentrations in local area of active MTrPs.[74-76] A decreased pH and increased CGRP results in a cascade of events. CGRP facilitates ACh release, magnifies AChR activity, and inhibits AChE activity. Bradykinin and substance P are inflammatory agents that contribute to muscle

nociception activation. This biochemical activity further perpetuates MEPPs thus creating a theoretical mechanism for MTrPs.

BENEFITS VS. RISKS OF TRIGGER POINT DRY NEEDLING

Safety of potential subjects is a primary concern. TDN is minimally invasive and carries a low risk. However there are potential adverse events associated with the invasive technique. An adverse event can be defined as "any ill effect, no matter how small, that is unintended and non-therapeutic."[29,76,77] In this operational definition, mild side effects are categorically labeled as an adverse event, even if they are harmless and transitory.

A prospective observational study of adverse events in 229,230 patients that received acupuncture was reported.[29,38,77] This study is arguably the most comprehensive investigation of adverse events resulting from needling therapy. The results of this study require taking into account that patients received multiple treatments (n=2.2 million) while the authors only reported events per patient and not events per treatment. Prevalence of adverse events per treatment is expectedly much lower given this fact. The most common adverse events were superficial bleeding/hematoma (6.14%), localized pain (2.04%), and fatigue (1.15%).[4,35,77,78] Uncommon adverse events included local infection (0.01%), vertigo (0.22%), and nausea (0.15%).[37,76,77] The reported adverse events are concerning but represent minor temporary conditions that are reversible. Following strict guidelines for clean needle procedures and location of needling (gastrocnemius) should further reduce the reported minimal risk.

Brady et al systematically queried patients that received TDN from a physical therapist to assess risk specifically associated in this setting. A total of 35 therapists participated and 7629 patient treatments were reported.[76,79] 1463 (19.18%) mild adverse events were reported.[37,76] Mild events that were the most prevalent included: bleeding; bruising; pain during and after treatment.[14,76,80-85] Less common events included: drowsiness; feeling faint; headache; and nausea.[76,86] The authors suggested that the reported percent was higher than the Witt study because the methodology was distinctly different with the patient reporting the side effects.[76,87] The higher percentage may then more accurately represent the patient's perceived experience versus the therapist. No severe adverse events occurred but the size of the sample is relatively small which must be considered. Despite this limitation, the authors report an estimated risk of severe adverse events to be ≤0.04%.[21,76,87-89]

CLINICAL EFFECTIVENESS OF TRIGGER POINT DRY NEEDLING

The current body of research investigating TDN effectiveness is small and does not unequivocally support widespread clinical use. There is emerging but limited evidence for a positive TDN treatment effect but maybe not more than placebo in some cases. The tepid conclusions by most SRs are warranted based on the evidence. The few number of studies are predominately characterized by limitations in methodology and heterogeneous grouping of musculoskeletal conditions.[21,87-90] The heterogeneity of subject populations increases the risk that a study may have included subjects with non-favorable prognostic factors for TDN treatment. Reported non-favorable prognostic factors include chronic pain, high pain intensity, poor quality of sleep, and repetitive

work.[14,36,47,53,87,90] Small sample size RCTs are also common, with many studies involving less than 50 subjects. The need for adequately powered, randomized placebo controlled trials is a common conclusion in most evidence reviews. Compounding this problem is the trend of most SRs to collate RCTs that include both acupuncture and TDN. As previously mentioned TDN differs from acupuncture in theory and clinical practice. TDN does not target meridians but rather trigger points within muscle.[8-11,47,53,91] Caution was taken when assessing the acupuncture literature while searching for TDN clinical effectiveness. This literature review will start with reported systematic reviews, then specifically focus on the regions of the infraspinatus/shoulder, low back/lumbar, and lower leg/gastrocnemius/foot/ankle.

A systematic review (SR) by Cummings and White reported 23 RCTs to establish evidence for trigger point needling efficacy.[91,92] The randomized control trials (RCT) included in this SR covered a wide scope of diagnoses ranging from unspecified myofascial pain to migraines. Sample sizes were generally small and 10 of the 23 RCT's were judged to be poor quality.[16,91] Five of these RCT's investigated direct TDN while the remainder included injected substances along with TDN. The authors reported that 8 of the wet needle trials concluded the effect was independent of the injected substance.[16,91] Any effect of needling intervention is likely because of the needle or placebo rather than injection of either saline or active drug.[9,11,91,93,94] Despite the heterogeneity and the poor quality of methodologies found, the authors state that needling appears to be an effective treatment, but it is not supported nor refuted beyond placebo which requires further research.[17,35,41,91,95] The conclusion was based on the collected results that demonstrated improvement in outcomes following needling intervention

regardless of dry vs. injected substance. This conclusion echoes previous findings of Paulett in 1947.[41,70,96]

An overview of all Cochrane Reviews on needling intervention (acupuncture and TDN) for the treatment of pain was completed in 2011. Lee and Ernst included 8 reviews (109 RCTs) related to a wide range of pain syndromes including: osteoarthritis; migraines; tension type headaches; neck disorders; rheumatoid arthritis; shoulder pain; low back pain; and lateral elbow pain.[67,96] Overall quality of the RCTs was reported as variable in each review.[28,96] Five of the eight reviews reported clinical effectiveness in reduction of pain for osteoarthritis, migraines, tension type headaches, neck disorders, and low back pain. The remainder of the Cochrane reviews reported inconclusive evidence for treatment effectiveness due to low number of published RCTs.[18,20,21,35,96]

A SR conducted within the framework of the Cochrane Collaboration, by Furlan et al, focused on low back pain.[21,37,79] The scope of the SR was broad including 35 RCT's using both acupuncture and TDN techniques. The authors' description definitively separates acupuncture from TDN. It is confusing as to why both were combined for this review. The included RCT's also covered a broad range of the stage of symptoms from nonspecific acute, subacute, and chronic low back pain. The authors reported that there was too few RCT's to come to any meaningful conclusions due in part to small sample sizes and poor methodological quality.[21,37,79] However, the authors' describe the collective data suggests TDN may be a useful addition to treatment for short term pain relief.[21,22,87]

Similar, muted, conclusions were drawn in a SR and meta-analysis by Tough and White. In contrast to the previously mentioned SR's, the authors limited inclusion to

needling of MTrPs only and excluded acupuncture treatment approaches. A total of 10 studies were identified for inclusion, while only 6 were included into the meta-analysis.[22,97] The meta-analysis was completed on RCTs that included a sham placebo control. The authors reported that even though the 6 studies were considered similar in intervention and outcome tool, the methodological diversity created a statistical heterogeneity (I^2=82.6%) that was higher than the recommended limit according to the Cochrane Handbook.[22,98] The statistical heterogeneity is a consequence of variability in population groups, number of treatments provided, and small sample sizes.[22,98-100] The authors acknowledge this limitation but suggest that needling combined with usual physical therapy care such as exercise is more effective at reduction in pain, based on two of the included studies.[18,22,99-101]

More recently, Kietrys et al completed a SR and meta-analysis with the focus of TDN effectiveness in upper quarter myofascial pain. The authors make strong conclusions that there is now "grade A evidence" to suggest TDN is effective for clinical pain relief.[18,102] Kietrys et al recommend TDN, compared to sham or placebo treatment, for immediate pain reduction based meta-analysis of four studies with a pooled effect size of 1.06 (95% CI: 0.05, 2.06).[18,102] A strong recommendation may be unsupported as the confidence interval is very wide and close to zero, suggesting the possibility of small, meaningless effect size. It is also reported that the pooled results of these four studies had high statistical heterogeneity (I^2=86.3%) and high risk for publication bias.[18,103] Based on meta-analysis of three studies, the authors cautiously recommend TDN, compared to sham or placebo, for reduction of pain at four weeks.[18,103] This conclusion, while cautious, was determined by an overall effect size of 1.07 (95% CI: -0.21, 2.35).[18,104] The

authors report that the confidence interval crosses zero suggesting the possibility there is no difference between treatments and high statistical heterogeneity of the three studies (I^2=84.2%).[18,34,102]

The authors' conclusions contradict the reported results. The available data for meta-analysis is limited and in one study other treatment was favored over TDN for immediate reduction in symptoms.[18,30,34,105-107] It is puzzling that the recommendation favored TDN as "grade A evidence," considering the limitations in calculated effect size confidence intervals and high heterogeneity of the comparison studies.[18,108-110] Despite the inconsistent interpretation of the data by the authors, there appears to be some evidence to support the use of TDN for immediate reduction of pain caused by MTrPs.[88,108-110]

Cotchett and colleagues completed a SR review of quasi-experimental investigations of TDN treatment for plantar fasciitis. The authors identified 3 trials and all trials reported a reduction in pain following TDN.[88,111] The characteristics of the trials limit the conclusions that can be drawn due to the nature of the quasi-experimental study design and threat to internal validity. Study sample sizes were very small (n<19), randomization did not occur, and overall quality was graded <13/27 on the Quality Index tool.[88,112,113] Other limitations include the combined acupuncture and TDN intervention approach, inconsistency and absence in outcome reporting, and overall statistical heterogeneity. Despite these limitations, there is a trend towards clinical effectiveness of TDN but poor quality of the included trials impedes definitive conclusions from being drawn.

An overall trend of statistical heterogeneity and poor methodology precludes strong guidance for the clinical use of TDN. Published SRs tend to use trials with known sources of bias and poor methodology. There is a lack of robust evidence to suggest the clinical effectiveness of TDN, if these lower quality studies were excluded from SR. However, there does appear to be a trend towards clinical benefit in some of the previous trials as well as more recently reported studies. This proposed investigation will focus on TDN of latent MTrPs in three regions: infraspinatus; erector spinaes; and gastrocnemius. The following research investigates these regional areas.

The clinical relevance of latent MTrPs was investigated in a pilot RCT by Calvo-Lobo et al.[113,114] A sample of 20 subjects with nonspecific shoulder pain and at least one active and latent MTrP in the infraspinatus muscle were randomized to receive a single session of TDN treatment to the active MTrP (control group) or the active and latent MTrPs (experimental group). Pain intensity rated on the numeric pain rating scale, pain pressure threshold, and grip strength were measured at baseline, immediately following treatment, and 1 week post treatment. The experimental group that received TDN to an active and latent MTrP, demonstrated a greater increase in pain pressure threshold that was statistically significant $t(40)= .019$, $p<0.05$, $d=1.06$ compared to the control group.[113,115] The effect size was also large, suggesting a meaningful difference in mechanosensitivity between groups.[113,115,116]

Drawing upon the importance of appropriately matched interventions, Koppenhaver et al reported on a quasi-experimental study in which 66 subjects diagnosed with mechanical low back pain received one TDN treatment.[83,116-118] Outcome measures were Oswestry Disability Index (ODI), pain pressure threshold (PPT), and ultrasound

imaging of the lumbar multifidus thickness at rest and contracted. Measurements were taken at baseline, immediately following treatment, and one week later. The sample of subjects was divided in to responders and non-responders based on a clinical improvement score of 30% change in ODI after one week.[116]

The authors reported significant improvement in muscle contraction thickness and pain sensitivity at 1 week for responders than non-responders.[116] While the change in muscle contraction thickness and PPT was below the minimal detectable change (MDC of 11% and 4.3 to 9.8N/cm^2 respectively), as reported by the authors, the trend for greater improvement was observed in the responders group.[116] Responders also demonstrated a one-week mean improvement score of 62.1% on the ODI.[116,119] Identification of responders and non-responders, or those most likely to benefit from TDN treatment may prove beneficial for future RCT research and especially clinical practice.

A RCT by Arias-Buria and colleagues examined TDN treatment for post-operative shoulder patients, either open reduction for proximal humerus or repair of the rotator cuff.[119] Twenty subjects were randomized to physical therapy group or physical therapy plus one session of TDN group over the course of one week.[119] Subjects that received TDN experienced statistically greater improvement in activities of daily living and strength as measured by the Constant-Murley outcome tool.[18,21,113,119-121] Despite the small sample size, this change in function for acute symptoms continues to support a trend for the inclusion of TDN into physical therapy management.

Evidence to establish the role of TDN in physical therapy management is growing. There is emerging evidence to support the use of TDN for the shoulder, heel pain and LBP.[18,21,88,89,91,113,120-123] The limited evidence points towards a positive TDN

treatment effect but maybe not more than placebo in some cases. A more definitive conclusion may be drawn with research that is adequately powered and appropriately designed. Identification of those that may benefit most should be a research priority.

PLACEBO CONTROL DISCUSSION

The common argument against TDN is that it is a ritualistic intervention that causes a placebo or in some cases nocebo effect. The argument for non-specific effects or stating that an intervention is not better than placebo can be misleading to clinicians and patients.[122,124-126] This is especially true when the intervention is difficult to sham inertly and methodology is poor.[88,89,91,123,127] TDN is an invasive procedure causing measureable neurophysiologic stimulation and tissue disruption.[124-127] A truly inert intervention serving as the control treatment for TDN may not be possible. A sham intervention, either a blunt needle or superficial needling insertion, could have a biological effect on the subject further complicating the argument.

The effects of TDN may be more than placebo. Mayoral and colleagues randomly assigned 40 subjects to receive either TDN or the placebo controlled treatment described as superficial cutaneous needle insertion.[127] The inclusion criteria for the sample of subjects included the following: diagnosed with knee osteoarthritis and scheduled for total knee arthroplasty; presence of MTrPs in the tensor fascia latae, hip adductors, hamstrings, quadriceps, gastrocnemius, or popliteus.[127] The authors did not provide further description of MTrPs prevalence. All subjects were blinded to the intervention and placed under anesthesia.[127] The control group received a superficial cutaneous needle

insertion while the treatment group received one bout of TDN to MTrPs prior to total knee arthroplasty.[127]

Since the treatment group started with a higher VAS baseline values, a variation rate was used to measure change.[127] The authors reported the TDN group demonstrated significantly decreased pain intensity in the first month following total knee arthroplasty compared to control.[127] The degree of pain reduction observed in the first month for the treatment group was the matched by the control group at 6 months.[127] Also, the use of analgesics was significantly reduced in the TDN group as compared to control.[18,116,120,127]

This unique placebo controlled study suggests that TDN may be effective for short-term pain control beyond placebo. The application of one treatment in the context of individuals with longstanding history of pain is also compelling support for TDN use. However, as the author's acknowledged, the sample size is small and susceptible to type two error.[127,128]The dosage, number, and location of MTrPs were not described in much detail thus providing very little guidance for clinical use.

Preliminary evidence exists suggesting benefit of TDN intervention in reducing pain intensity in the short term.[18,116,120,127,128] The small number of heterogeneous studies with small sample sizes provides some reasoning but limited guidance to physical therapists. However, these shortcomings culminate into hesitant recommendations for TDN use in clinical practice. This supporting evidence creates an environment not unlike LBP intervention research before sub grouping subjects.

BIOMECHANICAL RESPONSE TO NEEDLING

The exact therapeutic mechanism of TDN is unknown. There is likely a mechanical and neurophysiologic response. Once the needle is inserted into the myofascia, clinicians will describe a phenomenon of tissue grasp of the needle separate from a LTR.[128,129] Advancing diagnostic techniques have introduced early evidence to explain the mechanical response to TDN as well as the immediate physiologic changes that result.

Subcutaneous grasp of the needle has been documented in both animal and human investigations. This needle grasp can be significant enough to result in "tenting" of the skin when attempting to remove the needle.[128] In fact, the needle pullout force has been measured to increase by 167% with needle rotational manipulation.[129,130] This significant shift in pullout force required suggests a unique biomechanical change in not only the muscle but also the subcutaneous layers.

In early investigations using rat models, subcutaneous collagen bundles where found to be oriented more parallel to each other following needle insertion and rotation.[128,130] This myofascial reorientation caused by mechanical coupling to the needle may transmit mechanical signals through afferent sensory nerve fibers and also initiate a local inflammatory response. Manipulation of the needle can include rotation but is often described as a rapid up and down motion or sparrow pecking.[130] Ultrasound elastography of this needle manipulation has shown tissue displacements of up to 4cm away from the treatment site.[68,130] Tissue displacement via needle sparrow pecking could create a biomechanical signal or modulation of local afferent sensory input.[124,130]

MTrPs theory centers on the presence of abnormal depolarization of motor end plates creating a localized sarcomere shortening.[68,124] Domingo et al investigated the neuromuscular damage created by needling using animal modeling.[124] Multiple axonal fragmentation including the motor endplate was observed post TDN using immunohistochemistry stain in the area of puncture.[124] During the first 24 hours, electron microscopy showed myelin disappearance followed by Schwann cell activity at the synaptic cleft.[124]Re-innervation following nerve damage was observed at 72 hours.[124] An inflammatory response was also observed within the muscle, after 24 hours.[124] Satellite cellular activity was observed at 72 hours. Myoblasts followed by myotubes and myofibrillogenesis represented the first step of muscle regeneration.[124,131] Complete tissue regeneration was demonstrated at 1 week.[124]

An earlier investigation reported a corresponding inhibitory effect observed in the TDN of rabbits. The spontaneous electrical activity within the MTrP region was significantly reduced following TDN.[131,132] The decreased electrical activity recorded may be a result of the biomechanical disruption of the motor end plate reported in the previous animal study.[124,132] It is unknown if these results can be applied to human or pathological tissue. More than likely, a similar biomechanical process is occurring after TDN in human subjects. Salom-Moreno et al reported significant decrease in spasticity following TDN in patients who had previously suffered a stroke.[32,132] The authors theorized an intrinsic change occurred citing alteration to the synaptic motor unit and structural overlap of the sarcomere as a mechanism for this immediate change.[32,132]

BIOMECHANICAL STIFFNESS

Skeletal muscle at rest is exceptionally elastic. Independent of contractile activity a muscle will maintain tension when stretched then return to its original shape. In comparison, an electrogenic contraction results in tissue shortening and tension development followed by re-lengthening to original shape when activation ends.[32] The elasticity of skeletal muscle is therefore dependent on the non-contracted state as well as the contracted state whether it is voluntary or involuntary.[32] Stiffness is the measurement of elasticity and requires the following: an explanation of the type of load; the location and direction of application; and the type of the deformation.[29] The operational definition of elasticity is the material's resistance to deformation.[29] When a structure demonstrates highly elastic characteristics it is measurably very stiff.

Muscle and soft tissue are traditionally described in terms of longitudinal elasticity. This is a source of confusion from a clinical standpoint because flexibility is then equated to elasticity. In the clinic, a subject with increased flexibility demonstrates range of motion exceeding functional norms. It is incorrect to state that this is also a demonstration of increased elasticity.

The measurement of stiffness in a clinical setting is relevant and may contribute to the development of a more complete model for understanding biomechanics.[4] Altered muscle stiffness, either increased or decreased, has been identified as a possible source for injury risk and a biomarker for intervention effectiveness.[4,35,78] Too much stiffness may result in injury due to the increased peak forces, loading rates and shock.[4] MTrPs are localized areas of increased stiffness within the muscle but the direct relationship of MTrPs and injury is not well established and poorly understood. However, MTrPs could

impact the performance of the muscle and the increased stiffness may contribute to localized trauma.

MEASUREMENT OF STIFFNESS

The MyotonPRO® device imparts a mechanical perturbation or impulse with a small probe that is placed on the superficial skin.[37] The probes impulse exerted on the superficial muscle is of short duration (15 milliseconds) and involves a light mechanical force (up to 0.6 N).[79] The device measures the resultant dampened wave oscillation following the impulse and the biomechanical property of stiffness is calculated using Young's modulus. An example of the acceleration graph and formula follows in Figure 2.1.[37]

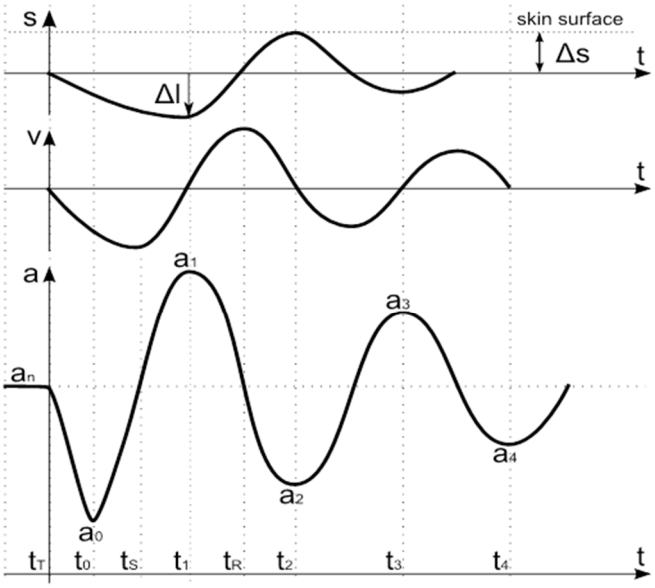


Figure 2.1: MyotonPro® measurement waveforms (displacement, velocity, acceleration).

S displacement (tissue oscillation);

ΔS pre-compression of subcutaneous tissues above the muscle being measured;

Δl maximum deformation;

V velocity of oscillation;

a acceleration of oscillation;

t time in millisecond;

t_T start of the mechanical impulse;

a_1 maximum acceleration. Maximum tissue resistance to the mechanical impulse;

t_1 the time when maximum deformation was reached;

t_r the time when tissue returned the shape from deformation;

a_2 maximum opposite acceleration due to the tissue inertia;

t_2 the time when maximum opposite deformation was reached;

a_3 maximum acceleration of the second period of oscillation which takes place due to the restored residual mechanical energy in the tissue being measured.

Stiffness formula

Biomechanical Stiffness [N/m]: $S = a_{max} \cdot m_{probe} / \Delta l$

a_{max} = a_1 max acceleration

m_{probe} = probe mass

Measurement of intervention outcomes requires careful consideration of the validity and reliability of the measurement device. New or novel approaches in clinical research deserve greater scrutiny. Myotonmetric measurement results are reported with good to excellent inter and intratester reliability (ICC 0.80-0.99) in individuals with normal and neurologically abnormal muscle tone.[14,80-85] The MyotonPro® has also been

used to investigate intervention effects of resting skeletal muscle stiffness following medication to reduce rigidity in Parkinson's disease.[86]

An investigation of reliability and validity of the MyotonPro® was conducted using polymetric gel-based tissue phantoms (Figure 2.2).[87] The study results demonstrated excellent interrater reliability, ICC = 0.99, SEM = 0.42 N/m, MDC = 0.97 N/m.[87] The MyotonPro® was validated using a 100N load cell on each tissue phantom as comparison with significant positive relationship r=0.96(Figure 2.3).[87]

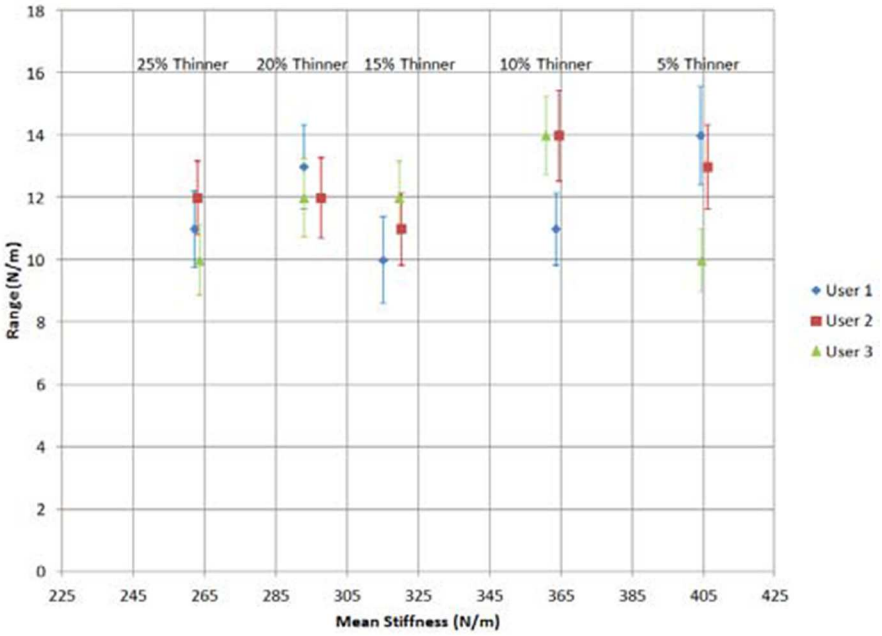


Figure 2.2: Intrarater stiffness measurement for 5 tissue phantoms.

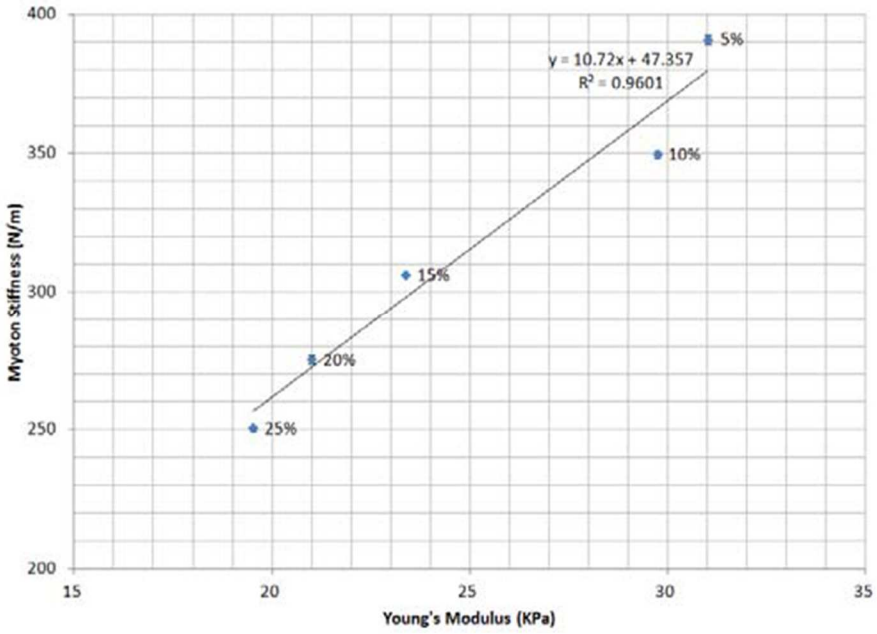


Figure 2.3: Correlation MyotonPRO® stiffness (N/m) to Young's Modulus (KPa)

The myotonometer has the potential to aid in the diagnosis and treatment outcome evaluation of multiple pathologies seen in a physical therapy setting. While initial investigations have demonstrated some promise for clinical utilization of the MyotonPRO®, robust research investigating measurement properties and clinical utility is lacking.[14,36,87] The inclusion of this measurement approach into current practice provides objective data that is actionable in the diagnostic and intervention process. The MyotonPro® measurement may also serve as a clinically meaningful outcome tool. This handheld device is a safe, non-invasive alternative to more expensive diagnostic procedures.

Preliminary observations suggest that muscular pathologies and injuries have unique elastic/stiffness properties that could be characterized with novel imaging techniques.[8-11] Originally reported by Sikdar et al, ultrasound combined with external

vibration (ultrasound elastography) allowed researchers to quantify tissue stiffness and change in that stiffness by measuring the speed at which the vibration waveform travelled.[92] Since then more advanced and reliable approaches have developed. SWE uses the ultrasound beam to record shear waves that propagate perpendicular to the beam producing a shear modulus.[16] The shear modulus represents the stiffness of the tissue.[16] SWE has been shown to be valid, and able to reproduce stiffness parameters of superficial and deep musculoskeletal tissues.[9,11,93,94] Recent research has investigated the use of SWE in skeletal muscle and preliminarily linked local alterations of muscle stiffness (e.g., "trigger points") to chronic musculoskeletal pain conditions.[17,35,95] Previous studies have found SWE measures to be highly reliable across a wide variety of muscle groups.[133] Previous studies have also reported a strong linear relationship between muscle shear modulus and muscle force.[94,105,134] While SWE demonstrates great promise as a laboratory research tool, its large size and high cost (greater than $100,000) makes it unsuitable for translational clinical trials and potential wider adoption throughout physical therapy.

SUMMARY

The integrated hypothesis proposes the origin of MTrPs may occur following biomechanical overload of the muscle structure.[70] MTrPs are postulated to occur following biomechanical stress of the muscle which precipitates the development of a taut band.[67] In theory, with MTrPs representing a contracted portion of muscle, the resultant stiffness measured would be greater than surrounding, non-contracted tissue. The presence of MTrPs in muscle may give rise to increased tissue stiffness as a result of

the contracted fibers.[28] Recently, the quantification of MTrPs biomechanical stiffness and the change following TDN has been reported using a SWE.[18,20,35] A trend for improvement following TDN is emerging from more recent investigations but outcome measurement is often limited to subjective reports of pain and function. Objective in vivo measurement of the biomechanical structural properties of muscle is a complimentary approach to current clinical assessment. This investigation will use the MyotonPro® to characterize the biomechanical stiffness of MTrPs pre and post TDN intervention. This pragmatic and novel approach may identify a clinically relevant biomarker for trigger point identification and response of clinical TDN intervention.

CHAPTER 3 – METHODOLOGY

INTRODUCTION

Measurement of soft tissue stiffness before and after trigger point dry needling (TDN) may prove to be a useful, and valid approach to quantifying physiological change. This chapter provides the description of the research design and methodology to measure biomechanical stiffness of a myofascial trigger point (MTrP) before and after TDN. The inclusion and exclusion criteria for subject participation and method of recruitment is described. The instrumentation and procedure for data collection and analysis are presented. The specific aims for phase one are: investigate the test retest reliability of the MyotonPRO® and shear wave elastography (SWE) measurement during three separate conditions of muscle contraction; investigate the concurrent validity of the MyotonPRO® comparative to the SWE during three separate conditions of muscle contraction.

This study consisted of two phases conducted at AMEDD Center and School, San Antonio, TX and at Bradley University, Peoria, IL. In the first phase, reliability and concurrent validity of the MyotonPRO® and SWE was investigated in 30 asymptomatic individuals. The first phase was conducted at AMEDD Center and School utilizing the available SWE machine and MyotonPRO® instrumentation. The second phase was conducted at Bradley University using the MyotonPRO® to investigate biomechanical stiffness change following TDN in 60 subjects with palpable muscle MTrPs.

INSTRUMENTATION

All SWE images were obtained using a Supersonic Aixplorer® ultrasound system (Supersonic Imagine®, Aix-en-Provence, France) with a 50mm 10-2 MHz linear array. The elastographic image is a grey-scale (B-mode) image with a color overlay that represents the shear modulus in kPa. The mean shear modulus within the selected area of interest is recorded as the SWE stiffness value. SWE measurement uses focused ultrasound radiation forces causing a wave to travel horizontal to the point of application through tissue, to estimate material properties.[135] The measurement estimates Young's modulus based on the shear wave velocity of ultrasound propagation.[135]As wave velocity increases the Young's modulus increases, indicating a stiffer material.[16] The Young's modulus (kPa) is measured in real time with acquisition lasting less than 6 seconds.[135]

Biomechanical stiffness measurements were obtained using the MyotonPRO® (Myoton® AS, Tallinn, Estonia) by applying a mechanical impulse to the skin, which is transmitted to the underlying soft tissue and muscle (0.58 N for 15 ms).[37,79] The mechanical impulse compresses the tissue and muscle responds by a damped natural oscillation. The oscillation of the muscle is recorded by an accelerometer located at the probe end. The peak acceleration (p) is measured after the termination of the impulse. The acceleration signal is integrated twice to determine the displacement signal. The force generated by the mass of the probe is proportional to the acceleration of the probe. The dynamic stiffness (S) in MyotonPRO® is expressed as $S = mp/d$, where m is the mass of the probe (18 g), p is the maximum amplitude of the oscillation in the acceleration signal, and d is the amplitude of the displacement signal at the end of the impulse time.[87]

The stiffness parameters are calculated from the acceleration signal and are comparable to shear modulus in kPa.

PHASE ONE: RESEARCH DESIGN

The purpose of the first phase was to investigate the reliability and concurrent validity of the MyotonPRO® to the criterion of SWE over increasing muscular contractions. This first phase was a prospective single group design with repeated measures. Subjects were assigned to one cross sectional group. Separate SWE and MyotonPRO® stiffness measurements were collected in a randomized order on the infraspinatus muscle, erector spinae muscles, and gastrocnemius muscle. Measurements of the individual muscles (infraspinatus, multifidus, and gastrocnemius) were acquired on the left side at rest, during sub-maximal isometric contraction, and during a maximal voluntary isometric contraction (MVIC) for each muscle as described below. The MVIC was identified by the maximum isometric value recorded by a dynamometer during a muscle test. The 40% and 80% of the MVIC represented sub-maximal contraction as recorded. For all conditions, 3 measures were taken and averaged for data analysis.

SAMPLE SIZE ESTIMATION

Power analysis was performed using z-transformation to estimate sample size for correlation. With 80% power; 95% significance level; to detect a simple correlation *r* (r=0.5); the required sample size is 29.[97] Total enrollment of 30 subjects will provide adequate precision around reliability estimates (intraclass correlation coefficients [ICC] with 95% CIs).

PARTICIPANT SELECTION AND RECRUITMENT

A sample of 30 asymptomatic subjects was recruited from all Department of Defense beneficiary categories (active duty, retiree, dependents, etc.) between the age of 18 and 65 years of age. Subject selection was equitable without limitations to race, ethnicity or gender. Potential participants responded to word of mouth or flyer posted around Joint Base San Antonio. Prescreening recruitment of potential participants consisted of a brief description of the study and inclusion/exclusion criteria. Interested participants reported their gender and age and then simply stated whether or not they believed that they meet all of the inclusion/exclusion criteria for study participation.

INCLUSION AND EXCLUSION CRITERIA

Subjects must meet all the following criteria.

Inclusion criteria (all of the following)

a) Age 18 to 65 years
b) Free from musculoskeletal pain for 6 months
c) Able to perform repeated maximal isometric muscle contraction in the upper and lower quarter.
d) Full active range of motion of the upper and lower quarter.

Exclusion criteria (any of the following)

a) Current musculoskeletal impairment
b) Body mass index > 31
c) Recent (6 month) history of surgery
d) History of systemic inflammatory disease

e) Known pregnancy

f) Inability to lie prone

g) Inability to read and understand English

CONSENT PROCESS

The study Primary Investigator (PI), and Research Assistant conducted the consent process in the presence of a witness with the subject utilizing the approved informed consent in a private setting. The investigator informed the subject that the study involves research and explain the purpose and procedures entailed in this study. Furthermore, the subjects were informed of the approximate amount of subjects involved in the study. In addition, any foreseeable risks, discomforts, and benefits were explained. The voluntary nature of the participation was stressed. Study personnel will remind subjects, throughout their participation, that they may elect to withdraw from the study at any time. Subjects were assured that a decision not to participate will have no effect on their military status or ability to access health care; yet, if the subject chooses to participate he/she was informed that all records identifying the subject are maintained confidentially by the PI in a password protected electronic file and all hard copies are maintained in a locked file cabinet that only the PI and study team have access to. Subjects electing to withdraw from the study will not participate in any data collection or other procedures associated with this study. The investigative team may terminate a subject's participation in the study at any time he/she feels this to be in the subject's best interest (i.e., safety, health, etc). Moreover, subjects were provided with the appropriate contact information of whom to speak to about their rights and whom to speak with should the subject have any questions.

Subjects were given ample time to ask questions, read and understand the consent form and take it home (if he/she chooses) so the research can be discussed with friends and family prior to participation. Upon completion of the informed consent process and after all concerns were addressed the subject, the individual obtaining consent along with a partial witness signed the approved IRB consent forms. A copy of the signed documents was offered to the subject, and the original signed document was placed in the subject's study record. The informed consent process occurred and all parties prior to any/all study related procedures signed the informed consent document.

SUBJECT SCREENING PROCEDURES

Participants satisfying all inclusion and exclusion criteria were enrolled in the study. After providing informed consent, volunteers received a short screening examination. The screening examination consisted of answering questions regarding their medical history and current symptoms and a brief physical examination. Anthropometric data (height, weight, BMI) was collected via clinical measurement. The focused physical examination consisted of the following:

1. Visual inspection
2. Functional active range of motion of the shoulder (reaching hand behind head and reaching hand behind back), and lower quarter (squat, toe/heel walk).
3. Active range of spinal range of motion in standing: flexion, extension, side bending. Lumbar spine clearing maneuvers (quadrant test and posterior to anterior pressure to the spine).
4. Resisted shoulder, low back, and calf manual muscle test.

DATA COLLECTION PROCEDURE

For participants enrolled in the first phase of the study, the initial visit included a demographic and medical history questionnaire. Basic demographic information such age, sex, ethnicity, past medical history, height, and body mass was collected to describe the participant sample. The screening examination was followed by ultrasonic SWE and MyotonPRO® measurements of muscle stiffness/elasticity.

MEASUREMENT POSITIONS

Infraspinatus: The participant was seated in an upright position with the left side of the body against a wall, in a straight back chair (Figure 3.1). The arm positioned by the side in neutral, elbow in 90 degrees flexion, and wrist in neutral. The HHD was anchored to the wall so that the pad contacted the forearm proximal to the distal radial styloid process. Participants were instructed to eternally rotate their humerus with the forearm against the HHD with the trunk in an upright position. The MyotonPRO® and SWE measurements were taken at two fingers breadth below the center spine of the left scapula (Figure 3.1).[136]

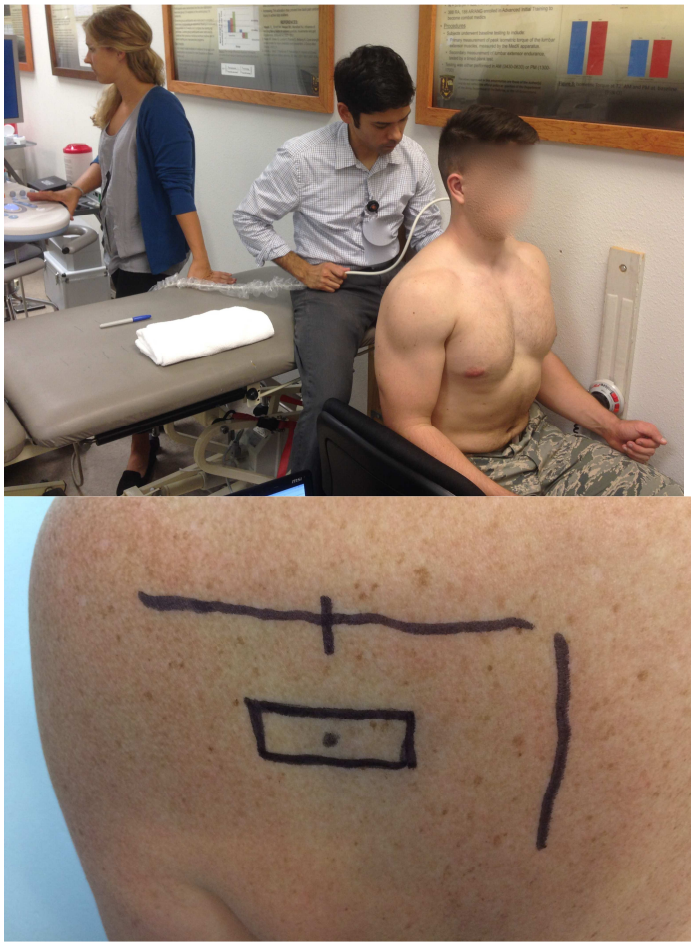


Figure 3.1: Subject positioning for isometric infraspinatus contraction and measurement location outlined two fingers breadth below the center spine of the left scapula

Erector spinae: The participant was placed in prone on a full length, padded table with arms resting at their sides or hanging off the table at approximately 90 degrees shoulder flexion. Three adjustable straps where used to stabilize the participant to the table (Figure 3.2). One strap was placed at the level of the greater trochanter across the hips to secure the pelvis. The second strap was placed at the knees superior to the popliteal crease to secure the lower extremities. A third strap fixated the HHD at thoracic

level 7 spinous process, and the strap was anchored to the table. A towel was used between the HHD and T7 spinous process for subject comfort. The MyotonPRO® and SWE location for measurement was standardized to the lumbar level 4 on the left side, by bisecting the muscle bulk lateral to the spinous process. The measurement location was outlined while at rest on the palpable muscle bulk one-finger breadth from the spinous process (Figure 3.2).[136]

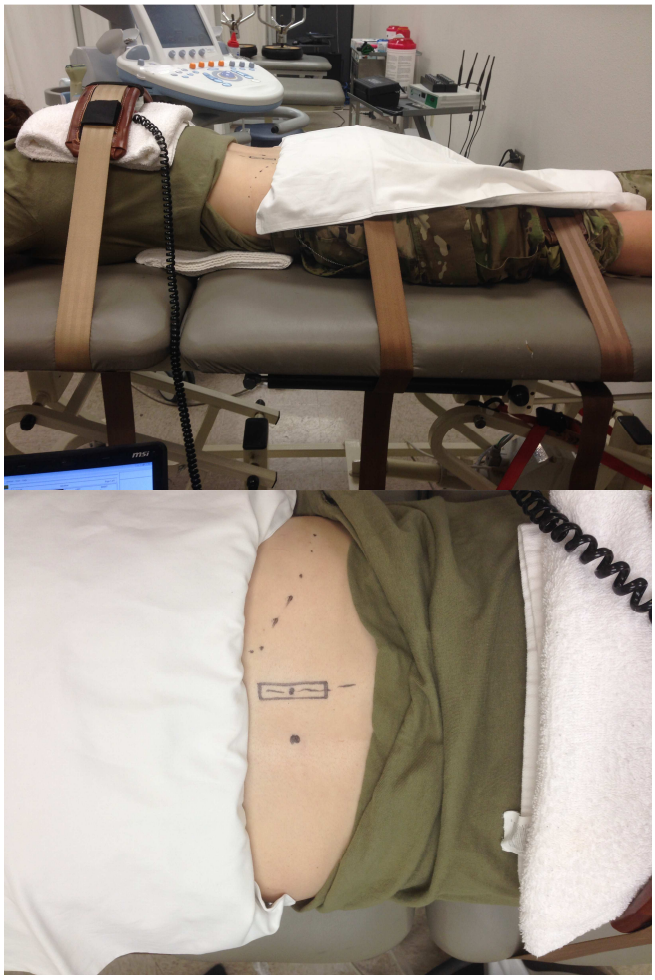


Figure 3.2: Subject positioning and belt placement for erector spinae isometric contraction. Erector spinae measurement location with iliac crest and L4 spinous process identified with rectangle transducer outlined on the palpable muscle belly.

Gastrocnemius: The participant was prone, shoes off with feet hanging unsupported off edge of the table, and knees resting in 0 degrees extension. The trunk and lower extremities were anchored to the table by a strap just above the popliteal crease and across the pelvis at the level of the greater trochanters. The ankle position was maintained at 0 degree neutral for isometric with the dynamometer pad placed at the first metatarsal head and HHD anchored to the wall (Figure 3.3). Measurements were taken at four fingerbreadths below popliteal crease in the belly of the left medial gastrocnemius (Figure 3.3).[136]

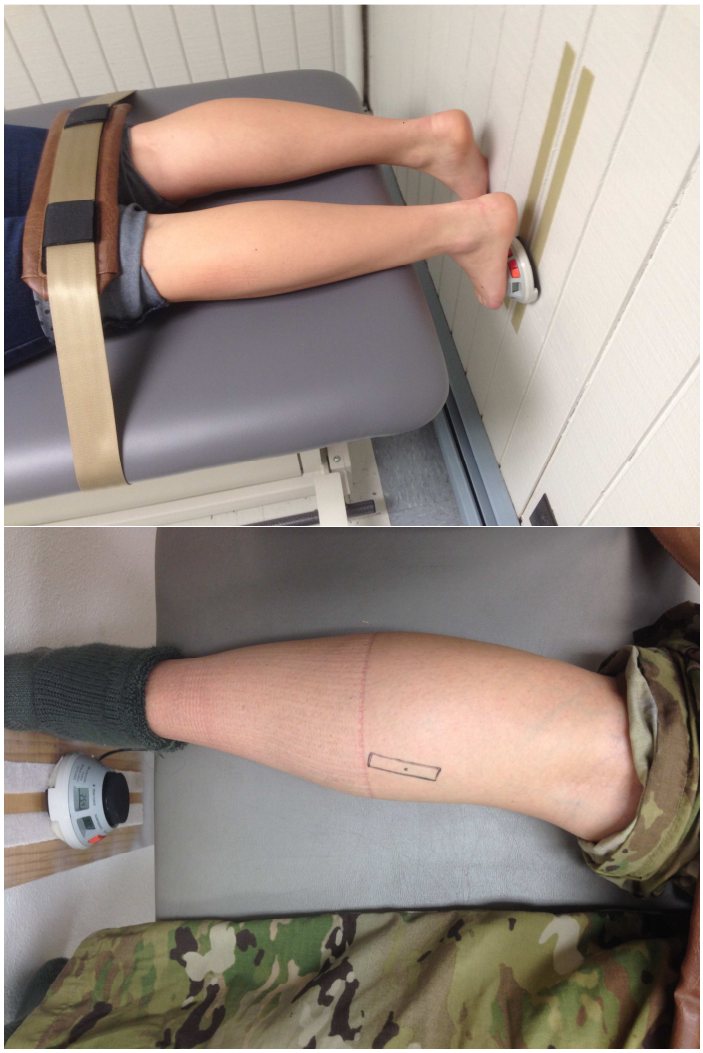


Figure 3.3: Subject positioning for isometric gastrocnemius contraction in prone. Medial gastrocnemius measurement location identified four fingerbreadths below popliteal crease in the belly of the left medial gastrocnemius.

MEASUREMENT

SWE and MyotonPRO® techniques were used to measure muscle stiffness under 3 conditions: rest and 2 intensity levels of isometric contraction. For the rest condition, the participants were instructed to relax during a 30-second period while measures of SWE and MyotonPRO® stiffness were measured. Participants then performed 2 repetitions of a maximum voluntary isometric contraction (MVIC) to determine and set a

submaximal threshold. The submaximal thresholds were viewed as clinically applicable and functional in respect to activities of daily living. A 40% and 80% MVIC levels were chosen to allow for the <6 seconds contraction needed to acquire a SWE image.[16] 40% and 80% goals were set with +/- 2.5% threshold range to account for observed variance in contraction control.[137] Participants were instructed to perform the designated contraction within the predetermined range for no longer than 6 seconds. Participants viewed the amount of force applied against the HHD via a display on an external monitor placed directly in their field of view. Three repeated measurements were conducted for both the SWE and MyotonPRO® at each muscle location for each contraction state (resting, 40%, 80%). The order of muscle, contraction intensity, and measurement device was randomized. Example SWE measurement image of 40% MVIC in the infraspinatus, erector spinae, and gastrocnemius is provided (Figure 3.4). The stiffness color scale shown to the left of the figure with red representing higher magnitude of stiffness and blue lower magnitude of stiffness.

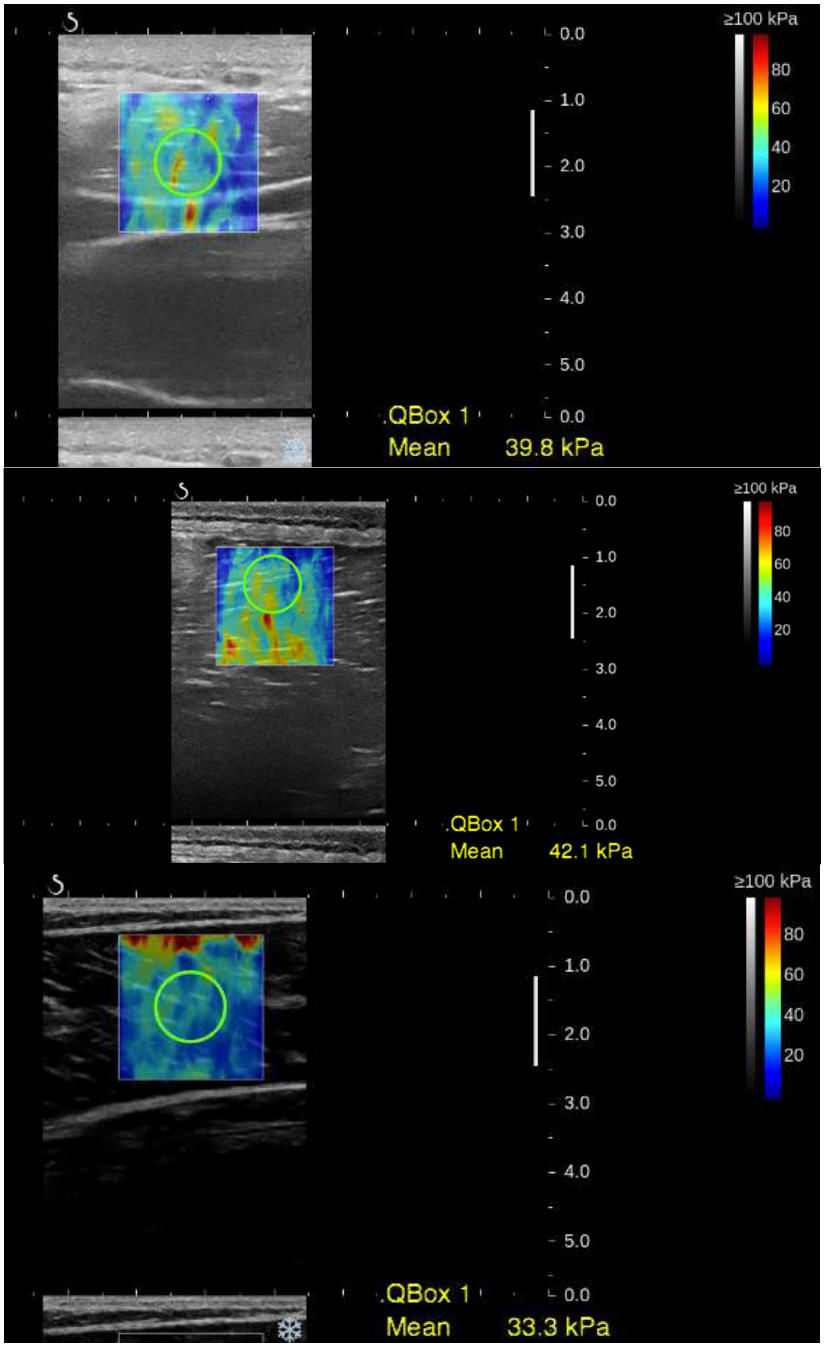


Figure 3.4: Example SWE measurement image of 40% MVIC in the infraspinatus, erector spinae, and gastrocnemius.

DATA ANALYSIS

Statistical analyses were performed using SPSS 22.0 software (IBM SPSS Inc, Armonk, NY). Multiple one way repeated measures analysis of variance (ANOVA) with Bonferroni post hoc was conducted to evaluate for differences in muscle stiffness between the three levels of muscle contraction (rest, 40% MVIC, and 80% MVIC) for each measurement tool (MyotonPRO® and SWE) and for each muscle (infraspinatus, erector spinae, and gastrocnemius). Pearson's product-moment correlation was conducted to assess the relationship between stiffness measured by the MyotonPRO® and SWE (ROI 5mm and 10mm) in three muscles during rest, 40%MVIC, and 80% MVIC. Intra-rater reliability was calculated using a two way mixed model, intraclass correlation coefficient single measure and a mean of 3 measures. The reliability for a single measurement was estimated using the first two measurement variables and the "single measures" output from SPSS (model 3,1).[102] The reliability when using a mean of 3 measurements was estimated using the first 3 measurement variables and the "average measures" output from SPSS (model 3,3).[102] Statistical significance was set a priori for all analyses at $p < .05$. The following guideline was used to determine the strength of the ICC: <0.25 no correlation; 0.25-0.5 fair; 0.5-0.75 moderate to good; and >0.75 good to excellent correlation.[103]

PHASE TWO: RESEARCH DESIGN

This second phase was a case series multi group design with repeated measures. The purpose of phase two was to investigate the immediate and short-term (24hrs) biomechanical effect of dry needling a latent myofascial trigger point in the infraspinatus, erector spinae, or gastrocnemius of healthy subjects. A sample size of 60 (20 per group) was based off reported latent trigger point prevalence in a healthy population.[101] 60 healthy individuals between the ages of 18 and 65, without musculoskeletal complaints, and who have palpable, latent MTrPs were recruited via word of mouth from Bradley University and assigned to a group. The 3 groups were formed by the location of the MTrP: shoulder (infraspinatus), calf (gastrocnemius), or low back (erector spinae). Subjects with MTrPs in more than one of the three muscles were only assigned to one group. Participants were excluded if they have any precautions to TDN treatment (anticoagulant medications, bleeding disorders, known pregnancy) or have signs or symptoms requiring medical referral. Primary study variable was biomechanical stiffness. Stiffness was measured using the MyotonPRO® instrumentation. Baseline measurements were taken followed by TDN to the latent MTrPs. Follow up stiffness measurements were collected immediately after TDN and again at 24 hours post TDN intervention.

INCLUSION AND EXCLUSION CRITERIA

Subjects must meet all the following criteria. The inclusion criteria for study participant eligibility in this study includes:

a. Age 18 to 65 years
b. Body mass index of 30 or less
c. Reported good general health

The following exclusion criteria for study participant ineligibility in this study includes:

a. Infectious disease (e.g. HIV, Hepatitis B, Hepatitis C)
b. Active systemic disease (e.g. cancer, diabetes, peripheral vascular disease, rheumatoid arthritis, lupus erythema, lymphedema, fibromyalgia, epilepsy)
c. Any surgery in the last 12 months
d. Local infection, wound, or compromised immune system
e. Neurologic condition (e.g. impaired or decreased sensation or pain perception)
f. Current lower limb musculoskeletal injury
g. Lumbar radiculopathy or current low back pain
h. Trigger point injection, dry needling, or acupuncture in the past 6 months
i. Medications that affect muscle function including: nonsteroidal anti-inflammatories; statins; anti-coagulants; and muscle relaxers
j. Pregnancy
k. Needle phobia
l. Unable or unwilling to provide consent

CONSENT PROCESS

Subjects were enrolled in the study once informed consent was provided. The study PI conducted the consent process in the presence of a witness with the subject utilizing the approved informed consent in a private setting. The investigator informed the subject that the study involved research and explained the purpose and procedures entailed in this study. Furthermore, the subjects were informed of the approximate amount of subjects involved in the study. In addition, any foreseeable risks, discomforts, and benefits were explained. The voluntary nature of the participation was stressed. Study personnel reminded subjects, throughout their participation, that they might elect to withdraw from the study at any time. Subjects who were students of the university were assured that a decision not to participate has no effect on their academic status; yet, if the subject chooses to participate he/she was informed that all records identifying the subject are maintained confidentially by the PI in a password protected electronic file and all hard copies are maintained in a locked file cabinet that only the PI has access to. Subjects electing to withdraw from the study did not participate in any data collection or other procedures associated with this study. The investigative team may terminate a subject's participation in the study at any time he/she feels this to be in the subject's best interest (i.e., safety, health, etc). Moreover, subjects were provided with the appropriate contact information of whom to speak to about their rights and whom to speak with should the subject have any questions.

Subjects were given ample time to ask questions, read and understand the consent form and take it home (if he/she chooses) so the research can be discussed with friends and family prior to participation. Upon completion of the informed consent process and after all

concerns were addressed the subject, the individual obtaining consent signed the approved IRB consent forms. A copy of the signed documents was offered to the subject, and the original signed document was placed in the subject's study record. The informed consent process occurred and all parties prior to any/all study related procedures signed the informed consent document.

SUBJECT SCREENING PROCEDURE

Participants satisfying all inclusion and exclusion criteria were enrolled in the study. After providing informed consent, volunteers received a short screening examination. The screening examination will consist of answering questions regarding their medical history and current symptoms and a brief physical examination. Anthropometric data (height, weight, BMI) was collected via clinical measurement. The focused physical examination consisted of the following:

1. Visual inspection
2. Functional active range of motion of the shoulder (reaching hand behind head and reaching hand behind back), and lower quarter (squat, toe/heel walk).
3. Active range of spinal range of motion in standing: flexion, extension, side bending. Lumbar spine clearing maneuvers (quadrant test and posterior to anterior pressure to the spine).
4. Resisted shoulder, low back, and calf isometric manual muscle test.

DATA COLLECTION PROCEDURE

After a standardized screening history and physical examination, MyotonPRO® measurement assessments were made of the latent MTrP while in a resting prone position. Identification of the latent MtrP will be located in the gastrocnemius, infraspinatus, and erector spinae of the lumbar spine. All needling treatment was performed with FDA approved (FDA regulation # 880.5580) disposable 0.30 x 50-60 mm stainless steel Seirin J-type needles (Seirin, Japan). Needles were stored in the original sterile packaging from the manufacturer until immediately before use. To assist in the reduction of infection risk and protection of the participants, the site was cleaned with alcohol prior to treatment and PI performing the needling treatment wore gloves and handled needles using aseptic techniques. Each needle insertion used a "pistoning" or "sparrow pecking" technique. Once inserted through the skin and into the muscle to a depth of less than 3 centimeters, the pistoning technique was used for 1 minute. Any incident of a localized twitch response was recorded. MyotonPRO® measurements were collected to evaluate the immediate and short-term effects of TDN treatment on the biomechanical stiffness, immediately after treatment, and again at 24 hours.

DATA ANALYSIS

Statistical analysis was performed using SPSS 22.0 software (IBM SPSS Inc, Armonk, NY). Descriptive statistics was performed to describe the sociodemographic and health characteristics of the entire sample. Means, standard deviations, mean differences, and 95% confidence intervals were computed for continuous data. One way repeated measures analysis of variance (ANOVA) with Bonferroni post hoc was conducted to evaluate for difference in muscle stiffness pre and post TDN (immediately and 24 hours). The analysis was repeated in a subgroup of individuals that demonstrated a localized twitch response during TDN.

FUNDING FOR THE STUDY

This work was funded by the Army Medical Department Advanced Technology Initiative (AAMTI), through the Telemedicine and Advanced Technology Research Center (TATRC). This work was supported by the Telemedicine and Advanced Technology Research Center (TATRC) at the US Army Medical Research and Materiel Command.

SUMMARY

In this chapter, the methodology for the research proposal was detailed. TDN clinical effectiveness and the role of biomechanical stiffness measurement are yet to be elucidated. The project entailed two separate phases to answer the following research questions: What is the concurrent validity of the MyotonPRO® as compared to the criterion of SWE in the measurement of biomechanical stiffness in the infraspinatus,

erector spinae, or gastrocnemius of healthy subjects over increasing muscle contraction? What is the reliability of the MyotonPRO® measurement? What is the biomechanical response of a latent MTrP to TDN in the infraspinatus, erector spinae, or gastrocnemius measured using the MyotonPRO®?

CHAPTER 4: RESULTS

INTRODUCTION

This chapter will discuss the results for investigating the reliability and validity of biomechanical measurement using shear wave elastography (SWE) and the MyotonPRO®. We will then discuss the results of trigger point dry needling (TDN) latent myofascial trigger points (MTrPs) and the effects it has on measured stiffness using the MyotonPRO®. Descriptive statistics, including measures of central tendency (means) and dispersion (95% confidence interval (CI)) for continuous variables were calculated to summarize the data. There were no dropouts by subjects participating in the study.

SPECIFIC AIM 1

The first specific aim was to investigate the reliability and concurrent validity of the MyotonPRO® to the criterion of SWE over increasing muscular contractions. We hypothesized that the biomechanical measurement across increasing muscle contractions would demonstrate a trend of increasing stiffness. The 2 measurement devices would demonstrate a positive correlation.

ANALYSIS SPECIFIC AIM 1

A sample of 30 subjects (13 female, 17 male) was enrolled in the study. Data presented are mean (standard deviation). The mean age was 28 (5.76) with a mean height of 1.74 (0.10) meters and mean mass of 78.69 (14.77) kilograms. The sample's mean body mass index (BMI) was 25.67 (2.38). Table 4.1 summarizes this demographic data.

Table 4.1 Demographic Data (n=30)

Characteristic	Value
Age (years)	27.87 (5.76)
Height (m)	1.74 (0.10)
Mass (kg)	78.69 (14.77)
BMI (kg/m^2)	25.67 (2.38)
Sex (n)	
Female	13
Male	17

Values represent mean (standard deviation) unless otherwise indicated.
BMI: Body Mass Index

Stiffness was measured across three levels of muscle contraction using both the shear wave ultrasound and the MyotonPRO® in all subjects. Shear wave ultrasound measurements were further separated into two different sized regions of interest (ROI), 5mm and 10mm. Results of the statistical tests follow below.

The three levels of muscle contraction elicited statistically significant changes in stiffness as measured by the MyotonPRO® (N/m) in all three muscles (Table 4.2). The MyotonPRO® demonstrated a low coefficient of variation for resting conditions (2-3%). The MyotonPRO® coefficient of variation increased during active muscle contraction but still remained low, ranging from 4-9%. Infraspinatus contraction was statistically significantly different at the different time points during rest, 40%, and 80% contraction intensities, $F(2,58) = 58.34$, $p < .001$. Erector spinae contraction was statistically

significantly different at the different time points during rest, 40%, and 80% contraction intensities, $F(2,58) = 20.00$, $p < .001$. Gastrocnemius contraction was statistically significantly different at the different time points during rest, 40%, and 80% contraction intensities, $F(2,58) = 48.65$, $p < .001$.

MyotonPRO® data presented below are mean (95% CI) followed by the mean difference (95% CI) (Table 4.2). MyotonPRO® infraspinatus stiffness (N/m) increased from 265.8 (248.9, 282.6) at rest to 490.7 (416.6, 564.9) at 40% MVIC, a statistically significant increase of 225.0 (141.8, 308.2), $p < .001$. The measured stiffness increased from 490.7 (416.6, 564.9) at 40% MVIC to 576.5 (491.6, 661.4) at 80% MVIC, a statistically significant increase of 85.78 (53.21, 118.33), $p < .001$.

MyotonPRO® erector spinae stiffness increased from 289.4 (259.3, 319.5) at rest to 418.1 (332.9, 503.3) at 40% MVIC, a statistically significant increase of 128.7 (53.9, 203.6), $p < .001$. The measured stiffness of 418.1 (332.9, 503.3) at 40% MVIC increased to 469.3 (367.7, 503.3) at 80% MVIC, a statistically significant increase of 51.2 (5.3, 97.0), $p = .025$.

Gastrocnemius resting stiffness increased from 326.2 (299.3, 353.0) to 588.9 (491.7, 686.2) at 40% MVIC, a statistically significant increase of 262.8 (154.4, 371.1), $p < .001$. The measured stiffness of 588.9 (491.7, 686.2) at 40% MVIC increased to 658.0 (558.5, 757.6) at 80% MVC, a statistically significant difference of 69.1 (37.8, 100.4), $p < .001$.

Table 4.2 MyotonPRO® muscle stiffness values stratified by contractile condition.

Contraction condition	Mean (95% CI)	CV%	Mean Difference (95%CI)
Infraspinatus resting	265.8 (248.9, 282.6)	3%	
Infraspinatus 40% MVIC	490.7 (416.6, 564.9)*	9%	225.0 (141.8, 308.2)
Infraspinatus 80% MVIC	576.5 (491.6, 661.4)*	8%	85.8 (53.2, 118.3)
Erector spinae resting	289.4 (259.3, 319.5)	3%	
Erector spinae 40% MVIC	418.1 (332.9, 503.3)*	6%	128.7 (53.9, 203.6)
Erector spinae 80% MVIC	469.3 (367.7, 503.3)*	6%	51.2 (5.3, 97.0)
Gastrocnemius resting	326.2 (299.3, 353.0)	2%	
Gastrocnemius 40% MVIC	588.9 (491.7, 686.2)*	5%	262.8 (154.4, 371.1)
Gastrocnemius 80% MVIC	658.0 (558.5, 757.6)*	4%	69.1 (37.8, 100.4)

*$p < 0.05$ significant difference between all measured contraction conditions

The SWE measurement for 5mm and 10mm demonstrated the same coefficient of variation. This coefficient of variation was ranged between 7 and 30%. The resting measure demonstrated a similar trend for being lower than the active measurement. Overall, the variation was greater than observed in the MyotonPRO®.

The shear elastic modulus, as measured by shear wave elastography, was statistically different for gastrocnemius 5mm ROI (Table 4.3) across the three contraction conditions, $F(2,58) = 61.18$, $p < .001$. There were no significant differences between contraction conditions for the infraspinatus or the erector spinae using the 5mm ROI. The SWE shear elastic modulus using 10mm ROI was statistically significant for 40% and 80% MVIC, as compared to the resting condition in the erector spinae muscle $F(2,58) = 18.64$, $p < .001$. There was no significant difference between the 40% and 80% MVIC. There were no differences between contraction conditions for the gastrocnemius and infraspinatus (Table 4.3).

The 5mm ROI gastrocnemius resting stiffness (kPA) group mean (95% CI) was 23.5 (19.9, 27.2), 40% MVIC was 66.0 (54.9, 77.1), and 80% MVIC was 86.8 (73.0, 100.6). The mean difference between gastrocnemius rest to 40% was 42.5 (28.6, 56.3), *P*<.001. The mean difference between gastrocnemius 40% and 80% was 20.8 (7.4, 34.2), *P*<.001. The mean difference between gastrocnemius rest and 80% was 63.3 (46.3, 80.2), *P*<.001.

Table 4.4, 10mm ROI erector spinae muscle resting stiffness (kPA) group mean (95% CI) was 16.5 (14.1, 18.9), 40% MVIC was 25.9 (21.0, 30.7), and 80% MVIC was 29.7 (24.4, 35.0). The mean difference between erector spinae rest to 40% was 9.4 (3.6, 15.1), *P*=.001. The mean difference between erector spinae rest and 80% was 13.2 (7.0, 19.4), *P*<.001.

Table 4.3 Shear wave elastography muscle stiffness (kPA) values stratified by contractile condition. 5mm Region of interest.

Contraction condition	Mean (95%CI)	CV%	Mean Difference (95%CI)
Infraspinatus resting	23.9 (18.8, 29.0)	19%	
Infraspinatus 40% MVIC	29.4 (24.7, 34.2)	20%	5.6 (-0.4, 11.5)
Infraspinatus 80% MVIC	27.1 (23.6, 30.6)	22%	2.3 (-2.4, 7.0)
Erector spinae resting	23.5 (18.2, 28.7)	16%	
Erector spinae 40% MVIC	29.8 (23.5, 36.0)	30%	6.4 (-2.3,15.1)
Erector spinae 80% MVIC	28.8 (23.1, 34.5)	31%	-1.0 (-6.7, 4.7)
Gastrocnemius resting	23.5 (19.9, 27.1)	7%	
Gastrocnemius 40% MVIC	66.0 (54.9, 77.1)*	22%	42.46 (28.58, 56.34)
Gastrocnemius 80% MVIC	86.8 (73.0, 100.6)*	20%	20.81 (7.42, 34.21)

*$p < 0.05$ significant difference between all measured contraction conditions

Table 4.4 Shear wave elastography muscle stiffness (kPA) values stratified by contractile condition. 10mm Region of interest.

Contraction condition	Mean (95%CI)	CV%	Mean Difference (95%CI)
Infraspinatus resting	27.7 (23.7, 31.7)	19%	
Infraspinatus 40% MVIC	29.8 (25.5, 34.1)	20%	2.0 (-3.1, 7.1)
Infraspinatus 80% MVIC	29.1 (26.2, 31.9)	22%	-0.7 (-4.4, 3.0)
Erector spinae resting	16.5 (14.1, 18.9)	16%	
Erector spinae 40% MVIC	25.9 (21.0, 30.7)**	30%	9.4 (3.6, 15.1)
Erector spinae 80% MVIC	29.7 (24.4, 35.0)**	31%	3.9 (-1.0, 8.8)
Gastrocnemius resting	18.2 (15.5, 21.0)	7%	
Gastrocnemius 40% MVIC	55.6 (46.7, 64.6)*	22%	37.4 (25.6, 49.2)
Gastrocnemius 80% MVIC	79.6 (68.3, 91.0)*	20%	24.0 (12.9, 35.1)

*$p < 0.05$ significant difference between all measured contraction conditions
**$p < 0.05$ significant difference between measured resting contraction intensity only

The following guideline was used to determine the strength of the ICC: <0.25 no correlation; 0.25-0.5 fair; 0.5-0.75 moderate to good; and >0.75 good to excellent correlation.[103] Intrarater reliability estimates were excellent (ICC > 0.93) for all MyotonPRO® measures for both single measures and based on an average of 3 measures (Table 4.5). Intrarater reliability estimates for the SWE measures were lower when using a single measure and improved based on a mean of 3 measurements (ICC = 0.56 to 0.98) in each muscle across all contraction conditions (Table 4.5).

Table 4.5 Intrarater Reliability

Number of Measurements	MyotonPRO®	Shear Wave Elastography	
	$ICC_{3,k}$ (95% CI)	5mm ROI $ICC_{3,k}$ (95% CI)	10mm ROI $ICC_{3,k}$ (95% CI)
Infraspinatus resting			
Single	0.95 (0.90, 0.97)	0.79 (0.65, 0.88)	0.74 (0.58, 0.85)
Mean of 3	0.98 (0.97, 0.99)	0.92 (0.85, 0.96)	0.89 (0.80, 0.95)
Infraspinatus 40% MVIC			
Single	0.93 (0.88, 0.97)	0.67 (0.48, 0.81)	0.74 (0.58, 0.86)
Mean of 3	0.98 (0.96, 0.99)	0.86 (0.74, 0.93)	0.90 (0.81, 0.95)
Infraspinatus 80% MVIC			
Single	0.93 (0.88, 0.97)	0.30 (0.07, 0.53)	0.46 (0.23, 0.66)
Mean of 3	0.98 (0.96, 0.99)	0.56 (0.19, 0.78)	0.72 (0.48, 0.86)
Erector spinae resting			
Single	0.99 (0.97, 0.99)	0.80 (0.66, 0.89)	0.71 (0.54, 0.84)
Mean of 3	1.0 (0.99, 1.0)	0.92 (0.85, 0.96)	0.88 (0.78, 0.94)
Erector spinae 40% MVIC			
Single	0.97 (0.94, 0.98)	0.57 (0.36, 0.74)	0.56 (0.35, 0.74)
Mean of 3	0.99 (0.98, 0.99)	0.80 (0.63, 0.90)	0.79 (0.62, 0.89)
Erector spinae 80% MVIC			
Single	0.99 (0.98, 0.99)	0.60 (0.40, 0.76)	0.55 (0.34, 0.73)
Mean of 3	1.0 (0.99, 1.0)	0.81 (0.66, 0.91)	0.78 (0.60, 0.89)
Gastrocnemius resting			
Single	0.99 (0.98, 1.0)	0.91 (0.85, 0.96)	0.95 (0.91, 0.97)
Mean of 3	1.0 (0.99, 1.0)	0.97 (0.95, 0.99)	0.98 (0.97, 0.99)
Gastrocnemius 40% MVIC			
Single	0.97 (0.95, 0.99)	0.72 (0.56, 0.84)	0.83 (0.72, 0.91)
Mean of 3	0.99 (0.98, 1.0)	0.89 (0.80, 0.94)	0.94 (0.87, 0.97)
Gastrocnemius 80% MVIC			
Single	0.98 (0.97, 0.99)	0.69 (0.51, 0.82)	0.69 (0.52, 0.82)
Mean of 3	0.99 (0.99, 1.0)	0.87 (0.76, 0.93)	0.87 (0.76, 0.93)

MVIC: Maximum voluntary isometric contraction. ROI: Region of interest

Scatter plots were created comparing the measurement techniques across each muscle showed a positive correlation between MyotonPRO® and SWE (Figure 4.1-4.6). Pearson's correlation coefficient was conducted to determine the magnitude of the correlation between both measures. The following guideline was used to determine the strength of the association.[138] A small correlation ranges 0.1 to 0.3. A moderate correlation ranges between 0.3 and 0.5. A strong correlation is greater than 0.5. The correlation between measures was strong for gastrocnemius (r=0.71). (Table 4.6)

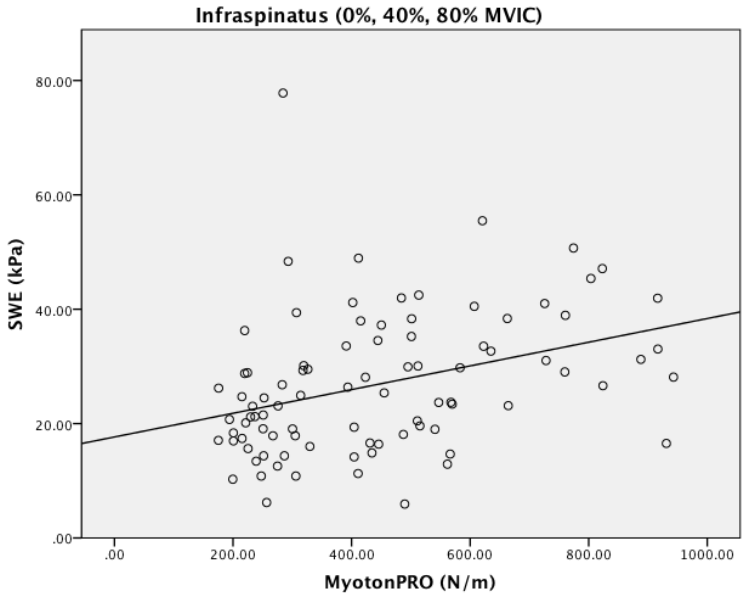


Figure 4.1: Scatter plot of SWE ROI 5mm and MyotonPRO® measurement across 0%, 40%, and 80% MVIC in the infraspinatus.

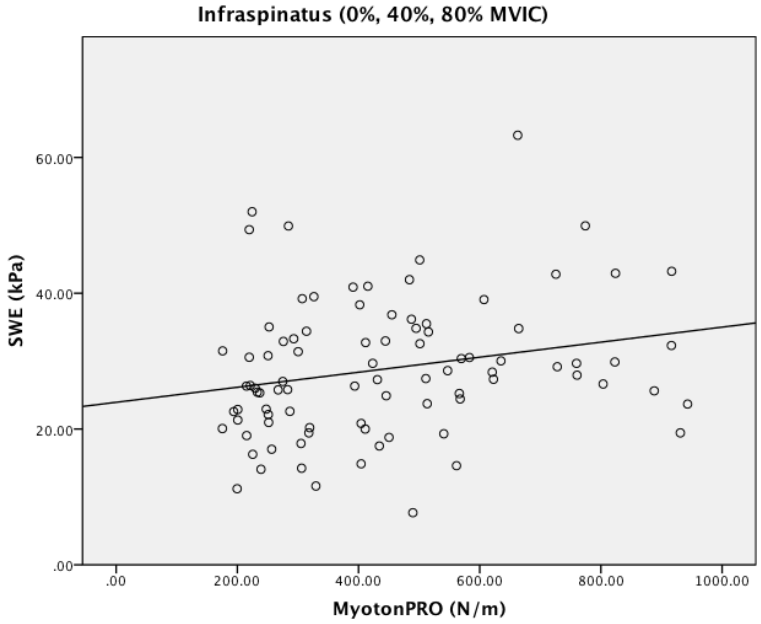


Figure 4.2: Scatter plot of SWE ROI 10mm and MyotonPRO® measurement across 0%, 40%, and 80% MVIC in the infraspinatus.

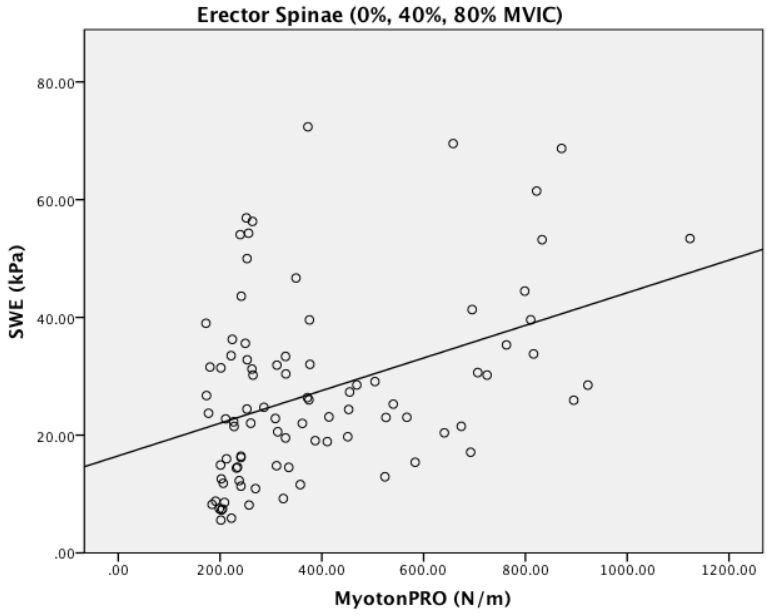


Figure 4.3: Scatter plot of SWE ROI 5mm and MyotonPRO® measurement across 0%, 40%, and 80% MVIC in the erector spinae.

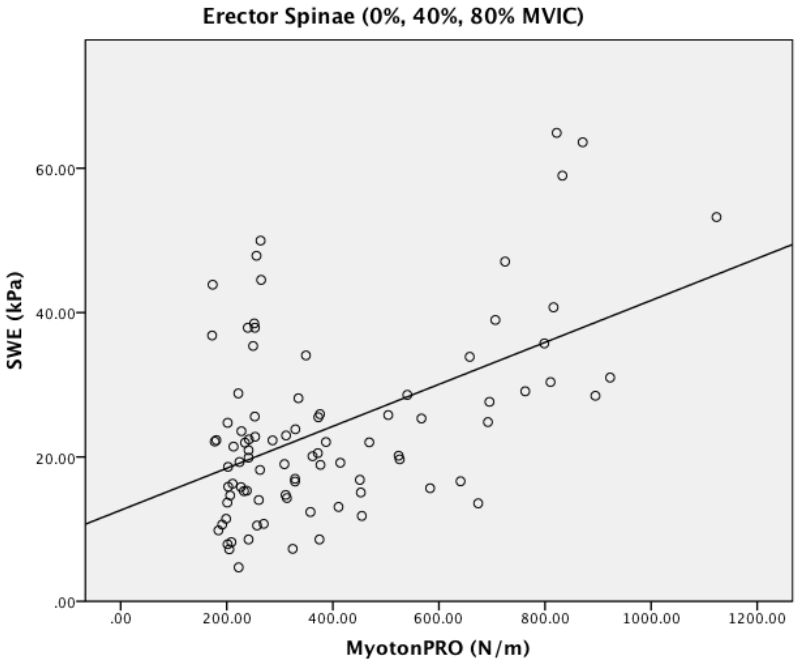


Figure 4.4: Scatter plot of SWE ROI 10mm and MyotonPRO® measurement across 0%, 40%, and 80% MVIC in the erector spinae.

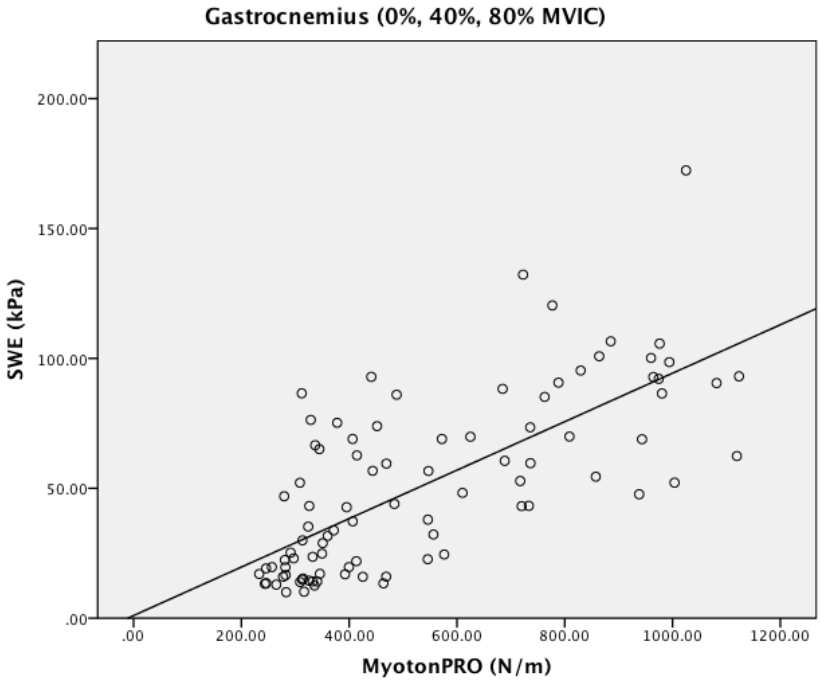


Figure 4.5: Scatter plot of SWE ROI 10mm and MyotonPRO® measurement across 0%, 40%, and 80% MVIC in the gastrocnemius.

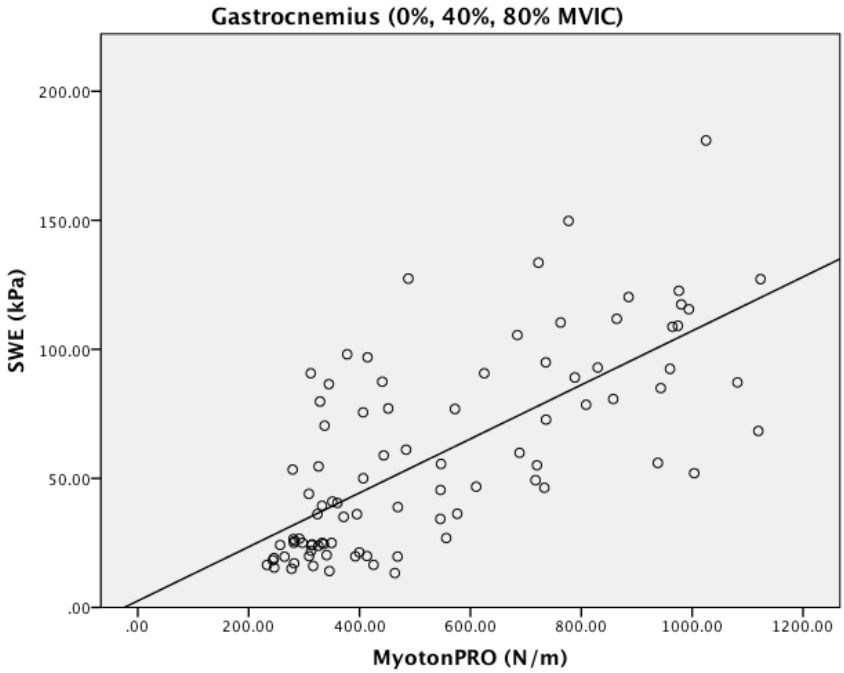


Figure 4.6: Scatter plot of SWE ROI 5mm and MyotonPRO® measurement across 0%, 40%, and 80% MVIC in the gastrocnemius.

Table 4.6: Pearson's correlation coefficient between MyotonPRO® and Shear Wave Elastography SWE	ROI 5mm	ROI 10mm
Muscle (0%, 40%, 80% MVIC)		
Infraspinatus	0.35*	0.23*
Erector spinae	0.40*	0.51*
Gastrocnemius	0.71*	0.71*

*Correlation is significant $p < 0.05$
MVIC: Maximum voluntary isometric contraction.

SPECIFIC AIM 2

The second specific aim of this study was to investigate the biomechanical effects of MTrPs to TDN intervention using the MyotonPRO®. We hypothesized that an immediate decrease in MTrP stiffness would occur following TDN.

ANALYSIS SPECIFIC AIM 2

The second phase of this study investigated the change in stiffness following trigger point dry needling (TDN) in a latent myofascial trigger point (MTrP) in one of three muscles (infraspinatus, erector spinae, and gastrocnemius). A sample of 60 subjects (31 female, 29 male) was enrolled in the study. Subjects were assigned in groups of 20 based on the location of the MTrP (infraspinatus, erector spinae, gastrocnemius).

Data presented are mean (standard deviation). The mean age for the sample was 23 (2.99) years with a mean height of 1.74 (0.09) meters and mean mass of 74.02 (13.63) kilograms. The sample's mean body mass index (BMI) was 24.17 (2.90). Table 4.7 summarizes this demographic data.

Table 4.7 Demographic Data

Characteristic	Value
Age (years)	23 (2.99)
Height (m)	1.74 (0.09)
Mass (kg)	74.02 (13.63)
BMI (kg/m^2)	24.17 (2.90)
Sex (n)	
Female	31
Male	29

Values represent mean (standard deviation) unless otherwise indicated.
BMI: Body Mass Index

Muscle stiffness mean measurement decreased immediately after TDN in all the groups (Table 4.8). The gastrocnemius MTrP group significantly decreased immediately after TDN, $F(2,38) = 12.62$, $p < 0.001$. The infraspinatus and erector spinae stiffness decrease was not statistically significant. All groups demonstrated a mean increase in stiffness 24 hours post TDN compared to baseline. The stiffness increase at 24 hours was not statistically significant.

Table 4.8 Muscle stiffness values before and after dry needling.

	MyotonPRO® (N/m)	
Infraspinatus	Mean (95% CI)	Mean Difference (95% CI)
Pre	291.1 (264.5, 317.7)	
Post	279.8 (251.7, 307.8)	-11.4 (-26.7, 4.0)
24 hour	302.6 (275.2, 330.0)	11.5 (-1.1, 24.1)
Erector Spinae		
Pre	225.9 (187.9, 263.8)	
Post	220.5 (177.01, 263.9)	-5.4 (-27.6, 16.8)
24 hour	237.5 (196.62, 278.4)	11.7 (-15.8, 39.1)
Gastrocnemius		
Pre	329.0 (284.3, 373.6)	
Post	296.8 (263.8, 398.1)*	-32.2 (-51.2, -13.2)
24 hour	353.6 (309.1, 398.1)	24.7 (-11.2, 60.5)

*p < 0.05 significant difference

A one-way ANOVA was repeated in the subgroup of individuals that demonstrated a localized twitch response (LTR) in the infraspinatus, erector spinae, and gastrocnemius (Table 4.9). A total of 30 subjects from the sample of 60 experienced an LTR broken up into the following groups: infraspinatus 8; erector spinae 7; and gastrocnemius 15. The LTR subgroup of subjects demonstrated a decrease in mean stiffness immediately after TDN. The erector spinae group change in stiffness was significant, $F(2,7) = 5.88$, $p=0.017$. The gastrocnemius group change in stiffness was significant, $F(2,13) = 11.71$, $p<0.001$. The decrease in stiffness was absent in all groups after 24 hours with measurements returning to near baseline values.

Table 4.9 Muscle stiffness values before and after dry needling in subjects with a localized twitch response.

	MyotonPRO® (N/m)	
Infraspinatus (n=8)	Mean (95% CI)	Mean Difference (95% CI)
Pre	276.6 (228.4, 324.9)	
Post	256.9 (203.7, 310.1)	-19.8 (-50.2, 10.7)
24 hour	284.6 (235.3, 334.0)	8.0 (-19.9, 35.9)
Erector Spinae (n=7)		
Pre	223.3 (172.0, 274.6)	
Post	189.3 (141.9, 236.7)*	-34.0 (-67.1, -0.9)
24 hour	227.1 (161.4, 293.0)	3.9 (-43.8, 51.5)
Gastrocnemius (n=15)		
Pre	353.1 (300.5, 405.8)	
Post	310.9 (272.0, 349.9)*	-42.2 (-63.8, -20.6)
24 hour	376.6 (324.6, 428.6)	23.5 (-23.5, 70.4)

*$p < 0.05$ significant difference

SUMMARY

The results of this study supported the hypothesis for both specific aim 1 and specific aim 2. The MyotonPRO® and SWE demonstrated a positive relationship across the chosen contraction conditions, ROI 5mm (0.35-0.71) and 10mm (0.23-0.71). The MyotonPRO® demonstrated the ability to discriminate stiffness between different muscle contraction intensities. Lastly, the MyotonPRO® in both the erector spinae and gastrocnemius group measured a significant immediate decrease in stiffness when a LTR was observed during TDN of the latent MTrP.

CHAPTER 5: DISCUSSION

INTRODUCTION

A study was conducted using two phases to investigate the biomechanical response of TDN to a latent myofascial trigger point (MTrP) in the infraspinatus, erector spinae, or gastrocnemius measured using the MyotonPRO®. The first phase investigated the reliability and concurrent validity of MyotonPRO® during three different conditions of muscle contraction. The first phase was completed using healthy subjects performing resting and isometric contraction at 40% and 80% of their maximum voluntary contraction (MVIC). The second phase was conducted on a different sample of healthy subjects with a latent MTrP. Biomechanical stiffness was measured pre and post trigger point dry needling (TDN) in either the gastrocnemius, erector spinae, or infraspinatus. The focus of this chapter will be on interpreting the findings of the study and relating it to existing literature. We will discuss the specific aims and describe the impact of the results on clinical practice. Future research will be proposed and limitations of this investigation will be discussed. A summary of the entire project will conclude this chapter.

DISCUSSION: SPECIFIC AIM 1

The quantitative measurement of muscle stiffness in the clinic is a new approach to objectifying one aspect of the biomechanical state of the muscle. The purpose of this phase of the study was to investigate the concurrent validity and reliability of the MyotonPRO® as compared to the criterion of shear wave elastography (SWE) in the

measurement of biomechanical stiffness in the infraspinatus, erector spinae, and gastrocnemius of healthy subjects over increasing muscle contraction.

Stiffness measurement provides enhanced understanding of the musculoskeletal impairments at the tissue level, and baseline measures to possibly track rehabilitation treatment effectiveness in the short and long term. The results from this study suggest both measurement techniques are reliable for use in the clinic. Specifically, the single and average of 3 measures demonstrated excellent reliability for MyotonPRO®. Using one MyotonPRO® measurement or an average of 3 measures in the clinical setting will provide equitable measurement reliability leaving the decision up to the clinician as to which approach to use. A single SWE measurement intraclass correlation coefficient (ICC) model 3,1 demonstrated lower reliability (ICCs 0.30-0.95). A mean of 3 SWE measurements (ICC 3,3) improved reliability over the single measures approach in every case (ICC 0.56-0.98). However, the reliability of a mean of 3 for the infraspinatus 80% MVIC measurement was ICC=0.56 which is under the very minimum of acceptable at 0.70.[104] Preference should be given to the mean of 3 measures, as the total time invested to capture additional measures is small. This supports previous recommendation for an average of three ultrasound measures given the relatively small amount of time required to capture additional measurements.[102]

This study provides support for the MyotonPRO® to detect different states of muscle contraction, which were theorized to reflect varying conditions of stiffness. Increases in mean muscle stiffness with greater muscle contraction intensities were hypothesized. Previous studies found muscle stiffness to be linearly related to muscle force during isometric contraction.[30,105-107] The MyotonPRO® demonstrated the ability to

discriminate between different muscle contraction intensities. Observable increases in stiffness occurred between resting, 40% MVIC, and 80% MVIC conditions in the three chosen muscles. The magnitude of the mean differences was greater between resting and contraction (40% or 80% MVIC) than between the active contractions themselves. The certainty of this discriminative ability can be reflected in the low coefficient of variation for the MyotonPRO® due to a smaller dispersion of measured values.

Discriminate validity was not consistently demonstrated with the SWE measurements. Only the 5mm ROI gastrocnemius and 10mm ROI erector spinae were statistically significant across contraction conditions. While overall mean values for stiffness increased between resting and contraction for each muscle tested, they were not consistently different. The SWE at 5mm ROI demonstrated greater coefficient of variation percentages. Observable plateau of SWE stiffness between 40% and 80% MVIC was present in the infraspinatus and erector spinae. This may indicate that muscle stiffness changes at these levels cannot be detected with the SWE for some muscles. Alternatively, other surrounding muscles may have been recruited with higher contraction levels. Skeletal muscle rarely contracts in isolation from the surrounding musculature. Rather groups of muscles share the contraction based on the load required to complete the movement pattern.[108] Load sharing during isometric contraction was demonstrated with elbow flexion resulting in measureable SWE stiffness plateauing in brachialis compared to biceps brachii.[108] This load sharing could explain the plateau of stiffness values with SWE. This observed plateau was not observed in the MyotonPRO measurements and may be unique to the SWE technique. Discreet measurement of a

section of muscle using SWE may be very different than the surface measurement of MyotonPRO®.

Certainty of the mean value for SWE measurement may be questioned due to the relatively high coefficient of variation. Use of SWE during dynamic conditions of muscle contraction may result in a measurement that is less precise. Controlling for SWE measurement location with respect to depth is unrealistic as the muscle fibers and tissue alter position during contraction while the transducer remains static on the skin. MyotonPRO® may be less susceptible to this as a superficial measurement.

Few recommendations exist to standardize SWE technical settings. Kot et al suggested utilizing a mean value of elastic modulus as the ROI size does not influence the measurement.[111] This was not observed in our study as 5mm and 10mm ROI mean values significantly differed for six out of the nine contraction conditions. The MyotonPRO® and SWE demonstrated a positive relationship across the chosen contraction conditions, ROI 5mm (0.35-0.71) and 10mm (0.23-0.71). This is encouraging evidence for the clinical use of MyotonPRO® in substitution of SWE. One previous study reported an inability to significantly correlate the SWE to a mechanical stiffness meter in resting neck musculature.[112] However the mechanical device used in this prior study does not operate using the principle of Young's modulus.[114] The MyotonPRO® and SWE both operate using the principle of Young's modulus to estimate a measure of stiffness, but a cautious recommendation is warranted because the values of Young's modulus may depend heavily on the methods by which it is obtained.[115] The MyotonPRO® relies on indentation of the tissue which may be localized to superficial

structures.[115] Thus the interpretation of superficial muscle stiffness may be unrelated to a smaller and deeper measurement provided by SWE.

In summary, dynamic muscular conditions create challenges to measurement of stiffness but could serve as a relevant biomarker for health monitoring.[117,118,139] MyotonPRO® may represent a reliable and valid approach to clinical measurement regionally across muscle contraction conditions due to the superficial technique but may not be as specific to localized tissue at depth with SWE.

DISCUSSION: SPECIFIC AIM 2

Previous research has not fully explained the underlying therapeutic mechanism of TDN for MTrPs. Spontaneous electrical activity has been reported in the location of latent MTrPs.[58] The hyper-excitability of the motor end plate in latent MTrPs may contribute to localized sustained contraction of muscle fibers and subsequent muscle cramping, pain and tenderness.[140] TDN treatment has been shown to decrease pain, increase pressure pain threshold, improve range of motion, and decrease muscle tone.[109,141-143] There is likely both mechanical and neurophysiologic effects occurring with TDN treatment but these effects may be limited to immediate and short term changes.[144] Therefore the purpose of this study was to investigate the biomechanical effect of TDN to a latent MTrP in the infraspinatus, erector spinae, or gastrocnemius measured using the MyotonPRO®.

The quantification of MTrPs biomechanical stiffness and the immediate change following TDN has been reported using a SWE.[35] Maher et al reported the stiffness of a MTrP in the upper trapezius decreased 29.5% immediately following TDN in a sample of

seven subjects.[35] In the present study, a significant immediate decrease in stiffness was measured in both the erector spinae and the gastrocnemius when a localized twitch response (LTR) was observed. The erector spinae stiffness decreased 15% and the gastrocnemius stiffness decreased 11% from measured baseline. This change was followed by a measured return to near baseline at 24 hours post needling. The Maher et al study did not report 24 hour results. TDN in symptomatic subjects with active MTrPs may result in different stiffness measurements over the course of 24 hours.

Decreased motor end plate activity and improved physiologic conditions may affect the measured stiffness of the latent MTrP. Significant reduction of spontaneous electrical activity within the MTrP region following TDN has been reported.[131,132] All groups demonstrated a trend of decreased stiffness but this was only significant in the gastrocnemius group with the largest mean difference of -32.2 N/m. A decrease in local muscle stiffness while at rest indicates a physiologic dampening of the latent MTrP. The exact duration of decreased stiffness is unknown, however, it does not appear to last greater than 24 hours. The immediate but temporary effects of TDN are similarly reported in other manual therapy treatments such as spinal manipulation.[145]

The mean difference for infraspinatus, erector spinae, and gastrocnemius was also greater in those with a LTR. The LTR was observed in 30 of the 60 subjects, and 15 of those where in the gastrocnemius latent MTrP group. The role and clinical importance of LTR in treatment is not clearly established in research and may not be essential to treatment effectiveness.[146,147] Eliciting a LTR is theorized to interrupt the mechanical, chemical, and electrical contributions to the MTrP.[60] However, the mechanism of action remains to be elucidated. LTR during TDN treatment has been correlated to a decrease or

normalization in motor end plate activity.[126,131,148-150] Changes to the local MTrP's biochemistry have been shown to occur following LTR.[74,75] The decreased spontaneous electrical activity recorded may be a result of the biomechanical disruption of the motor end plate.[124] Pistoning the needle can cause mechanical injury to the surrounding tissue including the neuromuscular junction.[124]

In conclusion, the immediate decrease in stiffness is an objective variable of the effect of TDN, independent of the subjective nature of pain measurement. TDN of latent MTrPs in the gastrocnemius and erector spinae caused a significant decrease in biomechanical stiffness of the muscle in those that also presented with a LTR. Clinical observation of LTR combined with measurement of biomechanical stiffness may be a beneficial biomarker for successful outcome.

RECOMMENDATIONS FOR FUTURE RESEARCH

Stiffness contributes to biomechanical stability.[151,152] Further, stiffness may affect muscle performance and increase the risk of musculoskeletal injury in the lower extremity.[4] The relationship between stiffness and injury is yet to be fully explained. Further research investigating norms of stiffness of healthy musculoskeletal tissues in various populations and participants with musculoskeletal pathology is recommended. Those studies will provide a basis for research investigating ways to modify stiffness for protective and therapeutic intervention.

In this study TDN significantly decreased the stiffness of latent MTrPs within the erector spinae and gastrocnemius group. The infraspinatus group mean decreased but was not significant. We recommend future research investigating stiffness changes in

individuals with symptomatic active MTrPs and monitoring duration of change during the first 24 hours following TDN. These changes in stiffness should be compared to other outcome tools to determine a level of decrease that is clinically meaningful. Exploring the role of TDN in modifying stiffness could assist in appropriate patient matched intervention and selective management of musculoskeletal pain or injury. There appears to be a relationship between stiffness change and LTR, which should be investigated further. Also, future studies are necessary to determine if an LTR is clinically meaningful for outcomes in symptomatic subjects and whether the change in stiffness is related to overall patient improvement in other outcome measures such as pain and function.

LIMITATIONS

The limitations of the study investigating specific aim 1 should be acknowledged. Healthy participants free from pain were used to measure stiffness changes during three contraction conditions. The results of first phase may have limited generalizability to other people in the population specifically those with muscle dysfunction or pain. Also the MyotonPRO® is susceptible to measurement interference from subcutaneous fat. Recommendations to exclude subjects based on BMI does not specifically account for the localized superficial tissue overlaying the muscle of interest. The SWE is not susceptible to subcutaneous tissue interference which could adversely affect the correlation overall. However, by using varying muscle contraction intensities conditions, we attempted to represent altered states of muscle stiffness.

The chosen levels for contraction intensities provided large intervals (0%, 40%, 80% MVIC) for the assessment of discriminate validity. Other magnitudes of differences

in muscle contraction may be clinically important and should be investigated to fully assess discriminate validity. Another limitation of the first phase of the study, the measurements of stiffness were taken of the gastrocnemius, infraspinatus, and erecter spinae in the lumbar region. The reliability and discriminate validity values may be different in other muscles in the body. The methods of the first phase of the study did not investigate the reliability of the examiner techniques when using the measurement devices. The location and orientation of the measurement was strictly controlled. The controlled aspect of the measurements gives insight to a true comparison between measurement tools but it may not carry over into day-to-day clinical measurement.

In the second phase of this study, the primary limitation is the absence of a control or sham group. While immediate changes occurred in measured stiffness, it is unknown whether the change in stiffness can be attributed other variables. A placebo control group would be beneficial for future research. Another limitation is the reported reliability issues with MTrP identification.[61,62] However, the reliability is reported to improve with experienced clinicians and using standardized diagnostic criteria.[64,65] In the study, the measures were taken in healthy subjects with latent MTrP located in the gastrocnemius, infraspinatus, and erecter spinae in the lumbar region. Results may vary in other musculature and it is unknown if a similar effect will occur in active MTrPs or in symptomatic subjects. The clinical meaningfulness of an immediate change in stiffness decrease is not known and was not addressed by this study.

SUMMARY

Structural changes in skeletal muscle can occur with injury and chronic pain causing abnormal function.[1-3] Muscle that undergoes structural change may lead to altered elasticity and increased risk of injury.[153] Preliminary observations suggest that muscular injuries have unique stiffness properties that can be characterized with novel measurement techniques.[8-11] Measurement of tissue stiffness affords an opportunity to progress the understanding of muscle structural deficits such as MTrPs that may be related to injury.[12,13]

MTrPs are characterized as hyperalgesiac taut fibers of skeletal muscle.[19,55] The taut fibers within the muscle create palpable bands or nodules that may cause local pain, and refer pain elsewhere with soft tissue examination.[19] MTrPs are localized areas of increased stiffness within the muscle but the direct relationship of MTrPs and injury is not well established and poorly understood. MTrPs are postulated to occur following biomechanical stress of the muscle which precipitates the development of a taut band.[67] Gerwin et al proposed that submaximal repetitive muscle contractions, sustained postures, and acute maximal overload could lead to the evolvement of the MTrP.[67,68] Biomechanical overload results in an energy crisis with persistent small muscle fiber contraction around the motor endplate. The taut band is theorized to continue due to motor end plate dysfunction following muscle fiber injury.[68,71,72]

Muscle stiffness is a measureable variable that affects the performance of movement and risk of injury.[154] Stiffness affects shock absorption and contraction of the individual muscle tendon, limb, or system.[153] Evidence demonstrates that muscle stiffness can be modified though exercise.[155-157] TDN interventions are also used to target MTrPs,

which are stiff bands within muscle. The objective measurement of stiffness may serve as a useful outcome tool to understand the role of TDN intervention in clinical practice. The measurements of biomechanical properties may also assist future investigations into the mechanism of action of TDN. The purpose of this study was to first investigate the reliability and concurrent validity of the measurement of muscle stiffness using novel technology. The second specific aim of this study was to investigate the biomechanical effects of TDN to MTrPs using the MyotonPRO® to measure stiffness.

We conducted a two-phase study. In the first phase of the study, a sample of 30 asymptomatic subjects was recruited from all Department of Defense beneficiary categories (active duty, retiree, dependents, etc.) between the age of 18 and 65 years of age. We compared the stiffness measurements of the MyotonPRO and the SWE at the infraspinatus, erector spinae, and gastrocnemius. Muscle stiffness measurements where collected during rest, 40% and 80% MVIC.

Multiple one way repeated measures analysis of variance (ANOVA) with Bonferroni post hoc was conducted to evaluate for differences in muscle stiffness between the three levels of muscle contraction (rest, 40% MVIC, and 80% MVIC) for each measurement tool (MyotonPRO® and SWE) and for each muscle (infraspinatus, erector spinae, and gastrocnemius). The three levels of muscle contraction elicited statistically significant changes in stiffness as measured by the MyotonPRO® (N/m) in all three muscles. The shear elastic modulus, as measured by shear wave elastography, was statistically different for gastrocnemius 5mm ROI across the three contraction conditions, $F(2,58) = 61.18$, $p < .001$. There were no significant differences between contraction conditions for the infraspinatus or the erector spinae using the 5mm ROI. The

SWE shear elastic modulus using 10mm ROI was statistically significant for 40% and 80% MVIC, as compared to the resting condition in the erector spinae muscle $F(2,58) = 18.64$, $p < .001$. There was no significant difference between the 40% and 80% MVIC. There were no differences between contraction conditions for the gastrocnemius and infraspinatus using the SWE.

Intrarater reliability was calculated using a two way mixed model, intraclass correlation coefficient single measure and a mean of 3 measures. Statistical significance was set a priori for all analyses at $p< .05$. The following guideline was used to determine the strength of the ICC: <0.25 no correlation; 0.25-0.5 fair; 0.5-0.75 moderate to good; and >0.75 good to excellent correlation.[103]Intrarater reliability estimates were excellent (ICC > 0.93) for all MyotonPRO® measures. Intrarater reliability estimates for the SWE measures were lower when using a single measure and improved based on a mean of 3 measurements (ICC = 0.56 to 0.98) in each muscle across all contraction conditions

Pearson's product-moment correlation was conducted to assess the relationship between stiffness measured by the MyotonPRO® and SWE (ROI 5mm and 10mm) in three muscles during rest, 40%MVIC, and 80% MVIC. The following guideline was used to determine the strength of the association.[138] A small correlation ranges 0.1 to 0.3. A moderate correlation ranges between 0.3 and 0.5. A strong correlation is greater than 0.5. The correlation between measures was strong for gastrocnemius (r=0.71).

In conclusion of the first phase, the MyotonPRO® demonstrated excellent measurement reliability in a laboratory setting. The MyotonPRO® also demonstrated the ability to discriminate stiffness at different levels of contraction. The MyotonPRO® is

less expensive and more portable than the SWE. This first phase provided the necessary criteria for the MyotonPRO® to be used in the second phase of the study.

In the second phase of this study, a sample of 60 healthy individuals between the ages of 18 and 65, without musculoskeletal complaints, and who have palpable, latent MTrPs were recruited. The 3 groups were formed by the location of the MTrP: shoulder (infraspinatus), calf (gastrocnemius), or low back (erector spinae). MyotonPRO® stiffness measurements were collected at the latent MTrP while in a resting prone position. TDN was performed to the MTrP and any incident of a localized twitch response was recorded. Repeat stiffness measurements were collected immediately after TDN treatment, and again at 24 hours.

One way repeated measures ANOVA with Bonferroni post hoc was conducted to evaluate for difference in muscle stiffness pre and post TDN (immediately and 24 hours). The analysis was repeated in a subgroup of individuals that demonstrated a localized twitch response during TDN. Muscle stiffness mean measurement decreased immediately after TDN in all the groups. The gastrocnemius MTrP group significantly decreased immediately after TDN, $F(2,38) = 12.62$, $p < 0.001$. The infraspinatus and erector spinae stiffness decrease was not statistically significant.

A total of 30 subjects from the sample of 60 experienced an LTR broken up into the following groups: infraspinatus 8; erector spinae 7; and gastrocnemius 15. The LTR subgroup of subjects demonstrated a decrease in mean stiffness immediately after TDN. The erector spinae and gastrocnemius group decrease in stiffness was significant.

In conclusion, the results of this study met the goals for both specific aim 1 and specific aim 2. The MyotonPRO® and SWE demonstrated a positive relationship across

the chosen contraction conditions, ROI 5mm (0.35-0.71) and 10mm (0.23-0.71). The MyotonPRO® demonstrated the ability to discriminate stiffness between different muscle contraction intensities. Lastly, the erector spinae and gastrocnemius group demonstrated a significant immediate decrease in stiffness when a LTR was observed during TDN of the latent MTrP. Future studies are necessary to investigate the connection between MTrP stiffness and clinical outcomes in subjects with musculoskeletal injury.

APPENDIX A

IRB APPROVAL NOTICES

Brooke Army Medical Center

INFORMED CONSENT DOCUMENT

PROTOCOL TITLE: Using Structural Health Monitoring to Improve Diagnosis and Treatment of Chronic Pain in U.S. Service Members: Translation to a Novel Handheld Device - Phase One

PRINCIPAL INVESTIGATOR: Shane Koppenhaver,
LTC, SP, USA

If you choose not to participate in this research study, your decision will not affect your eligibility for care or any other benefits to which you are entitled.

DESCRIPTION/PURPOSE OF RESEARCH:
You are being asked to consider participation in this research study. The purpose of this study is to gather data about the stiffness and function of the shoulder, back and calf muscles using advanced measurement equipment. The novel devices are ultrasound imaging called Shear-Wave Elastography and mechanical elastography called MyotonPRO.

This study will enroll approximately 30 subjects at AMEDD Center and School over a period of approximately 12 months.

During your participation in this study, you will be asked to make 1 outpatient visits with LTC Shane Koppenhaver or with one of the associate investigators on this study. It will not be necessary for you to return once you have completed the study session.

You have been selected to participate in this study because you are healthy and do not currently have pain.

PROCEDURES:
As a participant, you will undergo the following procedures:

Examination Procedures
If you agree to participate in this research study, you will first undergo a brief examination that consists of your completing questionnaires about how your general medical history. Then you will receive a screening physical examination to ensure that you don't have pain and can complete all the study procedures. The questionnaires will take approximately 5 minutes to complete, and the physical examination will take approximately an additional 10 minutes to complete. The

physical examination will consist of visual inspection, range of motion, and lumbar spine clearing maneuvers.

Ultrasound Imaging & Elastography Procedures
As a part of each physical evaluation, we will use an ultrasound imager to measure the function of your muscle in your shoulder, back, and calf. Ultrasound is a machine that transmits sound waves through the body and records the echoes as the sound waves move through different structures in the body. The echoes are transformed into images that can be viewed on a screen. Elastography is an additional capability that allows the ultrasound machine to measure the stiffness within a specified region of the ultrasound image. During the ultrasound measurements you will be asked to lie on your stomach. A gel will be placed on your skin to help transmit the sound waves. The ultrasound device will then be placed on your skin and you will be asked to lift one arm against resistance. The MyotonPro is also used in during the physical examination with the ultrasound. The MyotonPRO measurement provides a brief and light tap similar to the pressure of your finger pressing into your skin. The device measures the stiffness of your muscle directly underneath.

If you need a procedure requiring additional informed consent, a separate consent form will be given to you before that procedure.

RISKS OR DISCOMFORTS:
The risks associated with participation in this study are minimal. There are no known risks from the ultrasound measurements and it has been found safe to use over the abdominal region of pregnant women. There is a risk of some muscle soreness in your shoulder, back or calf from lifting against resistance. Based on our experience this type of soreness is common meaning that it occurs in 1% to 25% of participants. If present, however, the soreness should be minor and similar to working out in the gym.

There may also be unforeseen risks associated with this study.

BENEFITS:
There is no guarantee you will receive any benefit from this study other than knowing that the information may help future patients.

PAYMENT (COMPENSATION):
You will not receive any compensation (payment) for participating in this study.

ALTERNATIVES TO PARTICIPATION:
Choosing not to participate in this study is your alternative to volunteering for the study.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:
Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing

regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), other U.S. government agencies, and the BAMC Institutional Review Board.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities. Additionally, although efforts are made to protect your study records, it is possible that your confidentiality may be breached by unplanned loss of your records.

ENTITLEMENT TO CARE:
In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries.

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the Brooke Army Medical Center Protocol Coordinators, (210) 916-2598 or BAMC Judge Advocate General, (210) 916-8585.

BLOOD & TISSUE SAMPLES:
No blood or tissue samples will be taken as part of this study.

VOLUNTARY PARTICIPATION:
The decision to participate in this study is completely voluntary on your part. No one has coerced or intimidated you into participating in this project. You are participating because you want to. The Principal Investigator or one of his associates has adequately answered any and all questions you have about this study, your participation, and the procedures involved. If significant new findings develop during the course of this study, that may relate to your decision to continue participation, you will be informed.

You may withdraw this consent at any time and discontinue further participation in this study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must notify LTC Koppenhaver or another study investigator; no other procedures need to be taken. Your condition will continue to be treated in accordance with acceptable standards of medical treatment.

The investigator of this study may terminate your participation in this study at any time if he feels this to be in your best interest.

CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the AMEDD C&S Physical Therapy faculty and will be available to answer any questions concerning procedures throughout this study.

Principal Investigator: LTC Shane Koppenhaver, PT, PhD, OCS
Phone: (210) 221-8410 or (210)-722-3671

Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent.

A signed and dated copy of this form will be given to you.

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

If the patient has a stamp plate, please stamp here:

SIGNATURE OF CONSENTING INDIVIDUAL
(Can only be signed by an investigator or staff whose name is listed in the protocol and approved to consent)

_____
Printed Name of Consenting Individual

_____ _____
Signature of Consenting Individual Date

SIGNATURE OF WITNESS TO THE CONSENT/ASSENT PROCESS
I certify that the above signed research participant has freely and voluntarily provided written consent to participate in this research study.

_____
Printed Name of Witness

_____ _____
Signature of Witnessing Individual Date

BRADLEY UNIVERSITY
Information and Consent Form

Study Title: Dry Needling of Myofascial Trigger Points: Quantification of the Biomechanical Response Using a Myotonometer.

Introduction: You are being asked to participate in a research study. Your participation is voluntary. Your decision to participate or not to participate will have no effect on your academic standing, or job status. Please ask questions if there is anything you do not understand. The purpose of this study is to learn about the effect of dry needling on trigger point stiffness in the lower back, shoulder blade, and calf muscle.

What is involved in the study?

Dry needling is a technique that utilizes a thin, solid needle to treat muscle trigger points, or muscle knots. Sterile single-use disposable needles are used to minimize risk of infection. As a participant you will receive dry needling to a trigger point located in your calf muscle. This study requires three separate measurement sessions over a 24 hour period. The intervention of dry needling takes place at the first session only and will take approximately 15 minutes to complete. You will be asked to return at 24 hours for repeat measurement of the trigger point stiffness, which should last approximately 10 minutes each. Total time involves less than 1 hour. Dry needling does NOT occur on the second and third measurement session.

All participants will complete a brief health history questionnaire to determine eligibility. The health history information will be collected and saved as de-identified data using subject identification number instead of your proper name. As

a volunteer participant you will be asked to lie face down on a padded treatment table. The primary investigator will locate any trigger points in your calf, low back or back of your shoulder blade. The calf muscle, low back, and shoulder blade will be exposed and palpated to locate a myofascial trigger point. If a trigger point is found that will be the location of the dry needling measurement. The primary investigator will wash hands, put on gloves and sterilize the skin. Stiffness of the trigger point will be measured with a device that provides a brief and light impulse similar to the pressure of your finger pressing into your skin. The device measures the stiffness of your tissue directly underneath. There have been no side effects reported with this measurement. Following baseline measurement, a solid thin needle will be inserted through your skin into the trigger point and moved slightly up and down. The small movement up and down can result in a small muscle fiber contraction and twitching can be felt in the muscle. The dry needling intervention lasts less than 1 minute. Dry needling of the trigger point occurs once and only repeated one time if the muscle does not contract. The needle is removed and properly disposed of. Stiffness measurements are immediately repeated following the dry needling and again 24 hours later.

How many people will take part in the study?

It is anticipated that no more than 60 persons will participate in this research.

How long will I be in the study?

You will be in the study for approximately 1 day. The initial treatment and measurement session lasts 15 minutes. You will be measured once again without

treatment the next day to monitor changes in the muscle. The second and third measurement session will last 10 minutes each.

What are the risks of participating in the study?

Dry needling may cause an increase in pain for one to two days followed by an expected improvement in the overall pain state. The increased pain is related to overactive shortened muscle bands that have not been released and to the soreness caused by the "twitching" of the muscles. Any time a needle is used there is a risk of infection. However, we are using new, disposable and sterile needles, and infections are extremely rare. In the event of a suspected local infection you will be instructed to follow up with your primary care physician. A needle placed into the muscle may disrupt small blood vessels that can result in bleeding or bruising. In the event of bleeding a small, sterile cotton ball will be applied with pressure until it stops. A bandage will be placed over the area. If bruising occurs, application of ice will help. You may also experience any of the following during treatment: A feeling of relaxation, an increase in energy level, dizziness, nausea, sweating, or irritation at the site of needle insertion. Fortunately, all these complications are readily reversible and temporary. Pregnancy may be a reason to not participate or to stop participation in this study. If you are or become pregnant, please notify the primary investigator.

What are the benefits of participating in the study?

You will not benefit from being in this research study. We hope to gather information that may help people in the future.

What other options are there?

This type of treatment may be received outside of this Study.

What about Confidentiality?

All reasonable efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Raw data will be stored in a locked file, in the PI's locked office of a building with restricted access. Research data will be destroyed when appropriate. Personal identification will not be used in electronic database.

Organizations or individuals that may inspect and/or copy your research records for quality assurance and data analysis include groups such as: The Committee on the Use of Human Subjects in Research (CUHSR).

What are the costs?

There are no costs for participation in this study. In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge at your own expense. No funds have been set aside to compensate you in the event of injury. You will receive no payment for taking part in this study.

What are my rights?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time.

Who should I call with questions or problems study?

Questions about this study may be directed to the researcher or the research advisor in charge of this study: Professor Joseph Kelly at (309) 677-2545 during normal business hours.

If you have general questions about being a research participant, you may contact the CUHSR office at (677-3877) during normal business hours. The Chairperson of this committee will discuss the matter with you.

Documentation of informed consent

You are voluntarily making a decision to participate in this study. Your signature means that you have read and understood the information presented and have decided to participate. Your signature also means that the information on this consent form has been fully explained to you and all your questions have been answered to your satisfaction. If you think of any additional questions during the study, you should contact the researcher(s).

I agree to participate in this study Date

_____ _____

Signature of Participant or legally authorized representative

_____

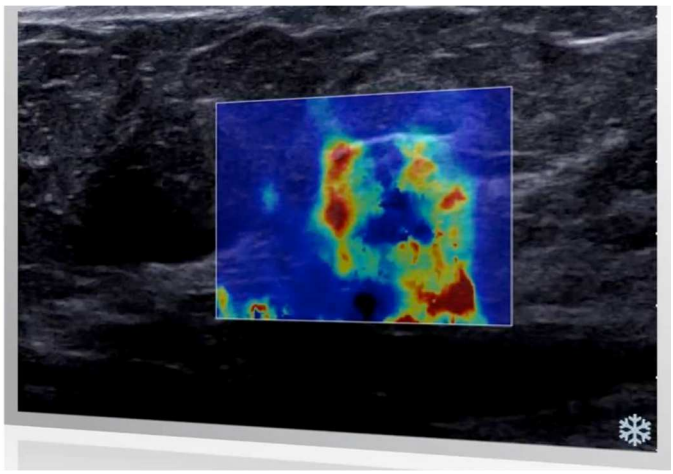
_____

Printed Name

APPENDIX B

SUBJECT RECRUITMENT FLYER

Amazing Technology



FREE Muscle Examination

Volunteers needed for research examining the function of the muscles of the shoulder, back, and calf using new Elastography technology.

To qualify for our research, you must:

- Be between 18-65 years old
- Painfree in either the shoulder, back, or calf
- No surgery in the last 6 months

To learn more about our study, please contact:
Joseph Kelly (309) 677 – 2545
muscle.research.study@gmail.com
Center for Physical Therapy Research
Graduate School at the Academy of Health Sciences
Army Medical Department Center and School (AMEDDC&S)

PI information for Back of flyer:

FREE Muscle Exam Study
Joseph Kelly
(309) 677 – 2545
muscle.research.study@gmail.com

FREE Muscle Exam Study
Joseph Kelly
(309) 677 – 2545
muscle.research.study@gmail.com

FREE Muscle Exam Study
Joseph Kelly
(309) 677 – 2545
muscle.research.study@gmail.com

FREE Muscle Exam Study
Joseph Kelly
(309) 677 – 2545
muscle.research.study@gmail.com

FREE Muscle Exam Study
Joseph Kelly
(309) 677 – 2545
muscle.research.study@gmail.com

FREE Muscle Exam Study
Joseph Kelly
(309) 677 – 2545
muscle.research.study@gmail.com

FREE Muscle Exam Study
Joseph Kelly
(309) 677 – 2545
muscle.research.study@gmail.com

Study Principle Investigator:
LTC Shane Koppenhaver PT, PhD
Director of Research & Assistant Professor US Army Baylor University Doctoral Physical Therapy Program
3599 Scott Rd. Suite 1301
Fort Sam Houston, TX 78234
Cell: (210) 722-3671
shanekoppenhaver@mac.com

Joseph Kelly PT, OCS
PhD student
Nova Southeastern University
(309) 677 – 2545
muscle.research.study@gmail.com

Advertisement used in email/newsletters will be one of two forms, each of which includes a link that will take potential volunteers to an online version of above flyer.

- Volunteers are needed to participate in a study researching imaging of low back muscles. To qualify, volunteers must be between 18 and 65 years of age, and not have current low back pain or a history of spinal surgery.

REFERENCES

1. Kiesel KB, Uhl T, Underwood FB, Nitz AJ. Rehabilitative ultrasound measurement of select trunk muscle activation during induced pain. *Man Ther* 2008;13(2):132–138.

2. Asche C, Kirkness C, McAdam-Marx C, Fritz J. The Societal Costs of Low Back Pain. *J. Of Pain & Palliat Care Pharmacother* 2007;21(4):25–33.

3. MacDonald D, Moseley GL, Hodges PW. Why do some patients keep hurting their back? Evidence of ongoing back muscle dysfunction during remission from recurrent back pain. *Pain* 2009;142(3):183–188.

4. Butler RJ, Crowell HP III, Davis IM. Lower extremity stiffness: implications for performance and injury. *Clin Biomech* 2003;18(6):511–517.

5. Gaskin DJ, Richard P. The Economic Costs of Pain in the United States. *J Pain* 2012;13(8):715–724.

6. Manchikanti L, Helm S, Fellows B, et al. Opioid epidemic in the United States. *Pain Physician* 2012;15(3 Suppl):ES9–38.

7. Deyo RA, Mirza SK, Turner JA, Martin BI. Overtreating Chronic Back Pain: Time to Back Off? *J Am Board Fam Med* 2009;22(1):62–68.

8. Sarvazyan A, Hall TJ, Urban MW, Fatemi M, Aglyamov SR, Garra BS. An Overview of Elastography: An Emerging Branch of Medical Imaging. *Curr Med Imaging Rev* 2011;7(4):255–282.

9. Itoigawa Y, Sperling JW, Steinmann SP, et al. Feasibility assessment of shear wave elastography to rotator cuff muscle. *Clin Anat* 2014;28(2):213-218.

10. Hatta T, Yamamoto N, Sano H, Itoi E. In Vivo Measurement of Rotator Cuff Tendon Strain With Ultrasound Elastography: An Investigation Using a Porcine Model. *J Ultrasound Med* 2014;33(9):1641–1646.

11. Carlsen J, Ewertsen C, Lönn L, Nielsen M. Strain Elastography Ultrasound: An Overview with Emphasis on Breast Cancer Diagnosis. *Diagnostics* 2013;3(1):117–125.

12. Raiteri BJ, Hug F, Cresswell AG, Lichtwark GA. Quantification of muscle co-contraction using supersonic shear wave imaging. *J Biomech* 2016;49(3):493–495.

13. Ates F, Hug F, Bouillard K, et al. Muscle shear elastic modulus is linearly related to muscle torque over the entire range of isometric contraction intensity. *J Electromyogr Kinesiol* 2015;25(4):703–708.

14. Aird L, Samuel D, Stokes M. Quadriceps muscle tone, elasticity and stiffness in older males: Reliability and symmetry using the MyotonPRO. *Arch Gerontol*

Geriatr 2012;55(2):e31–e39.

15. Harting J, Rutten GM, Rutten ST, Kremers SP. A Qualitative Application of the Diffusion of Innovations Theory to Examine Determinants of Guideline Adherence Among Physical Therapists. *Phys Ther* 2009;89(3):221–232.

16. Shinohara M, Sabra K, Gennisson J-L, Fink M, Tanter M. Real-time visualization of muscle stiffness distribution with ultrasound shear wave imaging during muscle contraction. *Muscle Nerve* 2010;42(3):438–441.

17. Ballyns JJ, Shah JP, Hammond J, Gebreab T, Gerber LH, Sikdar S. Objective sonographic measures for characterizing myofascial trigger points associated with cervical pain. *J Ultrasound Med* 2011;30(10):1331–1340.

18. Kietrys DM, Palombaro KM, Azzaretto E, et al. Effectiveness of Dry Needling for Upper-Quarter Myofascial Pain: A Systematic Review and Meta-analysis. *J Orthop Sports Phys Ther* 2013;43(9):620–634.

19. Simons DG, Travell JG. Myofascial origins of low back pain. 1. Principles of diagnosis and treatment. *Postgrad Med* 1983;73(2):66,68–70, 73 passim.

20. France S, Bown J, Nowosilskyj M, Mott M, Rand S, Walters J. Evidence for the use of dry needling and physiotherapy in the management of cervicogenic or tension-type headache: A systematic review. *Cephalalgia* 2014;34(12):994-1003.

21. Furlan AD, Van Tulder M, Cherkin D, et al. Acupuncture and dry-needling for low back pain: an updated systematic review within the framework of the cochrane collaboration. *Spine* 2005;30(8):944–963.

22. Tough EA, White AR. Effectiveness of acupuncture/dry needling for myofascial trigger point pain. *Phys Ther Rev* 2011;16(2):147–154.

23. Iglesias-González JJ, Muñoz-García MT, Rodrigues-de-Souza DP, Alburquerque-Sendín F, Fernández-de-las-Peñas C. Myofascial trigger points, pain, disability, and sleep quality in patients with chronic nonspecific low back pain. *Pain Med* 2013;14(12):1964–1970.

24. Rutten GM, Degen S, Hendriks EJ, Braspenning JC, Harting J, Oostendorp RA. Adherence to Clinical Practice Guidelines for Low Back Pain in Physical Therapy: Do Patients Benefit? *Phys Ther* 2010;90(8):1111–1122.

25. Fernández-de-las-Peñas C, Dommerholt J. Myofascial Trigger Points: Peripheral or Central Phenomenon? *Curr Rheumatol Rep* 2013;16(1):395.

26. Ge H-Y, Fernández-de-las-Peñas C, Yue S-W. Myofascial trigger points: spontaneous electrical activity and its consequences for pain induction and propagation. *Chin Med* 2011;6(1):13.

27. Gerwin RD. The Taut Band and Other Mysteries of the Trigger Point: An Examination of the Mechanisms Relevant to the Development and Maintenance of the Trigger Point. *J Musculoskelet Pain* 2008;16(1-2):115–121.

28. Chen Q, Bensamoun S, Basford JR, Thompson JM, An K-N. Identification and Quantification of Myofascial Taut Bands With Magnetic Resonance Elastography. *Arch Phys Med Rehabil* 2007;88(12):1658–1661.

29. Baumgart E. Stiffness--an unknown world of mechanical science? *Injury* 2000;31 Suppl 2:S–B14–23.

30. Maïsetti O, Hug F, Bouillard K, Nordez A. Characterization of passive elastic properties of the human medial gastrocnemius muscle belly using supersonic shear imaging. *J Biomech* 2012;45(6):978–984.

31. Klauser AS, Miyamoto H, Bellmann-Weiler R, Feuchtner GM, Wick MC, Jaschke WR. Sonoelastography: Musculoskeletal Applications. *Radiology* 2014;272(3):622–633.

32. Simons DG, Mense S. Understanding and measurement of muscle tone as related to clinical muscle pain. *Pain* 1998;75(1):1–17.

33. Chen Q, Basford J, An K-N. Ability of magnetic resonance elastography to assess taut bands. *Clin Biomech* 2008;23(5):623–629.

34. Hong CZ. Lidocaine injection versus dry needling to myofascial trigger point. The importance of the local twitch response. *Am J Phys Med Rehabil* 1994;73(4):256–263.

35. Maher RM, Hayes DM, Shinohara M. Quantification of dry-needling and posture effects on myofascial trigger points using ultrasound shear-wave elastography. *Arch Phys Med Rehabil* 2013;94(11):1–21.

36. Mullix J, Warner M, Stokes M. Testing muscle tone and mechanical properties of rectus femoris and biceps femoris using a novel hand held MyotonPRO device: relative ratios and reliability. *WPHS* 2012;1(1):1–9.

37. Peipsi A, Kerpe R, Jäger H, Soeder S, Gordon C, Schleip R. Myoton Pro: A Novel Tool for the Assessment of Mechanical Properties of Fascial Tissues. *J Bodyw Mov Ther* 2012;16(4):527.

38. *Physical Therapists & the Performance of Dry Needling*. American Physical Therapy Association; 2012:1–140.

39. Hong C-Z. Needling Therapy for Myofascial Pain Control. *Evid Based Complement Alternat Med* 2013;2013:1–2.

40. Brav E, Sigmond H. The Local and Regional Injection Treatment of Low Back

Pain and Sciatica. *Ann Intern Med* 1941;15(5):840–852.

41. Paulett JD. Low Back Pain. *Lancet* 1947;2:272–276.

42. Steinbrocker O. Therapeutic Injections in Painful Musculoskeletal Disorders. *JAMA* 1944;125(6):397–401.

43. Legge D. A History of Dry Needling. *J Musculoskel Pain* May 2014:1–7.

44. FitzGibbon S. Should Dry Needling for Myofascial Pain be Within the Scope of Practice for Physical Therapy? *OPTP* 2011;23(4):212–218.

45. Ghia J, Mao W, Toomey T, Gregg JM. Acupuncture and Chronic Pain Mechanisms. *Pain* 1976;2(3):285–299.

46. Lewit K. The Needle Effect in the Relief of Myofascial Pain. *Pain* 1979;6(1):83–90.

47. Chang S. The meridian system and mechanism of acupuncture. *Taiwan J Obstet Gynecol* 2012;51(4):506–514.

48. Rickards LD. Therapeutic needling in osteopathic practice: An evidence-informed perspective. *Internat J Osteopath Med* 2009;12(1):2–13.

49. Johnson MI. The clinical effectiveness of acupuncture for pain relief--you can be certain of uncertainty. *Acupun Med* 2006;24(2):71–79.

50. Amaro J. When Acupuncture Becomes "Dry Needling." *Dyn Chiro* 2008;26(12):1–4.

51. Miller DW. Acupuncture by Any Other Name is Acupuncture:The Fight Against Professional Plundering Continues. *Am Acupunct* December 2012:19–22.

52. American Association of Acupuncture and Oriental Medicine (AAAOM) Position Statement on Trigger Point Dry Needling (TDN) and Intramuscular Manual Therapy (IMT). *Am Acupunct* November 2012:22–23.

53. Dommerholt J. Dry needling — peripheral and central considerations. *J Man Manipulative Ther* 2011;19(4):223–227.

54. Kalichman L, Vulfsons S. Dry Needling in the Management of Musculoskeletal Pain. *J Am Board Fam Med* 2010;23(5):640–646.

55. Dommerholt J, Simons DG. Myofascial Pain Syndrome—Trigger Points. *J Musculoskel Pain* 2008;16(3):211–228.

56. Travell J, Rinzler S, Herman M. Pain and Disability of the Shoulder and Arm: Treatment by Intramuscular Infiltration with Procaine Hydrochloride. *JAMA* 1942;120:417–422.

57. Travell J, Rinzler S. The Myofascial Genesis of Pain. *Postgrad Med* 1952;11:425–434.

58. Ge H-Y, Arendt-Nielsen L. Latent Myofascial Trigger Points. *Curr Pain Headache Rep* 2011;15(5):386–392.

59. Celik D, Mutlu EK. Clinical Implication of Latent Myofascial Trigger Point. *Curr Pain Headache Rep* 2013;17(8):353.

60. Hong CZ, Simons DG. Pathophysiologic and electrophysiologic mechanisms of myofascial trigger points. *Arch Phys Med Rehabil* 1998;79(7):863–872.

61. Myburgh C, Larsen AH, Hartvigsen J. A Systematic, Critical Review of Manual Palpation for Identifying Myofascial Trigger Points: Evidence and Clinical Significance. *Arch Phys Med Rehabil* 2008;89(6):1169–1176.

62. Lucas N, Macaskill P, Irwig L, Moran R, Bogduk N. Reliability of physical examination for diagnosis of myofascial trigger points: a systematic review of the literature. *Clin J Pain* 2009;25(1):80–89.

63. Simons DG, Travell JG, Simons LS. *Travell and Simons' Myofascial Pain and Dysfunction: the Trigger Point Manual*. Vol 2nd ed. Baltimore, MD: Lippincott Willians and Wilkins; 1999.

64. Tough EA, White AR, Richards S, Campbell J. Variability of criteria used to diagnose myofascial trigger point pain syndrome--evidence from a review of the literature. *Clin J Pain* 2007;23(3):278–286.

65. Myburgh C, Lauridsen HH, Larsen AH, Hartvigsen J. Standardized manual palpation of myofascial trigger points in relation to neck/shoulder pain; the influence of clinical experience on inter-examiner reproducibility. *Man Ther* 2011;16(2):136–140.

66. Barbero M, Bertoli P, Cescon C, Macmillan F, Coutts F, Gatti R. Intra-rater reliability of an experienced physiotherapist in locating myofascial trigger points in upper trapezius muscle. *J Man Man Ther* 2012;20(4):171–177.

67. Gerwin RD, Dommerholt J, Shah JP. An expansion of Simons' integrated hypothesis of trigger point formation. *Curr Pain Headache Rep* 2004;8(6):468–475.

68. McPartland JM, Simons DG. Myofascial Trigger Points: Translating Molecular Theory into Manual Therapy. *J Man Manipulative Ther* 2006;14(4):232–239.

69. Simons DG. New Views of Myofascial Trigger Points: Etiology and Diagnosis. *Arch Phys Med Rehabil* 2008;89(1):157–159.

70. Bron C, Dommerholt JD. Etiology of Myofascial Trigger Points. *Curr Pain*

Headache Rep 2012;16(5):439–444.

71. Hubbard DR, Berkoff GM. Myofascial Trigger Points SHow Spontaneous Needle EMG Activity. *Spine* 1993;18(13):1803–1807.

72. Simons DG. Do endplate noise and spikes arise from normal motor endplates? *Am J Phys Med Rehabil* 2001;80(2):134–140.

73. Dommerholt J. Dry Needling in Orthopaedic Physical Therapy Practice. *OPTP* 2004;16(3):11–16.

74. Shah JP, Phillips TM, Danoff JV. An in vivo microanalytical technique for measuring the local biochemical milieu of human skeletal muscle. *J Appl Physiol* 2005;99(5):1977–1984.

75. Shah JP, Danoff JV, Desai MJ, et al. Myofascial Pain Syndrome: Correlation between the Irritability of Trigger Points and the Prevalence of Local Twitch Responses during Trigger Point Injection. *Arch Phys Med Rehabil* 2012;89(1):250–256.

76. Brady S, McEvoy J, Dommerholt J, Doody C. Adverse events following trigger point dry needling: a prospective survey of chartered physiotherapists. *J Man Manipulative Ther* 2014;22(3):134–140.

77. Witt CM, Pach D, Brinkhaus B, et al. Safety of Acupuncture: Results of a Prospective Observational Study with 229,230 Patients and Introduction of a Medical Information and Consent Form. *Forsch Komplementmed* 2009;16(2):91–97.

78. Rees SS, Murphy AJ, Watsford ML, McLachlan KA, Coutts AJ. Effects of proprioceptive neuromuscular facilitation stretching on stiffness and force-producing characteristics of the ankle in active women. *J Strength Cond Res* 2007;21(2):572–577.

79. Ditroilo M, Hunter AM, Haslam S, De Vito G. The effectiveness of two novel techniques in establishing the mechanical and contractile responses of biceps femoris. *Physiol Meas* 2011;32(8):1315–1326.

80. Chuang L, Wu C, Lin K. Reliability, Validity, and Responsiveness of Myotonometric Measurement of Muscle Tone, Elasticity, and Stiffness in Patients With Stroke. *Arch Phys Med Rehabil* 2012;93(3):532–540.

81. Marusiak J, Kisiel-Sajewicz K, Jaskólska A, Jaskólski A. Higher muscle passive stiffness in Parkinson's disease patients than in controls measured by myotonometry. *Arch Phys Med Rehabil* 2010;91(5):800–802.

82. Marusiak J, Jaskólska A, Budrewicz S, Koszewicz M, Jaskólski A. Increased muscle belly and tendon stiffness in patients with Parkinson's disease, as

measured by myotonometry. *Mov Dis* 2011;26(11):2119–2122.

83. Chuang L-L, Lin K-C, Wu C-Y, et al. Relative and absolute reliabilities of the myotonometric measurements of hemiparetic arms in patients with stroke. *Arch Phys Med Rehabil* 2013;94(3):459–466.

84. Zinder SM, Padua DA. Reliability, validity, and precision of a handheld myometer for assessing in vivo muscle stiffness. *J Sport Rehabil* 2011:1–8.

85. Bizzini M, Mannion AF. Reliability of a new, hand-held device for assessing skeletal muscle stiffness. *Clin Biomech* 2003;18(5):459–461.

86. Marusiak J, Jaskólska A, Koszewicz M, Budrewicz S, Jaskólski A. Myometry revealed medication-induced decrease in resting skeletal muscle stiffness in Parkinson's disease patients. *Clin Biomech* 2012;27(6):632–635.

87. Dougherty J, Schaefer E, Nair K, Kelly J, Masi A. Repeatability, Reproducibility, and Calibration of the Myotonpro® on Tissue Mimicking Phantoms. *ASME 2013 SBC.* January 2013:V01AT20A026.

88. Cotchett MP, Landorf KB, Munteanu SE. Effectiveness of dry needling and injections of myofascial trigger points associated with plantar heel pain: a systematic review. *J Foot Ankle Res*2010;3(1):18.

89. Tough EA, White AR, Cummings TM, Richards SH, Campbell JL. Acupuncture and dry needling in the management of myofascial trigger point pain: A systematic review and meta-analysis of randomised controlled trials. *Eur J Pain* 2009;13(1):3–10.

90. Huang Y-T, Lin S-Y, Neoh C-A, Wang K-Y, Jean Y-H, Shi H-Y. Dry Needling for Myofascial Pain: Prognostic Factors. *J Alt Compl Med* 2011;17(8):755–762.

91. Cummings TM, White AR. Needling therapies in the management of myofascial trigger point pain: A systematic review. *Arch Phys Med Rehabil* 2001;82(7):986–992.

92. Sikdar S, Shah JP, Gebreab T, et al. Novel applications of ultrasound technology to visualize and characterize myofascial trigger points and surrounding soft tissue. *Arch Phys Med Rehabil* 2009;90(11):1829–1838.

93. Peltz CD, Haladik JA, Divine G, Siegal D, Holsbeeck M, Bey MJ. ShearWave elastography: repeatability for measurement of tendon stiffness. *Skeletal Radiol* 2013;42(8):1151–1156.

94. Yoshitake Y, Takai Y, Kanehisa H, Shinohara M. Muscle shear modulus measured with ultrasound shear-wave elastography across a wide range of contraction intensity. *Muscle Nerve* 2014;50(1):1–11.

95. Eby SF, Song P, Chen S, Chen Q, Greenleaf JF, An K-N. Validation of shear wave elastography in skeletal muscle. *J Biomech* 2013;46(14):2381–2387.

96. Lee MS, Ernst E. Acupuncture for pain: an overview of Cochrane reviews. *Chin J Integr Med* 2011;17(3):187–189.

97. Lachin JM. Introduction to sample size determination and power analysis for clinical trials. *Control Clin Trials* 1981;2(2):93–113.

98. Ekstrom RA, Osborn RW, Hauer PL. Surface Electromyographic Analysis of the Low Back Muscles During Rehabilitation Exercises. *J Orthop Sports Phys Ther* 2008;38(12):736–745.

99. DiLorenzo L, Traballesi M, Morelli D, et al. Hemiparetic Shoulder Pain Syndrome Treated with Deep Dry Needling During Early Rehabilitation: A Prospective, Open-Label, Randomized Investigation. *J Musculoskel Pain* 2004;12(2):25–34.

100. Ma C, Wu S, Li G, Xiao X, Mai M, Yan T. Comparison of miniscalpel-needle release, acupuncture needling, and stretching exercise to trigger point in myofascial pain syndrome. *Clin J Pain* 2010;26(3):251–257.

101. Grieve R, Barnett S, Coghill N, Cramp F. The prevalence of latent myofascial trigger points and diagnostic criteria of the triceps surae and upper trapezius: a cross sectional study. *Physiotherapy* June 2013:1–7.

102. Koppenhaver SL, Parent EC, Teyhen DS, Hebert JJ, Fritz JM. The Effect of Averaging Multiple Trials on Measurement Error During Ultrasound Imaging of Transversus Abdominis and Lumbar Multifidus Muscles in Individuals With Low Back Pain. *J Orthop Sports Phys Ther* 2009;39(8):604–611.

103. Portney L, Watkins M. *Foundations of Clinical Research: Applications to Practice*. Vol 3rd ed. Pearson Prentice Hall; 2009:594–595.

104. DeVon HA, Block ME, Moyle-Wright P, et al. A psychometric toolbox for testing validity and reliability. *J Nurs Scholarsh* 2007;39(2):155–164.

105. Bouillard K, Nordez A, Hug F. Estimation of individual muscle force using elastography. *PLoS ONE* 2011;6(12):e29261.

106. Bouillard K, Hug F, Guevel A, Nordez A. Shear elastic modulus can be used to estimate an index of individual muscle force during a submaximal isometric fatiguing contraction. *J Appl Physio* 2012;113(9):1353–1361.

107. Koo TK, Guo J-Y, Cohen JH, Parker KJ. Quantifying the passive stretching response of human tibialis anterior muscle using shear wave elastography. *Clin Biomech* 2014;29(1):33–39.

108. Bouillard K, Nordez A, Hodges PW, Cornu C, Hug F. Evidence of changes in load sharing during isometric elbow flexion with ramped torque. *J Biomech* 2012;45(8):1424–1429.

109. Hsieh Y-L, Kao M-J, Kuan T-S, Chen S-M, Chen J-T, Hong C-Z. Dry needling to a key myofascial trigger point may reduce the irritability of satellite MTrPs. *Am J Phys Med Rehabil* 2007;86(5):397–403.

110. Tsai C-T, Hsieh L-F, Kuan T-S, Kao M-J, Chou L-W, Hong C-Z. Remote Effects of Dry Needling on the Irritability of the Myofascial Trigger Point in the Upper Trapezius Muscle. *Am J Phys Med Rehabil* 2010;89(2):133–140.

111. Kot BCW, Zhang ZJ, Lee AWC, Leung VY-F, Fu SN. Elastic Modulus of Muscle and Tendon with Shear Wave Ultrasound Elastography: Variations with Different Technical Settings. Kellermayer MS, ed. *PLoS ONE* 2012;7(8):e44348.

112. Akagi R, Kusama S. Comparison Between Neck and Shoulder Stiffness Determined by Shear Wave Ultrasound Elastography and a Muscle Hardness Meter. *Ultrasound Med Biol* 2015;41(8):2266–2271.

113. Calvo-Lobo C, Pacheco-da-Costa S, Hita-Herranz E. Efficacy of Deep Dry Needling on Latent Myofascial Trigger Points in Older Adults With Nonspecific Shoulder Pain. *J Geri Phys Ther* March 2015:1.

114. Matsubara T, Arai Y-CP, Shiro Y, et al. Comparative Effects of Acupressure at Local and Distal Acupuncture Points on Pain Conditions and Autonomic Function in Females with Chronic Neck Pain. *Evid Based Complement Alternat Med* 2011;2011(2):1–6.

115. McKee CT, Last JA, Russell P, Murphy CJ. Indentation Versus Tensile Measurements of Young's Modulus for Soft Biological Tissues. *Tissue Engineering* 2011;17(3):155–164.

116. Koppenhaver SL, Walker MJ, Su J, et al. Changes in lumbar multifidus muscle function and nocioceptive sensitivity in low back pain patient responders versus non-responders after dry needling treatment. *Man Ther* 2015;20(6):769-776.

117. Andonian BJ, Masi AT, Aldag JC, et al. Greater resting lumbar extensor myofascial stiffness in younger ankylosing spondylitis patients than age-comparable healthy volunteers quantified by myotonometry. *Arch Phys Med Rehabil* 2015;96(11):2041–2047.

118. Agyapong-Badu S, Warner M, Samuel D, Stokes M. Measurement of ageing effects on muscle tone and mechanical properties of rectus femoris and biceps brachii in healthy males and females using a novel hand-held myometric device. *Arch Geront Geri* 2016;62:59–67.

119. Arias-Buria J, Valero-Alcade R, Cleland J, Salom-Moreno J, Ortega-Santiago R,

Atin-Arratibel M, Fernandez-de-las-Penas F. Inclusion of trigger point dry needling in a multimodal physical therapy program for postoperative shoulder pain: a randomized clinical trial. *J Manip Physiol Therapeut* 2015:1–9.

120. Cotchett MP, Munteanu SE, Landorf KB. Effectiveness of Trigger Point Dry Needling for Plantar Heel Pain: A Randomized Controlled Trial. *Phys Ther* April 2014.

121. Liu L, Huang Q-M, Liu Q-G, et al. Effectiveness of dry needling for myofascial trigger points associated with neck and shoulder pain: a systematic review and meta-analysis. *Arch Phys Med Rehabil* 2015;96(5):944–955.

122. Birch S. A review and analysis of placebo treatments, placebo effects, and placebo controls in trials of medical procedures when sham is not inert. *J Altern Complement Med* 2006;12(3):303–310.

123. Furlan AD, Yazdi F, Tsertsvadze A, et al. A Systematic Review and Meta-Analysis of Efficacy, Cost-Effectiveness, and Safety of Selected Complementary and Alternative Medicine for Neck and Low-Back Pain. *Evid Based Complement Alternat Med* 2012;2012(3):1–61.

124. Domingo A, Mayoral O, Monterde S, Santafé MM. Neuromuscular Damage and Repair after Dry Needling in Mice. *Evid Based Complement Alternat Med* 2013;2013(4):1–10.

125. Srbely JZ, Dickey JP, Lee D, Lowerison M. Dry needle stimulation of myofascial trigger points evokes segmental anti-nociceptive effects. *J Rehabil Med* 2010;42(5):463–468.

126. Hsieh Y-L, Chou L-W, Joe Y-S, Hong C-Z. Spinal cord mechanism involving the remote effects of dry needling on the irritability of myofascial trigger spots in rabbit skeletal muscle. *Arch Phys Med Rehabil* 2011;92(7):1098–1105.

127. Mayoral O, Salvat I, Martín MT, et al. Efficacy of Myofascial Trigger Point Dry Needling in the Prevention of Pain after Total Knee Arthroplasty: A Randomized, Double-Blinded, Placebo-Controlled Trial. *Evid Based Complement Alternat Med* 2013;2013(2):1–8.

128. Langevin HM, Churchill DL, Cipolla MJ. Mechanical signaling through connective tissue: a mechanism for the therapeutic effect of acupuncture. *FASEB J.* 2001;15(12):2275–2282.

129. Langevin HM, Churchill DL, Fox JR, Badger GJ, Garra BS, Krag MH. Biomechanical Response to Acupuncture Needling in Humans. *J Appl Physiol* 2001;91:2471–2478.

130. Langevin HM, Konofagou EE, Badger GJ, et al. Tissue displacements during acupuncture using ultrasound elastography techniques. *Ultrasound Med Bio*

2004;30(9):1173–1183.

131. Chen JT, Chung KC, Hou CR, Kuan TS, Chen SM, Hong CZ. Inhibitory effect of dry needling on the spontaneous electrical activity recorded from myofascial trigger spots of rabbit skeletal muscle. *Am J Phys Med Rehabil* 2001;80(10):729–735.

132. Salom-Moreno J, Sanchez-Mila Z, Ortega-Santiago R, et. al. Changes in spasticity and widespread pressure pain sensitivity, and baropodometry after the application of dry needling in patients who have had a stroke: a randomized controlled trial. *J Manipulative Physiol Ther* 2014;37(8):569–579.

133. Lacourpaille L, Hug F, Bouillard K, Hogrel J-Y, Nordez A. Supersonic shear imaging provides a reliable measurement of resting muscle shear elastic modulus. *Physiol Meas* 2012;33(3):N19–N28.

134. Lapole T, Tindel J, Galy R, Nordez A. Contracting biceps brachii elastic properties can be reliably characterized using supersonic shear imaging. *Eur J Appl Physiol* 2014;115(3):497–505.

135. Gennisson J-L, Deffieux T, MacE E, Montaldo G, Fink M, Tanter M. Viscoelastic and anisotropic mechanical properties of in vivo muscle tissue assessed by supersonic shear imaging. *Ultrasound in Med Bio* 2010;36(5):789–801.

136. Delagi E, Perotto A. *Anatomic Guide for the Electromyographer: the Limbs and Trunks*. Vol 5 ed. Springfiled, IL: Charles C. Thomas; 2011:124–196– 332.

137. Fukutani A, Miyamoto N, Kanehisa H, Yanai T, Kawakami Y. Influence of the intensity of a conditioning contraction on the subsequent twitch torque and maximal voluntary concentric torque. *J Electromyogr Kinesiol* 2012;22(4):560–565.

138. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Vol 2nd ed. Lawrence Erlbaum Associates; 1988.

139. Chuang L, Wu C, Lin K. Myotonometric measurement of muscular properties of hemiparetic arms in stroke patients. In: Kim C. *Rehabilitation Medicine.* InTech 2012.

140. Xu Y-M, Ge H-Y, Arendt-Nielsen L. Sustained Nociceptive Mechanical Stimulation of Latent Myofascial Trigger Point Induces Central Sensitization in Healthy Subjects. *J Pain* 2010;11(12):1348–1355.

141. Llamas-Ramos R, Pecos-Martín D, Gallego-Izquierdo T, et al. Comparison of the Short-Term Outcomes Between Trigger Point Dry Needling and Trigger Point Manual Therapy for the Management of Chronic Mechanical Neck Pain: A Randomized Clinical Trial. *J Orthop Sports Phys Ther* 2014;44(11):852–861.

142. Mejuto-Vázquez MJ, Salom-Moreno J, Ortega-Santiago R, Truyols-Domínguez S, Fernández-de-las-Peñas C. Short-Term Changes in Neck Pain, Widespread Pressure Pain Sensitivity, and Cervical Range of Motion After the Application of Trigger Point Dry Needling in Patients With Acute Mechanical Neck Pain: A Randomized Clinical Trial. *J Orthop Sports Phys Ther* 2014;44(4):252–260.

143. Pecos-Martín D, Montañez-Aguilera FJ, Gallego-Izquierdo T, et al. Effectiveness of Dry Needling on the Lower Trapezius in Patients With Mechanical Neck Pain: A Randomized Controlled Trial. *Arch Phys Med Rehabil* 2015;96(5):775–781.

144. Cagnie B, Dewitte V, Barbe T, Timmermans F, Delrue N, Meeus M. Physiologic Effects of Dry Needling. *Curr Pain Headache Rep* 2013;17(8):348.

145. Hegedus EJ, Goode A, Butler RJ, Slaven E. The neurophysiological effects of a single session of spinal joint mobilization: does the effect last? *J Man Manip Ther* 2013;19(3):143–151.

146. Boyles R, Fowler R, Ramsey D, Burrows E. Effectiveness of trigger point dry needling for multiple body regions: a systematic review. *J Man Manip Ther* 2015;23(5):276-293.

147. Koppenhaver SL, Walker MJ, Rettig C, et al. The association between dry needling-induced twitch response and change in pain and muscle function in patients with low back pain: a quasi-experimental study. *Physiotherapy* 2017;103(2):131–137.

148. Chou L-W, Kao M-J, Lin J-G. Probable Mechanisms of Needling Therapies for Myofascial Pain Control. *Evid Based Complement Altern Med* 2012;2012(1):1–11.

149. Abbaszadeh-Amirdehi M, Ansari NN, Naghdi S, Olyaei G, Nourbakhsh MR. The neurophysiological effects of dry needling in patients with upper trapezius myofascial trigger points: study protocol of a controlled clinical trial. *BMJ Open* 2013;3(5).

150. De Meulemeester K, Calders P, Dewitte V, Barbe T, Danneels L, Cagnie B. Surface Electromyographic Activity of the Upper Trapezius Before and After a Single Dry Needling Session in Female Office Workers With Trapezius Myalgia. *Am J Phys Med Rehabil* 2017:6.

151. Granata KP, Padua DA, Wilson SE. Gender differences in active musculoskeletal stiffness. Part II. Quantification of leg stiffness during functional hopping tasks. *J Electromyogr Kinesiol* 2002;12(2):127–135.

152. Blackburn JT, Riemann BL, Padua DA, Guskiewicz KM. Sex comparison of extensibility, passive, and active stiffness of the knee flexors. *Clin Biomech* 2004;19(1):36–43.

153. Watsford ML, Murphy AJ, McLachlan KA, et al. A Prospective Study of the Relationship between Lower Body Stiffness and Hamstring Injury in Professional Australian Rules Footballers. *Am J Sports Med* 2010;38(10):2058–2064.

154. Pearson SJ, McMahon J. Lower limb mechanical properties: determining factors and implications for performance. *Sports Med* 2012;42(11):929–940.

155. Kubo K, Morimoto M, Komuro T, et al. Effects of Plyometric and Weight Training on Muscle-Tendon Complex and Jump Performance. *Med Sci Sports Ex* 2007;39(10):1801–1810.

156. Spurrs RW, Murphy AJ, Watsford ML. The effect of plyometric training on distance running performance. *Eur J Appl Physiol* 2003;89(1):1–7.

157. Burgess KE, Connick MJ, Graham-Smith P, Pearson SJ. Plyometric vs. isometric training influences on tendon properties and muscle output. *J Strength Cond Res* 2007;21(3):986–989.