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Validation of a Pressure Pain Threshold Scale in Patients Diagnosed with Myofascial Pain Syndrome and Fibromyalgia

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By

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Abstract
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Background: Palpation is an examination technique used to diagnose and treat myofascial pain syndrome (MPS) and fibromyalgia (FM). Currently, there is no validated technique for classifying the results. A valid and reliable pressure pain threshold scale (PPTS) may provide a means for clinicians to grade, document, and report findings. The purpose of this dissertation was to validate a PPTS in patients diagnosed with MPS and FM. **Design and Methods:** An observational study. Participants who met the inclusion criteria were placed into three equal groups: MPS, FM, and control. All participants underwent one, two-part testing sessions using the American College of Rheumatology criteria. Part-I consisted of palpation with a digital pressure sensor and part-II utilized an algometer. For each tender point (18-total), the participants graded their level of discomfort using the visual analog scale (VAS) and manual tender point rating survey (MTPS) and the examiner graded their response using the PPTS (e.g. ordinal scale with increasing severity from 0-4). **Analysis:** Intrarater reliability was calculated using the intraclass correlation coefficient model 3, k. Concurrent validity between the PPTS, VAS, and MTPS was calculated using the spearman rank correlation coefficient. A receiver operating characteristic curve was used to determine the minimal cut-off value between groups. **Results:** Eighty-four participants were included in the analysis. The PPTS had good intrarater reliability (ICC ≥.88). A moderate to excellent relationship was found between the PPTS and VAS for all groups with the algometer and digital pressure sensor (rho ≥.61). A moderate to excellent relationship was found between the PPTS and MTPS for all groups with the algometer (rho≥.68) and for the MPS and control group with the digital pressure sensor (rho ≥.71). There was a little to moderate relationship (rho=.01-.50) between the PPTS and MTPS for the FM group with the digital pressure sensor. A cut-off value of 2 on the PPTS differentiated

participants with MPS and FM from controls. **Discussion:** The results provide preliminary evidence validating the PPTS for patients with MPS and FM. Future research should determine interrater reliability, diagnostic accuracy, and efficacy of the PPTS with other chronic pain and orthopedic conditions.

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Chapter 1

1.0 Overview

Manual pressure palpation is a clinical examination technique used by physical therapists to examine and treat chronic musculoskeletal pathologies such as myofascial pain syndrome (MPS) and fibromyalgia (FM). This technique is taught in physical therapy education programs as part of the musculoskeletal clinical examination.[1,2] Despite the expected standard of teaching palpation, there is lack of agreement for objectively and reliably measuring the technique, magnitude of pressure, minimal pain threshold, and patient reactivity level. This creates a gap in communication among clinicians and challenges the efficacy of this examination technique.

Based upon the paucity of evidence, a more accurate assessment of this technique is necessary for clinical practice and research. One way of objectifying manual palpation is through the use of a valid and reliable pressure pain threshold scale (PPTS) that provides a method to measure and communicate the procedures for clinicians and researchers. This chapter will present the need for validating a PPTS and the purpose of the investigation. The specific research questions, relevance, significance, and practical application of this investigation will also be discussed.

1.1 Problem Statement

Palpation of bony structures and soft-tissue for tenderness (pain provocation) is performed by clinicians to assess the presence of a musculoskeletal pathology, differentiate tissues at fault as well as a means to postulate reactivity level, and severity of pathology.[3] Currently, there is no consensus on an objective and reliable method of grading manual pressure palpation despite what is taught in physical therapy education programs and defined in the Guide

to Physical Therapist Practice.[2,4] The challenge lies in the subjective nature of palpation among clinicians which includes: 1) the amount of digital pressure to apply, 2) methods used to quantify or rank patient responses, and 3) interpretation of findings. This lack of consensus is problematic since palpation is part of the examination process for many musculoskeletal pathologies and is often used in clinical practice as a means of documenting change.

A valid and reliable PPTS is essential to the examination and diagnosis of musculoskeletal pathology. In particular, chronic pain conditions such as MPS and FM are dependent upon the findings from manual pressure palpation of tender points and trigger points (TrPs) since medical tests and imaging are inconclusive.[5,6] It is estimated that up to 54% of women and 45% of men may suffer from MPS with the most common age range between 27 to 50 years.[7-9] It is also estimated that more than 5 million Americans have FM with a higher presence among women ages 35-60 years.[3,10] In a 2012 study, Gaskin et al[11] estimated the total cost for treating chronic pain conditions in the United States was between $560 to $635 million dollars. Several researchers have found that patients with chronic pain conditions incur higher annual healthcare costs when compared to matched controls.[12-14] Despite the routine use of palpation in diagnosing MPS and FM, there is a lack of consensus regarding a standardized method of assessment and interpretation of findings. Wolf et al[15] and Okifuji et al[16] were the first researchers to use a manual pressure palpation protocol that included a rating scale for manual digital pressure with patients diagnosed with FM. The aforementioned authors did not report any validation or clinimetric data for the scales. These protocols have lacked further study since their original publication in the 1990's. Currently, no studies exist that have validated a PPTS.

The lack of consensus for measuring, documenting, and communicating manual pressure palpation for patients with MPS and FM creates a weakness in the standard physical therapy

examination when compared to other testing procedures such as goniometry which has been standardized based on procedures and normative values.[17,18] Many clinicians' routinely use minimal to moderate graded pressure with no standardized method. Thus, it is imperative that a valid and reliable scale is created since palpation is a standard component of the examination process.

1.2 Research Purpose

To date, there are no valid and reliable pressure pain threshold scales for use in research or clinical practice. The existing manual palpation protocols and scales have limited support in the literature and our knowledge has not advanced since these scales were proposed in the 1990's.[15,16] Therefore, the purpose of this investigation was to develop a valid and reliable PPTS in order to provide an objective means of assessing pressure pain thresholds and create a reliable method of communication among clinicians for individuals with a diagnoses characterized by MPS and FM. These conditions were chosen based on their high prevalence among chronic pain conditions and are also dependent upon the manual palpation examination for their diagnosis.

1.3 Research Questions

The purpose for this investigation was to validate a new PPTS in patients diagnosed with MPS and FM. This investigation included five research questions outlined below:

Q1: What is the intrarater reliability of a 5-point PPTS in participants with MPS, FM, and healthy individuals (control group)?

- ***Research Hypothesis (H_1):*** There will be good intrarater reliability (ICC >.75) using the 5-point PPTS in participants with MPS, FM, and healthy individuals
- *Null Hypothesis (H_{01})*: There will not be good intrarater reliability (ICC >.75) using the 5-point PPTS in participants with MPS, FM, and healthy individuals

Q2: Does a 5-point PPTS possess concurrent validity when compared to a 10cm (100mm) visual analog pain scale at 18 predetermined tender points in participants with MPS and FM?

- ***Research Hypothesis (H_2):*** The 5-point PPTS will have a moderate to excellent relationship (rho ≥ .50) with the 10cm visual analog scale at 18 predetermined tender points in participants with MPS and FM

- *Null Hypothesis (H_{02}):* The 5-point PPTS will not have a moderate to excellent relationship (rho ≥ .50) with the 10cm visual analog scale at 18 predetermined tender points in participants with MPS and FM.

Q3: Does a 5-point PPTS possess concurrent validity when compared to a manual tender point survey scale at 18 predetermined tender points in participants with MPS and FM?

- ***Research Hypothesis (H_3):*** The 5-point PPTS will have a moderate to excellent relationship (rho ≥ .50) with the manual tender point survey scale at 18 predetermined tender points in participants with MPS and FM

- *Null Hypothesis (H_{03}):* The 5-point PPTS will not have a moderate to excellent relationship (rho ≥ .50) with the manual tender point survey scale at 18 predetermined tender points in participants with MPS and FM.

Q4: Does manual palpation pressure up to 4 kg/cm^2 measured by the Tekscan® Wireless ELF™ pressure sensor at 18 predetermined tender points produce a comparable response by the participant as algometry pressure up to 4 kg/cm^2 using the 5-point PPTS in participants with MPS, FM, and in healthy individuals (control group)?

- ***Research Hypothesis (H_4):*** The Tekscan® Wireless ELF™ pressure sensor will have a moderate to excellent relationship (rho ≥ .50) with the algometer when using the 5-point PPTS at 18 predetermined tender points in participants with MPS and FM

- *Null Hypothesis (H_{04}):* The Tekscan® Wireless ELF™ pressure sensor will not have a moderate to excellent relationship (rho ≥ .50) with the algometer when using the 5-point PPTS at 18 predetermined tender points in participants with MPS and FM

Q5: What is the cut-off value that differentiates participants with MPS and FM (combined) and healthy individuals (control group) using the 5-point PPTS?

- ***Research Hypothesis (H_5):*** A cut-off value of 2 will be the minimal difference on the 5-point PPTS that differentiates participants with MPS and FM and healthy individuals.

- *Null Hypothesis (H_{05}):* A cut-off value of 2 will not be the minimal difference on the 5-point PPTS that differentiates participants with MPS and FM and healthy individuals.

1.4 Relevance and Significance

Currently, there is no consensus on the assessment technique of manual pressure palpation despite what is taught in physical therapy education programs and what is defined in the Guide to Physical Therapy Practice.[1,2,4] This lack of consensus is problematic since pressure palpation is a component of the examination process for many musculoskeletal pathologies. In particular, the diagnoses of MPS and FM are dependent upon the findings from manual pressure palpation of tender points and trigger points (TrPs). Often, the interpretation of pressure palpation is subjective resulting in variable results among clinicians since no standard reference has been established.

Several systematic reviews examining the efficacy of manual pressure palpation for neck and back pain have found the overall reliability of manual palpation to be weak with no superior method established.[19-21] The common limitations reported among systematic reviews is the methodological variability and lack of standardization among studies which has created a gap in our knowledge about the manual palpation examination.[19-21] These results have created an unclear translation from research to clinical practice and the development of a reference standard for technique, amount of applied pressure, and interpretation of findings. Clinicians often adopt their own methods of manual palpation with no objective way of measuring, documenting, and communicating their findings.

Clinicians and researchers may use instruments such as pressure algometry to quantify a patient's pressure pain threshold.[22,23] Algometry is a valid and reliable measure with a broad utility for research.[24-27] Several different devices have been developed such as an algometer with wireless capability[28,29] and a smaller digital pressure sensor that uses a pressure sensing film.[30] This type of technology has portability and provides concurrent measures of the rate and amount

of force that is applied during the examination. However, these instruments can be expensive and may not be practical in many clinical settings.

Clinicians also tend to use patient related outcome measures (PROs) such as the numeric pain rating scale (NPRS) or visual analog scale (VAS) to measure and track a patient's progress.[31] The NPRS and VAS are commonly used in studies involving pressure pain thresholds using manual palpation and algometry.[31-33] The subjective nature of the measures is an inherent weakness and is often influenced by the patient's perception of pain which can change.[34] Despite this limitation, the NPRS and VAS are common outcome measures used to document and communicate a patient's pressure pain threshold. To date, clinicians do not have a means of independently and objectively measuring, documenting, and communicating their findings beyond the PROs and instruments such as algometry.

Chronic pain conditions such as MPS and FM depend on the manual pressure palpation examination for diagnosis since other medical tests (e.g. blood test) and imaging are inconclusive.[5,35] The primary clinical finding for all the aforementioned diagnoses is the patient's subjective report of pain or tenderness to palpation, which can be influenced by the amount of force applied and accuracy of palpation. This creates a need for a valid and reliable tool to measure manual pressure palpation and provide a means of communication among clinicians. In the 1990's, Wolf et al[15] and Okifuji et al[16] used a manual palpation protocol and scoring system in their research on FM. The scales were part of a larger diagnostic protocol for diagnosing FM patients; however, the scales clinimetric properties were never fully studied beyond the initial publications.

Due to the lack of consensus and standardization in the manual palpation assessment of MPS and FM, a valid and reliable pressure pain threshold scale (PPTS) may provide a means for

clinicians to measure, document, and communicate their findings. The overall efficacy of the manual pressure palpation assessment will be enhanced with the combined use of the PPTS, VAS, NPRS, and algometry. Both the clinician and patient can independently measure their results which may provide a higher level of objectivity than the methods currently being used.

1.5 Practical Application of Findings

To date, there are no valid and reliable pressure palpation threshold scales that have been universally accepted among researchers and clinicians. The development of a new PPTS will provide an objective way for clinicians to measure, document, and communicate their findings. In particular, the PPTS scale will provide a means for clinicians and researchers to objectively assess conditions such as MPS and FM beyond the standard protocols in existence.[15,16] The PPTS scale can be used as an outcome measure in research involving pressure pain thresholds using manual palpation and algometry.

1.6 Scope of the Investigation

This investigation required a number of resources. Permission from 3 facilities was required to obtain the desired sample size. Data collection was conducted at California State University Dominguez Hills in Carson, CA, South Bay Orthopedic Specialists Medical Center in Torrance, CA, and Fibromyalgia of Huntington Beach in Huntington Beach, CA. The permission letters can be seen in Appendix B.

1.7 Definition of Terms

The following terms represent the nomenclature that was used throughout this dissertation. The definitions are as follows:

1) *Fibromyalgia (FM):* A chronic widespread pain disorder that affects the joints, muscles, tendons, and soft-tissue of the body.[36]

2) *Myofascial pain syndrome (MPS)*: A syndrome characterized by chronic pain that is caused by multiple trigger points and fascial constriction.[10]
3) *Myofascial trigger points (TrPs):* A hyperirritable region in skeletal muscle associated with palpable nodules in taut bands of muscle fibers. TrPs are a hallmark sign of MPS.[10]
4) *Pain:* An unpleasant sensation occurring in varying degrees of severity as a consequence of injury, disease, or emotional disorders.[34]
5) *Manual palpation:* Manual examination of the soft-tissue structure by direct contact of the examiner by feeling with the hand or fingers.[37]
6) *Pressure algometry:* A mechanical form of pain assessment using a pressure gauge attached to a rubber tipped plunger.[38]
7) *Pressure sensor:* A computerized digital force sensors that measures the amount of pressure applied to the transducer film.[39]
8) *Pressure pain threshold (PPT)*: The amount of pressure that triggers a pain response.[40]
9) *Pressure pain threshold scale (PPTS):* A numeric rating scale that ranks the amount of manual pressure that triggers a pain response.

1.8 Summary

In summary, a valid and reliable PPTS will provide clinicians and researchers with an objective means of assessing pressure pain thresholds. The existing protocols and scales were developed in the 1990's and have not been further researched. There is a lack of knowledge regarding their validity, reliability, and clinimetric properties. This creates a weakness in the standard physical therapy examination due to the subjective nature of manual palpation. The diagnosis of chronic musculoskeletal pathologies such as MPS and FM are dependent upon findings from the manual pressure palpation examination. Development of a valid and reliable PPTS is necessary to improve the clinical examination and provide a consistent method of measuring, documenting, and communication among clinicians and researchers.

Chapter 2

2.0 Introduction

Manual pressure palpation is part of the standard physical therapy examination and is often used to detect the presence of TrPs and tender points in myofascial pain syndrome (MPS) and fibromyalgia (FM).[41] Despite the routine use of this technique there are few universally accepted protocols or objective scales used in clinical practice and research. Moreover, the scales that have been used lack known clinimetric properties. The purpose of this chapter is to review the literature on MPS and FM including the clinical presentation, prevalence, and diagnosis of these conditions. This chapter will also discuss pressure pain threshold (PPT) protocols, instrumentation, patient related outcome measures, and weaknesses in the manual palpation examination. Finally, the contribution of this dissertation to the current body of literature will be discussed.

2.1 Defining Myofascial Pain Syndrome and Fibromyalgia

Myofascial pain syndrome (MPS) and fibromyalgia (FM) are classified as chronic widespread pain conditions characterized by soft tissue tenderness, fatigue, anxiety, sleep disturbances, and depression.[3] Researchers have found the presence of myofascial trigger points (TrPs) in both MPS and FM[6,41,42] The growing prevalence and economic burden of these chronic pain conditions have stimulated more research over the past two decades resulting in a better understanding of their pathophysiology.[43]

MPS is described as a chronic muscular pain disorder affecting one or more muscles that results in a cluster of symptoms such as: local and referred pain, decreased range of motion (ROM), muscle weakness, and autonomic signs and symptoms caused by TrPs.[36,44] TrPs play a

central role in the pathophysiology and are defined as hyperirritable tender spots or nodules in discrete taut bands of muscle that can produce local or referred pain.[36] Current theory suggests that TrPs may be caused by several potential mechanisms including: local ischemia, eccentric overload, and submaximal sustained or concentric contractions.[36,45] TrPs are classified as being latent or active which is dependent upon their clinical presentation.[46] Latent TrPs may not produce a referred pain upon palpation but may restrict movement or cause muscle weakness.[46] Active TrPs are tender upon palpation and may cause a referred pain pattern which is often describe as "diffuse" or "radiating". Active TrPs may be a source of pain at rest. TrPs are different than tender points which elicits pain at the site of palpation.[46] TrPs are a common clinical finding in individuals diagnosed with FM as well.[47]

FM is characterized by chronic widespread musculoskeletal pain that primarily affects the joints, muscles, tendons, and soft-tissue.[48] Traditionally, FM has been categorized as a rheumatic-like disorder with accompanying psychological factors such as anxiety and depression.[5] More current hypotheses suggest that FM is caused by a neurochemical imbalance in the central nervous system that is associated with a heightened pain perception.[5,43] Individuals diagnosed with FM often have the triad of primary symptoms: tender points, fatigue, and sleep disturbances.[5,35] Patients may also present with other symptoms including but not limited to: depression, anxiety, cognitive difficulties (e.g. poor concentration), balance problems, irritable bowel syndrome, headaches, palpable tenderness, stiffness, tingling and numbness, as well as restless leg syndrome.[49] The triad of symptoms are a hallmark clinical finding for this condition.

In summary, MPS is a regional condition with specific TrPs that can refer pain while FM is characterized by chronic widespread pain and local tender points.[50] Both have unique clinical presentations but do have one related symptom: the trigger point (Table 2.1). Researchers have

found that the FM local tender points may also be active TrPs.[6,41,42] Thus, individuals with FM may develop TrPs at the tender point sites that can refer pain.[42,50,51] This research suggests a connection between the two conditions in which individuals with FM may also suffer from MPS or vice versa. Some researchers have postulated that FM may be concomitantly present in over 50% of patients diagnosed with MPS.[52]

Table 2.1 Primary Symptoms of MPS and FM [42,53]

Myofascial Pain Syndrome	Fibromyalgia
• TrPs (local and referred pain) • Fatigue and weakness • Decreased ROM • Autonomic signs and symptoms	• Tender points and TrPs • Fatigue and weakness • Sleep disturbances

2.2 Prevalence and Economic Burden

It is estimated that up to 54% of women and 45% of men may suffer from MPS with the most common age range between 27 to 50 years.[7-9] It is also estimated that more that 5 million Americans have FM with a higher presence among women ages 35-60 years.[3,10] FM is often underdiagnosed with 1 in 5 receiving an accurate diagnosis within an average of 5 years.[54,55] Both conditions are classified as chronic pain conditions which have a high economic burden for the U.S. The most recent U.S. statistics, from 2012, showed that the total cost for treating chronic pain disorders ranged between $560 to $635 million annually.[11]

2.3 Diagnosis of Myofascial Pain Syndrome

The diagnosis of myofascial pain syndrome (MPS) is often established from findings gathered during the clinical examination. Pertinent information gathered from the patient regarding their symptoms may include: type, intensity, duration, frequency and location of the pain, aggravating, and alleviating factors.[45] The clinical examination of TrPs may include the use of manual palpation pressure or pressure algometry to find the location and assess the pressure pain threshold of the identified region.[56] TrPs are considered active if the local and referred pain reproduces the concordant symptoms and described as a familiar pain.[57] The accuracy of TrPs assessment has been studied on a wide population including but not limited to: individuals diagnosed with whiplash[58], chronic non-specific low back pain[59], chronic headaches[60], chronic mechanical neck pain[61], temporomandibular joint disorders[62], and lateral epicondylalgia.[63] The standard TrPs diagnostic examination uses the recommended criteria established by Simon and Travell (Table 2.2).[64,65] Figure 2.1 illustrates common trigger point sites along the posterior neck, shoulders, trunk, and pelvis. Despite the widespread use of the TrPs examination there has been no true standardization including the amount of pressure and interpretation of findings. In 2008, Myburgh et al [37] conducted a systematic review (1965-2007) analyzing the effectiveness of manual pressure palpation in identifying TrPs. They found that the methodological quality of the majority of the studies was poor due to non-applicable study objectives and unreliable statistical calculations. In 2009, Lucas et al [66] conducted a systematic review (1965-2009) to determine the evidence regarding reliability of manual pressure palpation in identifying TrPs. They found that reliability estimates varied widely between studies. The authors concluded that no study to date has reported the reliability of TrPs assessment according to the recommended criteria by Travell

and Simons.[64] Other authors have found similar findings and have concluded that there is limited consensus among clinicians and researchers.[45,67]

Table 2.2 Travell and Simons Examination Criteria [64]
1) The clinician manually palpates and finds a taut band of muscle with a nodule.
2) Upon sustained palpation, the patient reports a painful sensation in an area consistent with the established referred pain pattern of the involved muscle.
3) The clinician quickly rolls his/her fingers over taut band and observes the presence of a visible or palpable local twitch response.
4) During palpation, the patient demonstrates a general pain response characterized by withdrawing from palpation, wincing, or verbalizing their discomfort.

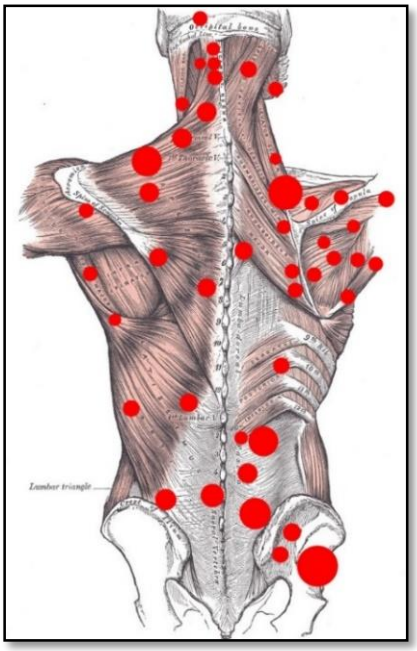

Figure 2.1 Trigger point sites along the posterior neck, shoulders, trunk, and pelvis. (Stock image license granted to Scott Cheatham)

2.4 Diagnosis of Fibromyalgia

Clinicians commonly use a standard examination process that is based upon the American College of Rheumatology (ACR) criteria for classification of fibromyalgia (FM).[15] The 1990 ACR criteria for diagnosing individuals with FM includes: history of widespread musculoskeletal pain for at least 3 months, bilateral axial pain that affects areas above and below the waist, and 11 out of 18 tender points.[68] The tender point examination includes assessing 18 predetermined tender points along the neck, back, arms, and legs (Figure 2.2) using either manual pressure palpation or pressure algometry.[69]

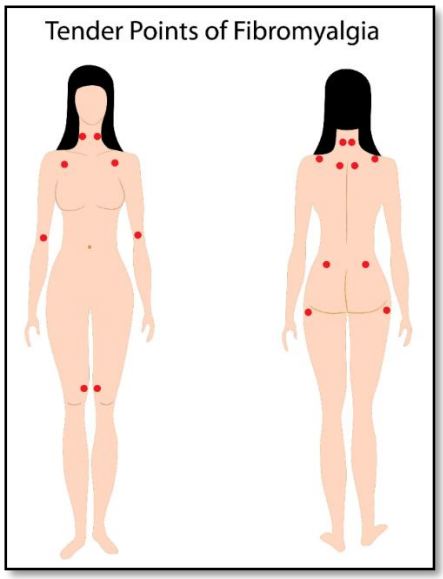

Figure 2.2 1990 American College of Rheumatology Tender Point Criteria
(Stock image license granted to Scott Cheatham)

In 1990, Wolfe et al[15] utilized a five point ranked scale and graded pressure using manual pressure palpation and pressure algometry to help quantify the ACR tender point criteria for the classification of FM. The five-point ordinal scale used anchoring "words" that correspond to each level. The rankings were as follows: 0-no pain, 1- mild pain (complaint of pain without

grimace, flinch, or withdrawal), 2- moderate pain (complaint of pain plus grimace or flinch), 3- severe (complaint of pain plus marked flinch or withdrawal), 4- unbearable (patient is untouchable). They further classified the score of 1 as "mild or greater" and a score of 2 as "moderate or greater". [15] The manual pressure palpation level was determined to be a maximum of 4kg/cm^2 (kilogram-force per square centimeter) of pressure using the thumb or the first 2 or 3 fingers (e.g. blanching of the nail). The force was applied at a rate of 1kg per second.[15] To establish reliability prior to data collection, investigators practiced the protocol and applied pressure to an algometer to quantify the amount of pressure palpation and rate of application to be used during the study. No reliability values were reported. Sixteen investigators participated in the data collection phase of the study. During data collection, the investigators tested 24 tender points and 6 control points along the body using this protocol for both palpation and algometry. Upon completion of the investigation, the authors established 18 pre-determined tender points with 11 of 18 being the minimum score for a classification of FM. The authors found that both manual palpation and algometry yielded a sensitivity of 88.4% and specificity of 81.1% in a sample of 293 participants diagnosed with FM when compared to a control group of 265 participants. The diagnostic classification of FM patients or control patients was based upon the clinical expertise of the primary investigator.[15] The authors determined that the term "painful" must be stated by the patient in order for the tender point to be considered positive (score of 1 or more). The term "tender" was considered as non painful (score of 0).[15] The authors omitted the 5-point scale and control points from the final criteria. This study provided the evidence for what is currently the ACR standard examination protocol for diagnosing FM (Table 2.3).

Table 2.3 1990 ACR Examination Protocol for Diagnosing FM [15]	
Patient Subjective Criteria	Clinical Examination Protocol
• Widespread musculoskeletal pain for at least 3 months • Bilateral axial pain that affects areas above and below the waist	• Palpate with thumb or first 2 or 3 fingers • Apply a maximum of 4kg/cm^2 of pressure at a rate of 1kg per second. • 11 out of 18 predetermined tender points are discovered. • Examiner documents provocation level using 5 point scoring system for each tender point. • The patient must report the term "painful" for a tender point to be considered positive.

In 1992, Cott et al[70] further assessed the validity and reliability of the ACR examination protocol against pressure algometry in subjects (N=15) diagnosed with FM. They found that the interrater agreement using the Kappa coefficient was .51 for manual palpation and .62 for algometry. The authors also found that the manual pressure palpation examination resulted in significantly more anatomical points being considered tender relative to algometry.[70] Jacobs et al[48] also found similar values in patients with FM.

In 1997, Okifuji et al[16] expanded the ACR examination protocol by adding a verbal eleven point numeric pain rating scale (NPRS) called the Manual Tender Point Survey (MTPS) scale. The MTPS is a 11-point ordinal scale with verbal descriptions used as anchor points (0=no pain and 10=worst pain ever experienced). The authors found that a reported pain severity score of 2/10 (sensitivity 88.57%, specificity 71.43%) was an optimal point for identifying a tender point in 70 subjects with FM when compared to a control group.[16]

Weakness in the ACR criteria and Wolf scale

The scale utilized by Wolf et al[15] was the first attempt at establishing a universally accepted pressure pain scale. The scale was part of larger diagnostic protocol and the clinimetric properties were never fully studied. For example, the ACR examination depends on the patient stating the term "pain" in order to consider a tender point to be positive. Okifuji et al[16] attempted to expand on the ACR criteria by adding a stricter protocol and the addition of the MTPS to quantify the patient's level of sensitivity at each tender point. However, their protocol was never further researched.

Later investigations began developing their own interpretation of the ACR tender point criteria and the Wolf scale. A study by Croft et al[71] evaluated the relationship between tender points, complaints of pain, and symptoms of depression, fatigue, and sleep quality in the general population. They reported using the ACR criteria to classify individuals but modified the interpretation of a tender point. They excluded the Wolf scale and replaced the ACR criteria with a new tender point classification of "definite tenderness." A positive tender point was considered the presence of any involuntary verbal or facial expression or a wince or withdrawal. Upon completion of the study, they determined that tender points are more a measure of distress rather than FM related pain.[71] Other authors have modified their interpretation of the ACR criteria which has yielded variable outcomes and interpretations.[72-76] The lack of standardization of scoring creates a weakness in the tender point exam and makes it a challenge to discriminate between individuals who have FM and the severity of the condition. Prescott et al[77] and Croft et al[72] found a correlation between the number of tender points and the type and severity of the pain in patients with FM. Thus, the non-standardized scoring and interpretation of tender points creates a weakness in the ACR examination process.

Emerging Criteria

In 2010, Wolf et al[78] conducted a preliminary investigation to modify the 1990 ACR examination protocol with the use of two questionnaires: Widespread Pain Index and the Symptom Severity Scale. These two questionnaires have been proposed by Wolfe et al to replace the traditional examination protocol. Preliminary data from Wolf et al[78] suggests that these questionnaires successfully classified subjects with FM in 88.1% (N=730) of cases in a sample of 829 patients with a sensitivity of 96.6% and specificity was 91.8%. Other authors have assessed the modified criteria and have produced mixed results. Bidari et al[79] found a lower sensitivity (58.9% versus 71.4%) in the 2010 modified criteria when compared to the 1990 criteria in a sample of 168 subjects diagnosed with FM. Other authors have found the modified criteria to have similar levels of sensitivity and specificity as the 1990 ACR criteria.[80-82] Due to mixed results, further studies are needed to validate these criteria. Currently, the 1990 ACR examination protocol is still the standard for diagnosing individuals with FM.[82]

2.5 Dimensions of Chronic Pain

Chronic pain is a multifaceted sensory and emotional experience that varies widely between individuals depending on the context and meaning of the pain and psychological state of the person.[83] A combination of biological, psychological, and social factors interacts to influence pain.[83] More specifically, cognitive and emotional factors have an important effect on pain perception and these relationships lie in the connectivity of brain regions controlling pain perception, attention or expectation, and emotional states.[83] Patients with chronic pain may have alterations in brain regions involved in cognitive and emotional modulation of pain which may provide an explanation of why patients with chronic pain may have both psychological distress and physical manifestations of pain.[84,85] Chronic pain may activate secondary mechanisms

within the central (central sensitization) and peripheral nervous system that can cause allodynia (sensitivity to non-noxious stimulus), hyperalgesia (increased sensitivity to pain), and hyperpathia (nocioceptive stimuli evokes exaggerated levels of pain) which often results in diminished function.[86] Clinician must consider these factors when examining and treating patients with FM and MPS.

FM and MPS may also be accompanied by other chronic conditions such as chronic headaches, temporomandibular disorder, irritable bowel syndrome, and interstitial cystitis/irritable bladder. Chronic pain conditions often cluster together in an individual. These conditions may fluctuate with one chronic condition becoming more dominant at a given point in time. [83,85] FM and MPS may also be clustered with other symptoms such as fatigue, poor sleep, poor cognition, and mood disturbances.[83,87]

The examination of the patient with chronic pain can be challenging due to the physiological and psychological changes that occur with these conditions. This is compounded by the clustering with other chronic conditions. Thus, the physical examination of these individuals through palpation, which is often required for diagnosis, may be difficult due to the variability in responses and magnification of pain severity by the patient.[72,88] Patients may present with allodynia, hyperalgesia, or hyperpathia, and also demonstrate an emotional fear response to testing due to the pain or past experience.

2.6 Standard Manual Palpation: Challenges

Several systematic reviews examining the efficacy of standard soft-tissue, motion, and pressure palpation for neck and back pain have found the overall reliability of palpation to be weak with no superior method established.[19-21] Manual pressure palpation for pain seemed to

have the greatest reliability followed by motion palpation and soft-tissue palpation. Among all studies, intrarater reliability was better than interrater reliability.[19-21] The common limitations reported among reviews were the methodological variability and lack of standardization among studies which has created a gap in our knowledge about the manual palpation examination.[19-21] Other studies on manual pressure palpation of nerves[89], pelvic landmarks[90], patellar position[91], forearm muscles[63], and upper extremity muscles[92,93] have produced similar variable outcomes. These results have created an unclear translation from research to clinical practice and the development of a reference standard for technique, amount of applied pressure, and interpretation of findings.

Clinicians often adopt their own methods of manual palpation with no objective way of measuring, documenting, and communicating their findings. If resources are available, clinicians may use instruments such as pressure algometry to quantify a patient's pressure pain threshold.[22,23] Also, clinicians may use patient related outcome measures (PROs) such as the numeric pain rating scale (NPRS) or visual analog scale (VAS) to measure and track a patient's progress.[31] These instruments and PROs are discussed in the following sections. To date, clinicians do not have a means of independently and objectively measuring their findings outside of these clinical tools.

2.7 Patient Related Outcome Measures

As mentioned above, Okifuji et al[16] expanded the ACR palpation protocol by using the MTPS which is an NPRS. Clinicians often use PROs such as the NPRS and VAS to measure and track a patient's progress.[31] These outcome measures are commonly used in studies involving pressure pain threshold testing using manual palpation and algometry.[31-33]

Investigations have shown that the NPRS has good test-retest reliability (r=.94-.96).[34,94-96] Investigations have shown that the VAS has good test-retest reliability (r=.94).[34] Other studies combining manual palpation pressure and the VAS for pain in subjects with FM have produced good results.[96,97] A strong association (ICC=.86-.95) exists between the NPRS and the VAS when used with chronic pain disorders such as MPS and FM.[34,94-96] The subjective nature of PROs is an inherent weakness and is often influenced by the various dimensions of chronic pain.[34] Despite this limitation, the NPRS and VAS are common outcome measures used to document and communicate a patient's pressure pain threshold. These outcome measures are further described in chapter 3.

2.8 Instrumentation used in the Assessment of MPS and FM

Algometry

Along with manual palpation, pressure algometry is used in the assessment of individuals with MPS and FM.[98] Pressure algometry is a mechanical form of pain assessment using a pressure gauge attached to a rubber tipped plunger.[38] The instrument is pressed against a pre-determined musculoskeletal region until a perceived maximum level of pain is produced.[99] Different types of algometry are available including hand-held spring loaded, digital, or computer based devices with a strain or pneumatic pressure gauge.[25,28,29] Newer computer based algometers, such as the J-Tech Tracker Freedom® algometer (Midvale, UT) (Figure 2.3), offer a level of objectivity and pressure standardization that may be absent from other non-computerized algometers as well as novel to the existing research on PPT scales.[99] The manufacturer reports an accuracy error of <± 0.5% (.05kg/cm^2) for this technology. [99] The accompanying software calibrates the algometer before each test and includes specific examination protocols such as the ACR tender point criteria for diagnosing FM.[15] The software visually guides the examiner, on

the monitor, as they apply pressure to the tender point site and then signals the examiner to stop when the pressure level is met. The J-Tech Tracker Freedom® algometer has been used in several investigations that examined lumbar spine mobilization[100], manual therapy for shoulder impingement[101], Acai berry consumption and pain[102], and the relationship between neck pain and physical activity[103].

Figure 2.3 J-Tech Tracker Freedom® Algometer

Several researchers have investigated the reliability of pressure algometry. Chesterton et al[26] examined the interrater reliability among 5 newly trained raters in assessing PPT using a digital algometer on the first dorsal interosseous muscle in 13 healthy subjects. The authors found good reliability among all raters (ICC=.90). Nussbaum and Downes[104] examined the reliability among 2 trained raters in assessing PPT using digital pressure algometry on the biceps brachii muscle over 3 consecutive days in 35 healthy subjects. The authors found good interrater reliability (ICC= .74-.89) among the raters.[104]

Persson et al [92] also examined the test-retest reliability of PPT in shoulder muscles over 4 sessions (Days 1,3,28,30) in 24 healthy female subjects (mean age 42 years). Two examiners used a digital algometer to measure the bilateral PPT over the trapezius and deltoid muscles. The authors found moderate to good interrater reliability among examiners for all sessions (ICC=.70-.94). Moderate to good reliability was found between points for each muscle: trapezius: right (ICC=.59-.77), left (ICC=.67-.84), deltoid: right (ICC= .66-.83), left (ICC=.70-.90).

Park et al[35] assessed the PPT using digital algometry in the diagnosis of MPS in 222 subjects (113 males, 108 females; mean age 43.2 years) using 5 trained raters. They evaluated the reliability, sensitivity, specificity, of applied pressure to six upper extremity muscles which included the: bilateral trapezius, infraspinatus, and extensor carpi radialis. One hundred fifty-six out of 222 subjects (72%) were diagnosed with MPS. The authors found good intrarater reliability among all muscles (Cronbach's alpha= .94-.98). The specificity of the applied pressure for each muscle was as follows: trapezius (55%), infraspinatus (70%), and extensor carpi radialis (80%). The sensitivity was as follows: trapezius (42%), infraspinatus (30%), and extensor carpi radialis (5%).[35] Other authors have found similar reliable outcomes in assessing PPT with algometry in the muscles of the temporomandibular joint,[105-107] neck,[108] shoulder,[57] and abdominal wall in women.[109,110] This research suggests that pressure algometry is a reliable measure of PPT among examiners over several sessions.

Wolfe et al[15] also used algometry in their 1990 investigation that led to the development of the ACR tender point criteria for the classification of FM. Please see above for more details on the performance of algometry in this investigation.

Digital Pressure Sensor

Standard manual palpation can be enhanced with the use of a digital pressure sensor to measure the pressure palpation force applied by the examiner. Bendtsen et al[111,112] first introduced this technology back in 1994 and coined it the "palpometer." The technology uses a thin pressure sensing film connected to data collection hardware. The preliminary studies in the 1990's reported this technology to be valid and reliable for measuring pressure pain thresholds.[112,113] A more recent study by Fryer et al[114] measured the reliability of the digital algometer to determine PPT of thoracic paraspinal tissue in 32 subjects. The subjects laid prone

while one examiner (blinded to the results) applied pressure at 3 predetermined thoracic paraspinal regions. The authors reported good intra-rater reliability (ICC=.95) for the three regions.[114] Futarmal et al[115] and Kothari et al[116] both looked at test-retest variability among clinicians (N=12, N=16) between a digital pressure sensor and manual palpation at predetermined sites on the hand and fingers. Both studies calculated the coefficient of variation and found lower test-retest variability among raters using the digital pressure sensor versus manual palpation.[115,116] Other studies have shown this technology to be valid and reliable for measuring PPT in craniofacial muscles[105,117,118] and intraoral structures.[119]

Tekscan® (South Boston, MA) has expanded this technology by creating a wireless version of the pressure sensor. The system uses a thin pressure sensing film connected to a wireless transmitter that sends concurrent data to a laptop computer (Figure 2.4). This is the same technology that Bendtsen et al[111,112] and Fryer et al[114] adapted for their investigations but with a wireless feature. Tekscan® reports an accuracy error of <±3% (.03kg/cm^2) for this technology.[120] The pressure sensor has been utilized in several research studies focusing on concussions,[58] balance,[121] knee joint biomechanics,[30] dentistry,[122] and gait.[123] To date, this technology has not been used for measuring manual PPT in individuals diagnosed with MPS and FM.

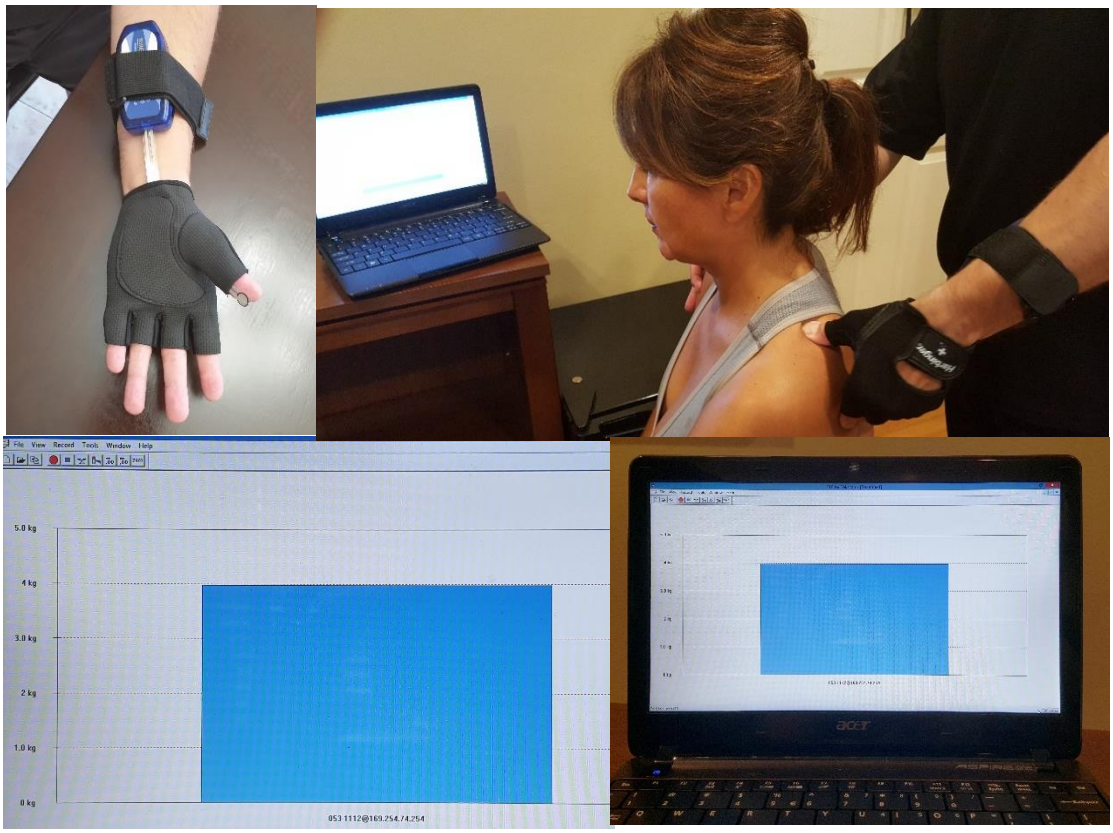

Figure 2.4 Tekscan® Digital Pressure Sensor with WiFi Transmitter

2.9 Summary of Literature

The clinical presentations of MPS and FM are unique except for one common variable: the presence of TrPs. Research from Alonso-Blanco et al[41] and Ge et al[42] suggests that individuals with FM also have concomitant TrPs at the predetermined tender point sites. Clinicians and researchers commonly diagnose tender points and TrPs using manual pressure palpation techniques that lack standardization and uniform reporting procedures.[37]

Currently, there is no consensus on the assessment technique of manual pressure palpation despite what is taught in physical therapy education programs and what is defined in the Guide to Physical Therapy Practice.[1,2,4] Chronic conditions such as MPS and FM depend on the manual pressure palpation examination for diagnosis since other medical tests (e.g. blood test) and imaging are inconclusive.[5,35] Wolf et al[15] and Okifuji et al[16] were the first to use a

manual palpation protocol (ACR diagnostic criteria) that included a rating scale for manual pressure palpation for diagnosing patients with FM. These protocols have lacked further study since their original publication in the 1990's.

Due to the lack of consensus and standardization in the palpation examination for chronic pain conditions such as MPS and FM, there is a need for a valid and reliable pressure pain threshold scale (PPTS). The primary clinical finding for all the aforementioned diagnoses is the patient's subjective report of pain or tenderness to palpation, which can be influenced by the amount of force applied and accuracy of palpation. The efficacy of a PPTS can be enhanced by the use of instruments such as a pressure sensor or algometer which can provide concurrent monitoring of rate and amount of pressure during the examination. The use of PROs such as the MTPS and VAS can also provide a good measure of the patient's perceived level of pain. Thus, the combined use of the PPTS, digital pressure sensor, computerized algometer, NPRS and VAS pain scales, and the 1990 ACR diagnostic criteria may provide a more valid and reliable assessment than the existing protocols that were published in the 1990's.

2.91 Contribution of this Dissertation

The development and utilization of a valid and reliable PPTS may have broad clinical application and provide a standardized way of assessing PPT as required for clinicians and researchers to communicate their findings. Moreover, a valid and reliably scale may also provide a clearer basis for identifying tissue reactivity as it can be better used in clinical studies for chronic pain conditions such as MPS and FM. For educators in physical therapy programs, a universally valid and reliable PPTS may enhance the teaching and interpretation of findings for manual pressure palpation.

Chapter 3

3.0 Introduction

This chapter outlines the methodology used to investigate the clinical questions for this dissertation project. This chapter will discuss the inclusion and exclusion criteria along with the recruitment methods used to recruit and assign participants to the designated groups. Methods of data collection with be outlined followed by the methods of data analysis. Last, the resources used for this investigation will be discussed with a final summary.

3.1 Purpose and Clinical Questions

The purpose of this dissertation was to validate a pressure pain threshold scale (PPTS) in patients diagnosed with myofascial pain syndrome (MPS) and fibromyalgia (FM). The validation of this new scale was determined by investigating the following clinical questions:

Q1: What is the intrarater reliability of a 5-point PPTS in participants with MPS, FM, and healthy individuals (control group)?

- ***Research Hypothesis (H_1):*** There will be good intrarater reliability (ICC >.75) using the 5-point PPTS in participants with MPS, FM, and healthy individuals
- *Null Hypothesis (H_{01})*: There will not be good intrarater reliability (ICC >.75) using the 5-point PPTS in participants with MPS, FM, and healthy individuals

Q2: Does a 5-point PPTS possess concurrent validity when compared to a 10cm (100mm) visual analog pain scale at 18 predetermined tender points in participants with MPS and FM?

- ***Research Hypothesis (H_2):*** The 5-point PPTS will have a moderate to excellent relationship (rho ≥ .50) with the 10cm visual analog scale at 18 predetermined tender points in participants with MPS and FM
- *Null Hypothesis (H_{02}):* The 5-point PPTS will not have a moderate to excellent relationship (rho ≥ .50) with the 10cm visual analog scale at 18 predetermined tender points in participants with MPS and FM

Q3: Does a 5-point PPTS possess concurrent validity when compared to a manual tender point survey scale at 18 predetermined tender points in participants with MPS and FM?

- ***Research Hypothesis (H_3):*** The 5-point PPTS will have a moderate to excellent relationship (rho ≥ .50) with the manual tender point survey scale at 18 predetermined tender points in participants with MPS and FM

- *Null Hypothesis (H_{03}):* The 5-point PPTS will not have a moderate to excellent relationship (rho ≥ .50) with the manual tender point survey scale at 18 predetermined tender points in participants with MPS and FM

Q4: Does manual palpation pressure up to 4 kg/cm^2 measured by the Tekscan® Wireless ELF™ pressure sensor at 18 predetermined tender points produce a comparable response by the participant as algometry pressure up to 4 kg/cm^2 using the 5-point PPTS in participants with MPS, FM, and in healthy individuals (control group)?

- ***Research Hypothesis (H_4):*** The Tekscan® Wireless ELF™ pressure sensor will have a moderate to excellent relationship (rho ≥ .50) with the algometer when using the 5-point PPTS at 18 predetermined tender points in participants with MPS and FM.

- *Null Hypothesis (H_{04}):* The Tekscan® Wireless ELF™ pressure sensor will not have a moderate to excellent relationship (rho ≥ .50) with the algometer when using the 5-point PPTS at 18 predetermined tender points in participants with MPS and FM.

Q5: What is the cut-off value that differentiates participants with MPS and FM (combined) and healthy individuals (control group) using the 5-point PPTS?

- ***Research Hypothesis (H_5):*** A cut-off value of 2 will be the minimal difference on the 5-point PPTS that differentiates participants with MPS and FM and healthy individuals.

- *Null Hypothesis (H_{05}):* A cut-off value of 2 will not be the minimal difference on the 5-point PPTS that differentiates participants with MPS and FM and healthy individuals.

3.2 Research Design and Approvals

This dissertation was a three group observational study that investigated the reliability and validity of the PPTS. This study received Institutional Review Board approval by Nova Southeastern University and California State University Dominguez Hills. The approval letters can be found in *Appendix A.* To successfully complete this project adequate resources needed to be utilized. The study used 3 data collection sites: (1) Fibromyalgia of Huntington Beach in Fountain Valley, CA, (2) South Bay Orthopedic Specialists Medical Center in Torrance, CA, and

(3) California State University Dominguez Hills in Carson, CA. The approval letters can be found in *Appendix B*. Data collection was conducted by one examiner who was the principal investigator (PI) for this study.

3.3 Participant Recruitment

Participant recruitment (convenience sampling) was conducted using several methods. First, the PI attended different community group meetings for individuals with MPS and FM at Fibromyalgia of Huntington Beach. The PI invited interested individuals to participate in the study and also provided an approved flyer (*Appendix C*). Second, the staff from South Bay Orthopedics Medical Group provided the flyer to potentially eligible patients with contact information for the PI. Patients had the choice to contact the PI, if interested in participating in the study. Third, participants were recruited from the campus community at California State University Dominguez Hills. The approved flyer was displayed in several campus locations and the PI visited various campus group meetings and invited individuals.

3.4 Description of Participants

Eighty-four participants (N=84) who met the inclusion and exclusion criteria and consented to participate were enrolled in the study.

Inclusion Criteria

Participants included in this investigation were 18 to 65 years of age and met the criteria for 1 of the 3 groups. All participants were required to read, speak and write English as needed to complete forms and consent. Each group consisted of 28 participants. The following criteria for each group is outlined below:

1. *Control group:* Individuals with no current or prior diagnosis consistent with MPS or FM. No integumentary injuries or abnormalities at the predetermined palpation sites.

2. *MPS group:* Individuals with a diagnosis of MPS that does not meet the American College of Rheumatology (ACR) diagnostic criteria for FM. No integumentary injuries or abnormalities at the predetermined palpation sites.
3. *FM group:* Individuals who met the criteria for a diagnosis of FM based upon the ACR diagnostic criteria. No integumentary injuries or abnormalities at the predetermined palpation sites.

Exclusion Criteria

Prior to testing, participants filled out a screening questionnaire (*Appendix D*) with questions that represent the following exclusion criteria which were used to determine ineligibility for this study. The exclusion criteria were as follows:

1. Current neurologic conditions (e.g. Multiple Sclerosis)
2. Current metabolic conditions (e.g. Diabetic Neuropathy)
3. Current systemic conditions (e.g. Rheumatoid Arthritis)
4. Any skin or connective tissue problems (e.g. Marfan Syndrome)
5. Current symptoms of numbness, tingling, burning, coldness, or pain in your back, hands, or feet.
6. Any prior surgeries that may affect their ability to participate in this study.
7. A pacemaker or electrical implant that may be affected by electronic equipment.
8. Currently taking medications that may alter a subject's sensation or affect their ability to participate in this study.
9. Current shingles or post-herpetic neuralgia.
10. Current open skin wounds on your neck, arms, back, or legs
11. Current integumentary injury or abnormalities at palpation sites.
12. Currently having other medical conditions or limited function that might affect participation.
13. The ability to tolerate testing duration (45 minutes) and procedures.
14. The ability to understand and complete all consent forms and questionnaires.

3.5 Participant Enrollment and Consent

Upon determining eligibility, participants were given an IRB approved consent form (*Appendix E*) to read and sign. The PI was available to answer any study related questions and

outline the testing procedures. Upon written consent, the PI began testing procedures or scheduled the participant for a future testing date. These forms are further discussed in section 3.9 testing procedures.

3.6 Patient Reported Outcome Measures

During testing, all participants used two outcome measures to assess their perceived level of discomfort at each predetermined tender point. They are outlined below:

Manual Tender Point Survey (MTPS): The MTPS is an 11-point numeric pain rating scale in which participant assigned a numerical value to quantify the perceived level of sensitivity they felt after the examiner tested each pre-determined point. The MTPS uses verbal descriptions as anchor points (0=no pain and 10=worst pain ever experienced) to help participants understand the scale. Numeric pain scales have been shown to be valid and reliable.[34,95,97] Okifuji et al[16] utilized this scale in their investigation that diagnosed individuals with FM (*Appendix F*).

Visual Analog Scale: The VAS is a pain assessment tool where the subject measures their pain level by marking a vertical line along a 10 cm (100 mm) horizontal line between two end points. The VAS has been shown to be valid and reliable (*Appendix F*).[34,35,95]

3.7 Pressure Pain Threshold Scale

The Pressure Pain Threshold Scale (PPTS) is a ranked scale newly designed for this investigation. The PPTS was used by the examiner during testing to measure the participant's reactivity level. The PPTS is a 5-point ranked scale that includes corresponding criteria for each level (Table 3.1). Wolf et al[15] developed a similar scale that used a scoring system but the clinimetric properties were never fully studied since their publication in the 1990's.

Grade	Interpretation	Criteria
0	No Pain	No signs of pain or discomfort with pressure.
I	Mild Pain	Tenderness reported without flinching to pressure.
II	Moderate Pain	Wincing or flinching to pressure.
III	Severe Pain	Signs of severe pain such as verbal gestures and withdrawing of body part to pressure.
IV	Noxious-Intolerable Pain	Unbearable pain, patient does not allow palpation to the specific area of pain.

Table 3.1. The Pressure Pain Threshold Scale

3.8 Instrumentation

Two clinical tools were used in this investigation. First, a digital pressure sensor was used to provide concurrent feedback of digital pressure during manual palpation. This technology has been validated and used before in prior studies.[78,79] Second, a pressure algometer was also used to provide concurrent feedback and as a comparison for the digital pressure sensor. Algometry is a valid and reliable tool that is commonly used in research involving individuals with MPS and FM.[35,92,104] A more comprehensive discussion of the clinimetric values of these instruments is provided in Chapter 2. A summary of these instruments is provided below:

Digital Pressure Sensor: The Tekscan® (South Boston, MA) Wireless ELF™ 2 computerized pressure system using the FlexiForce® sensor film was used during part I of the investigation. The EFL™ 2 system measured the pressure applied (up to 4km/cm^2) by the examiner during the examination process. The sensor film was attached to the thumb which measured the pressure that was applied by the examiner (Figure 2.4) The sensor was connected to the accompanying software via Wi-Fi transmitter. The computer screen displayed a concurrent numeric reading of the amount of pressure being applied by the examiner in kilogram-force per square centimeter while the software recorded the session. This allowed the examiner to observe the amount of pressure being applied at each predetermined point. The software and hardware were calibrated before each testing session.

Pressure Algometry: The JTECH (Midvale, UT) Tracker Freedom® wireless algometer was used with the accompanying Tracker 5® software to measure the pressure (up to 4km/cm^2) at each predetermined tender point in part II of the study. The algometer was connected to the computer via Bluetooth® wireless technology. The software visually guided the examiner, on the monitor, during testing. The computer screen displayed a concurrent numeric reading of the amount of pressure being applied by the examiner in kilogram-force per square centimeter while the software recorded the session. The subject also had a wireless remote button that they could press once their maximum level of discomfort was reached. This button stopped the test and the software immediately recorded the data. The software and hardware were calibrated before each testing session.

3.9 Testing Procedures

Prior to data collection, all participants filled out a questionnaire (*Appendix D*) to provide demographic information (age, body mass, gender, and arm dominance) and determine eligibility. If eligibility was determined, the participant was given an IRB approved consent form to read and sign (*Appendix E*). Once questions were answered to the prospective participant's satisfaction, written consent was obtained. All participants underwent the same testing procedure and were blinded from the examiner's scores and other participants enrolled in the study. Testing was conducted between the hours of 8 A.M. and 2 P.M. and participants were instructed to refrain from taking any medication (e.g. pain medication or muscle relaxants) that would interfere with outcomes prior to testing. Participants were blinded from the investigator's PPTS scores and from other participants enrolled in the study.

Reliability Testing: For the reliability portion of the study, the first 10 participants with the conditions of MPS or FM and the first 10 healthy participants (control group) underwent 1

day of testing which lasted approximately 45 minutes. Participants were then offered to return for a 2nd day of testing (approximately 45 minutes) within one week of the first session. Participants underwent the same testing procedure each day. Recruitment continued until a total of 20 participants were obtained for both the MPS and FM group and control group. After the reliability testing was complete, all other recruited participants underwent 1 day of testing which lasted approximately 45 minutes.

Testing Process: All participants underwent the same 2-part testing process that lasted approximately 45 minutes (*part I: 20 minutes, part II: 20 minutes*). Participants had the option to wear a gown with the back exposed and were instructed to wear their undergarments during testing. If not, clothing was move to expose the area of testing. All participants were placed in a seated position on a plinth or chair during testing. If the participant was unable to sit for the time period, they were placed in a prone or sidelying position. A mirror was placed in front of the participant to monitor their facial expressions during testing (Figure 3.1).

Prior to testing, the PI demonstrated the procedure with each participant using 2 control points: left thumb (Part I), dorsum of the right forearm (Part II). This was done to familiarize the participant with the testing procedures, scoring of the PRO's, and to answer any questions prior to testing. The control points were independent of the ACR 18 pre-determined points.[16] Each part of the examination will be outlined below:

Part I: Manual Palpation with Pressure Sensor: The PI applied a gradually increasing pressure to the American College of Rheumatology (ACR) 18 pre-determined points up to 4kg/cm^2 of pressure using the thumb and pressure sensor. The pressure was applied at a rate of 1kg per second for a total of 4 seconds at each point, one time.[15,16] The participant recorded their level of discomfort at each point using the MTPS and VAS pain scales once the PI reached

4kg/cm^2 of pressure or once a maximum level of pressure was felt (*Appendix F*). Participants were able to stop testing at any time by verbally telling the examiner. The PI simultaneously recorded the participant's response using the PPTS scale for each tender point (*Appendix G*). The pressure sensor was calibrated prior to testing each participant.

Part II: Algometry: The PI applied a gradual increasing pressure to the 18 pre-determined points up to 4kg/cm^2 of pressure using the computerized algometer. The pressure was applied at a rate of 1kg per second for a total of 4 seconds at each point, one time.[15,16] The participant recorded their level of discomfort at each point using the MTPS and VAS pain scales once the examiner reached 4kg/cm^2 of pressure or once a maximum level of pressure was felt (*Appendix F*). Participant's also had the choice to press a wireless button, once a maximum level of pressure was reached, to initiate an audio chime to stop testing. This also stopped the device from recording pressure. Participants were able to stop testing at any time by verbally telling the examiner. The PI simultaneously recorded the participant's response using the PPTS scale for each tender point (*Appendix G*). The algometer was calibrated prior to testing each participant.

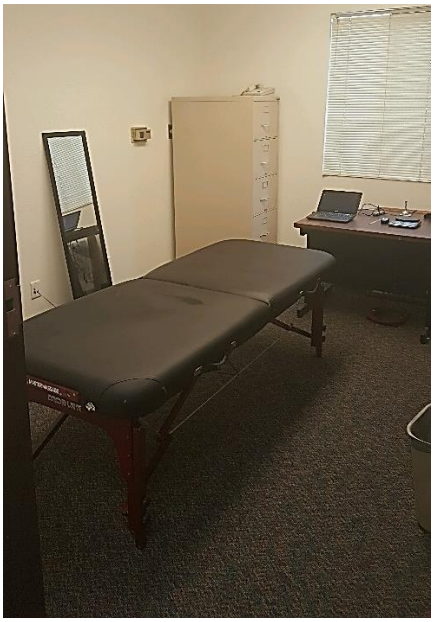

Figure 3.1 Testing lab at California State University Dominguez Hills

Tender points: The pre-determined tender points and control points were based upon the ACR diagnostic criteria for fibromyalgia[15] and by the work of Okifuji et al.[16] The test included 18 predetermined tender points and 2 control points along the neck, back, arms, and legs. Below is a list of the specific points (note: bilateral testing for 18 points and *2 control** points for a total of 20 points).

1) Posterior: (1) occiput (suboccipital muscle insertions), (2) trapezius (midpoint of the upper scapular border), (3) supraspinatus (above medial border of the scapular spine), (4) gluteal (upper outer quadrant of buttocks), (5) greater trochanter (posterior to trochanteric prominence)
2) Anterior: (6) low cervical (anterior intertransverse space C5-C7), (7) second rib (2nd costocondral junction), (8) lateral epicondyle (2cm distal to epicondyle), (9) knee (medial fat pad proximal to joint line**),** (10) *left thumbnail**, (11) *dorsum R forearm (junction of proximal 2/3 and distal 1/3) **

3.91 Sample Size and Power

Prior to data collection, an *a priori* power analysis was conducted using the G*Power software[124] for a moderate effect size (r=.30) as defined by Cohen.[125] Based upon this test, power was set at 0.8, alpha level equal to .05 for a sample size of N=84 using a 2 tailed test. Each of the three groups had 28 participants for a total of 84 study participants.

3.92 Data Analysis

Statistical calculations were conducted with SPSS v.22 (IBM SPSS, Chicago, IL). The various statistics used to calculate the data related to the clinical questions are described below. The P-value was considered significant at the .05 level using a two-tailed test ($\alpha 2 = .05$) for all clinical questions outlined below.

Participant Data: Descriptive data for age, body mass, height, and body mass index (BMI) was calculated for each group. Means standard error of mean (SEM), 95% confidence intervals (95% CI), and ranges of the ratio descriptive data from each group were calculated and presented in tabular format. Group differences were calculated using the ANOVA test for continuous level data and the Kruskall Wallis test for ordinal level data.

Question #1: *What is the intrarater reliability of a 5-point PPTS in participants with MPS, FM, and healthy individuals (control group)?* The intraclass correlation coefficient (ICC) model 3, K statistic was used to calculate intrarater reliability. The criteria for evaluating the reliability coefficient was as follows: <.75 = poor to moderate, ≥.75 = good reliability.[126]

Question #2: *Does a 5-point PPTS possess concurrent validity when compared to a 10cm (100mm) visual analog pain scale at 18 predetermined tender points in participants with MPS and FM?* The spearman rank correlation coefficient was used to calculate the data for this question (95% limits of agreement). The criteria for the evaluating the correlation coefficient was as follows: .00-.25 = little or no relationship, .25-.49 = fair relationship, .50-.75 = moderate to good relationship, and values greater than .75 = excellent relationship.[126]

Question #3: *Does a 5-point PPTS possess concurrent validity when compared to a manual tender point survey scale at 18 predetermined tender points in participants with MPS and FM?* The spearman rank correlation coefficient was used to calculate the data for this question (95% limits of agreement). The criteria for evaluating the correlation coefficient is outlined above in question #2.

Question #4: *Does manual palpation pressure up to 4kg/cm^2 measured by the Tekscan® Wireless ELF™ pressure sensor at 18 predetermined tender points produce a comparable response by the participant as algometry pressure up to 4kg/cm^2 using the 5-point PPTS in participants with MPS, FM, and in healthy individuals (control group)?* The spearman rank correlation coefficient was used to calculate the data for this question (95% limits of agreement). The criteria for evaluating the correlation coefficient is outlined above in question #2.

Question #5: *What is the cut-off value that differentiates participants with MPS and FM (combined) and healthy individuals (control group) using the 5-point PPTS?* The receiver operating characteristic (ROC) curve was used to calculate the data for this question. The ROC curve is an anchor based method of calculating the optimal cut-off value.[127] The optimal cut-off value is represented by the maximum sensitivity and specificity situated highest on the upper left side of the ROC curve.[128] The area under the curve (AUC) represents the probability of scores

accurately differentiating between patients. The AUC criteria ranges from 0.5 to 1. A score of 0.7 to 0.8 is considered an acceptable discriminating range and 0.8 to 0.9 is considered an excellent discriminating range.[129] The sensitivity, specificity, likelihood ratios, and predictive values were also calculated for this question based upon the previous work of Okifuji, et al.[16]

3.93 Resources

Internal grant funding from California State University Dominguez Hills was obtained for the amount of $4,000 which covered the costs for equipment, study related materials, and a $20 no-fee gift card given to each participant for completing the study.

3.94 Summary

This chapter details the methodology used to perform the investigation to validate a PPTS in participants with a diagnosis characterized by MPS and FM. A comprehensive research project such as this requires careful planning of appropriate testing protocols, data collection, and analysis. Internal validity was maximized through the selection of reliable instruments, strict adherence to a testing procedures, blinding the participants from the PI's scores and other participants enrolled in the study. External validity was ensured through the use of a standard testing protocol, outcomes measures, and validated instrumentation that have been used in prior research in individuals with MPS and FM. The outcomes of this investigation can only be generalized to the population studied.

Chapter 4: Results

4.0 Introduction

This chapter will provide a summary of the results of this investigation on validating a pressure pain threshold scale (PPTS) in individuals with myofascial pain syndrome (MPS) and fibromyalgia (FM). Participant demographic data and outcomes for the five clinical questions related to this investigation will be summarized in this chapter. For each clinical question, the results of part I: manual palpation with pressure sensor and part II: algometry will be discussed.

4.1 Participants

Eighty-four participants aged 18-65 (Mean 43.8) participated in the investigation. Statistical analysis revealed no significant differences (p>.21) between the MPS, FM, and control groups for age, height, body mass, and body mass index (BMI). The mean (continuous data), median (ordinal data), standard deviation (SD), range, and 95% confidence intervals (95% CI) for age, height, body mass, and BMI for each of the groups is listed in Table 4.1.

Table 4.1 Participant Demographics

Characteristics (n)		Total (84)	Control (28)	MPS (28)	FM (28)	Comparison p-value
Gender	**M/F**	18/66	9/19	7/21	2/26	
Age (years)	**Mean (SD)** **95% CI** **Range**	43.81 (14.59) 41.01-47.27 18-65	41.32 (13.62) 36.53-46.44 22-65	43.57 (16.50) 37.53-51.98 18-65	46.44 (13.65) 41.24-52.37 22-65	.42*
Height (inches)	**Mean (SD)** **95% CI** **Range**	64.95 (4.01) 64.13-66.18 48-76	65.25 (4.23) 63.89-66.18 59-76	64.57 (4.80) 62.69-66.26 48-74	65.03 (3.00) 63.84-66.18 61-74	.82*
Body Mass (lbs)	**Mean (SD)** **95% CI** **Range**	174.86 (38.94) 166.72-183.37 107-295	166.78 (34.56) 154.31-181.07 107-235	181.21 (42.57) 166.60-197.64 113-295	176.57 (39.70) 157.46-191.25 113-280	.37*
Body Mass Index	**Median** **95% CI** **Range**	27.76 27.90-30.86 19-61	25.55 25.15-30.06 20.9-45.9	29.00 28.41-34.33 20.7-61.0	28.75 26.29-31.68 19.0-43.9	.21**

FM: Fibromyalgia; MPS: Myofascial Pain Syndrome; n: number of subjects
M: male; F: female; SD: standard deviation; Group Comparison p-values: * ANOVA test; **Kruskall Wallis test

4.2 Aim #1

What is the intrarater reliability of a 5-point PPTS in participants with MPS, FM, and healthy individuals (control group)?

For this investigation, a reliability analysis was undertaken using the first 10 participants from the combined MPS and FM group and 10 participants from the control group for a total of 20 participants. The results of the selected measures for part I and II of testing are discussed below:

Part I: Manual Palpation with Pressure Sensor

The *digital pressure sensor* was used with the thumb to measure the amount of applied pressure at each predetermined tender point while the participant's response was graded using the PPTS. The intrarater reliability was good for the combined MPS and FM group (ICC model 3, k =.92) and the control group (ICC model 3, k =.91) (Table 4.2).

Part II: Algometry

The *algometer* was used to measure the amount of applied pressure at each predetermined tender point while the participant's response was graded using the PPTS. The intrarater reliability was good for the combined MPS and FM group (ICC model 3, k =.88) and the control group (ICC model 3, k=.90) (Table 4.2).

Table 4.2 Intrarater Reliability Values for Part I and Part II

	Group (n)	**ICC (3, k)**	**95% CI**
Part I: Manual palpation with pressure sensor	Control (10)	.91	.88-.93
	MPS/FM (10)	.92	.89-.94
Part II: Algometry	Control (10)	.90	.87-.92
	MPS/FM (10)	.88	.84-.91

FM: Fibromyalgia; MPS: Myofascial Pain Syndrome; n: number of subjects
ICC Model 3, k: intraclass correlation coefficient; CI: confidence interval

4.3 Aim #2

Does a 5-point PPTS possess concurrent validity when compared to a 10cm (100mm) visual analog pain scale at 18 predetermined tender points in participants with MPS and FM?

Part I: Manual Palpation with Digital Pressure Sensor

A good to excellent relationship (rho ≥ .76, p<.001) was found among all 18 points between the PPTS and the visual analog scale (VAS) for all three groups. The results for each group are displayed in *Appendix H*.

Part II: Algometry

A moderate to excellent relationship (rho ≥ .61, p<.001) was found among all 18 points between the PPTS and the VAS for all three groups. The results for each group are displayed in *Appendix H*.

4.4 Aim #3

Does a 5-point PPTS possess concurrent validity when compared to a manual tender point survey (MTPS) scale at 18 predetermined tender points in participants with MPS and FM?

Part I: Manual Palpation with Pressure Sensor

A moderate to excellent relationship (rho ≥ .71, p<.001) was found among all 18 points between the PPTS and the manual tender point rating survey (MTPS) for the MPS and control groups. A little to moderate relationship was found among all 18 points for the FM group (rho= .01-.50, p=.97-.007). The results for each group are displayed in *Appendix I*.

Part II: Algometry

A moderate to excellent relationship (rho ≥ .68, p<.001) was found among all 18 points between the PPTS and the MTPS for all three groups. The results for each group are displayed in *Appendix I.*

4.5 Aim #4

Does manual palpation pressure up to 4kg/cm^2 measured by the Tekscan® Wireless ELF™ pressure sensor at 18 predetermined tender points produce a comparable response by the participant as algometry pressure up to 4kg/cm^2 using the 5-point PPTS in participants with MPS, FM, and in healthy individuals (control group)?

A fair to excellent relationship (rho ≥ .41, p=.03) was found among all 18 points between the digital pressure sensor and algometer using the PPTS for all three groups. The results for each group are displayed in *Appendix J.*

4.6 Aim #5

What is the cut-off value that differentiates participants with MPS and FM (combined) and healthy individuals (control group) using the 5-point PPTS?

For this analysis, a receiver operating characteristic (ROC) curve was used to determine the minimal cut-off value that differentiated the MPS and FM group and control group. Participant data was dichotomized into two categories: (1) MPS and FM group and (2) control group. Also, the combined MPS and FM group was compared to the control group to determine sensitivity, specificity, likelihood ratios, and predictive values. The calculations of the ranked scores were adapted from the methods described by Okifuji et al[16].

Phase I: Manual Palpation with Pressure Sensor

For phase I: manual palpation, an optimal cut-off value of 2 (AUC .841, 95% CI .82-.86) differentiated participants in the MPS and FM group from the control group (Table 4.3).

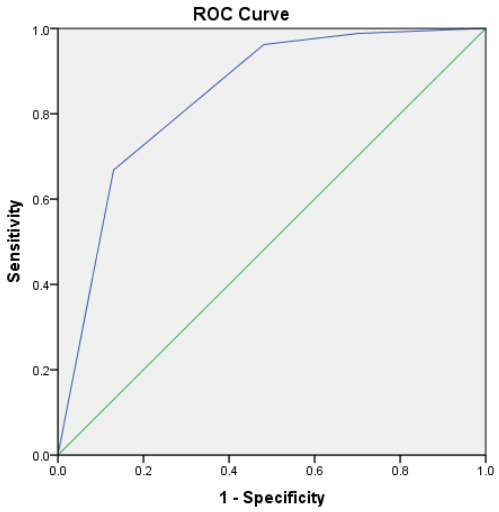

Table 4.3 ROC Curve (Part I: Manual Palpation)

When calculating the numerical threshold of manual palpation, a cut-off value of 2 (sensitivity=.22, specificity=.97) was determined to be the optimal threshold score to differentiate the MPS and FM group from the control group (Table 4.4). Thus, a ranked score of 2 or greater would be confirmative for individuals with MPS and FM.

Table 4.4 Numeric Threshold for PPTS (Part I: Manual Palpation)

Score	Sensitivity (95% CI)	Specificity (95% CI)	+ LR (95% CI)	-LR (95% CI)	PPV (95% CI)	NPV (95% CI)
0	.12 (.11-.15)	.33 (.29-.37)	.19 (.16-.23)	2.69 (2.54-2.71)	.28 (.24-.32)	.16 (.14-.18)
1	.35 (.32-38)	.71 (.66-.75)	1.19 (1.01-1.40)	.92 (.88-.96)	.70 (.66-.74)	.35 (.32-.38)
2	.22 (.19-.25)	.97 (.95-.98)	8.46 (4.89-14.65)	.80 (.78-.83)	.94 (.90-.97)	.38 (.36-.41)
3	.29 (.26-.32)	.99 (.97-.99)	24.42 (10.96-54.40)	.71 (.68-.74)	.98(.95-.99)	.41 (.38-.44)
4	.01(.004-.017)	1.0 (.99-1.00)	10.0 (.99-1.00)	.99 (.98-1.00)	1.0 (.63-1.00)	.33 (.31-.36)

FM: Fibromyalgia; MPS: Myofascial Pain Syndrome; n: number of subjects
LR: likelihood ratios; PPV: positive predictive values; NPV: negative predictive values; CI: confidence interval

Part II: Algometry

For phase II algometry, an optimal cut-off value of 2 (AUC .841, 95% CI .82-.86) differentiated participants in the MPS and FM group from the control group (Table 4.5).

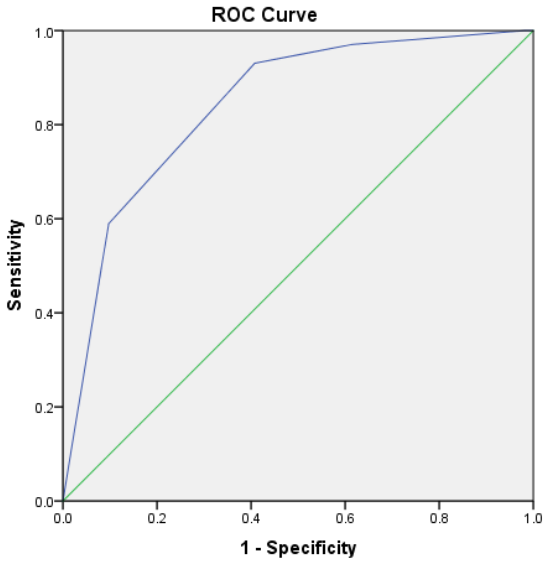

Table 4.5 ROC Curve (Part II: Algometry)

When calculating the numerical threshold of algometry, a cut-off value of 2 (sensitivity= .20, specificity=.96) was determined to be the optimal threshold score to differentiate the MPS and FM group from the control group (Table 4.6). Thus, a ranked score of 2 or greater would be a clinically meaningful cut-point for individuals with MPS and FM.

Table 4.6 Numeric Threshold for PPTS (Part II: Algometry)

Score	Sensitivity (95% CI)	Specificity (95% CI)	+ LR (95% CI)	-LR (95% CI)	PPV (95% CI)	NPV (95% CI)
0	.10(.08-.12)	.41(.37-.46)	.16(.13-.20)	2.19(2.13-2.25)	.25(.20-.29)	.18(.16-.21)
1	.31(.28-.34)	.67(.61-.70)	.91(.78-1.06)	1.04(1.0-1.09)	.65(.60-.69)	.32(.29-.35)
2	.20(.18-.23)	.96(.94-.97)	5.17(3.31-8.09)	0.83(.80-.85)	.91(.86-.94)	.38(.35-.40)
3	.37(.34-.40)	.97(.95-.98)	12.4(7.48-20.54)	.65(.62-.68)	.96(.93-.98)	.43(.40-.46)
4	.02(.01-.03)	1.0(.99-1.00)	10 (9.6-11.30)	.98 (.97-.99)	1.0 (.77-1.00)	.34(.31-.36)

FM: Fibromyalgia; MPS: Myofascial Pain Syndrome; n: number of subjects
LR: likelihood ratios; PPV: positive predictive values; NPV: negative predictive values; CI: confidence interval

4.7 Summary of Findings

The results of this investigation revealed good intrarater reliability (ICC ≥ .88) when using the PPTS with both the algometer and pressure sensor for all three groups. The PPTS was found to have a moderate to excellent relationship (rho ≥ .61) among all 18 points with the VAS for all three groups using both devices. The PPTS had a moderate to excellent relationship (rho ≥ .68) among all 18 points with the MTPS for all three groups using the algometer. The PPTS also had a moderate to excellent relationship (rho ≥ .71) among all 18 points with the MTPS for the MPS and control group using the pressure sensor. The PPTS had a little to moderate relationship (rho =.01-.50) among all 18 points with the MTPS for the FM group using the pressure sensor. When comparing the performance of the pressure sensor to the algometer, there was a fair to excellent relationship (rho ≥ .41) among all 18 point using the PPTS for all groups. The cut-off value of 2 on the PPTS differentiated participants with MPS and FM from healthy participants (controls).

4.8 Conclusion

This chapter provided a summary of the results from the statistical calculations for the five research questions developed for this investigation. Appendices H to J provide a more detailed summary of the calculations for research questions 2 to 4. The next section provides a discussion and interpretation of the results of this investigation.

Chapter 5: Discussion

5.0 Introduction

This chapter provides a summary and interpretation of the results of this investigation. The first section will provide a discussion of the finding for each research question, the related research, and the impact on clinical practice. The second section will discuss study limitation, delimitations, implications for physical therapy practice, and recommendations for future research.

5.1 Discussion: Aim #1 Reliability

Several systematic reviews have examined the efficacy of manual palpation of soft-tissue, motion, and pain. The consensus is that the reliability of palpation is weak with no superior method established.[19-21] When considering the available evidence, manual pressure palpation for pain has the greatest intrarater reliability followed by motion and soft-tissue palpation.[19-21] The existing examination protocols for myofascial pain syndrome (MPS) and fibromyalgia (FM) require manual pressure palpation and have similar challenges due to the poor methodology of supporting literature.[15,64] These issues create a problem for clinical practice since clinicians do not have a valid and reliable method of assessing these individuals.

The results of this study rejected the null hypothesis and supported the research hypothesis of good intrarater reliability among all three groups (ICC $\geq$ .88) using the PPTS. For the clinician, the PPTS may provide a consistent means of grading and communicating findings from the manual pressure palpation examination and can be used as a repeated measure throughout the treatment process. These findings build upon the previous research regarding the intrarater reliability of manual pressure palpation for pain.[19] Thus, a clinician can reliably measure pressure pain thresholds in MPS and FM patients using the PPTS. Such a consistent

method is necessary since the symptoms of individuals with chronic pain can fluctuate and change daily.[83,85] Future studies are needed to measure the interrater reliability of the PPTS in these individuals.

5.2 Discussion: Aim #2 and Aim #3 Concurrent Validity

Currently, there is no reference standard scale to compare to the PPTS. For this investigation, the concurrent validity of the PPTS was measured against the visual analog scale (VAS) and a numeric pain rating scale (NPRS) called the manual tender point rating survey (MTPS). Both, the VAS and NPRS are reliable scales ($r \geq .94$) that have a strong association (ICC=.86-.95) when used with chronic pain disorders such as MPS and FM.[34,94-96] The results of the analyses are discussed below.

For *Aim #2*, the results of the study rejected the null hypothesis and supported the research hypothesis of a moderate to excellent relationship between the PPTS and VAS for all three groups. Prior research combining manual pressure palpation and the VAS to assess pain in subjects with FM have produced good results.[96,97] For *Aim #3*, the results of the study rejected the null hypothesis and supported the research hypothesis of a moderate to excellent relationship between the PPTS and MTPS for the MPS and control group. However, there was a little to moderate relationship between the PPTS and MTPS for the FM group which resulted in a failure to reject the null hypothesis for this group. The variability in the FM group may be due to the sample population used for this investigation. All FM participants (n=28) reported having the condition for 2 years or more. Prior research suggests an association between reported pain severity and the duration of FM since diagnosis. Patients who have suffered from FM for more than 2 years report higher scores on the NPRS.[88,130] Also, the variability in the participants' pain level may have influenced their scores. Research suggests that individuals with FM and MPS

have variable levels of pain which can fluctuate each day.[42,131] This variability in pain may be due to a combination of biological, psychological, and social factors that interact to influence pain.[83]

Clinically, it appears that the VAS may have better utility than the MTPS for examining individuals with MPS and FM. The MTPS may have some utility for the examination of MPS but needs further study. For research, the VAS may be superior than the NPRS. The VAS has ratio measurement properties that allow for parametric calculations versus an ordinal scale (NPRS) which requires a non-parametric statistic.[132,133]

5.3 Discussion: Aim #4 Clinical Tools

Two clinical tools were used for this investigation: an algometer and digital pressure sensor. Algometry is a valid and reliable tool that is commonly used in research involving individuals with MPS and FM.[35,92,104] The digital pressure sensor is an emerging technology used in prior research for soft-tissue palpation but never for chronic pain.[111,112,114] The algometer was considered the comparison "gold standard" for this investigation.

When comparing the performance of the two instruments there was fair to excellent relationship for all groups which resulted in rejection of the research hypothesis and acceptance of the null hypothesis. The results suggest that the algometer may have the best overall performance and should not be interchangeable with the digital pressure sensor. When considering the utility of both devices, the algometer may be preferable for research and clinical practice. The digital pressure sensor may serve best in physical therapy education. The digital pressure sensor may provide a means for faculty and students to concurrently monitor the applied pressure during the manual pressure palpation examination. The clinical tools used in this study may enhance the manual pressure palpation examination process but may not be available in all

clinical settings due to cost. Lastly, although algometry is perhaps superior, palpation with a digital pressure sensor more closely resembles clinical practice and still maintains a ranking needed for change.

5.4 Discussion: Aim #5 Cut-off Value

The ordinal ranked format of the PPTS provides the clinician with a means of measuring, documenting, and reporting examination findings. The clinimetric properties of the previously used scales were never fully studied and eventually were modified or omitted by other researchers.[15,48,73,75] The findings from this study supported the research hypothesis that a cut-off value of 2 was the optimal threshold score that differentiated patients with MPS and FM from controls. Thus, a clinician may be able to discriminate between individuals based upon PPTS scoring. The original ACR criteria (at least 11/18 tender points) has been shown to be sensitive in diagnosing FM but unable to discriminate between individuals with FM and others chronic conditions or healthy subjects.[15,51,71,73] For example, in 10-20% of the general population (healthy individuals) the ACR tender point count has been shown to be 10/18 in females and 6/18 in males.[71,134]

Research has also shown that a decrease in the number of tender point sites correlates poorly with patient improvement.[135,136] Individuals with chronic pain also report higher pain levels than matched controls.[73,88] This may be because tender point counts are believed to be a general measure of distress that's influenced by cognitive and emotional aspects of pain perception.[137-139] It has been recommended that the assessment of pain severity at tender point sites may be a better measure of tenderness than the change in tender point count.[137] Thus, combining the ACR tender point criteria (at least 11/18) with the PPTS cut-off value of 2 may provide a more accurate method of differentiating between these individuals. The results from

this study provide preliminary evidence for this hypothesis, 79 % (22/ 28) of FM participants presented with a PPTS score of ≥ 2 at 11 or more tender points versus 40% (11/28) of MPS participants, and 0% (0/28) of control participants. The ability of the PPTS to discriminate between FM and MPS patients still needs to be explored. This is pertinent for clinical practice since up to 50% of patients diagnosed with MPS have FM.[52] The tender points in the upper body (cervical spine) tended to have higher reported scores that lower body tender points among all three groups. These findings are consistent with prior research demonstrating higher scores in the upper body tender points.[48,134,140]

5.5 Implications for Physical Therapy Practice

For this investigation, The PPTS was compared to the VAS and MTPS using the ACR tender point criteria.[16,34,42] Two instruments were also used in this investigation: an algometer and digital pressure sensor. The ACR protocol included pressure palpation of 18 pre-determined tender point sites. A pressure of up to 4kg/cm^2 at a rate of 1kg per second was applied to each tender point. The use of the instruments allowed the investigator to concurrently monitor and control the rate of pressure at each point while measuring the patient's sensitivity with the PPTS. Such methods were never done in prior research.[15,64] Pressure palpation can vary among tender points due to the type of tissues palpated, tissue density, and the patient's level and response to pain.[48] It appeared that the range of pressure (up to 4kg/cm^2) was deep enough to accurately assess tender point sensitivity among all 18 tender points for all groups.[15]

The results of this research suggest the combination of the PPTS, ACR criteria, patient related outcome measures, and clinical tools may enhance the examination process for these individuals. For MPS, the combination of the PPTS, VAS, MTPS, algometer or pressure sensor may yield the best results. For FM, the combination of the PPTS, VAS, MTPS, and algometer

may provide the best outcomes. This preliminary research suggests that the PPTS is a valid and reliable scale for MPS and FM. The PPTS may have efficacy for other chronic pain and orthopedic conditions. Future studies are needed to determine the full utility of the scale. Suggestions for future research are provided in the subsequent section.

5.6 Limitations

When considering the methodology and the results of this investigation, some limitations warrant discussion. A potential limitation of this investigation was age. The age (years) of participants ranged from 18-65 (Mean 43.8). The results cannot be generalized outside of this age range. Despite this limitation, the study participants did represent the common age range for individuals diagnosed with MPS and FM as well as the average age of patients receiving care in outpatient physical therapy clinics.[3,7-10,141] Another potential limitation is the clinical course of individuals with chronic pain disorders such as MPS and FM. Often times, these individuals may feel different levels of musculoskeletal pain or symptoms on different days. Variations in a patient's perceived pain is a confounding variable in this population and must be considered when interpreting the results of the research.[13,113] Other limitations include the fact that all of the assessments used technology that may not be available in all clinical settings. The outcomes of the PPTS may be different if used without a digital pressure sensor or algometer.

5.7 Delimitations

There are several delimitations that warrant discussion for this investigation. First, MPS and FM were the only diagnoses studied which limits the generalizability of the investigation to these conditions and not to all the known chronic pain conditions. MPS and FM both require a manual pressure palpation examination as part of the diagnosis and are some of the most studied conditions among chronic pain pathologies.[37,51,71,142] Second, the population studied contained

individuals with preexisting diagnoses of MPS and FM. This investigation did not attempt to determine the diagnostic accuracy of the PPTS. Future studies measuring the diagnostic value of the PPTS are warranted. Third, standard manual palpation was not measured in this investigation. The pressure sensor and algometer were used to help validate the PPTS. This technology allowed the examiner to concurrently measure the rate and amount of pressure that was applied during testing. Prior studies using standard manual palpation in this population have yielded variable results.[37,66,70,70] Fourth, intrarater reliability was measured for this investigation. This limits the reliability of the PPTS to one examiner. Clinician's will need to consider this when using the PPTS in clinical practice. Future studies are needed to establish reliablity among multiple clinicians.

5.8 Recommendations for Future Research

The results of this investigation provide evidence for the efficacy of the PPTS but are preliminary. Further research is necessary to validate the full utility of the PPTS. This section proposes recommendations for future research using the PPTS for clinical practice and education. For clinical practice, future investigations should focus on five key areas to further explore the utility of the PPTS. First, interrater reliability of the PPTS must be determined in order to establish its reliability among multiple clinicians. This investigation only measured intrarater reliability due to limited resources. Second, the diagnostic utility of the PPTS has yet to be determined. This investigation used participants with preexisting conditions. Future investigations are needed to measure the diagnostic properties of the PPTS in undiagnosed individuals suspected of having MPS and FM. Third, the efficacy of the PPTS for other chronic pain disorders (e.g. chronic fatigue syndrome) still needs to be investigated. Often, these conditions present with similar types of musculoskeletal pain.[143] Fourth, the PPTS may provide a

good assessment of pressure pain thresholds for general orthopedic conditions such as tendinopathy. Future studies are needed to confirm this hypothesis. Fifth, the efficacy of PPTS using standard manual palpation needs to be investigated. This study utilized technology that may not be available in all clinical settings. Future research should explore the validity of the PPTS using standard palpation in comparison with this technology.

The PPTS may be also be an effective teaching tool for physical therapy educators. The PPTS may provide a means for educators to measure, compare, and report a student's performance during the graded manual pressure palpation examination. Future studies should focus on three main areas of education. First, entry-level Doctor of Physical Therapy (DPT) programs may be able to use the PPTS in their orthopedic curriculums. Future studies should explore the efficacy of the PPTS to measure the performance of graded manual pressure palpation among 2nd and 3rd year DPT students. Second, postgraduate orthopedic physical therapy residency programs may be able to use the PPTS in their curriculums. Future studies should explore the efficacy of the PPTS as a teaching tool and repeated measure within the residency curriculum. Third, the PPTS may be useful as a standard communication tool for palpation among allied health professionals. Future studies should measure the efficacy of the PPTS in helping educators teach, measure, and compare graded manual pressure palpation among various allied health professionals in order to develop interdisciplinary standards.

5.9 Conclusion

The results from this study provide preliminary evidence validating the PPTS scale in individuals with MPS and FM. The PPTS may have utility for both clinicians and educators. The PPTS may provide an object means to measure, document, and communicate pressure pain thresholds. The efficacy of the PPTS can be enhanced by the use of instruments such as a digital

pressure sensor or algometer which can provide concurrent monitoring of the rate and amount of pressure during the examination. Future research is needed to further study the clinimetric properties of the PPTS. In particular, future studies are needed to determine interrater reliability, diagnostic accuracy, and efficacy of the PPTS as a teaching tool for physical therapy and interdisciplinary allied health education.

Appendix A

NOVA SOUTHEASTERN UNIVERSITY

MEMORANDUM

To: Scott Cheatham, PDT
HPD – College of Health Care Sciences

From: Matthew Seamon, Pharm.D., JD
Chair, Institutional Review Board

WHS for Dr. Seamon

Date: January 7, 2015

Re: *Validation of a Pressure Pain Threshold Scale in Patients with Diagnosed with Myofascial Pain Syndrome and Fibromyalgia* – NSU IRB No. 11261425Exp.

I have reviewed the revisions to the above-referenced research protocol by an expedited procedure. On behalf of the Institutional Review Board of Nova Southeastern University, *Validation of a Pressure Pain Threshold Scale in Patients with Diagnosed with Myofascial Pain Syndrome and Fibromyalgia* is approved in keeping with expedited review category #4. Your study is approved on **January 7, 2015** and is approved until **January 6, 2016**. You are required to submit for continuing review by **December 6, 2015**. As principal investigator, you must adhere to the following requirements:

1) CONSENT: You must use the stamped (dated consent forms) attached when consenting subjects. The consent forms must indicate the approval and its date. The forms must be administered in such a manner that they are clearly understood by the subjects. The subjects must be given a copy of the signed consent document, and a copy must be placed with the subjects' confidential chart/file.

2) ADVERSE EVENTS/UNANTICIPATED PROBLEMS: The principal investigator is required to notify the IRB chair of any adverse reactions that may develop as a result of this study. Approval may be withdrawn if the problem is serious.

3) AMENDMENTS: Any changes in the study (e.g., procedures, consent forms, investigators, etc.) must be approved by the IRB prior to implementation.

4) CONTINUING REVIEWS: A continuing review (progress report) must be submitted by the continuing review date noted above. Please see the IRB web site for continuing review information.

5) FINAL REPORT: You are required to notify the IRB Office within 30 days of the conclusion of the research that the study has ended via the IRB Closing Report form.

The NSU IRB is in compliance with the requirements for the protection of human subjects prescribed in Part 46 of Title 45 of the Code of Federal Regulations (45 CFR 46) revised June 18, 1991.

Cc: Dr. Morey Kobler
Dr. M. Samuel Cheng
Mr. William Smith

Institutional Review Board
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NOVA SOUTHEASTERN UNIVERSITY
Institutional Review Board

MEMORANDUM

To: Scott Cheatham, PDT
HPD – College of Health Care Sciences

From: Matthew Seamon, Pharm.D., JD
Chair, Institutional Review Board
WHS for Dr. Seamon

Date: April 10, 2015

Re: *Validation of a Pressure Pain Threshold Scale in Patients Diagnosed with Myofascial Pain Syndrome and Fibromyalgia* – NSU IRB No. 11261425Exp.

I have reviewed the amendments to the above-referenced research protocol by an expedited procedure. On behalf of the Institutional Review Board of Nova Southeastern University, the following amendments to *Validation of a Pressure Pain Threshold Scale in Patients Diagnosed with Myofascial Pain Syndrome and Fibromyalgia* are approved:

- Addition of two extra pre-determined tender points
- Updated Informed Consent Forms

Please note that this does not affect the continuing review date for this protocol.

Cc: Dr. Morey Kobler
Dr. M. Samuel Cheng
Mr. William Smith

3301 College Avenue • Fort Lauderdale, Florida 33314-7796
(954) 262-5369 • Fax: (954) 262-3977 • Email: *irb@nova.edu* • Web site: *www.nova.edu/irb*

CSUDH Institutional Review Board
for the Protection of Human Subjects in Research

Date: **January 20, 2015**

To: **Dr. Scott Cheatham, Dr. Matthew Seamon**
CC: File

From: **Judith Aguirre, IRB Compliance Coordinator**
CSUDH Institutional Review Board (IRB)

Subject: **#15-116 – "Validation of a Pressure Pain Threshold Scale in Patients with Diagnosed with Myofascial Pain Syndrome and Fibromyalgia"**
January 20, 2015 through January 6, 2016

The IRB at California State University, Dominguez Hills is pleased to inform you that it has reviewed your project and will honor the approval of Nova Southern University.

Your study is approved for one year beyond which time you must seek approval for a continuation of your study. Procedural changes or amendments must be reported to the IRB and no changes may be made without IRB approval except to eliminate apparent immediate hazards. Please notify the Office of Research and Funded Projects (a) if there are any adverse events that result from your study, and (b) when your study is completed.

If you have any questions, you may contact the Office of Graduate Studies and Research at (310) 243-2136.

Thank you.

Subject recruitment and data collection may not be initiated prior to formal written approval from the IRB Human Subjects Committee

Appendix B

HB Fibro **Fibromyalgia Huntington Beach California**

Community Organization

July 27, 2014

Institutional Review Board
Office of Grants and Contracts
Nova Southeastern University
3301 College Avenue
Fort-Lauderdale-Davie, Florida 33314-7796

Fibromyalgia Huntington Beach California with meetings at 11180 Warner #271, Fountain Valley, CA grants permission to Scott W. Cheatham to use the facility for the purpose of the research investigation titled: Validation of a Pressure Pain Threshold Scale in Patients Diagnosed with Myofascial Pain Syndrome and Fibromyalgia. Our organization understands the scope of the study and the expiration of this agreement will be based upon the time required to complete the study.

8/5/14

Renee A. Downing, CPT, RYT
Group Organizer

SOUTH BAY
ORTHOPAEDIC SPECIALISTS
MEDICAL CENTER*

Jerome H. Unatin, M.D., Inc.
General Orthopaedic
and Hand Surgery

Don P. Sanders, M.D., Inc.
Total Joint Replacement
Direct Anterior Hip Replacement
Athletic Injuries

Nicholas J. Silvino, M.D., Inc.
Sports Medicine,
Knee and Shoulder Surgery

Randolph C. O'Hara, M.D., Inc.
Spine Disorders,
Spine Surgery and Scoliosis

Andrew Y. Lim, M.D., Inc.
Shoulder, Elbow
Wrist and Hand Surgery

Stephen L. Nuccion, M.D., Inc.
Sports Medicine,
Shoulder and Knee Surgery

Keri Reese Zickuhr, M.D.
Ankle and Foot Surgery
General Orthopaedics

John V. Tiberi, M.D.
Total Joint Replacement
Partial Knee Replacement
General Orthopaedics

*Daniel M. Zinar, M.D., Inc.***
Fracture Reconstruction
and Trauma

Christine Rubin
Administrator

July 22, 2014

Institutional Review Board
Office of Grants and Contracts
Nova Southeastern University
3301 College Avenue
Fort-Lauderdale-Davie, Florida 33314-7796

South Bay Orthopedic Specialists Medical Center, located at 23560 Crenshaw Blvd. Suite 102, Torrance CA grants permission to Scott W. Cheatham to use the facility for the purpose of the research investigation titled: Validation of a Pressure Pain Threshold Scale in Patients Diagnosed with Myofascial Pain Syndrome and Fibromyalgia. Our facility understands the scope of the study and the expiration of this agreement will be based upon the time required to complete the study.

Christine Rubin
Practice Administrator
23560 Crenshaw Blvd. Suite 102
Torrance, CA 90505

23560 Crenshaw Boulevard • Suite 102 • Torrance, CA 90505 • tel: (310) 784-2355 • fax: (310) 517-1817 • www.southbayortho.com
* A Partnership of Medical Corporations ** Independent Associates

California State University
Dominguez Hills

DIVISION OF KINESIOLOGY & RECREATION
COLLEGE OF HEALTH, HUMAN SERVICES, & NURSING
1000 East Victoria Street • Carson, CA 90747
(310) 243-3761 • Fax (310) 217-6946

August 12, 2014

Institutional Review Board
Office of Grants and Contracts
Nova Southeastern University
3301 College Avenue
Fort-Lauderdale-Davie, Florida 33314-7796

The Division of Kinesiology and Recreation grants permission to Scott W. Cheatham to use the Division's lab facility for the purpose of the research investigation titled: Validation of a Pressure Pain Threshold Scale in Patients Diagnosed with Myofascial Pain Syndrome and Fibromyalgia. Our organization understands the scope of the study and the expiration of this agreement will be based upon the time required to complete the study.

8/12/14
Date

Michael P. Ernst, Ph.D.
Professor and Chair,
Division of Kinesiology and Recreation
NCAA Faculty Athletics Representative
College of Health, Human Services and Nursing
Cal State Dominguez Hills
1000 E. Victoria Street
Carson, CA 90747
310.243.3761
mernst@csudh.edu

Appendix C

NOVA SOUTHEASTERN UNIVERSITY

CALL FOR RESEARCH SUBJECTS

Do you have Myofascial Pain or Fibromyalgia?

If so you may be eligible to participate in a research study titled "Validation of a Pressure Pain Threshold Scale in Patients Diagnosed with Myofascial Pain Syndrome and Fibromyalgia". The study is investigating a new measurement scale to quantify Myofascial Pain Syndrome (MPS) and Fibromyalgia (FM) in both men and women.

Scott Cheatham, Physical Therapist and Assistant Professor at California State University Dominguez Hills, is conducting this study on patients diagnosed with MPS and FM and individuals without the diagnoses. A total of 100 men and women between the ages of 18 and 65 will participate in this study. If you are interested in participating, please notify Scott at the phone numbers or e-mail below.

Participants will receive a $20 gift card for completing the study

For more information please contact

Scott Cheatham PT, DPT, OCS
Director Pre-Physical Therapy Program
Division of Kinesiology, SAC 1138
California State University Dominguez Hills
1000 E. Victoria St. Carson, CA 90747
office # (310) 243-3794
cell #(310) 892-4376
e-mail: Scheatham@csudh.edu

Appendix D

Participant Screening Form

Participant Number: _____ Date_____

Age: _____ Height: _____ Weight: _____ Gender: M / F

Arm dominance: R or L (the hand you write with)

Please answer the medical questions below. If "yes" to any of the questions, please explain in the section below. Your information will remain confidential.

1.	Do you currently have any neurologic conditions? (e.g. Multiple Sclerosis)	Yes	No
2.	Do you currently have Osteoporosis or Diabetes?	Yes	No
3.	Do you currently have any systemic conditions? (e.g. Rheumatoid Arthritis)	Yes	No
4.	Do you currently have any skin or connective tissue problems? (e.g. Marfan's Syndrome)	Yes	No
5.	Do you currently have any numbness, tingling, burning, coldness, or pain in your back, hands, or feet?	Yes	No
6.	Have you had any prior surgeries that may affect your ability to participate in this study?	Yes	No
7.	Do you have a pacemaker or electrical implant that may be affected by electronic equipment?	Yes	No
8.	Are you currently taking medications which may alter your sensation or affect your ability to participate in this study?	Yes	No
9.	Do your currently have Shingles?	Yes	No
10.	Do you currently have any open skin wounds on your neck, arms, back, or legs?	Yes	No
11.	Do you believe you have any other medical conditions that might affect your ability to participate in this study?	Yes	No
12.	Do you have any problems with sitting or lying down for approximately 45 minutes or sensitivity to touch of your skin?	Yes	No

If "yes" to any questions above or if you have any other medical conditions, please explain: _____

_____

_____

Please list medications you are currently taking: _____

_____

_____

Investigator Signature/Printed Name

_____

Date

Appendix E

NOVA SOUTHEASTERN UNIVERSITY
Health Professions Division
College of Health Care Sciences
Physical Therapy Department

Consent Form for Participation in the Research Study Entitled

Validation of a Pressure Pain Threshold Scale in Patients Diagnosed with Myofascial Pain Syndrome and Fibromyalgia

Funding Source: None
IRB protocol #: 11261425Exp

Principal investigator(s)

Scott Cheatham PT, DPT, OCS
Director Pre-Physical Therapy Program
Division of Kinesiology, SAC 1138
California State University Dominguez Hills
1000 E. Victoria St. Carson, CA 90747
office # (310) 243-3794
email: Scheatham@csudh.edu

Dissertation Advisor:

Morey J. Kolber, PT, PhD, OCS
Associate Professor
Department of Physical Therapy
Nova Southeastern University
3200 S. University Drive
Fort Lauderdale, Florida
954.262.1615
fax:954.262.1783
Kolber@nova.edu

For questions/concerns about your research rights, contact:
Human Research Oversight Board (Institutional Review Board or IRB)
Nova Southeastern University
(954) 262-5369/Toll Free: 866-499-0790
IRB@nsu.nova.edu

Site Information

Fibromyalgia of Huntington Beach
11180 Warner #271 Fountain Valley, CA
310-892-4376

South Bay Orthopedic Specialists Medical Center
23560 Crenshaw Blvd. Suite 102 Torrance, CA
310-784-2355

California State University Dominguez Hills, Division of Kinesiology
1000 East Victoria St
Carson, CA 90747
310-243-3794

Initials: _____ Date: _____

What is the study about?

Palpation (touching) of bone, tendon and muscle for tenderness, which is when you touch something and it hurts is performed by physical therapists to assess the presence of injuries or problems. The goal of this investigation is to validate a scale that measures pressure pain levels in people with conditions that are known to have tenderness. Specifically these conditions are called Myofascial Pain Syndrome (MPS) and Fibromyalgia (FM).

Why are you asking me?

We are asking you to be part of this study since you have met the inclusion criteria for participation. We are asking for 100 participants however; our goal is to have 84 participants for this investigation. We are also asking the first 10 participants with the conditions of MPS and FM to take part in two testing sessions. We are also asking the first 10 participants without the condition of MPS and FM to take part in two testing sessions. The reason for this is to see if the testing tells us the same information when done a second time. We will ask each person to volunteer to take part in the 2 sessions until we get 10 from each of the 2 groups which will give us 20 participants.

What will I be doing if I agree to be in the study?

If you agree to be a part of this study you will participate in a one day session that will last approximately 45 minutes. If you agree to be tested twice you will participate in a second 45 minute session within 1 week of your first session.

During testing you will be able to sit on a padded table or in a chair. If you are unable to sit for very long, you can lie on your stomach or side during testing. You will have the option to wear a gown with the back exposed during testing. You will also have the option to wear your undergarments during testing. You will also be in front of the mirror so the examiner can monitor how you are feeling during testing.

There are two parts of the testing. *First,* the examiner will apply light pressure with his/her thumb using a pressure sensor to *20 specific areas* along your neck, back, arms, left

thumb, and legs *one time*. The pressure sensor is attached to the tip of the thumb and measures the amount of pressure. For each area, the examiner will ask you to provide a number from 0 (no pain) to 10 (extreme pain) that measures the amount of discomfort you felt and will record your response. After that, the examiner will ask you to draw a vertical line on a horizontal line indicating your level of discomfort. If you reach your limit of discomfort during testing, notify the examiner, the test will stop.

Second, the examiner will then apply light pressure using a computerized pressure device to each of the 20 specific areas *one time*. The computerized device will record the pressure being applied at each area. For each area, the examiner will again ask you to provide a number from 0 (no pain) to 10 (extreme pain) that measures the amount of discomfort you felt and will record your response. After that, the examiner will again ask you to draw a vertical line on a horizontal line indicating your level of discomfort. For this part of the test, you will have a wireless button in your hand that is connected to the computerized device. If you reach your limit of discomfort during testing, you can press the button, a sound similar to a doorbell will be heard and the test will stop.

The testing of the 20 specific areas may create a level of discomfort. You will be able to stop testing at any time. The examiner may also terminate testing if he/she feels that you are too uncomfortable or there is an apparent danger.

What are the dangers to me?

There is a chance of discomfort over the 20 areas being tested. The discomfort is basically tenderness which will more than likely go away once the examiner is no longer palpating you. There is a slight possibility of minor skin irritation to the site where the pressure is being placed. This risk of skin irritation is minimal and unlikely in the majority of individuals. If you experience any skin irritation during testing the test will stop immediately.

If you have any questions about the research, your research rights, or have a research-related injury, please contact Scott Cheatham, DPT the principal investigator or the advisor

Morey J. Kolber, PT, PhD. You may also contact the IRB at the numbers indicated above with questions as to your research rights.

Are there any benefits for taking part in this research study?

There are no direct benefits.

Will I get paid for being in the study? Will it cost me anything?

You will receive a $20 gift card for completing one 45 minute testing session. If you complete two 45 minute testing sessions you will receive two $20 gift cards. There are no costs to you or payments made for participating in this study.

How will you keep my information private?

Confidentiality will be maintained to the extent allowed by law. Data will be numerically coded so that it cannot be linked to you by name. Only the investigators will collect data and have access to the data. Data will be stored on paper forms and in a password protected file on a DVD. All paper forms and data files on the DVD will be stored in a locked cabinet in the office of the principle investigator at California State University Dominguez Hills for 36 months from the conclusion of this study.

All information obtained in this study is strictly confidential unless disclosure is required by law. The university IRB, Primary Investigator, and dissertation chair may review relevant research records.

What if I do not want to participate or I want to leave the study?

You have the right to leave this study at any time or refuse to participate. If you do decide to leave or you decide not to participate, you will not experience any penalty or loss of services you have a right to receive. If you choose to withdraw, any information collected about you **before** the date you leave the study will be kept in the research records for 36 months from the conclusion of the study but you may request that it not be used.

Initials: _____ Date: _____

Other Considerations:

If significant new information relating to the study becomes available, which may relate to your willingness to continue to participate, this information will be provided to you by the investigators.

Voluntary Consent by Participant:

By signing below, you indicate that

- this study has been explained to you
- you have read this document or it has been read to you
- your questions about this research study have been answered
- you have been told that you may ask the researchers any study related questions in the future or contact them in the event of a research-related injury
- you have been told that you may ask Institutional Review Board (IRB) personnel questions about your study rights
- you are entitled to a copy of this form after you have read and signed it you voluntarily agree to participate in the study entitled "Validation of a Pressure Pain Threshold Scale in Patients Diagnosed with Myofascial Pain Syndrome and Fibromyalgia"

Participant's Signature: _____ Date: _____

Participant's Name: _____ Date: _____

Signature of Person Obtaining Consent: _____ Date: _____

Appendix F

Participant Recording Form

Participant number: _____ Date: _____

Part I: Palpation / Part II: Algometry

Please draw a vertical line along the horizontal line indication the level of pain intensity felt and then rate your pain level from 0 to 10.

How severe is your pain? No pain — Worst pain imaginable Tender Point #1	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #2	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #3	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #4	**Pain Level** (0 to 10)

1

How severe is your pain? No pain — Worst pain imaginable Tender Point #5	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #6	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #7	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #8	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #9	**Pain Level** (0 to 10)

2

How severe is your pain? No pain — Worst pain imaginable Tender Point #10	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #11	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #12	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #13	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #14	**Pain Level** (0 to 10)

How severe is your pain? No pain — Worst pain imaginable Tender Point #15	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #16	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #17	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #18	**Pain Level** (0 to 10)
How severe is your pain? No pain — Worst pain imaginable Tender Point #19	**Pain Level** (0 to 10)

4

How severe is your pain?	**Pain Level** (0 to 10)
No pain — Worst pain imaginable	
Tender Point #20	

Appendix G

Validation of the PPTS: Data Collection Form

Participant Number: _____ Date_____

Phase I: Palpation					Phase II: Algometry		
Tender Point	PPTS	MTPS (0-10)	VAS		PPTS	MTPS (0-10)	VAS
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							

Pressure Pain Threshold Scale (PPTS)

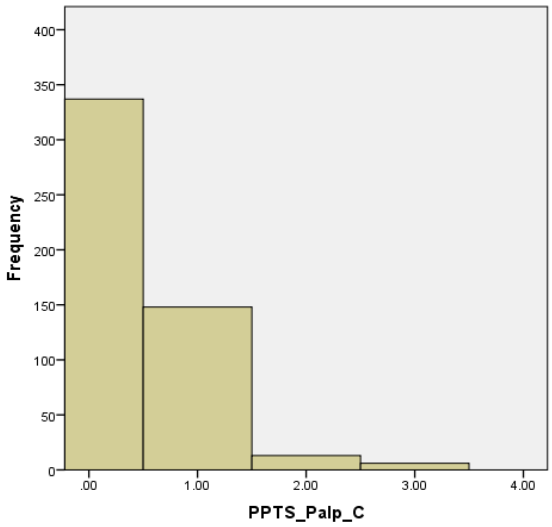
Grade	Interpretation	Criteria
0	No Pain	No signs of pain or discomfort with pressure.
I	Mild Pain	Tenderness reported without flinching to pressure.
II	Moderate Pain	Wincing or flinching to pressure.
III	Severe Pain	Signs of severe pain such as verbal gestures and withdrawing of body part to pressure.
IV	Noxious-Intolerable Pain	Unbearable pain, patient does not allow palpation to the specific area of pain.

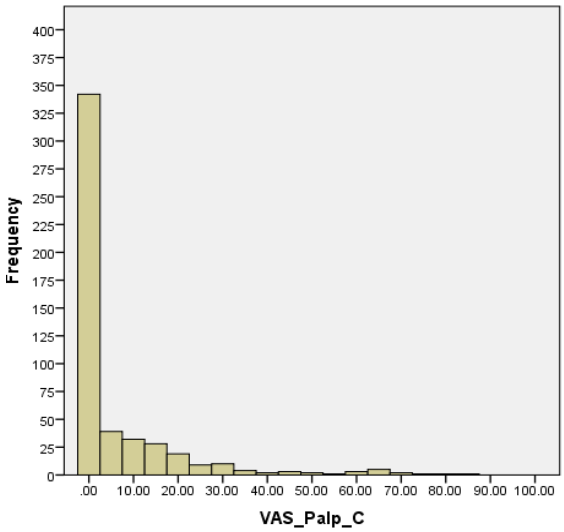
Appendix H

Aim #2: Does a 5-point PPTS possess concurrent validity when compared to a 10cm (100mm) visual analog pain scale at 18 predetermined tender points in participants with MPS and FM?

Part I: Manual Palpation with Pressure Sensor

Control Group Comparison



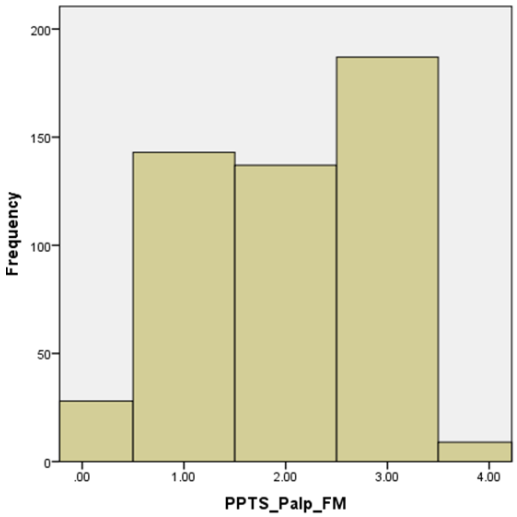


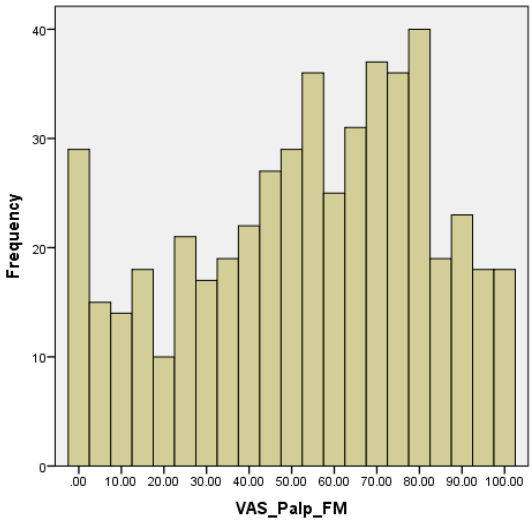
Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Palp_C	504	3.00	.00	3.00	.3810	.02671	.59963	.360
VAS_Palp_C	504	86.00	.00	86.00	6.4206	.61264	13.75364	189.163
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

Control Group Manual Palpation: PPTS compared to VAS			
Points	**Spearman rho**	**95% CI**	**Correlation p-value**
1	.89	.79 to .94	<.001
2	.93	.82 to .97	<.001
3	.97	.92 to .99	<.001
4	.80	.57 to .98	<.001
5	.97	.93 to 1.0	<.001
6	.81	.53 to .98	<.001
7	.99	.98 to 1.0	<.001
8	.99	.99 to 1.0	<.001
9	.93	.83 to .99	<.001
10	.86	.68 to .95	<.001
11	.83	.64 to .98	<.001
12	.84	.60 to .98	<.001
13	.79	.42 to .99	<.001
14	.78	.42 to 1.0	<.001
15	.76	.40 to 1.0	<.001
16	.92	.74 to 1.0	<.001
17	.93	.71 to 1.0	<.001
18	1.0	.98 to 1.0	<.001
CI: Confidence Interval			



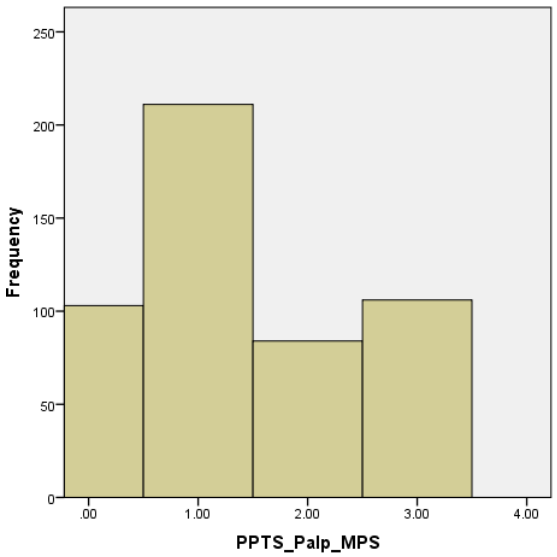


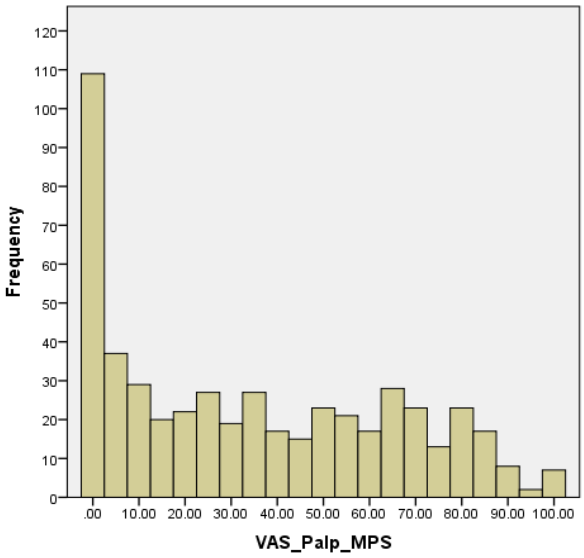
Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Palp_FM	504	4.00	.00	4.00	2.0119	.04342	.97476	.950
VAS_Palp_FM	504	100.00	.00	100.00	53.7321	1.25443	28.16180	793.087
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

FM Group Manual Palpation: PPTS compared to VAS			
Points	Spearman rho	95% CI	Correlation p-value
1	.93	.88 to .95	<.001
2	.88	.71 to .95	<.001
3	.92	.73 to .96	<.001
4	.90	.77 to .96	<.001
5	.91	.76 to .97	<.001
6	.93	.77 to .97	<.001
7	.93	.87 to .96	<.001
8	.91	.79 to .94	<.001
9	.82	.64 to .93	<.001
10	.79	.65 to .92	<.001
11	.77	.56 to .89	<.001
12	.83	.66 to .95	<.001
13	.94	.89 to .97	<.001
14	.89	.76 to .95	<.001
15	.88	.80 to .93	<.001
16	.91	.75 to .96	<.001
17	.89	.84 to .94	<.001
18	.94	.91 to .97	<.001
CI: Confidence Interval; Statistically significant p<.05			





Descriptive Statistics

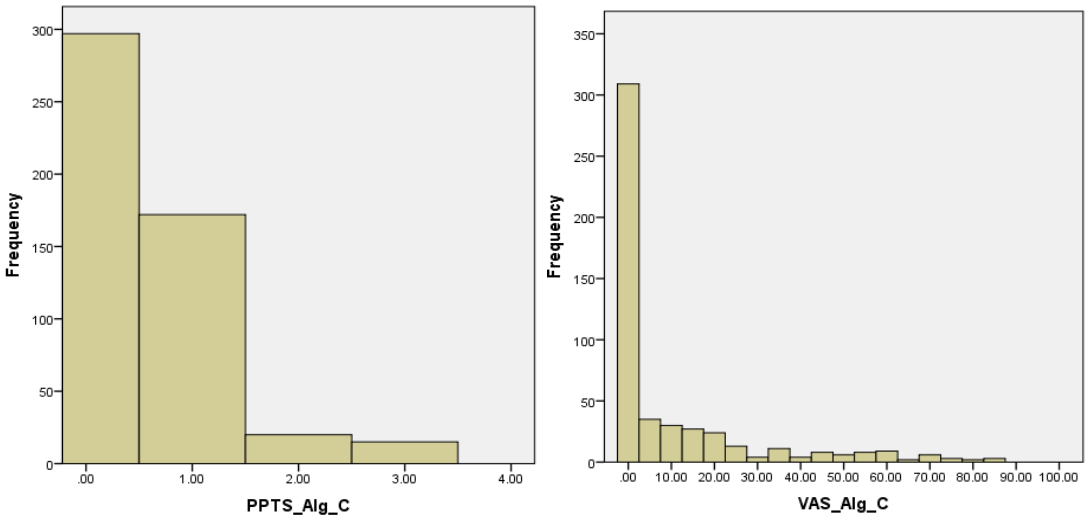
	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Palp_MPS	504	3.00	.00	3.00	1.3829	.04603	1.03333	1.068
VAS_Palp_MPS	504	100.00	.00	100.00	34.5615	1.33629	29.99967	899.980
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

MPS Group Manual Palpation: PPTS compared to VAS			
Points	Spearman rho	95% CI	Correlation p-value
1	.93	.86 to .94	<.001
2	.91	.81 to .94	<.001
3	.96	.85 to .99	<.001
4	.96	.88 to .98	<.001
5	.94	.81 to .99	<.001
6	.86	.62 to .93	<.001
7	.96	.91 to .99	<.001
8	.94	.84 to .98	<.001
9	.91	.83 to .93	<.001
10	.93	.87 to .94	<.001
11	.91	.72 to .96	<.001
12	.90	.76 to .96	<.001
13	.97	.92 to .99	<.001
14	.93	.76 to .98	<.001
15	.93	.84 to .98	<.001
16	.94	.86 to .96	<.001
17	.96	.88 to .99	<.001
18	.95	.82 to .99	<.001
CI: Confidence Interval; Statistically significant p<.05			

Part II: Algometry

Control Group Comparison

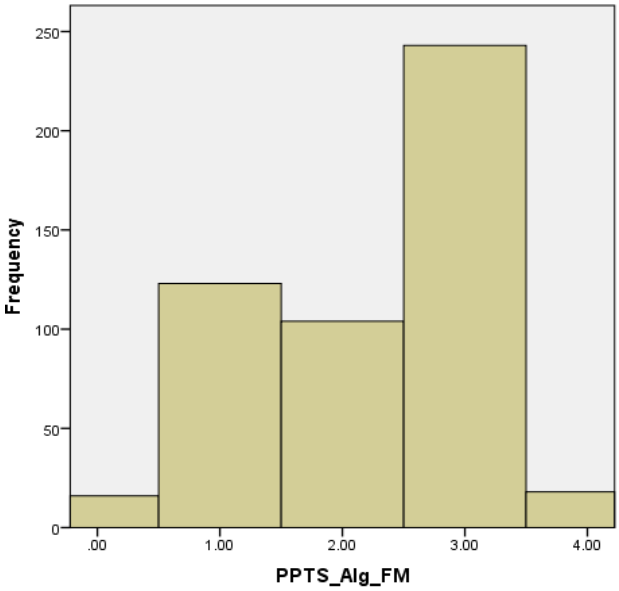


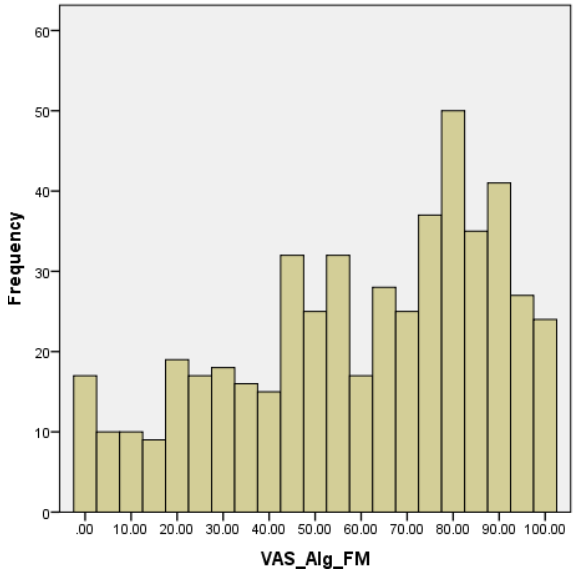
Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Alg_C	504	3.00	.00	3.00	.5099	.03177	.71334	.509
VAS_Alg_C	504	84.00	.00	84.00	10.3433	.82751	18.57753	345.124
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

Control Group Algometry: PPTS compared to VAS			
Points	Spearman rho	95% CI	Correlation p-value
1	.90	.76 to .97	<.001
2	.92	.81 to .97	<.001
3	.97	.91 to 1.0	<.001
4	.87	.61 to .99	<.001
5	.99	.96 to 1.0	<.001
6	.99	.95 to 1.0	<.001
7	.99	.97 to 1.0	<.001
8	.99	.98 to 1.0	<.001
9	.90	.76 to .96	<.001
10	.85	.67 to .97	<.001
11	.96	.88 to .99	<.001
12	.96	.88 to .99	<.001
13	.97	.90 to .99	<.001
14	.97	.93 to 1.0	<.001
15	.91	.54 to 1.0	<.001
16	.99	.97 to 1.0	<.001
17	.98	.94 to 1.0	<.001
18	.99	.95 to 1.0	<.001
CI: Confidence Interval; Statistically significant p<.05			



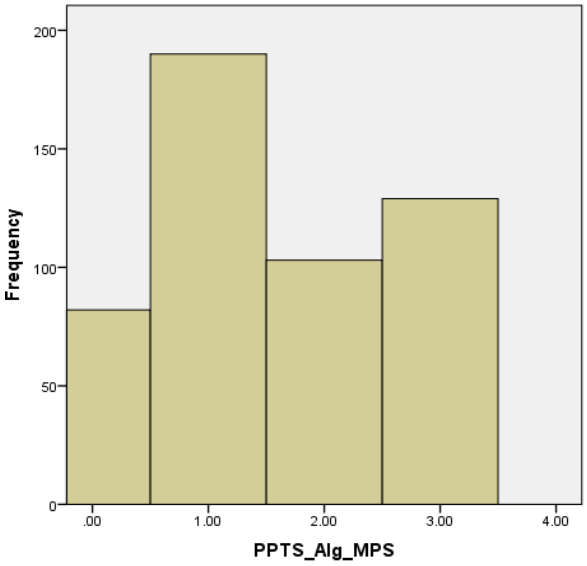


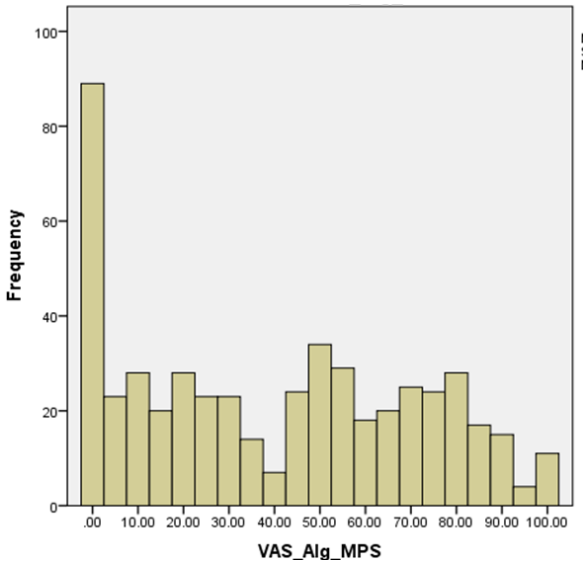
Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Alg_FM	504	4.00	.00	4.00	2.2460	.04313	.96817	.937
VAS_Alg_FM	504	100.00	.00	100.00	60.0556	1.23978	27.83295	774.673
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

FM Group Algometry: PPTS compared to VAS			
Points	Spearman rho	95% CI	Correlation p-value
1	.77	.49 to .91	<.001
2	.82	.60 to .94	<.001
3	.79	.49 to .94	<.001
4	.85	.62 to .94	<.001
5	.82	.64 to .94	<.001
6	.84	.51 to .94	<.001
7	.84	.65 to .95	<.001
8	.91	.71 to .97	<.001
9	.61	.22 to .86	<.001
10	.69	.43 to .88	<.001
11	.82	.61 to .91	<.001
12	.73	.28 to .90	<.001
13	.88	.77 to .94	<.001
14	.83	.59 to .90	<.001
15	.88	.79 to .92	<.001
16	.86	.69 to .92	<.001
17	.70	.29 to .95	<.001
18	.78	.24 to .96	<.001
CI: Confidence Interval; Statistically significant p<.05			





Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Alg_MPS	504	3.00	.00	3.00	1.5536	.04643	1.04240	1.087
VAS_Alg_MPS	504	100.00	.00	100.00	39.8552	1.36883	30.73010	944.339
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

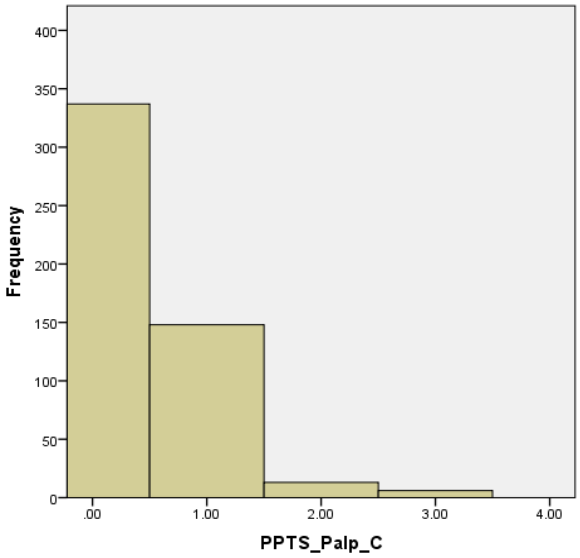
MPS Group Algometry: PPTS compared to VAS			
Points	Spearman rho	95% CI	Correlation p-value
1	.90	.80 to .94	<.001
2	.91	.83 to .94	<.001
3	.97	.92 to .99	<.001
4	.96	.91 to .97	<.001
5	.94	.81 to .96	<.001
6	.93	.84 to .96	<.001
7	.97	.92 to .99	<.001
8	.88	.70 to .98	<.001
9	.93	.85 to .95	<.001
10	.93	.87 to .95	<.001
11	.92	.83 to .95	<.001
12	.95	.91 to .97	<.001
13	.93	.80 to .96	<.001
14	.93	.85 to .96	<.001
15	.94	.84 to .99	<.001
16	.96	.90 to .99	<.001
17	.94	.85 to .98	<.001
18	.96	.83 to .99	<.001
CI: Confidence Interval; Statistically significant p<.05			

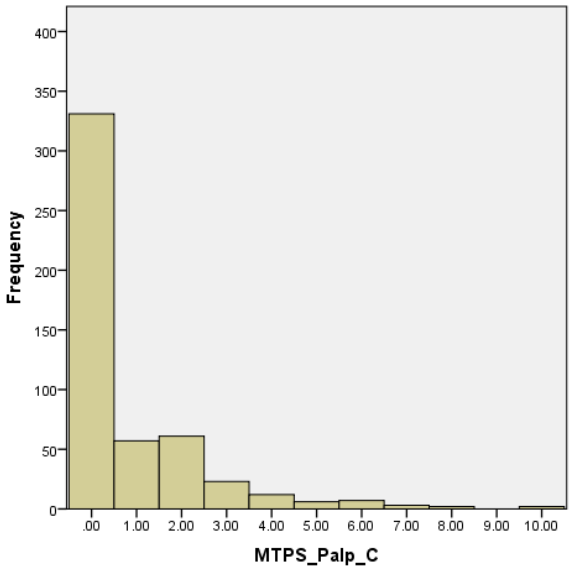
Appendix I

Aim #3: Does a 5-point PPTS possess concurrent validity when compared to a Manual Tender Point Survey Scale at 18 predetermined tender points in participants with MPS and FM?

Part I: Manual Palpation with Pressure Sensor

Control Group Comparison



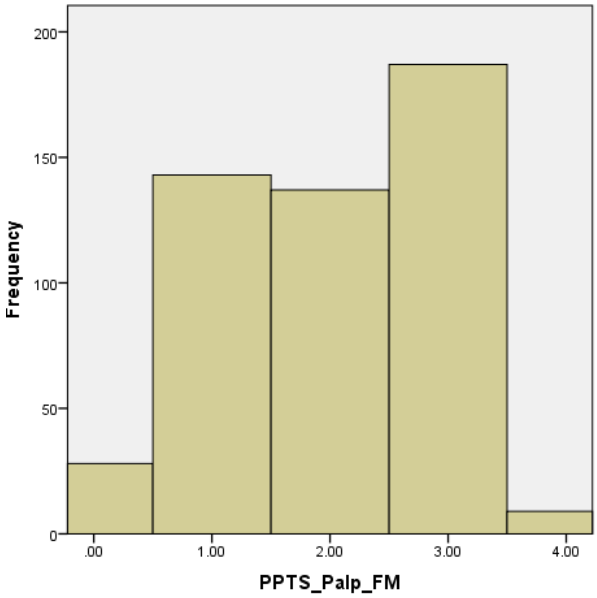


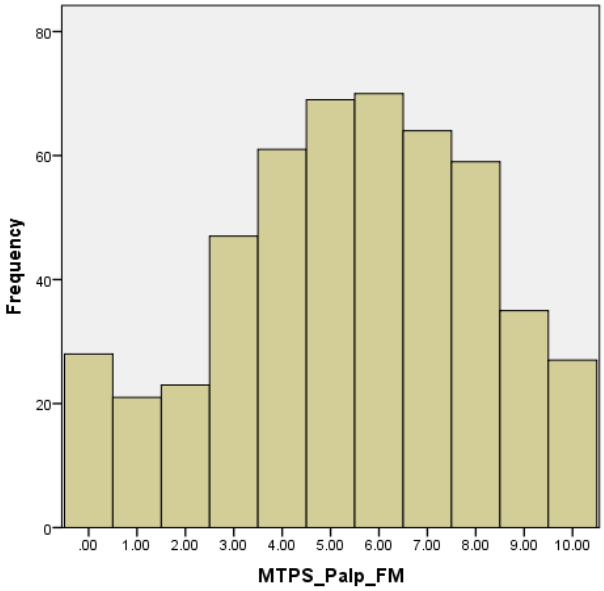
Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Palp_C	504	3.00	.00	3.00	.3810	.02671	.59963	.360
MTPS_Palp_C	504	10.00	.00	10.00	.8433	.06933	1.55650	2.423
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

Control Group Manual Palpation: PPTS compared to MTPS			
Points	Spearman rho	95% CI	Correlation p-value
1	.89	.68 to 1.0	<.001
2	.94	.80 to .99	<.001
3	.98	.94 to .99	<.001
4	.81	.58 to .99	<.001
5	.97	.93 to .99	<.001
6	.77	.53 to .99	<.001
7	1.0	.99 to 1.0	<.001
8	1.0	.99 to 1.0	<.001
9	.94	.84 to .99	<.001
10	.87	.76 to .96	<.001
11	.87	.66 to .97	<.001
12	.90	.77 to 1.0	<.001
13	.79	.52 to 1.0	<.001
14	.79	.43 to 1.0	<.001
15	.71	.38 to 1.0	<.001
16	.92	.65 to 1.0	<.001
17	.92	.76 to .1.0	<.001
18	1.0	1.0 to 1.0	<.001
CI: Confidence Interval; Statistically significant p<.05			



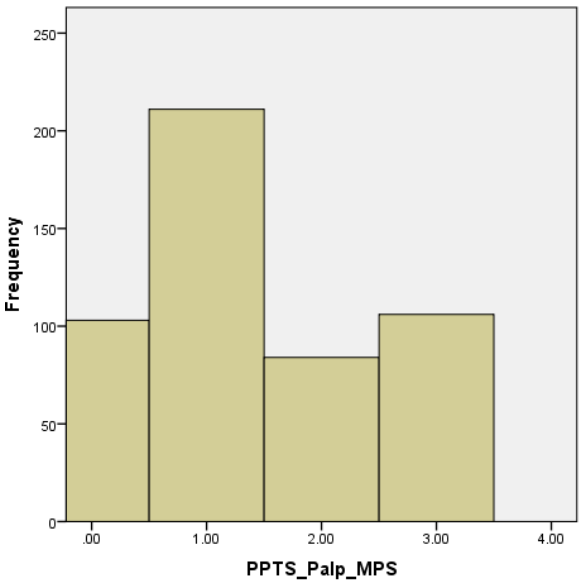


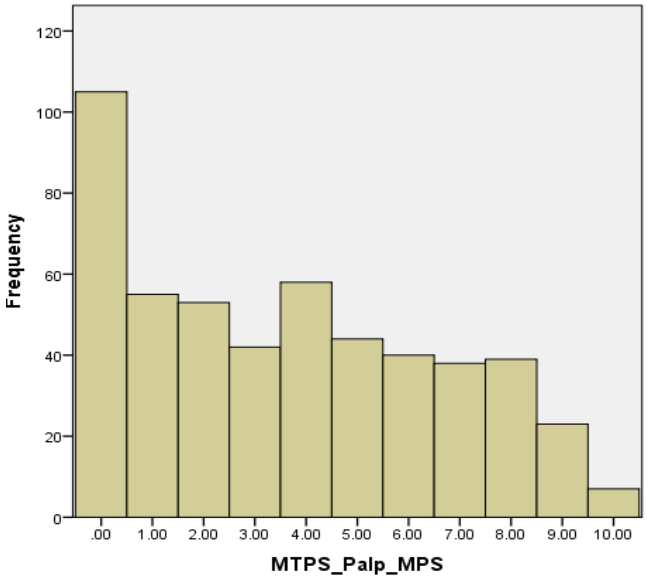
Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Palp_FM	504	4.00	.00	4.00	2.0119	.04342	.97476	.950
MTPS_Palp_FM	504	10.00	.00	10.00	5.4008	.11755	2.63899	6.964
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

FM Group Manual Palpation: PPTS compared to MTPS			
Points	Spearman rho	95% CI	Correlation p-value
1	.24	-.38 to .55	.23
2	.25	-.99 to .61	.20
3	.26	-.61 to .59	.17
4	.30	-.02 to .64	.13
5	.31	-.15 to .64	.11
6	.38	-.02 to .71	.05*
7	.01	-.43 to .42	.97
8	.32	-.14 to .73	.09
9	.41	-.04 to .79	.03*
10	.41	.03 to .72	.03*
11	.30	-.14 to .67	.12
12	.16	-.34 to .54	.42
13	.14	-.34 to .54	.49
14	.01	-.42 to .42	.97
15	.30	-.24 to .66	.12
16	.17	-.19 to .59	.39
17	.25	-.29 to .61	.21
18	.50	.11 to .78	.007*
CI: Confidence Interval; *statistically significant p<.05			





Descriptive Statistics

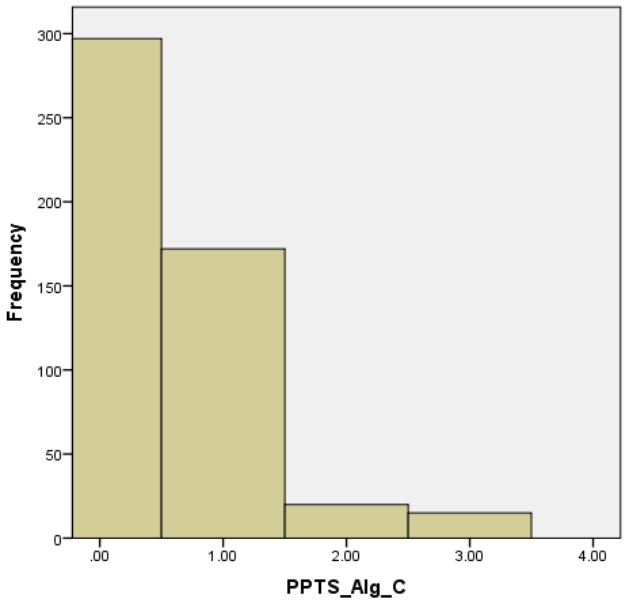
	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Palp_MPS	504	3.00	.00	3.00	1.3829	.04603	1.03333	1.068
MTPS_Palp_MPS	504	10.00	.00	10.00	3.6389	.13115	2.94424	8.669
Valid N (listwise)	504							

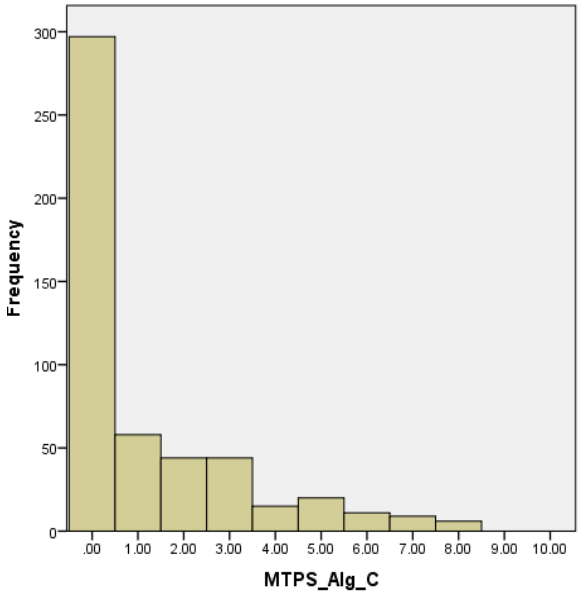
Descriptive Data: 18 points (Group n=28)

MPS Group Manual Palpation: PPTS compared to MTPS			
Points	Spearman rho	95% CI	Correlation p-value
1	.95	.90 to .96	<.001
2	.93	.86 to .96	<.001
3	.97	.91 to .99	<.001
4	.97	.91 to .99	<.001
5	.96	.90 to 1.0	<.001
6	.87	.77 to .94	<.001
7	.97	.92 to .99	<.001
8	.95	.85 to .99	<.001
9	.92	.83 to .95	<.001
10	.94	.89 to .97	<.001
11	.91	.81 to .96	<.001
12	.94	.85 to .97	<.001
13	.98	.94 to .99	<.001
14	.94	.83 to .98	<.001
15	.94	.79 to .98	<.001
16	.94	.86 to .97	<.001
17	.96	.87 to .99	<.001
18	.96	.86 to .99	<.001
CI: Confidence Interval; Statistically significant p<.05			

Part II: Algometry

Control Group Comparison



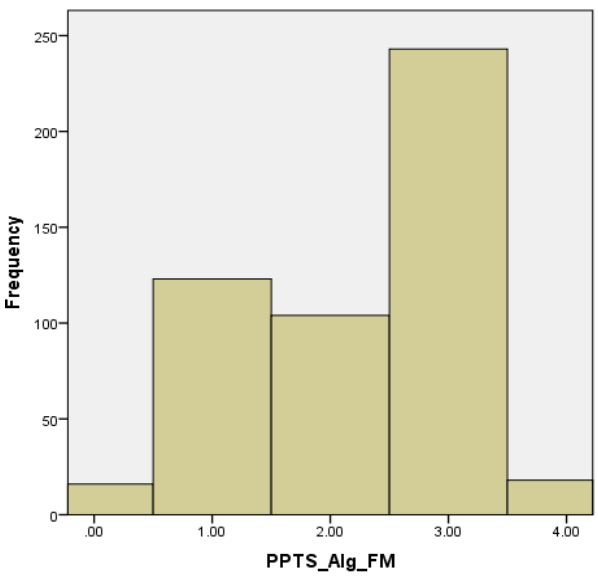


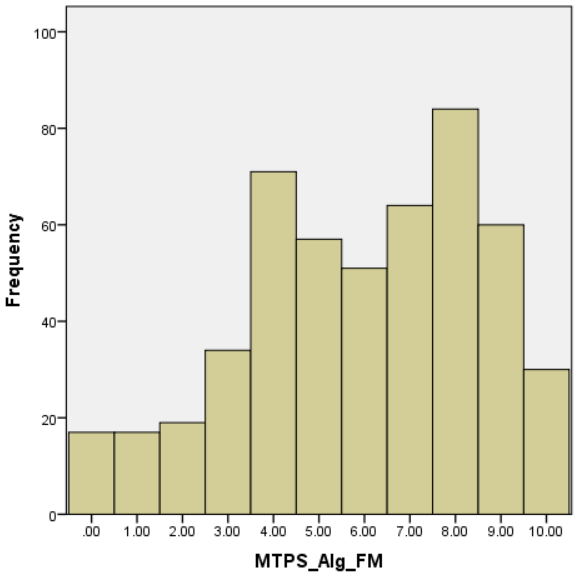
Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Alg_C	504	3.00	.00	3.00	.5099	.03177	.71334	.509
MTPS_Alg_C	504	8.00	.00	8.00	1.2202	.08521	1.91289	3.659
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

Control Group Algometry: PPTS compared to MTPS			
Points	**Spearman rho**	**95% CI**	**Correlation p-value**
1	.91	.75 to .96	<.001
2	.92	.70 to .99	<.001
3	.97	.89 to 1.0	<.001
4	.98	.92 to 1.0	<.001
5	.99	.95 to 1.0	<.001
6	.99	.96 to 1.0	<.001
7	.99	.98 to 1.0	<.001
8	.99	.97 to 1.0	<.001
9	.90	.67 to .97	<.001
10	.88	.69 to .98	<.001
11	.96	.87 to .99	<.001
12	.97	.88 to .99	<.001
13	.97	.92 to 99	<.001
14	.97	.91 to 1.0	<.001
15	.99	.97 to 1.0	<.001
16	.99	.98 to 1.0	<.001
17	.98	.92 to 1.0	<.001
18	.99	.96 to 1.0	<.001
CI: Confidence Interval; Statistically significant p<.05			



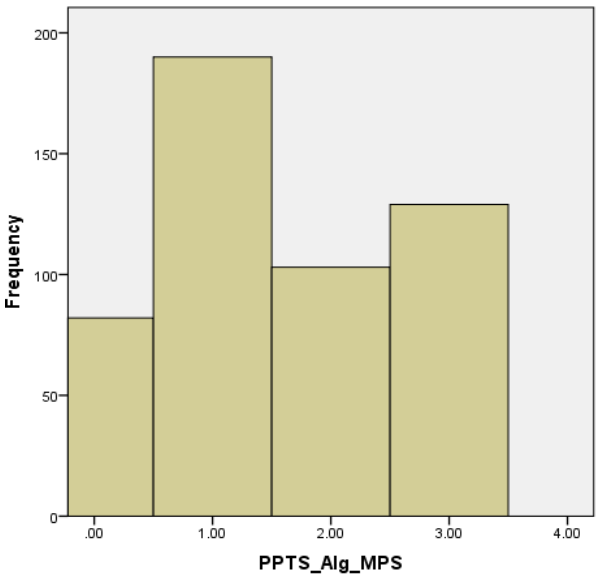


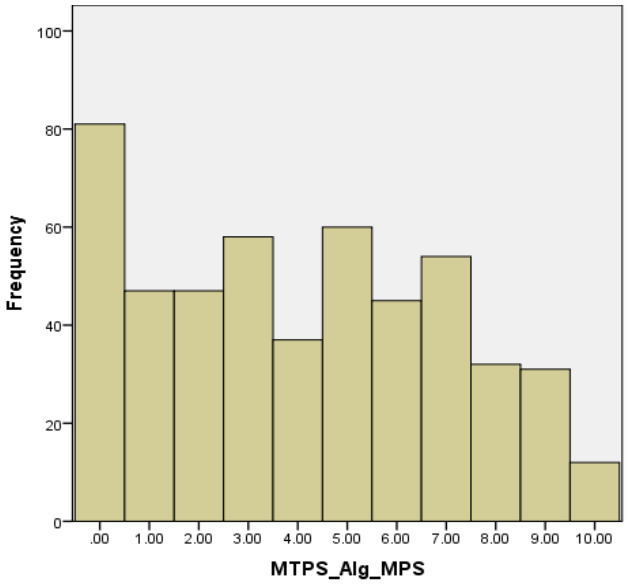
Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Alg_FM	504	4.00	.00	4.00	2.2460	.04313	.96817	.937
MTPS_Alg_FM	504	10.00	.00	10.00	5.9365	.11591	2.60217	6.771
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

FM Group Algometry: PPTS compared to MTPS			
Points	Spearman rho	95% CI	Correlation p-value
1	.79	.45 to .95	<.001
2	.78	.34 to .95	<.001
3	.83	.35 to .98	<.001
4	.85	.70 to .94	<.001
5	.85	.60 to .94	<.001
6	.87	.60 to .96	<.001
7	.94	.85 to .97	<.001
8	.92	.80 to .97	<.001
9	.68	.31 to .91	<.001
10	.74	.52 to .90	<.001
11	.82	.61 to .90	<.001
12	.75	.47 to .93	<.001
13	.86	.67 to .95	<.001
14	.83	.63 to .96	<.001
15	.91	.85 to .96	<.001
16	.85	.63 to .91	<.001
17	.71	.17 to .96	<.001
18	.78	.54 to .96	<.001
CI: Confidence Interval; Statistically significant p<.05			





Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Alg_MPS	504	3.00	.00	3.00	1.5536	.04643	1.04240	1.087
MTPS_Alg_MPS	504	10.00	.00	10.00	4.0992	.13182	2.95931	8.758
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

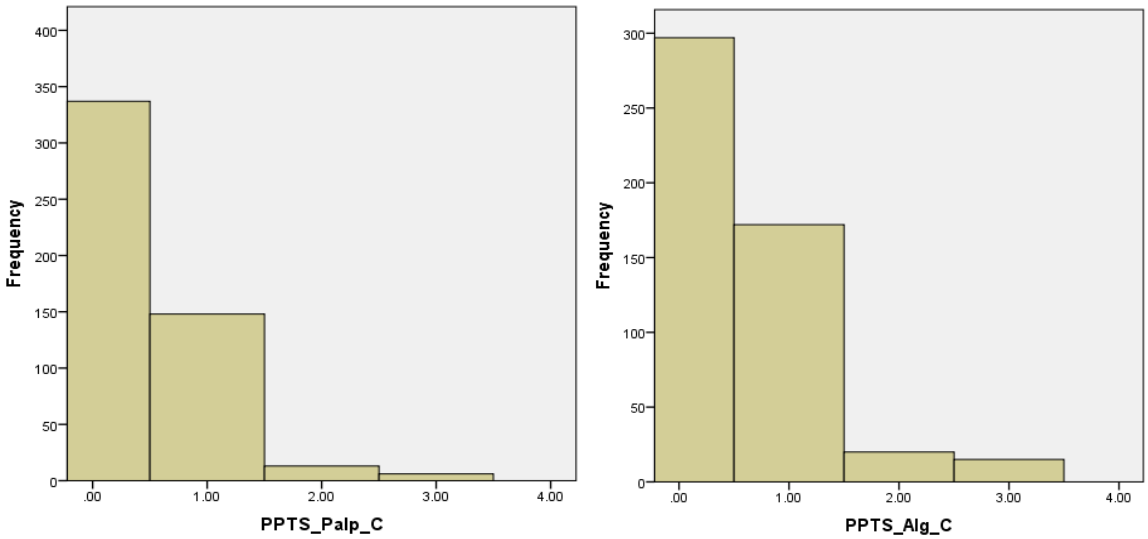
MPS Group Algometry: PPTS compared to MTPS			
Points	Spearman rho	95% CI	Correlation p-value
1	.79	.39 to .96	<.001
2	.78	.35 to .95	<.001
3	.83	.50 to .97	<.001
4	.85	.61 to .94	<.001
5	.85	.65 to .94	<.001
6	.87	.57 to .95	<.001
7	.94	.87 to .97	<.001
8	.92	.84 to .98	<.001
9	.68	.28 to .92	<.001
10	.74	.50 to .94	<.001
11	.82	.52 to .92	<.001
12	.75	.10 to .96	<.001
13	.86	.70 to .95	<.001
14	.83	.63 to .95	<.001
15	.91	.77 to .96	<.001
16	.86	.65 to .92	<.001
17	.71	.28 to .96	<.001
18	.78	.48 to .96	<.001
CI: Confidence Interval; Statistically significant p<.05			

Appendix J

Aim #4: Does manual palpation pressure up to 4 kg/cm^2 measured by the Tekscan® digital pressure sensor at 18 predetermined tender points produce a comparable response by the participant as algometry pressure up to 4 kg/cm^2 using the 5-point PPTS in participants with MPS, FM, and in healthy individuals (control group)?

Part I: Manual Palpation with Pressure Sensor

Control Group Comparison

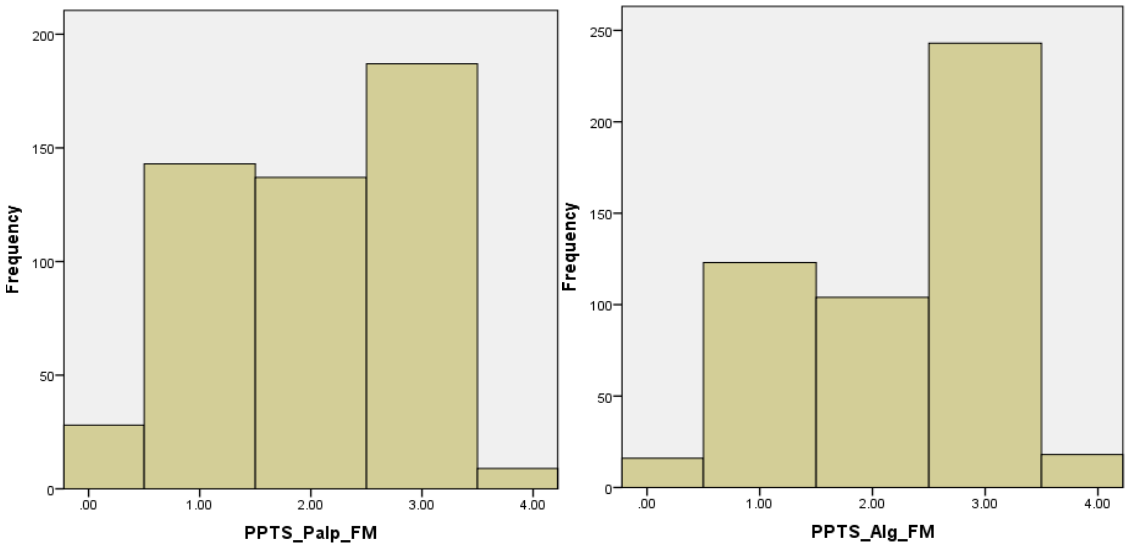


Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Palp_C	504	3.00	.00	3.00	.3810	.02671	.59963	.360
PPTS_Alg_C	504	3.00	.00	3.00	.5099	.03177	.71334	.509
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

Control Group: Digital Pressure Sensor compared to Algometer			
Points	Spearman rho	95% CI	Correlation p-value
1	.69	.39 to .84	<.001
2	.70	.49 to .94	<.001
3	.86	.64 to 1.0	<.001
4	.82	.61 to 1.0	<.001
5	.61	.16 to .90	.001
6	.83	.52 to 1.0	<.001
7	.42	.10 to .79	.03
8	.85	.47 to 1.0	<.001
9	.77	.57 to .90	<.001
10	.77	.63 to .95	<.001
11	.73	.46 to .92	<.001
12	.74	.52 to .87	<.001
13	.69	.41 to .99	<.001
14	.48	.23 to .77	.01
15	.41	.26 to .84	.03
16	.99	.98 to 1.0	<.001
17	.78	.50 to 1.0	<.001
18	.76	.42 to 1.0	<.001
CI: Confidence Interval; Statistically significant p<.05			

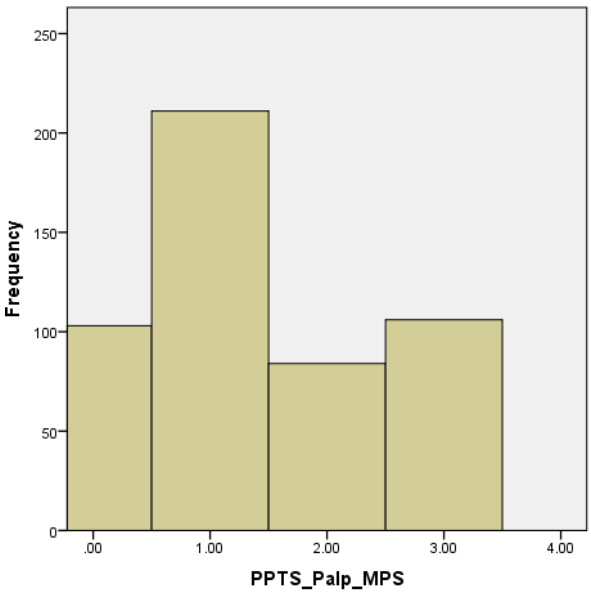


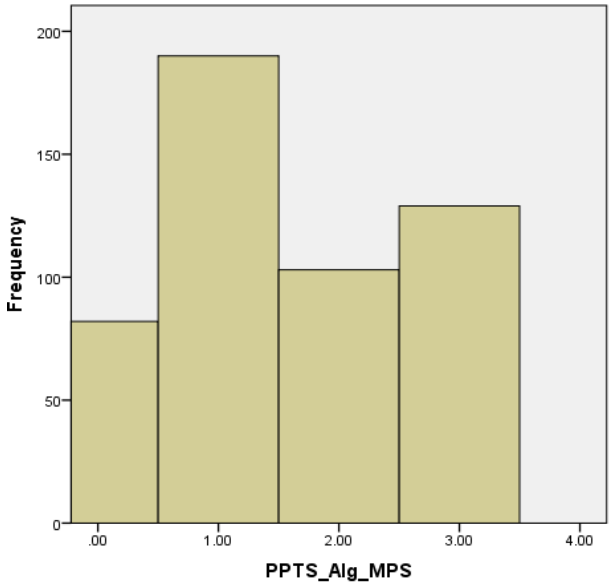
Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Palp_FM	504	4.00	.00	4.00	2.0119	.04342	.97476	.950
PPTS_Alg_FM	504	4.00	.00	4.00	2.2460	.04313	.96817	.937
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

FM Group: Digital Pressure Sensor compared to Algometer			
Points	Spearman rho	95% CI	Correlation p-value
1	.60	.38 to .78	.001
2	.88	.76 to .96	<.001
3	.74	.50 to .88	<.001
4	.67	.28 to .81	<.001
5	.69	.37 to .89	<.001
6	.74	.43 to .92	<.001
7	.75	.53 to .89	<.001
8	.70	.37 to .91	<.001
9	.85	.70 to .97	<.001
10	.73	.55 to .89	<.001
11	.90	.66 to .1.0	<.001
12	.65	.39 to .90	<.001
13	.59	.16 to .82	.001
14	.50	.17 to .72	.009
15	.80	.58 to .95	<.001
16	.82	.56 to .91	<.001
17	.59	.32 to .86	.001
18	.72	.34 to .91	<.001
CI: Confidence Interval; Statistically significant p<.05			





Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
PPTS_Palp_MPS	504	3.00	.00	3.00	1.3829	.04603	1.03333	1.068
PPTS_Alg_MPS	504	3.00	.00	3.00	1.5536	.04643	1.04240	1.087
Valid N (listwise)	504							

Descriptive Data: 18 points (Group n=28)

MPS Group: Digital Pressure Sensor compared to Algometer			
Points	Spearman rho	95% CI	Correlation p-value
1	.85	.68 to .94	<.001
2	.77	.45 to .92	<.001
3	.83	.70 to .94	<.001
4	.85	.69 to .94	<.001
5	.82	.65 to .91	<.001
6	.66	.51 to .82	<.001
7	.88	.72 to .99	<.001
8	.82	.64 to .97	<.001
9	.83	.59 to .96	<.001
10	.63	.28 to .83	<.001
11	.59	.14 to .85	<.001
12	.78	.43 to .93	<.001
13	.68	.38 to .87	<.001
14	.70	.36 to .90	<.001
15	.66	.44 to .83	<.001
16	.84	.74 to .91	<.001
17	.81	.63 to .91	<.001
18	.76	.60 to .93	<.001
CI: Confidence Interval; Statistically significant p<.05			

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