Concurrent validation of a pressure pain threshold scale for individuals with myofascial pain syndrome and fibromyalgia

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ABSTRACT

Background: Manual pressure palpation is an examination technique used in the classification of myofascial pain syndrome (MPS) and fibromyalgia (FM). Currently, there are no validated systems for classifying 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 investigation was to validate a PPTS in individuals diagnosed with MPS and FM. Intra-rater reliability, concurrent validity, minimum cut-off value, and patient responses were evaluated.

Methods: Eighty-four participants who met the inclusion criteria were placed into three groups of 28 ($N = 84$): MPS, FM, and asymptomatic controls. All participants underwent a two-part testing session using the American College of Rheumatology criteria for classifying FM. Part-1 consisted of manual palpation with a digital pressure sensor for pressure consistency and part 2 consisted of algometry. For each tender point (18 total), participants graded tenderness using the visual analog scale (VAS) while the examiner concurrently graded response using a five-point PPTS.

Results: The PPTS had good intra-rater reliability ($ICC \geq .88$). A moderate to excellent relationship was found between the PPTS and VAS for all groups with the digital pressure sensor and algometer ($\rho \geq .61$). A minimum cut-off value of 2 on the PPTS differentiated participants with MPS and FM from asymptomatic controls.

Discussion: The results provide preliminary evidence validating the PPTS for individuals with MPS and FM. Future research should further study the clinimetric properties of the PPTS with other chronic pain and orthopedic conditions.

Levels of Evidence: 2c.

Clinical Trial Registration: ClinicalTrials.gov registration No. NCT02802202.

KEYWORDS

Chronic; muscle; pain; syndrome; tender; trigger; points; fatigue

Introduction

Clinicians perform manual pressure palpation to assess the presence of a musculoskeletal pathology, differentiate tissues at fault as well as a means to postulate condition reactivity, and severity of pathology [1]. Chronic musculoskeletal pathologies such as myofascial pain syndrome (MPS) and fibromyalgia (FM) are dependent upon the findings from manual pressure palpation of tender points and trigger points since medical tests and imaging are often inconclusive [2,3]. It has been postulated that FM may be concomitantly present in over 50% of patients diagnosed with MPS [4]. An estimated 54% of women and 45% of men may suffer from MPS with the most common age range between 27 and 50 years [5–7]. It is also estimated that more than 5 million Americans have FM with a higher presence among women ages 35–60 years [1,8]. Total financial costs for treating chronic pain disorders in 2012 ranged between \$560 and \$635 million annually [9].

For clinicians, the possible presence of the two conditions in individuals makes it a challenge to classify and treat due to overlapping symptoms (e.g. fatigue, sleep disturbances) and clinical presentation. The examination often depends upon manual pressure palpation for confirmation of the condition. MPS is often described as a regional condition with specific trigger points (TrPs) that can refer pain while FM is characterized by chronic widespread pain and local tender points [10]. Thus, the manual palpation examination is the best way to discriminate between the two conditions.

Currently, there is no consensus on an objective and reliable method of grading manual pressure palpation despite instruction provided in medical and allied health education programs. The challenge lies in the subjective nature of palpation among clinicians which includes: (1) the amount of digital pressure applied, (2) methods used to quantify or rank patient responses, and (3) interpretation of findings. This lack of consensus may lead to

variability in both reporting and interpretation of palpation outcomes. Several systematic reviews examining the efficacy of palpation for neck and back pain have found overall reliability of manual pressure palpation to be weak with no superior method established [11–13]. Moreover, this variability may confound the examination process for many musculoskeletal pathologies.

A valid and reliable pressure pain threshold scale (PPTS) is essential to the examination and diagnosis of musculoskeletal pathology. The most notable scale was published by Wolfe et al. in 1990 [14]. The five-point ordinal ranked scale (0-no pain to 4-severe pain) was initially used in the study that validated the 1990 American College of Rheumatology (ACR) examination criteria for diagnosing Fibromyalgia. However, the researchers found that the scale was not sensitive enough for detecting tender points and omitted the scale from the final criteria [14]. Nevertheless, the scale is referenced in many common textbooks and often used by clinicians even though the scale's clinimetric properties have not been reported. Since then, several similar scales have been used in clinical research over the years but their clinimetric properties have not been evaluated beyond their original publications [14–18].

Later researchers began to use the visual analog scale (VAS) to provide a way for patients to quantify the amount of discomfort felt during manual pressure palpation [19–21]. Other studies combining manual pressure palpation and the VAS for pain in subjects with FM have reported good results [22,23]. However, the subjective nature of the measure is an inherent weakness and is often influenced by the various dimensions of chronic pain [24]. Despite this limitation, the VAS is commonly used in chronic pain research [23–26].

Researchers and clinicians also use instruments such as pressure algometry to help quantify a patient's pressure pain threshold [27,28]. Several different devices have been developed such as algometers with wireless capability [29,30] and smaller digital pressure sensors [31]. Pressure algometry is a valid and reliable measure that has been used in chronic pain research [32–35]. Furthermore, researchers have used pressure algometry as a reference standard in studies measuring the reliability of manual pressure palpation in patients with MPS and FM [36–39]. Both algometry and the VAS have been shown to have good sensitivity ($\geq 77\%$) and specificity ($\geq 80\%$) in patients with FM [22,23]. The benefit of algometry is the ability to concurrently quantify the amount of pressure applied and felt by the patient during the examination. However, these instruments can be expensive and may not be practical in many clinical settings forcing the clinician to rely on manual pressure palpation.

Due to the lack of consensus and standardization in the manual palpation assessment, clinicians often adopt their own assessment methods and interpretations of the existing literature which is sparse. Thus, the purpose

of this investigation was to determine the validity of the proposed PPTS and explore its utility for patients with MPS and FM. Through this investigation, we attempted to determine the following: (1) intra-rater reliability of the PPTS, (2) concurrent validity of the PPTS with the VAS, (3) the minimum cut-off value that differentiates individuals with MPS and FM from asymptomatic controls, and (4) if manual palpation produced a comparable participant response to algometry.

Methods

Study design

This investigation was a validation study of a newly developed PPTS. This study was approved by the California State University Dominguez Hills Institutional Review Board (IRB) (No. 15-116). All participants agreed and completed an approved consent before participating in this investigation. Data collection was conducted in the university kinesiology department laboratory.

Participants

Eighty-four participants ($M = 18$, $F = 66$; mean age = 43.8 ± 14.6 years; height = $1.6 \pm .01$ m; body mass = 79.3 ± 17.7 kg; body mass index = 27.76 ± 2.4) were recruited via convenience sampling (e.g. flyers) from the local community, university campus, and local support groups in the Southern California area. Participants enrolled in this investigation were 18–65 years of age and met the inclusion criteria for 1 of the 3 groups. All participants were required to read, speak and write English in order to complete the study related forms and consent. Each group consisted of 28 participants. The following inclusion criteria for each group are outlined below: (1) *Control group*: Individuals with no current or prior diagnosis consistent with MPS or FM. (2) *MPS group*: Individuals with a diagnosis of MPS that did not meet the ACR diagnostic criteria for FM. (3) *FM group*: Individuals who met the criteria for a diagnosis of FM based upon the ACR diagnostic criteria.

Exclusion criteria included the following: integumentary injuries or abnormalities at the predetermined palpation sites, neurologic conditions (e.g. Multiple Sclerosis), metabolic conditions (e.g. Diabetic Neuropathy), or systemic conditions (e.g. Rheumatoid Arthritis), connective tissue disorders (e.g. Marfan Syndrome), shingles or post-herpetic neuralgia, prior surgery that may affect ability to participate in the study, pacemaker or electrical implant that may be affected by electronic equipment, inability to tolerate testing duration (45 min) and procedures, and medications that could alter a subject's sensation or affect their ability to participate in this study.

Study protocol

Prior to data collection, all participants completed a questionnaire to provide demographic information (age, body mass, height, and body mass index) and determine eligibility. All eligible participants were then given an IRB

approved consent form to read and sign. All participants underwent the same testing procedure by one investigator and were blinded from the examiner's scores and other participants enrolled in the study. Testing was conducted between the hours of 8 AM and 2 PM 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.

Each participant was tested using the 1990 ACR examination criteria for classifying FM which includes testing 18 predetermined tender point along the neck, back, arms, and legs (Figure 1) using manual pressure palpation (e.g. thumb) with a digital sensor and pressure algometry [40]. The palpation pressure was applied at a rate of 1 kg per second for a total of 4 s at each tender point up to 4 kg/cm² of pressure [14,18]. A response of 'painful' from the participant was needed for a tender point to be considered positive. A score of 11/18 positive tender points classifies individuals as having FM [40].

Tender Points of Fibromyalgia

Figure 1. American College of Rheumatology Tender Points.

Table 1. Pressure pain threshold scale.

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

Outcome measures

All participants used a 100 mm VAS to quantify their perceived level of palpable tenderness at each tender point. The VAS has good test-retest reliability ($r = .94$) when used with chronic pain disorders such as MPS and FM [23–26].

The PPTS was used by the examiner to quantify the participant's sensitivity at each tender point. The PPTS is a five-point ranked scale that includes corresponding criteria for each level (Table 1).

Instruments

Two clinical instruments were used in this investigation. First, the Tekscan® (South Boston, MA) Wireless ELF™ 2 computerized pressure system using the FlexiForce® sensor film was used to provide concurrent feedback of digital pressure during manual pressure palpation with the thumb. The sensor film was attached to the thumb, which measured the pressure that was applied by the examiner (Figure 2). The sensor was connected to the accompanying software via Wi-Fi transmitter. The

Figure 2. Tekscan® Wireless ELF™ 2 with FlexiForce® pressure sensing film.

Windows® based 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. The manufacturer reports an accuracy error of $\leq \pm 3\%$ ($.03 \text{ kg/cm}^2$) for this technology, which has been validated and used in several investigations focusing on concussions, balance, knee joint biomechanics, and gait [31,41–44]. Prior palpation studies have used this technology, which is potentially superior to standard manual palpation [45–47]. We used this technique to ensure consistent pressure.

Second, The JTECH (Midvale, UT) Tracker Freedom® wireless algometer (Figure 3) was used with the accompanying Tracker 5® software to measure the pressure at each predetermined tender point as a comparison for the digital pressure sensor. The algometer was connected to the computer via Bluetooth® wireless technology. During testing, the software visually guided the examiner via feedback provided on the monitor. The Windows® based 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 manufacturer reports an accuracy error of $\leq \pm 0.5\%$ ($.05 \text{ kg/cm}^2$) for this technology [48]. The 1990 ACR examination criteria are integrated into the Tracker 5® software allowing the examiner to test and record pressure at each tender point. The software automatically calibrated before each testing session. Algometry is a valid and reliable tool that is commonly used in research and clinical practice involving individuals with MPS and FM [49–51].

Reliability testing

The first 10 participants with the conditions of MPS or FM and the first 10 asymptomatic controls participated in the reliability portion of the study and underwent a day of testing, which lasted 45-min. Participants then completed a 2nd testing session (approximately 45 min) within one week of the first and completed the same

testing procedures. Recruitment continued until a total of 20 participants were obtained. After the reliability testing was completed, all other recruited participants underwent 1 day of testing which lasted approximately 45 min.

Testing procedures

All subjects participated in a two-part testing sessions using the 1990 ACR examination criteria tender point examination criteria. Part-1 consisted of manual palpation with thumb and digital pressure sensor and part-2 utilized an algometer. 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. This helped the examiner accurately grade the patient's reaction based upon the PPTS which, specific to grade II and above, includes facial and body expressions.

Prior to testing, the investigator demonstrated the procedure with each participant using two control points: left thumb (part 1), dorsum of the right forearm (part 2). This was done to familiarize the participant with the testing procedures, scoring of VAS, and to answer any questions prior to testing. The control points were independent of the ACR 18 predetermined points [18]. Each part of the examination will be outlined below.

Part 1: Manual Palpation: The investigator applied a gradually increasing pressure to each of the predetermined tender points using the thumb and pressure sensor, one time [14,18]. The graded pressure was concurrently monitored on the computer screen for each tender point. The participant recorded their level of tenderness at each point using the VAS once the investigator reached 4 kg/cm^2 of pressure or once a maximum level of pressure was felt. Participants were able to stop testing at any time by verbally telling the examiner. The investigator simultaneously recorded the participant's response using the PPTS scale for each tender point. The pressure sensor was calibrated prior to testing each participant.

Figure 3. JTECH (Midvale, UT) Tracker Freedom® wireless algometer.

Part 2: Algometry: The investigator applied a gradual increasing pressure to each of the predetermined points using the computerized algometer, one time [14,18]. The graded pressure was concurrently monitored on the computer screen for each tender point. The participant recorded their level of tenderness at each point using the VAS once the examiner reached 4 kg/cm² of pressure or once a maximum level of pressure was felt. Participants were able to stop testing at any time by verbally telling the examiner. The investigator simultaneously recorded the participant's response using the PPTS scale for each tender point. The algometer was calibrated prior to testing each participant.

Statistical Analysis

Statistical calculations were conducted with SPSS v.22 (IBM SPSS, Chicago, IL). Prior to data collection, an a priori power analysis for the Spearman correlation statistic was conducted for a moderate effect size which yielded a sample size of $N = 84$ [52,53]. The alpha level was set at .05 level using a two-tailed test. Participant descriptive data for age, body mass, height, and body mass index (BMI) was calculated for each group. Means, standard deviation, 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 Kruskal Wallis test for ordinal level data.

The intraclass correlation coefficient (ICC) model 3, 3 statistic was used to calculate intra-rater reliability for all 18 tender points. The criteria for evaluating the reliability coefficient were as follows: $<.75$ = poor to moderate, $\geq.75$ = good reliability [54]. *Concurrent validity* between the PPTS and VAS was calculated for each of the 18 tender points using the spearman rank correlation coefficient (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 [54].

A receiver operating characteristic curve (ROC) was used to determine the minimal cut-off value that differentiated the MPS and FM group and control group. Participant data were dichotomized into two categories: (1) MPS and FM group and (2) control group. The optimal cut-off value is represented by the maximum sensitivity and specificity situated highest on the upper left side of the ROC [55]. The area under the curve (AUC) represents the probability of scores accurately differentiating between patients. The AUC criteria range from 0.5 to 1. A score of 0.7–0.8 is considered an acceptable discriminating range and 0.8–0.9 is considered an excellent discriminating range.

A performance comparison of manual palpation and the algometer was calculated using the Spearman

Table 2. PPTS descriptive data for each group (all 18 points).

	Median	Range	Interquartile range
MPS/FM group (N = 56)			
Manual palpation	2.00	0.00–4.00	2.00
Algometry	2.00	0.00–4.00	2.00
Control group (N = 28)			
Manual palpation	0.00	0.00–3.00	0.00
Algometry	0.00	0.00–3.00	0.00

*Median data reported for ordinal level data; Interquartile Range (Q3-Q1); MPS: myofascial pain syndrome; FM: fibromyalgia.

Table 3. VAS descriptive data for each group (all 18 points).

	Mean (SD)	95% CI	Range
MPS/FM group (N = 56)			
Manual palpation	44.15 ± 30.62	42.20–46.04	0.00–100.00
Algometry	49.95 ± 31.00	48.01–51.76	0.00–100.00
Control group (N = 28)			
Manual palpation	6.42 ± 13.75	5.26–7.67	0.00–86.00
Algometry	10.34 ± 18.58	8.76–12.10	0.00–84.00

Notes: VAS: Visual Analog Scale (100 mm); CI: confidence interval; SD: standard deviation; MPS: myofascial pain syndrome; FM: fibromyalgia.

rank correlation coefficient (95% limits of agreement) to determine if a comparable response by the participants occurred. The pressure algometer was considered the reference standard for this investigation.

Results

Eighty-four participants aged 18–65 (mean 43.81 ± 14.59) years participated in the investigation and were included in the data analysis. There were no adverse events or participant dropouts during data collection. Statistical analysis revealed no significant differences ($p > .21$) between the MPS, FM, and control groups for age, height, body mass, and BMI. Descriptive data for the PPTS and VAS scores for all groups can be found in Tables 2 and 3.

Reliability of the PPTS

An intra-rater reliability analysis of the PPTS was conducted 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. For part 1 (manual palpation), the intra-rater reliability of the PPTS was good for the combined MPS and FM group (ICC model 3, 3 = .92) and the control group (ICC model 3, 3 = .91). For part 2 (algometry), the intra-rater reliability of the PPTS was good for the combined MPS and FM group (ICC model 3, 3 = .88) and the control group (ICC model 3, 3 = .90) (Table 4).

Concurrent validity

For part 1 (manual palpation), a good to excellent relationship ($p \geq .76, p < .001$) was found among all 18 points between the PPTS and the VAS for all three groups (Table 5).

A moderate to excellent relationship ($\rho \geq .71, p < .001$) was found between the PPTS and the NPRS for the MPS and control group. A little to moderate relationship was found for the FM group ($\rho = .01-.50, p = .97-.007$).

For part 2 (algometry), a moderate to excellent relationship ($\rho \geq .61, p < .001$) was found among all 18 points between the PPTS and the VAS for all three groups (Table 5).

A moderate to excellent relationship ($\rho \geq .68, p < .001$) was found between the PPTS and the NPRS for all three groups.

Minimal cut-off score

For part 1 (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 (Figure 4). For part 2 (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 (Figure 4). Both, manual palpation and algometry had similar outcomes. Thus, a ranked score of 2 or greater differentiated individuals with MPS and FM from healthy controls.

Manual palpation versus algometry

When comparing the participant responses between manual palpation with the pressure sensor to the algometer, there was a fair to excellent relationship ($\rho \geq .41$) among all 18 points using the PPTS for all groups.

Discussion

The purpose of this investigation was to determine the validity of a newly developed PPTS and explore its utility for patients with MPS and FM. Through this investigation, we attempted to determine the following: (1) intra-rater reliability of the PPTS, (2) concurrent validity of the PPTS

with the VAS, (3) the minimum cut-off value that differentiates individuals with MPS and FM from asymptomatic controls, (4) and if manual palpation produced a comparable participant response to algometry.

Reliability of the PPTS

The results of this investigation demonstrated good intra-rater reliability of the PPTS for all three groups (ICC $\geq .88$). Several systematic reviews examining the efficacy of standard palpation for neck and back pain have found the overall reliability of manual pressure palpation to be weak with no superior method established [11–13]. The existing examination protocols for MPS and FM require manual pressure palpation and have similar challenges due to the poor methodology of supporting literature [14,56]. 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. Such a consistent method is necessary since the symptoms of individuals with chronic pain can fluctuate and change daily [57,58]. Future studies are needed to measure the inter-rater reliability of the PPTS in these individuals.

Figure 4. ROC curve for manual palpation and algometry.

Table 4. Intra-rater reliability values for Part I and Part II.

	Group (n)	ICC (3, 3)	95% CI
Part 1: Manual palpation with pressure sensor	Control (10)	.91	.88–.93
	MPS/FM (10)	.92	.89–.94
Part 2: Algometry	Control (10)	.90	.87–.92
	MPS/FM (10)	.88	.84–.91

Notes: FM = fibromyalgia; MPS = myofascial pain syndrome; n = number of subjects.

ICC Model 3, k; intraclass correlation coefficient; CI = confidence interval.

Table 5. Concurrent validity of the PPTS and VAS (all 18 points).

	Group (n)	Spearman rho (CI)*	Correlation p-value
Part 1: Manual palpation with pressure sensor	FM (28)	.77 (.56–.89) to .94 (.91–.97)	<.001**
	MPS (28)	.86 (.62–.93) to .97 (.92–.99)	<.001**
	Control (28)	.76 (.40–1.0) to 1.0 (.98–1.0)	<.001**
Part 2: Algometry	FM (28)	.61 (.22–.86) to .91 (.71–.97)	<.001**
	MPS (28)	.88 (.70–.98) to .97 (.92–.99)	<.001**
	Control (28)	.85 (.67–.97) to .99 (.95–1.0)	<.001**

Notes: FM = fibromyalgia; MPS = myofascial pain syndrome; (n) = number of subjects; (CI) = 95% confidence interval.

*Range of scores for all 18 points, p-value: **statistically significant $p < .05$.

Concurrent validity

A moderate to excellent relationship was found between the PPTS and VAS with manual palpation and algometry for all groups ($p \geq .61$). Prior research combining manual pressure palpation and the VAS to assess pain in subjects with FM has produced good results [22,23]. Due to lack of previously validated palpation scales, the VAS was used as a reference standard for this investigation. Research has suggested that individuals with MPS and FM have variable levels of pain which can fluctuate each day [37,59]. This variability in pain may be due to a combination of biological, psychological, and social factors that interact to influence pain [58]. Clinically, the combined use of the PPTS by the clinician and VAS by the patient may provide a more comprehensive analysis of the dimension of pain in this population.

Minimal cut-off score

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 have not been fully studied and eventually were modified or omitted by other researchers [14,39,60,61]. The findings from the current study demonstrated that a cut-off value of 2 on the PPTS was the optimal threshold score that differentiated patients with MPS and FM from asymptomatic 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 reported to be sensitive in diagnosing FM but unable to discriminate between individuals with FM and others chronic conditions or healthy subjects [14,60,62,63]. 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 [62,64].

Research also suggests that a decrease in the number of tender point sites correlates poorly with patient improvement [65,66]. Individuals with chronic pain also report higher pain levels than matched controls [60,67]. This may be because tender point counts are believed to be a general measure of distress that is influenced by cognitive and emotional aspects of pain perception [68–70]. 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 [68]. 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 of this study provide preliminary evidence for this hypothesis, 79% (22/28) of FM participants presented with a PPTS score of ≥ 2 at eleven or more tender points versus 40% (11/28) of MPS participants, and 0% (0/28) of control participants.

Manual palpation versus algometry

Manual palpation with a digital pressure sensor (part 1) and algometry (part 2) were used for this investigation. Due to inherent limitations in the manual pressure palpation examination, a digital pressure sensor was utilized to concurrently monitor the amount of manual pressure applied by the examiner. This technology allowed the examiner to monitor the amount of applied pressure while still being able to feel pressure with the thumb. This technology has also been used in prior palpation studies and has been shown to be superior to standard manual palpation [45–47]. To the authors' knowledge, this technology has not been used in manual pressure palpation studies involving individuals with MPS and FM.

Pressure algometry is a valid and reliable tool that has been used as a reference standard in palpation studies involving individuals with MPS and FM [45–47]. The pressure algometer was considered the comparison reference standard for this investigation. When comparing the performance of manual palpation and algometry there was fair to excellent relationship ($p \geq .41$, $p = .03$) for all three groups. The results suggest that the algometer may have the best overall performance and should not be interchangeable with manual palpation using 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 musculoskeletal education and 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.

Implications for clinical practice

For this investigation, the PPTS was compared to the VAS using the 1990 ACR examination criteria [18,24,59]. Two instruments were also used in this investigation: a digital pressure sensor and algometer. The 1990 ACR criteria included pressure palpation of 18 predetermined tender point sites. A pressure of up to 4 kg/cm² at a rate of 1 kg per second was applied to each tender point. This is the first study that utilizes instruments that allow the investigator to concurrently monitor and control the rate of pressure at each point while measuring the patient's response with the PPTS in this population [14,56]. 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 [39]. It appeared that the range of pressure (up to 4 kg/cm²) was deep enough to accurately assess tender point sensitivity among all

18 tender points for all groups [14]. The results of this investigation suggest that the combination of the PPTS, VAS, ACR criteria, and clinical instruments may enhance the examination process for these individuals. For MPS, the combination of the PPTS, VAS, algometer, or pressure sensor may yield the best results. For FM, the combination of the PPTS, VAS, and algometer may provide the best outcomes. These preliminary results suggest 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.

Limitations

When considering the methodology and the results of this investigation, some limitations warrant discussion. 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 [62,63,71,72]. 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 digital 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. While this has the benefit of standardization it may limit the clinical utility of the scale when used without the pressure sensor. Prior studies using standard manual palpation in this population have yielded variable results [38,70,71,73]. Fourth, intra-rater reliability wasn't measured for this investigation. This limits the reliability of the PPTS to one examiner. Clinicians will need to consider this when using the PPTS in clinical practice. While one could surmise that standardization of pressure, as performed in this investigation, would produce comparable results between examiners, future studies are needed to definitively establish reliability among multiple clinicians. Fifth, a potential limitation of this investigation was age. The age (years) of participants ranged from 18 to 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 [1,5–8,74]. Sixth, the clinical course of individuals with chronic pain disorders such as MPS and FM needs to be considered. Often, 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 [75,76]. 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.

Recommendations for future research

Further research is necessary to validate the full utility of the PPTS. This section proposes recommendations for future research in five key areas to further explore the utility of the PPTS. First, inter-rater reliability of the PPTS must be determined in order to establish its reliability among multiple clinicians. This investigation only measured intra-rater reliability due to limited resources. Second, the diagnostic utility of the PPTS has yet to be determined. This investigation involved 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 [77]. Fourth, the PPTS may provide an objective 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.

Conclusion

The results from this study provide preliminary evidence validating the PPTS scale for individuals with MPS and FM and may have utility for both clinicians and researchers. The PPTS may provide objective means to measure, document, and communicate pressure pain thresholds. Moreover, 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. However, future research is needed to further evaluate the clinimetric properties of the PPTS.

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