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Study Protocol

The Effects of Active Range of Motion with Overpressure on the Fascia Displacement of the Upper Trapezius Muscle among Individuals With and Without Myofascial Pain Syndrome: A Retrospective Case-Control Study Protocol

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Abstract

Background: Myofascial Pain Syndrome (MPS) is a persistent pain on the shoulders and cervical spine related to limitation of motion (LOM), muscle weakness, and loss of function. It is a cumulative, repetitive injury causing disability among the middle-aged working population. This study will determine the differences in upper trapezius' superficial and deep fascia displacements among participants with and without MPS based on the effects of cervical active range of motion (AROM). **Methods**: This is a retrospective records review study with two interlinked parts. In the reliability study, the Tracker will determine the physiotherapy interns' intertester and intratester reliability in assessing the musculoskeletal ultrasound videos. Using MedCalc Software and the Bland-Altman plot, the single measures ICC will determine the reliability. In determining clinically acceptable use of the Tracker, a <0.40 cut-off reliability will be used. In the case-control study, physiotherapy interns will assess 2,904 musculoskeletal ultrasound videos. The difference between the superficial and deep fascia displacements will be determined using paired t-test and the mean differences using an independent t-test. A significant difference between groups will be determined using a *p*-value of <0.05. **Expected Results**: This study expects that cervical AROM with overpressure will displace the superficial and deep fascia of the upper trapezius, particularly among patients with MPS. Proving the correlation between LOM and altered fascia displacement will help rehabilitation professionals create new manual therapy techniques and emphasize the use of existing fascia-related treatments.

***Key Words**: MPS, cervical AROM, superficial and deep fascia, fascia displacement, upper trapezius*

INTRODUCTION

Myofascial Pain Syndrome (MPS) is a persistent pain on the shoulders and cervical spine related to decreased range of motion, muscle weakness, and loss of function.[1] It is a cumulative, repetitive injury causing disability, especially among the middle-aged working population.[2] The syndrome frequently involves postural muscles, such as the upper trapezius, enclosed by superficial and deep fascia.[3]

A limited cervical range of motion (cervical LOM) is a clinical presentation of MPS. Cervical LOM is usually accompanied by a complaint of pain, tightness, or local twitch response on the area.[4] Studies identified that LOM was directly attributed to restricted fascia slide, causing movement restriction due to stiffness.[5] Albeit indirect evidence for altered fascia displacement, one study reported a borderline increase in linear fascia displacement in elbows with lateral epicondylalgia compared to elbows without lateral epicondylalgia (p=0.06). An altered fascia displacement may be present in 102 participants with and without a clinically diagnosed musculoskeletal condition.[6] A study reported a 20% decrease in thoracolumbar fascia mobility and shear strain of participants with chronic low back pain after repeated trunk flexion and extension.[7]

Another main feature of MPS is the presence of Myofascial trigger points (MTrPs). MTrPs are due to muscle overuse or trauma, psychological stress from worksite tasks, daily lifting of heavy objects, or sustained repetitive activities.1 These are associated with adhesion points in the fascia forming a new line of force within it, limiting its mobility; thus, causing myofascial restrictions promoting dysfunctional movement patterns and limiting the range of motion (ROM).[8,9]

The superficial fascia, also termed subcutaneous tissue, is the structure that links the skin with the bone to the deep fascia.[10] The structural link between the superficial fascia and muscle suggests that muscle motions could affect the superficial fascia.[11] Meanwhile, the deep fascia covering the upper trapezius can possess adhesion points from repetitive strain injuries that cause myofascial restrictions and dysfunctional movement patterns.[8,9] The fascia displacement is influenced by subtle movements produced by the three-layered mobile collagen bundles.[12] These enable the fascia to move easily without too much friction with adjacent layers.[9] Correspondingly, the fascia tightens and loses its pliability because of postural malpositioning and repetitive strain injuries.[13]

The superficial and deep fascia displacements can be scanned in real-time using musculoskeletal ultrasound (MSUS). An MSUS provides high-resolution images, allowing sequential evaluations of the individual's musculoskeletal system.[14] The fascia appears as hyperechoic lines on hypoechoic striated muscles.[15] Intratester and intertester reliability of the sonographers were pronounced to be good to excellent in one study (ICC of the first examiner = 0.92-0.96; ICC of the second examiner = 0.86-0.98) in measuring upper trapezius' thickness measurements.[14]

A pilot study that used the Tracker by Douglas Brown and Wolfgang Christian concluded that the software might be a valuable tool for quantifying deep fascia displacement due to its high intratester and intertester reliability.[16] This measures the fascia displacement on MSUS images using cross-correlation techniques.[14] Several studies have revealed that software operators have high reliability in measuring fascia displacement at L2-L3 interspace, gastrocnemius, and fascia lata.[17-19] The software converts the fascia displacement into data points, enabling comparison between normal and limited mobility.[20]

At present, the superficial and deep fascia displacement of the upper trapezius at the end of active cervical movement has not been investigated. We hypothesize that decreased fascia displacement may be associated with reduced movement. By this, the study aims to determine the differences in upper trapezius' superficial and deep fascia displacement in participants with and without MPS using the Tracker as an effect of cervical AROM.

This study will primarily investigate the role of fascia movement on the upper trapezius' superficial and deep fascia on patients with and without MPS during cervical AROM with overpressure. Significantly restricted fascia movement in MPS than non-MPS participants could characterize MPS clinically. Furthermore, this study is delimited on diagnostic accuracy (i.e., sensitivity, specificity, likelihood ratios) of musculoskeletal ultrasound in examining the presence of MPS.

METHODS

Protocol Trial Registry. This study has been registered in the Philippine Health Research Registry with the registry ID of PHRR210302-003264.

Ethical Considerations. The study, with protocol number SI-2020-046-R2, has been authorized by the Ethics Review Committee of the University of Santo Tomas-College of Rehabilitation Sciences (UST-CRS). This study will be conducted according to the Declaration of Helsinki, Good Clinical Practice Guidelines of the Philippine Health Research Ethics Board, and the Data Privacy Act of 2012.

Study Design. This research is a retrospective records review of non-analyzed 7,560 MSUS videos of 360 participants with and without MPS. Particularly, this consists of two interlinked parts - the reliability study and the case-control study.

Participant Recruitment and Selection. This study selected 360 participants using purposive sampling. In the process, pamphlets were distributed face-to-face, and online posters were shared through social media platforms. The scanning was done at the Physiotherapy Skills Laboratory of the University of Santo Tomas.

This study included 180 MPS patients who met at least five major and one minor of Simon's MPS diagnostic criteria.[21] The major criteria consist of pain in the upper trapezius, referred pain in an expected body area from a trigger point, presence of spot tenderness along the length of a taut band, limited cervical ROM, and a palpable taut band on the upper trapezius muscle. In comparison, the minor criteria include a jump sign on the tender spot, symptom reproduction by pressure application on the tender spot, and reduced pain when stretching the affected muscle.

The 180 non-MPS participants had no cervical pain, cervical movement restrictions, pain, nor tenderness on both shoulders. Furthermore, this study did not include participants with musculoskeletal conditions that can mimic MPS signs and symptoms based on the participants' self-report including fibromyalgia, cervical strains and sprains, tension headache, regional pain syndrome, whiplash injury, cervical radiculopathy, spinal abnormalities, and spinal surgery within the past six months. Likewise, it excluded participants who were pregnant or who received physical therapy in the past six months.

Acquisition of MSUS Videos. The MSUS videos were obtained from both MPS and non-MPS participants. While seated, the participants were instructed to perform two sets of cervical movements. Each set included these cervical movements: flexion, extension, right lateral flexion, left lateral flexion, right rotation, and left rotation. Using a metronome, the participants completed all cervical movements at 5-second intervals. From the third to the fifth second, the research assistant applied overpressure to the participant's head. The upper trapezius' superficial and deep fascia were then scanned using the HS1 Konica Minolta MSUS machine, which had a linear-array broadband transducer with a frequency range of 5-14 MHz. At the middle-upper border of the shoulder, the linear transducer head was positioned at a right angle during cervical flexion and extension and parallel during cervical lateral flexion and rotation to the upper trapezius muscle. The PT-Sonographer scanned the right shoulder followed by the left shoulder while the participant performed all the cervical movements. As instructed, the participants repeated all the cervical movements three times without resting.

Outcome Measures

Tracking Software. The Tracker is a modeling tool for analyzing images and videos, which is developed by Wolfgang Christian and Douglas Brown and included in the Java Code Library of Open Source Physics.[20] Using this tracking software, the physiotherapy interns will identify and mark the feature of interest on the MSUS video start frame. The Tracker, by design, will follow the feature of interest frame-by-frame using the cross-correlation technique until the end of the MSUS video and will measure the superficial and deep fascia displacement in millimeters.

Assessors. Using the Tracker, six physiotherapy interns will quantify the superficial fascia displacements, and six physiotherapy interns will quantify the deep fascia displacements at the end of cervical AROM.

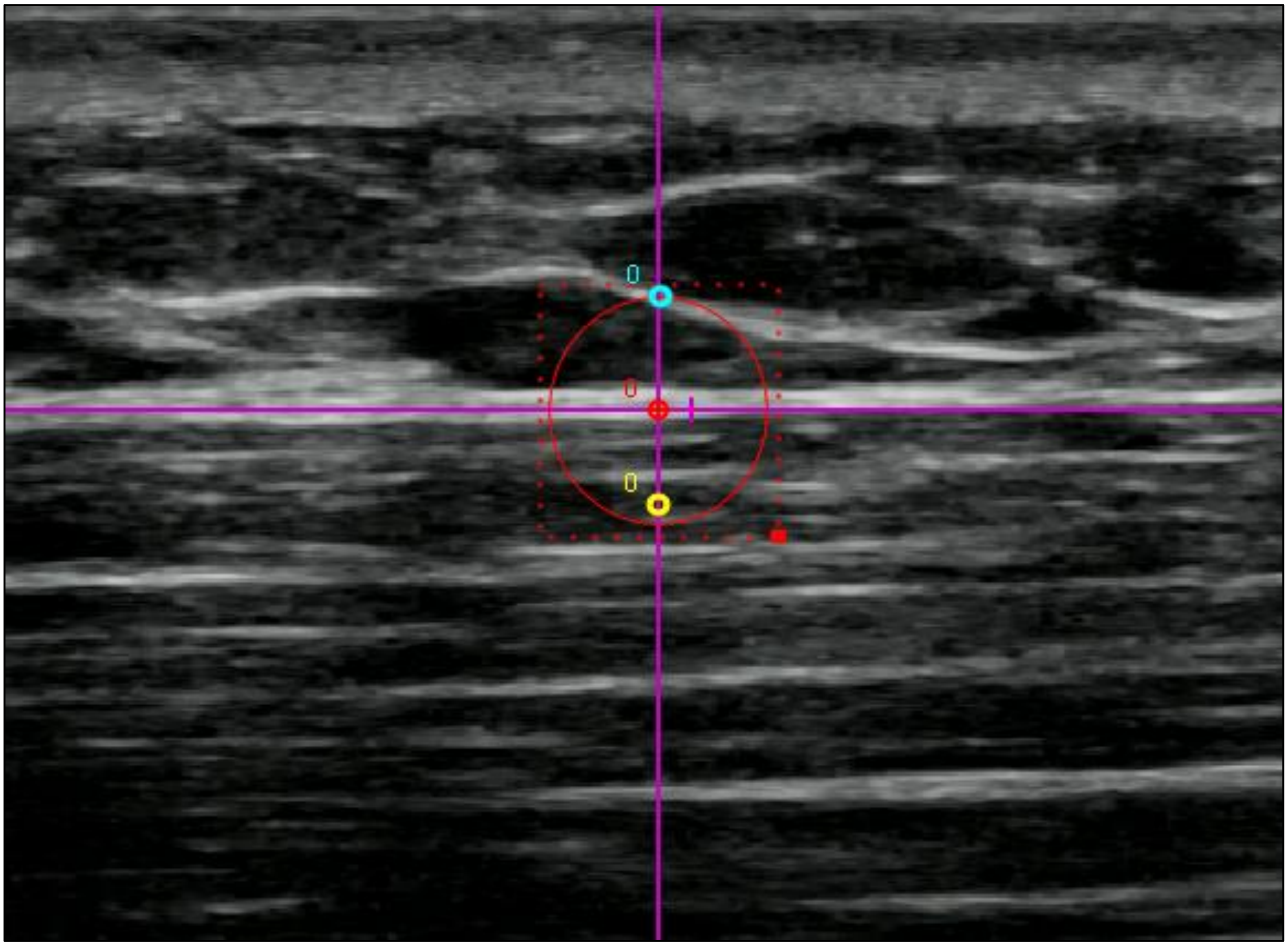
Tracking. The physiotherapy interns will identify the test image (Figure 1) on the MSUS video using the Tracker. The physiotherapy interns will set these coordinate axes:

a. The X-axis on the identified superficial and deep fascia, and;

b. The Y-axis at point 424 (the screen's center).

A match between the test image and the search area will be made. The Tracker will utilize the differences between the Red Blue Green (RGB) values to fit the test image and the search area. The RGB difference will be determined by the

Fig. 1. Tracking of MSUS Image Using Tracker © V.D.



Note: The test image (dot) is at the zero-coordinate axis (purple cross). The search area surrounds the test image. The X-axis (blue & red dot) is on the superficial and deep fascia, respectively. The Y-axis (vertical purple line) is at point 424, the center of the screen. The template (broken lines) encloses the deep and superficial fascia above the upper trapezius (yellow dot).

pixels. The RGB difference will be calculated using the following formula:

RGB difference = $\sum [(\Delta Ri)^2 + (\Delta Gi)^2 + (\Delta Bi)^2$

Where:

i repeats over all pixels

$\Delta R_i = \text{Red}_{i\ (\text{test image})} - \text{Red}_{i\ (\text{template})}$

$\Delta G_i = \text{Green}_{i\ (\text{test image})} - \text{Green}_{i\ (\text{template})}$

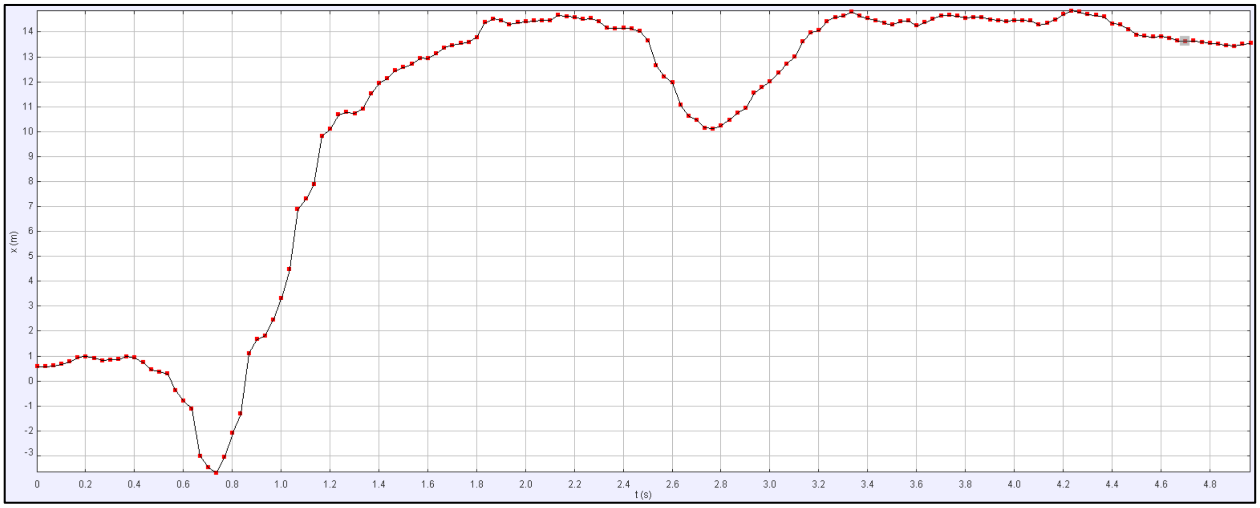
$\Delta B_i = \text{Blue}_{i\ (\text{test image})} - \text{Blue}_{i\ (\text{template})}$

The Tracker will determine the best match score using this formula:

Match score = (mean RGB difference / match RGB difference) -1

The 20 % evolution rate will be used so that the new template will contain 20% of the matched image and 80% of the previous template. The auto mark will be set to at least four, indicating that the Tracker will automatically mark the next template. The Tracker will quantify the distance between the two distant x-axis mass displacements (see Figure 2). The total displacement of the test image will be equal to the sum of the individual x-displacements.

Fig. 2. Displacement of Fascia © V.D



Note: The two extreme displacements reflect the test images' farthest displacement from the zero-coordinate axis. The y-axis represents the horizontal displacement from the zero-coordinate axis measured in millimeters. The x-axis represents the time measured in seconds. The combined values are equal to the test image's total displacement.

Sample Size Calculation.

Part 1: Intra Reliability and Inter Reliability Testing. For each level of fascia displacement, six physiotherapy interns will read 19 MSUS videos to determine their intertester reliability. The sample size calculator by Arifin[22] determined the number of MSUS videos to be assessed by the physiotherapy interns. These determinants were used in the sample size calculation:

a. Minimum acceptable kappa of 0.40

b. Expected reliability of 0.70

c. 0.05 significance level (two-tailed)

d. Power equal to 0.80

e. Number of raters/repetitions per subject: 6

f. Drop-out of 10%

For Part 2: Case-Control Study. The PT-Sonographer scanned 600 shoulders of 300 participants*.* Out of 7200 total videos collected, 2,904 videos will be assessed. The number of MSUS videos per cervical movement was determined using G*Power 3.9.1.2.23 These determinants were used in the sample size calculation:

a. The difference between two independent means

b. One-tailed independent samples t-test

c. A-priori power analysis

d. A moderate effect size equal to 0.30

e. 0.05 alpha value

f. Power equal to 0.95

g. Allocation ratio N2/N1 of 1

Part 1: Intra Reliability and Inter Reliability Testing. Each physiotherapy intern will read 19 MSUS videos three times to determine their intratester reliability. To prevent recall bias, the physiotherapy interns should either:

a. Quantify the fascia displacement of all five MSUS videos before proceeding to the second round MSUS reading or;

b. Read the same MSUS video one hour apart.

Procedures. Given the three years of experience of the primary investigator on using musculoskeletal ultrasound, the physiotherapy interns will undergo training focused on quantifying the superficial and deep fascia displacements using the Tracker. The training will proceed:

a. Didactics of tracking MSUS videos for 30 minutes.

The physiotherapy interns will learn the basic principles and the procedure in quantifying the superficial and deep fascia displacements using the Tracker.

b. Guided tracking of superficial and deep fascia displacements of five pre-determined MSUS videos.

The primary investigator will select five MSUS videos and identify the test image on the superficial and deep fascia with the physiotherapy interns before tracking the MSUS videos.

c. Random guided tracking of five MSUS videos showing superficial fascia displacement and five MSUS videos showing deep fascia displacement.

The primary investigator will guide the physiotherapy interns to identify the test image on the MSUS videos. A volunteer from the physiotherapy interns will select an MSUS video whose test image is challenging to identify.

The primary investigator will randomly select 19 MSUS videos from 360 MSUS videos using a random number generator. He will then send restricted Google Drive Folder links containing the 19 coded MSUS videos (10 MPS: 9 non-MPS) to the physiotherapy interns.

For each level of fascia displacement, six physiotherapy interns will determine their intertester reliability by reading 19 MSUS videos using the Tracker. While for their intratester reliability, they will determine it by reading each of the five MSUS videos with a Tracker thrice at least one hour apart.

Statistical Analysis Used. MedCalc Statistical Software Version 20.009 in Windows will be used in determining the reliability of the 12 physiotherapists. The Bland-Altman plot or difference plot will determine the intratester reliability and compare the rater's two measurement techniques.[24] Confidence intervals will be displayed for the average difference and the limits of agreement. A p-value <0.05 indicates a significant difference between measurements.

The assessors will determine the direction and quantify three times the upper trapezius' superficial and deep fascia displacement. The agreement of those scores will be evaluated. The ICC will determine the intertester reliability of the three assessors in quantifying the linear displacement of the fascia using the Tracker.[24] The ICC scores will be interpreted as poor if <0.20, fair if 0.21-0.40, moderate if 0.41-0.60, good if 0.61-0.80, and very good if 0.81-1.00.[24] Stochkendahl's recommended cut-off reliability score of <0.40 will determine clinically useful evaluation tools.[25]

Part 2: Case-Control Study

Procedures. The primary investigator will randomly select 2,904 MSUS from 7,200 MSUS videos using a random number generator.[21] The primary investigator will then send restricted Google Drive Folder links to the physiotherapy interns with the coded MSUS videos (1,452 MPS: 1,452 non-MPS). Afterward, for each cervical movement, clinical diagnosis, and fascia level, the differences between the superficial and deep fascia displacements of 121 MSUS videos in the first set and 121 MSUS videos in the second set will be determined.

Statistical Analysis Used. The demographic characteristics of participants (i.e., age, gender, chronicity, bilaterality of symptoms, and occupation) in both the MPS and non-MPS groups will be presented using descriptive statistics.

MPS and non-MPS participants will be matched based on age and gender. Furthermore, MedCalc Statistical Software Version 20.009 in Windows will analyze the data using paired samples t-test to determine the differences in the superficial and deep fascia displacements between the first and second sets of MSUS videos. The difference in mean superficial and deep fascia displacements between MPS and non-MPS groups will be compared using an independent samples t-test. A p-value of <0.05 will indicate a significant difference.

Additionally, a subgroup analysis will be performed based on the chronicity of symptoms.

EXPECTED RESULTS

The authors expect that cervical AROM with overpressure will cause displacement of the superficial and deep fascia of the upper trapezius muscle, particularly in patients with MPS. Proving a statistical correlation between LOM and altered fascia displacement will help in characterizing MPS objectively and clinically. Also, it will assist rehabilitation professionals in emphasizing the use of treatments and even creating new manual therapy techniques that will improve fascia mobility.

Individual author's contributions

V.D., L.,T; Conceptualized the research's overall idea, wrote the research proposal, supervised the performance of the entire research study, supervised the co-authors in performing experiments, revisions, and write-up; C.D., A.C; Served as the liaison between the author and the co-authors, distributed and assigned co-authors for equal assignment and work distribution, reviewed resources for the related literature of the study for instrumentation and analytic purposes, managed and administered the indentures such as informed consent forms and requisite documents for the proposal, developed and designed the methodological framework of the study; S.A., P.C., E.D., D.I., I.P., A.S. C.A., M.C., K.E. J.I. M.Q., J.R., A.S.; reviewed resources for the related literature of the study for instrumentation and analytic purposes, managed and administered the indentures such as informed consent forms and requisite documents for the proposal, developed and designed the methodological framework of the study; P.C., E.D., D.I.; initiated the creation of visualization and data presentation through tables and illustrations.

Disclosure statement

The authors declare this study is not funded by any government and non-government organization or institution.

Conflicts of interest

The primary investigator of this study, Prof. Valentin C. Dones III, Ph.D., is a member of the Review Board of The Philippine Journal of Allied Health Sciences (PJAHS). Mr. Lyle Patrick Tangcuangco, MSPT, is also a member of the Editorial Staff of PJAHS.

The student authors declare and certify that they have no affiliations nor involvement in any organization or institution with a financial interest, such as educational grants, honoraria, membership, employment, consultancies, equity interests, and patent license agreements, and non-financial interest, including personal or professional relationships, knowledge, and beliefs, relative to the research topic and the materials discussed in this manuscript.

Supplementary Material

Supplementary Material A. Guidelines for Reporting Reliability and Agreement Studies (GRRAS)- For the Reliability Testing.

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