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Mitchell T. Maione Nova Southeastern University

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The Relationship Between Rehabilitative Ultrasound Imaging and the Modified Prone Straight Leg Raise Test to Identify Multifidus Weakness.

by

Mitchell T. Maione, PT, DPT, OCS, MTC, CFC

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

> Nova Southeastern University College of Health Care Sciences Physical Therapy Department

ABSTRACT

Background: Low back pain (LBP) is often associated with lumbar spinal instability (LSI). The multifidus muscle is considered a stabilizer of the spine and has been studied extensively with Rehabilitative Ultrasound Imaging (RUSI). There may be a relationship between clinical signs of LSI, decreased cross-sectional area (CSA) of the multifidus and weakness. Having the ability to detect multifidus weakness without the use of RUSI may serve to be invaluable to the clinician in detecting multifidus weakness. **Purpose**: To investigate the relationship between the modified prone straight leg raise test (MPSLR) and CSA of the multifidus muscle as measured by RUSI and to investigate the relationship between MPSLR and RUSI findings with the presence of low back pain symptoms that interfere with regular daily activities. Subjects: Participants consisted of two groups of subjects. One group (n=30, 87% male) comprised individuals in general good health, aged 18-55, without history of back pain. The second group (n=36, 56% male) comprised individuals aged 18-55, with history of low back pain within the past 12 months. Methodology: Subjects performed a MPSLR test to identify multifidus weakness. All subjects repeated the same test with concurrent RUSI to visualize the multifidus and measure its CSA. Results: A significant association between a positive MPSLR, asymmetry of the multifidus, and pain was observed (p < .001). A correlation between a positive MPSLR and moderate reduced CSA average (r = .049, p = .696) was not observed. A sensitivity of 94% and a specificity of 63% was also discovered in the ability of the MPSLR test to detect asymmetry of the multifidus muscle within subjects. A positive MPSLR combined with a high Oswestry score of 25-30 further reinforced the probability of pain (p < .001) Conclusion: The MPSLR test demonstrated a strong association between a positive test and asymmetry of the multifidus muscle within subjects. Clinical Relevance: The MPSLR test can be used to identify patients at risk for LBP symptoms due to asymmetrical changes in the multifidus muscle of the lumbar spine, and aid in directing an appropriate rehabilitation approach to those patients in need of specific multifidus exercise prescription.

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CHAPTER 1: INTRODUCTION

Background Information and Study Relevance

Many North American adults today suffer from the malady known as low back pain (LBP).¹ While all the afflicted may experience discomfort or pain in the same general region, the precise location, type of pain, and etiology differ among cases. The series of diagnostic methods selected by the clinician, therefore, may not be identical from patient to patient. For example, many cases of LBP are associated with lumbar segmental instability (LSI), yet there is no single test that all clinicians can rely on to confirm the instability while identifying a causative factor, such as muscle weakness. The definition of LSI has evolved over the past several decades, but the most widely accepted description was proposed by Panjabi in 1992.² His model of the stabilizing system of the spine consisted of three subsystems: the passive, or osteoligamentous subsystem; the active, or musculotendinous subsystem; and the neural control subsystem. Panjabi's model gave way to the definition of LSI as being "a significant decrease in the capacity of the stabilizing system of the spine to maintain the intervertebral neutral zones within the physiological limits so that there is no neurological dysfunction, no major deformity, and no incapacitating pain."³ The challenge, then, is for the clinician to identify the exact subsystem at fault.

Currently, LSI is diagnosed by assessing the retrodisplacement (anterior-toposterior translation) of lumbar vertebrae on lateral radiographs taken at end range spinal flexion and extension.^{4,5} Conducting this assessment is out of the scope of physical therapist practice and therefore not immediately useful in a clinical setting. Although many researchers have described clinical tests for the detection of LSI,^{2,6-8} the most routinely employed tests are the passive lumbar extension test (PLE) and the prone instability (PI) test. For the PLE test, the subject assumes a prone position, with both lower extremities supported on the treatment table. The examiner then elevates the subject's lower extremities concurrently to a height of about 30 cm from the treatment table, while maintaining the knees extended and providing a gentle pull on the legs. A positive test is determined by subject reports of "low back pain" or a "very heavy feeling on the low back" or "feeling as though the low back was coming off." ⁵

The PI test is conducted by having the subject assume a prone position with only the torso resting on the treatment table, while both feet are resting firmly on the floor. The examiner imparts a passive accessory intervertebral motion (PAIVM) testing procedure by directing a posterior-to-anterior force via the spinous process of the spinal segment to be tested. The subject is asked to report any pain provocation symptoms during the PAIVM test. The subject then raises both lower extremities from the floor, simultaneously, and the PAIVM testing is reapplied. A positive test occurs when pain is elicited during the first part of the test but disappears when the test is repeated with the lower extremities raised from the floor.⁸

Both of these tests have demonstrated only a limited ability to detect LSI.^{8,9} Additionally, these tests are unable to identify which of the subsystems is the causative factor that results in a positive test. For instance, if the neural control subsystem were the cause of LSI, then rehabilitation approaches that target the active subsystem may not produce desired outcomes. Having the ability to identify an impairment in the active subsystem, such as weakness of the multifidii muscles as a causative factor, could

provide a clinician with direction in establishing a therapeutic plan of care that addresses the root source of instability, and possibly help achieve desired outcomes.

Electromyography (EMG) can be used to detect the level of activity of a contracting muscle and is currently considered the gold standard for assessing a suspected case of LSI due to multifidus weakness. However, EMG also has its limitations. While considered a reliable tool for assessing activity in contracting muscles, EMG is invasive, costly, and presents other challenges such as the risk for infection. Another issue is that surface electrodes are accurate in recording activity from superficial muscles, but lack the same accuracy in recording activity from deeper musculature. Assessment of deeper musculature can be performed via indwelling electrodes, but this technique is significantly more invasive and considered inappropriate in routine physical therapy clinical practice.¹⁰

Over the past decade, mounting evidence has grown on the relationship between diminished activity of the deep musculature of the spine and the presence of chronic cervical, lumbar, and pelvic pain. Rehabilitative Ultrasound Imaging (RUSI) has emerged as a clinical tool that physical therapists can use to detect the alterations in neuromuscular control. RUSI uses high-frequency sound waves that produce pictures of anatomical structures beneath the skin, allowing a clinician to view inside the body. Because ultrasonic images are captured in real time, they show not only the morphology of various muscles or muscle groups but also a muscle's ability to contract and ultimately its movement pattern, so that a clinician can record the cross-sectional area (CSA) of a targeted contracting muscle. To obtain clinically relevant information, a connection between structure and function must be determined. Research has shown that RUSI is a

valid discriminative tool for measuring deep trunk muscular contraction in subjects with LBP,¹¹ but most studies that target the multifidus using RUSI fail to make a correlation between the image and the actual function of a muscle.

RUSI can also be utilized to guide therapeutic intervention, and is becoming a common tool for physical therapists to observe contractions in the deep muscles of the spine during patient training.¹²⁻¹⁵ Because RUSI, unlike X-ray imaging, does not produce potentially harmful ionizing radiation exposure, it is considered a much safer imagining modality.

While it has been demonstrated that RUSI is a beneficial tool to assist subjects in activating a voluntary contraction of the multifidus muscle, operational definitions of "improved performance" remain questionable.¹⁴ In motions that require lumbar extension, for example, the activity level of the multifidus (78%) is greater than that of the iliocostalis lumborum muscle (65%).¹⁴ Given the fact that lumbar extension activates the multifidus muscle, it can be concluded that sagittal plane motions of the extremities that intersect the coronal plane will also activate the multifidus, as seen in activities such as the prone straight-leg raise. It has also been reported that multifidus muscle activity is increased to control lumbar motion in the transverse plane, as well as contributing to spinal extension during the prone straight-leg raise maneuver.¹⁶ Therefore, it can be hypothesized that if a subject performed a prone straight-leg raise maneuver and the ipsilateral pelvis were unable to maintain its orientation in the transverse plane, the contralateral multifidus can be identified as the weak muscle contributing to pelvic displacement. The prone straight-leg raise (PSLR) maneuver may serve as a valid clinical tool that can be utilized by clinicians to detect weakness of the multifidii muscles.

The aim of this study was to seek a relationship between the results of a modified prone straight-leg raise test (MPSLR) and RUSI to identify patients that present with LSI due to a decrease in multifidus activation. The prone straight-leg raise maneuver that was explored in this study was slightly altered from the original test. In the original test, the subject assumed a prone position and was instructed to perform a straight-leg raise actively, while RUSI was used to detect recruitment of the muscle. This test did not confirm pelvic displacement in the transverse plane and has clinical relevance only if used with RUSI. In this study, the test was conducted with the subject in the prone position while the examiner palpated the anterior superior iliac spines (ASIS) of the innominate bones bilaterally. The subject was then asked to perform an active straight-leg raise into hip extension with knee extension while the examiner monitored the ASIS. If the multifidus is weak, the contralateral muscle will fail to maintain a level pelvis, and the pelvis will become displaced in the transverse plane. This can be detected as an increase in pressure at the examiner's fingers under the ipsilateral ASIS. Therefore, a positive prone straight-leg raise test on the right, for example, would cause an increase in pressure on the palpating fingers on the right, due to a weak multifidus on the left and its inability to maintain the orientation of the pelvis in the transverse plane. Without the use of RUSI, the examiner can detect pelvic displacement both visually and through palpation, making this modified test an improved assessment tool compared to the original version. Our study aims to demonstrate that the information obtained from the MPSLR is consistent with that obtained by RUSI, and that potentially MPSLR could be utilized as a standalone test to identify patients that present with LSI due to a decrease in multifidus activation

This study also explored the clinical relevance of the findings by investigating the relationship between the results of the MPSLR test and changes in the CSA of the multifidus muscle (which were measured using RUSI), as well as correlating MPSLR and RUSI findings with the presence of low back pain symptoms that interfere with regular daily activities. The latter aim of the study will help establish the functional significance of these tests. The study evaluated both healthy individuals and individuals with LBP, to determine how specific these test results are to the population with LBP. For the purposes of this study, LBP was defined as pain which is limited to the lumbar region and is episodic in nature. Common complaints of LBP due to instability are described as being elicited with increased activity level, transitional movements, assuming an erect posture from a flexed position, lifting maneuvers, and increased symptoms with unsupported prolonged sitting.^{17,18}

Many clinicians rely on the use of standard questionnaires in an attempt to quantify pain reports and/or self-reported functional limitations. Among the most reliable questionnaires is the Oswestry Disability Index (ODI).^{19,20} The ODI is an index derived from the Oswestry Low Back Pain Questionnaire used by clinicians and researchers to quantify disability caused by low back pain, and is currently considered to be the gold standard for measuring the degree of disability in a person with low back pain.^{19,20} The questionnaire aims to report functional limitations in areas such as pain intensity, lifting, ability to care for oneself, ability to walk, ability to sit, ability to stand, social life, sleep quality, and ability to travel. Each of the 20 questions is scored on a scale of 0 to 5, with the first statement indicating the least amount of disability and the last statement indicating most severe disability. The patients select the statement most closely

resembling their situation. The clinician calculates the score from 0 (no disability) to 100 (maximum disability). The ODI was utilized in this project to record a baseline of self-reported functional limitations to be compared to the findings of the MPSLR test.

Research Questions and Hypotheses

This study aims at answering the following research questions:

RQ1: Are there significant differences in the proportion of positive MPSLR results between the symptomatic (LBP) and asymptomatic (no LBP) groups?

H1: The proportion of individuals with positive MPSLR results will be significantly higher (p<0.05) in the symptomatic group.

RQ2: Are there significant differences in the multifidus cross-sectional area as measured by RUSI, when comparing the symptomatic (LBP) and asymptomatic (no LBP) groups?

H2: The cross-sectional area of the multifidi as measured by RUSI will be significantly lower (p<0.05) in the symptomatic group. The asymptomatic group will have measurements that are not significantly different from published norms for cross-sectional area of the multifidus (discussed in the experimental protocol section).

RQ3: Do findings from the MPSLR test correlate with CSA measurements of the multifidus muscle as shown by **RUSI**?

H3: For subjects who test positive on the modified prone straight leg raise (MPSLR) test, there will be at least a moderate (>0.3) correlation with a reduced cross-sectional area of the multifidus measured using RUSI, when compared to those who test negative.

RQ4: Do findings from the MPSLR test correlate with patient self-report of disability as measured by the Oswestry Low Back Disability Questionnaire?

H4: Subjects who test positive on the modified prone straight leg raise (MPSLR) will have significantly higher (p<0.05) disability ratings than those who test negative.

Abbreviations/Important Terms

- ASIS Anterior superior iliac spine
- CSA Cross-sectional area
- EMG Electromyography
- IRB Institutional Review Board
- LBP Low back pain
- LSI Lumbar spinal instability
- MPSLR Modified-prone straight-leg raise
- MVIC Maximum voluntary isometric contraction
- ODI Oswestry disability index
- PAIVM Passive accessory intervertebral motion
- PI Prone instability
- PIVM Passive intervertebral motion
- PLE Passive lumbar extension
- PSLR Prone straight-leg raise
- RUSI Rehabilitative ultrasound imaging
- $TrA-Transversus \ abdominis$

CHAPTER 2: REVIEW OF THE LITERATURE

Spinal Instability

For more than a decade, physical therapy researchers have focused on studying the deep musculature of the spine and its ability to stabilize the individual moving segments of the vertebral column. From this research, many definitions of spinal instability and a variety of ways to identify it have been suggested.^{5,7,8,21-23} Spinal instability was originally described by Panjabi as a displacement of part of a moving segment exceeding that found in the normal spine.²³ White²⁴ would later define lumbar instability as the "loss of ability of the spine to maintain its pattern of displacement under physiological loads, with no initial or additional neurological deficit, no major deformity, and no incapacitating pain". As referenced in chapter 1, Panjabi described three independent subsystems utilized to achieve spinal stability: the active subsystem, the passive subsystem, and the control subsystem. All three of these subsystems work in unison on the spine to provide resistance to displacement of a movement segment.^{4,5} The active subsystem, along with the control subsystem, consists of primarily muscles, tendons, and neural tissue. The passive subsystem consists of passive structures such as the vertebrae, the zygapophyseal joints and their capsules, ligaments of the spine, and passive tension from musculotendinous units. These three subsystems are primarily responsible for the stability of the spine. Coinciding within the subsystems are two zones described by Panjabi³: the elastic zone and the neutral zone. The elastic zone is described as the motion available at the end limits of spinal movement, and is produced against substantial internal resistance. In this zone, passive structures are placed under tension resulting in a decrease in flexibility. The neutral zone is described as being the initial

available range of motion during which spinal motion is produced with minimal internal resistance. It is said to be the zone with the highest degree of spinal flexibility. An increase in the size of the neutral zone, relative to the total range of motion of the moving segment, will increase the amount of laxity within the moving segment. Panjabi suggested that an increase in the size of the neutral zone may be the best indicator of spinal instability.

Many research studies have focused on diagnosing and interpreting spinal instability.^{4,5,7-9,17,18,21,22,24,25} Although different clinical tests were utilized in these studies, few have provided the clinician with anything other than minimal accuracy in diagnosing instability.

Hicks et al examined the interrater reliability of common clinical examination procedures used to identify subject with segmental lumbar instability.⁸ Along with observation of active range of motion of the lumbar spine and using a ligamentous laxity scale, the authors employed several manual tests, including passive intervertebral motion testing (PIVM), the prone instability test (PI), and the posterior shear test. PIVM was performed in the prone position and conducted by imparting a posterior-to-anterior force via the spinous processes of the lumbar vertebrae and then assigning a number to the amount of laxity found. The prone instability test, as described in chapter 1, was performed in the traditional manner and used primarily as a pain provocation tool. The posterior shear test was performed with the subject in a standing position and the arms crossed over the abdominal area. The examiner produced an anterior-to-posterior shear force through trunk while stabilizing the pelvis with the heel of the opposite hand and palpating the interspinous spaces between the motion segments. A positive test was based on reports of symptom provocation and not on the detection of intersegmental motion. These results were compared to, and agreed with, previous studies in that PIVM testing is not a reliable clinical assessment tool for detecting LSI. The PI test demonstrated higher levels of reliability; however, the researchers recognized that the validity of these tests need to be examined.

In a criterion-related validity study, Abbott et al⁷ examined 138 male and female patients with reoccurring or chronic low back pain ranging in age from 20 to 75 years. The aim of the study was to validate the use of manual assessment for the detection of lumbar instability by using PIVM or passive accessory intervertebral motion testing (PAIVM). Flexion and extension radiographs were taken and the measurement of sagittal plane translation of each motion segment was measured and compared to the findings of the manual assessment. PIVM and PAIVM testing proved to be highly specific but lacked sensitivity, resulting in only moderate validity for detecting spinal instability.⁷

Although various tests and measurements have been investigated and suggested for use over the past decade, few of them have determined the sensitivity and specificity of the measures used. Kasai et al⁵ devised the passive lumbar extension test (PLE) and not only examined the specificity and sensitivity of the test, but looked at the positive likelihood ratio of the test as well. The authors then compared the findings, specificity, and sensitivity of the PLE with those of the instability catch sign, the painful catch sign, and the apprehension sign. The PLE test was administered with the subject in the prone position. Both lower extremities were then raised, passively, to a lever of about 30cm from the examination table while maintaining both knees in extension. The examiner then imparted a gentle pull on both lower extremities. A positive test was determined by

subject reports of "low back pain" or a "very heavy feeling on the low back" or "feeling as though the low back was coming off."⁵ The instability catch sign was observed by asking the subject to bend forward in a standing position, as far as possible, and then return to an erect position. Subjects who were unable to return to the erect position due to sudden pain were deemed as having lumbar instability. The painful catch sign was observed by having the subjects raise both lower extremities off of the examination table from a supine position with the knees extended and then having them return the extremities back to the table. Subjects whose legs fell quickly back to the examination table due to sudden lower back pain were also deemed as having spinal instability. Finally, the apprehension sign was deemed positive if the subject reported a sensation of lumbar collapse due to pain when performing ordinary acts such as forward bending, side-to-side movements of the trunk, and sit-to-stand transfers.⁵ The results of these testing procedures were then compared to radiological assessments of lumbar instability. The authors reported that the PLE showed a higher specificity and sensitivity than the other aforementioned tests, however, they acknowledged that the majority of the subjects had relatively severe clinical symptoms and the pain reports were ambiguous. Additionally, there were no correlations made to specific structures of the active subsystem of the stabilizing unit. The PLE test used in their study elicited pain symptoms by way of stressing the passive subsystem. The catch test required muscle activity, however, not necessarily the deep musculature of the spine. Pain was elicited with the catch test with attempts to actively lower the LEs back to the table by way of an eccentric contraction of the hip flexors, most likely the psoas major. Given that the psoas major attaches to the anterior vertebral bodies of the lumbar vertebrae, the anterior shear force

that would be imparted on the lumbar segments would, theoretically, stress the passive subsystem as well.

Alqarni et al⁹ conducted a systematic review of LSI tests and identified only the passive lumbar extension test (PLE) as a useful tool in orthopaedic clinical practice to diagnose LSI; however, no correlation to activity or performance of the trunk musculature was made. Since the PLE test, like many others, is considered positive with provocation of symptoms, it fails to inform the clinician as to which of the subsystems are implicated.

Biely et al suggested that the most common pathology associated with lumbar instability is "altered intervertebral disc and ligamentous support of a spinal segment."^{25(p12)} They also note that not all patients with increased passive subsystem laxity report symptoms or demonstrate the signs of clinical instability. This fact questions not only the accuracy of previously mentioned clinical tests that stress the passive system, but also sheds light as to why they are criticized by some²⁶ as being an inadequate indicator of clinical instability.

Several studies have focused on addressing the active subsystem with various exercise programs that target the musculature of the lumbar area, in particular the multifidus muscle, and correlated those findings with patient signs and symptoms.^{10,27-30} Many studies have identified the multifidus as the primary muscle that controls spinal stability, as well as assuming a role as a rotator of the vertebral spine while giving opposition to the flexion forces of the abdominals.^{9,10,28,29,31} Due to its inferior attachment on the transverse processes of the vertebrae and superior attachment onto the spinous processes of multiple vertebrae, spanning 2 to 4 levels, the multifidus is well

suited for segmental stabilization.³¹ It has been documented that following an acute episode of low back pain, the multifidus muscle undergoes changes in size, as well as decreased amplitude of contraction. These changes have been associated with the multifidus' inability to maintain segmental spinal stability.³²

The rotary role of the multifidus has been described as being activated concentrically contralaterally and eccentrically ipsilaterally during rotational movements of the trunk.^{28,33} These contractions are in direct opposition to the actions of the internal and external oblique muscles. The oblique muscles are considered the prime rotators of the spine, however, contraction of these muscles also produces flexion of the trunk. The multifidii are active during trunk rotation, not only as synergistic muscles to rotation but as "anti-flexors" of the spine as well.²⁸ Valencia and Munroe have demonstrated, via EMG study, that the multifidus was also highly active with prone hip extension movements in healthy adults.²⁹

Lonnemann et al³³ studied the muscular morphology of the lumbar multifidus in eight human cadavers by both gross and chemical dissection. Their research suggests that the interweaving of the muscle fibers between fascicles of the various layers of the muscle must be considered together to interpret the muscle's actions. Based on their findings, the multifidus is a multifunctional muscle that can move the lumbar spine in three planes as well as providing stabilization to the lumbar spine. They concluded that the four layers of the lumbar multifidus may act bilaterally to produce posterior rotation in the sagittal plane (trunk extension) and to control forward rotation in the sagittal plane (trunk flexion). All four layers may act unilaterally to laterally rotate the lumbar spine in the frontal plane (side-bending) to the same side, and to control lateral rotation in the

frontal plane to the opposite side. All four layers of muscle may also act to stabilize the lumbar segments in all three planes.³³ Multifidus activity has been reported during trunk rotational movements.^{30,32,34} The prone hip extension maneuver challenges the ability of the trunk muscles, including the multifidus, to control spinal motion in the transverse plane. This is due to the multifidii's ability to maintain the orientation of the lumbar spine when lower extremity movements result in lumbar rotation.³⁰

Hides et al³² studied 39 subjects with acute, first-episode, unilateral low back pain. They assigned each subject to one of two groups. Subjects in group 1 received medical treatment only, whereas subjects in group 2 received medical treatment and specific, localized, exercise therapy. They concluded that multifidus muscle recovery was not spontaneous on remission of painful symptoms in patients in group 1. Muscle recovery was more rapid and more complete in patients in group 2 who received exercise therapy. The authors suggest that a lack of localized muscle support may be one reason for the high recurrence rate of low back pain following the initial episode. Providing a clinician with accurate and easily administered diagnostic testing should prove invaluable in the detection of multifidus weakness. The proposed study aims to serve that purpose.

Several researchers been reported that the multifidii play a significant role in lumbar extension.^{10,35,36} Ng et al¹⁰ measured the EMG activity of the iliocostalis lumborum and the multifidus muscles to examine fatigue levels during an isometric trunk holding test. The trunk holding test was described as having the subject lie prone over two treatment tables, with the pelvis and lower extremities supported on one table and the upper body supported on the second table. The pelvis and lower extremities were stabilized with straps over the hips, knees, and ankles. The subjects were asked to place

their hands under their forehead and to isometrically extend their spines while the second table was lowered, resulting in a suspended torso. The position was held for 60 seconds. The researchers reported that the activity level of the multifidii during the trunk holding test was greater (P<.005) than that of the iliocostalis lumborum muscle. These results demonstrate that in motions that require lumbar extension, the activity level of multifidi (78%) is greater than that of the iliocostalis lumborum muscle (65%).

Okubo et al³⁵ investigated the EMG activity of the multifidus and the transversus abdominis during a variety of lumbar stabilization exercises. The exercises performed included an elbow-to-toe plank position with contralateral arm and leg lifts, quadruped position with contralateral arm and leg lifts, supine bridging with alternating leg lifts, side-lying elbow to foot plank, and abdominal crunches. The exercise that demonstrated the highest level of multifidus activity was the supine bridge position with alternating leg lifts. The level of multifidi activity reported was explained by the researchers as being a result of the spine being placed in an extended position while maintaining a level pelvis.³⁵

Ekstrom et al³⁶ investigated the EMG level of the lumbar multifidus and longissimus muscles. Using surface EMG electrodes, they measured the activity level of the muscles in various lumbar stabilization exercises. The multifidi were reported as having the highest level of activity (92%) during the prone lumbar extension exercise with end range resistance. Additionally, the prone lumbar extension to neutral exercise, the resisted lumbar extension while sitting exercise, and the prone lumbar extension with upper and lower extremity lifting exercise produced muscle activity levels of 77% to 82%.

Given the fact that lumbar extension activates the multifidus muscle, it can be concluded that sagittal plane motions of the extremities that intersect the coronal plane will also activate the multifidus. It has been reported that multifidus muscle activity is increased to control lumbar motion in the transverse plane as well as contributing to spinal extension during the prone straight-leg raise maneuver.¹⁶ Therefore, it can be hypothesized that if a subject performed a prone straight-leg raise maneuver and the ipsilateral pelvis were unable to maintain its orientation in the transverse plane, then the contralateral multifidus could be identified as the muscle contributing to this displacement due to weakness. A similar study, recently conducted by Nelson-Wong et al,³⁴ investigated the frontal plane displacement of the pelvic girdle during side-lying active hip abduction to predict the risk of low back pain in individuals who perform prolonged standing activities. Subjects were in the side-lying position with the lower extremity aligned with the body, and received instructions to lift the top thigh and leg towards the ceiling without allowing the pelvis to tip forward or backward. Data collected included visual observations of pelvic displacement, as well as self-report levels of difficulty maintaining a level pelvis. The subjects then completed a 2-hour standing protocol, and correlations between low back pain development and anterior pelvic displacement during the active abduction test were made. The results revealed that the active hip abduction test was a "promising" clinical tool to predict individuals who may be at risk for low back pain development.³⁴ The authors concluded that a lack of trunk muscular stability contributed to the frontal displacement of the pelvis during unsupported lower extremity hip abduction.

Previously mentioned studies^{9,10,16,28,29,33,37,38} that demonstrated the multifidii's ability to control spinal motions in the horizontal plane indicate that the prone straight-leg raise (PSLR) maneuver may serve as a valid clinical diagnosis tool that can be utilized by clinicians to detect weakness of the multifidii muscles.

In terms of intervention, several studies have investigated the effects of multifidii training programs. O'Sullivan et al²⁷ conducted a study where 44 patients with spondylolysis or spondylolisthesis were assigned randomly to two treatment groups. Group 1 underwent a 10-week specific exercise program involving the specific training of the deep abdominal muscles, with co-activation of the lumbar multifidus. The control group (group 2) underwent treatment as directed by their treating practitioner. The specific exercise group showed a statistically significant reduction in pain intensity and functional disability levels, which was maintained at a 30-month follow-up. The control group showed no significant change in these parameters after intervention or at follow-up. The authors concluded that a "specific exercise" treatment approach appears more effective than other commonly prescribed conservative treatment programs in patients with chronically symptomatic spondylolysis or spondylolisthesis.

Other authors have investigated the effectiveness of training regimens in increasing the cross sectional area (CSA) of the multifidus muscle. In a study conducted by Danneels et al,³⁹ fifty-nine patients were randomly assigned to one of three groups. Each group completed 10 weeks of one of the following training regimens: stabilization training (group 1), stabilization training combined with dynamic resistance training (group 2), or stabilization training combined with dynamic-static resistance training (group 3). The results demonstrated that the CSA of the multifidus muscle was

significantly increased at all levels after training in group 3. In contrast, no significant differences were found in groups 1 and 2. The static holding component between the concentric and eccentric phase was found to be critical in inducing muscle hypertrophy. These findings also support other studies that reported the multifidi's role in static leveling of the pelvis in the horizontal plane. Based on the previously mentioned studies that demonstrated the multifidi's ability to control spinal motions in the horizontal plane, the prone straight-leg raise (PSLR) maneuver may serve as a valid clinical tool that can be utilized by clinicians to detect weakness of the multifidi muscles.

In a randomized controlled trial conducted by Koumantakis et al,⁴⁰ fifty-five patients with recurrent, nonspecific back pain were randomized into either a trunk muscle stabilizing training program, which included general exercises, or a general exercise only program. Of note was the fact that none of the patients demonstrated clinical signs suggestive of spinal instability. Each group received 8 weeks of exercise intervention with collection of outcome data including self-reported pain, disability, cognitive status using the McGill pain questionnaire, the Roland-Morris Disability questionnaire, and the pain self-efficiency questionnaire. Outcome data were collected immediately after the interventions and at 3-months following the conclusion of the program. The results revealed that a specific program that focused on stabilization exercises did not appear to provide additional benefits for patients with sub-acute back pain who do not demonstrate clinical instability. Recurring, chronic back pain is not always associated with instability and the results of this study support the need for a clinical evaluation tool that would identify instability, as described as Panjabi's active subsystem, to determine the most efficient use of a stabilizing program.

Rehabilitative Ultrasound Imaging, Multifidus Assessment, and Training

Rehabilitative Ultrasound Imaging (RUSI) has been used in many studies to observe the lumbar multifidus muscle.^{15,16,39-49} Some have used it to measure the cross sectional area (CSA) of the muscle, whereas others have used it as a biofeedback mechanism to enhance motor control. Regardless of how it was used, this tool has proven to be reliable in accurately measuring activity of the multifidii muscles. Lin et al ⁴⁹ reported in 2009 that good reliability was obtained in measuring the deep musculature of the upper dorsal neck region, at both rest and at 50% maximum voluntary isometric contractions (MVIC), when performing cervical extension. Ten subjects without neck pain or headache were recruited for this study. RUSI measurements of the rectus capitus posterior major, obliquus capitis superior, splenius capitis, and the semispinalis capitis were obtained at rest and during MVIC, and repeated again after 10 minutes from the initial measurement. All measurements were recorded by the same rater. ICC results ranged from 0.87 to 0.99 for thickness measurements made at rest, and from 0.90 to 0.98 for thickness measurements made with a 50% MVIC.⁴⁹ These findings revealed that RUSI demonstrated good reliability in measuring the deep musculature of upper dorsal neck region.

Koppenhaver et al⁴⁵ conducted a clinical measurement reliability study to investigate the improvements in precision when averaging multiple measurements of percent change in muscle thickness of the transversus abdominis (TrA) and the lumbar multifidus muscle using RUSI. They studied 30 subjects with nonspecific low back pain and obtained thickness measurements of the TrA and lumbar multifidus at rest and during standardized tasks.⁴⁵ When compared to using a single measurement, the standard error

of measurement decreased by 25% when using a mean of two measurements, and by 50% when using a mean of three measurements. No significant gains in precision were observed by averaging more than three measurements.

Ferreira et al reported that RUSI is a valid discriminative tool for measuring deep trunk muscular function in subjects with LBP. The results of their discriminative analysis showed no significant differences between RUSI and EMG to observe and record the activity of the transversus abdominis and the internal obliquus abdominis.¹¹

Chouteau et al reported that needle EMG activity measurements of the lumbar paraspinal muscles were highly reliable, with excellent interrater reliability, with the caveat that they had to be performed by well-trained and qualified electromyographers.³⁷ On the other hand, Wallwork et al demonstrated a high interrater reliability between experienced and novice assessors of the lumbar multifidus using RUSI (ICC2,3 = 0.96for L2-3 and ICC2, 3 = 0.97 for L4-5).⁴³ Teyhen et al also reported good to excellent reliability (ICC = 0.86-0.94) among novice raters in assessing lateral trunk musculature using RUSI.⁵⁰ Both of these studies indicate that RUSI results can be reliably obtained with basic training, and the literature shows that RUSI is a reliable, valid tool for assessing the deep musculature of the trunk, as well as being less invasive, more cost effective, and less prone to complications than EMG.^{11,38,43,50} The cross-sectional area of the multifidus muscle has been shown to be smaller in individuals with a history of LBP, as compared to healthy subjects.⁴⁴ The differences in size and symmetry of the multifidus in individuals with LBP may be a contributing factor to LSI and subsequently the symptoms. RUSI has the ability to visualize a muscle contraction and record its change in CSA; however, most studies that target the multifidus using RUSI fail to make a

correlation between an image and the actual function of a muscle. Clearly, a connection between structure and function must be determined in order to obtain clinically relevant information.

Brenner et al¹⁵ investigated the activity level of the multifidus using RUSI following spinal manipulation in a published case report. Of importance in this study was the extremity motion utilized to record multifidii muscle activity. With their subject lying prone, they performed an alternating upper extremity lifting task. This maneuver alters the horizontal orientation of the trunk, requiring the multifidii to activate in an effort to control the degree of horizontal displacement. RUSI was utilized to detect the ability of the multifidii muscles to thicken during activation following a thrust manipulation treatment. The researchers reported that the subject had an increase in the ability to thicken the multifidii during a prone upper extremity lifting task one day after the manipulation. Although the researchers were unable to make any cause-and-effect claims, the results of this study provided preliminary evidence that changes in multifidii activation was not only influenced by manipulation, but that RUSI provided a convenient way to investigate and document said changes.¹⁵

Although the multifidus muscle has been shown to demonstrate atrophic changes following an incident of LBP, many individuals with LBP may be able to sustain high levels of activity. Hides et al⁴² investigated the CSA of the multifidus in elite cricket players with LBP, and the effect that a specific training regimen targeting the multifidus had on the CSA. The study included two groups, one with LBP (n=10) and one without LBP (n=16). Following an initial assessment of multifidus CSA, the groups participated in a 13-week exercise program. The group without LBP performed general strengthening

and aerobic exercises in the gym. The LBP group received education and instruction in contracting the multifidus using therapist tactile cueing and RUSI as a biofeedback tool. Following the 13-week program, the CSA of the multifidus was measured and compared to the initial assessment as well as with the other group. In all subjects with LBP, the side of the pain was associated with a smaller CSA of the multifidus. The LBP group that utilized RUSI as a feedback mechanism to activate and train the multifidus showed an increase in CSA and improved symmetry of the multifidii . The LBP group also reported a decrease in pain.

Koppenhaver et al⁴⁵ further examined the association between changes in multifidus muscle thickness and clinical improvement following spinal manipulation. Eighty-one participants with LBP underwent 2 thrust manipulation treatments and 3 assessment sessions of the multifidus, transversus abdominis (TrA), and the internal obliquus (IO) abdominis using RUSI. The multifidus was assessed at the L4-L5 and L5-S1 levels, with the subject at rest and during submaximal contraction. A contraction was elicited by having the subject perform a contralateral arm lift with a small hand weight while in the prone position. An increase in multifidus thickness was observed following the manipulation procedure, but not in the TrA or IO. Decreased LBP-related disability was associated with an increase in multifidus thickness one week following the intervention, suggesting that increases in multifidus thickness may lead to better clinical outcomes in patients with LBP and reduced muscle CSA.

Contrary to the previous two studies, Macdonald et al¹⁶ studied the behavior of the multifidus muscle in people with recurrent low back pain during symptom remission, and compared their findings with those of a healthy group. The subjects in the recurrent

low back pain group performed several different lower extremity movements: an active supine straight leg raise, a crook-lying active straight-leg raise, and a prone active straight leg raise. RUSI was used to measure the thickness percentage change in the multifidus muscle at the L4-L5 and L5-S1 spinal levels. The percent thickness change of the multifidus muscle was greater in the recurrent low back pain group than in the healthy group during the prone straight leg raise task; and greater in both groups with the prone straight leg raise task, when compared to the crook lying straight leg raise or the supine straight leg raise. The researchers concluded that during symptom remission, subjects with recurrent low back pain may have greater activity in at least some portion of the lumbar multifidus.¹⁶ The researchers caution that they were unable to determine whether all of the multifidus fibers, superficial and deep, responded similarly. This study does, however, provide evidence of the multifidii's role in the task of raising the lower extremity in the prone position.

In a study conducted by Sions et al,⁴⁶ two examiners used RUSI to perform thickness assessments of the lumbar multifidus at rest and during a contralateral limb lift. Their aim was to compare the intra-examiner and inter-examiner reliability for multifidus muscle thickness assessment in older vs younger adults. Thirty subjects aged 60 to 85 years were recruited for the older adult group, and 31 subjects aged 18-40 years comprised the younger adult group. One of the two examiners had 1.5 years of RUSI training and the other, who was considered a novice, had only performed 10 previous RUSI examinations. Assessment of the lumbar multifidus thickness was made at rest, by the first examiner, with the subject lying prone and on no more than 5 degrees of extension. The US transducer was placed over the L4-L5 interspinous space and an image

was taken. Using a split screen function, the subject was asked to perform an isometric contralateral limb lift and a second image was taken. The second examiner then repeated the same procedure on the same subject. The results showed that within-day inter-examiner procedural reliability for multifidus thickness measurements was comparable in younger adults (ICC = 0.90-0.92 and older adults (ICC 0.86-0.90). Similar results were obtained for between-day intra-examiner and inter-examiner reliability of younger adults (ICC = 0.84-0.94) and older adults (0.86-0.93). These results indicate that RUSI is a reliable tool for the assessment of lumbar multifidus thickness in younger adults. The researchers caution that, in older adults, RUSI can be used to assess changes in the mutifidus muscle over time however, detection of small changes are best achieved with a single examiner.⁴⁶

Further association between LBP and multifidus CSA size was reported by Gildea et al⁴⁴ in a study designed to correlate the size and symmetry of trunk musculature, including the multifidus muscle, in ballet dancers with and without LBP. Assessment of the multifidus thickness was made with magnetic resonance imaging (MRI) on 31 subjects, both male and female. The subjects comprised three groups: those without low back or hip pain (n=8), those with LBP only (n=13), and those with both low back and hip pain (n=10). Dancers without LBP or hip pain had a larger multifidus CSA compared to those with LBP at the L3-L5 levels, and those with both hip and low back pain at the L3 and L4 levels on the right side. Dancers who had hip pain and LBP had larger CSA of the multifidus on the left side of L4-L5 compared to those with LBP only. The CSA of other muscles investigated (the erector spinae, the psoas major, and the quadratus lumborum) did not differ between groups. The results demonstrated that in classical

dancers, hip and low back pain are associated with smaller CSA size of the multifidus muscle while these changes were not associated with the side of pain.⁴⁴

RUSI can also be utilized to guide therapeutic intervention and is becoming a common tool for physical therapists to observe contractions in the deep muscles of the spine during patient training. Several authors have reported the use of RUSI as a visual form of biofeedback when training patients to target the multifidus muscle. Van et al^{12} conducted a study to determine whether RUSI is an effective tool to enhance the ability of subjects to activate the multifidus muscle during isometric contractions. All subjects received initial explanation of the anatomical location of the multifidus muscle, as well as instructions in performing an isometric contraction of the muscle. The subjects were randomly assigned to two separate groups where two different forms of biofeedback were provided. One group received verbal feedback on the contraction of the multifidus, which was recorded as knowledge of results (KR) alone. The KR group was instructed to perform an isometric contraction of the multifidus muscle by "swelling out" the muscle without creating lumbar or pelvic motion. The second group received biofeedback in the form of visual observation of the ultrasound image using RUSI, which was recorded as KR plus visualization. The KR plus visualization group were instructed to lift their lower extremity while lying in a prone position. Both groups improved their ability to activate the multifidus muscle (p<.001), however, the group that used RUSI as a form of biofeedback demonstrated greater retention in their ability to activate the multifidus from week 1 to week 2 (p>.90, non-significant difference between weeks, indicating the skill was retained), while the group that received knowledge of results alone decreased in their ability to retain the motor skill (p<.05, significant difference between weeks).

Additionally, Herbert et al¹³ conducted a similar study where subjects were assigned to different groups receiving either continuous or variable feedback using RUSI. After eight training sessions, over a 4-week period, both groups demonstrated improvements in multifidus recruitment, but the variable feedback groups demonstrated continued success of multifidus recruitment 3 to 4 months after training. Although these studies demonstrated an ability to visualize the multifidus using RUSI, neither study made a correlation between multifidus recruitment and LSI.

The use of RUSI by novice raters has been studied by Teyhan et al⁵⁰ Their study was designed to determine the inter-rater reliability of ultrasound imagining among novice raters when assessing the deep musculature of the trunk for morphological characteristics at both rest and during contraction. Included in the testing protocol were the multifidii muscles. The study included two physical therapists and four student physical therapists. Each examiner received 20 hours of training by one of the investigators experienced in ultrasound imagining. To assess the thickness of the multifidus, the raters measured the muscle at the posterior most portion of the L4-L5 zygapophyseal joint. Images of the muscle were obtained at rest and with maximum contraction. A contraction was elicited in the prone position with the subject performing a contralateral arm lift form a 120-degree abducted position, and with a handheld weight in hand. The results revealed an overall ICC greater than .85, which indicates good-toexcellent reliability.

Although studies have shown that the multifidus is subjected to atrophy without spontaneous recovery following an acute injury to the low back,³² assessing the degree of muscle wasting is just as important. Stokes et al⁴⁸ examined the CSA of the multifidus in

a total of 120 male and female subjects without a history of low back pain. The multifidus was measured at the posterior aspect of the L4-L5 level. The authors reported that males demonstrated larger multifidii muscles than females. At the L4 level, the CSA was 7.87 cm^2 for males and 5.55 cm^2 for females. At the L5 level, males measured 8.91 cm² while females measured 6.65 cm². These figures proved an excellent reference point for the proposed study.

Other researchers have determined that CSA measurement of the multifidii muscles is independent of subject positioning. Colderon et al⁴⁷ measured the CSA of the multifidii muscles of 20 subjects. Measurements were taken at the level of L5, bilaterally, with the subject in prone and side lying. The CSA of the multifidus was highly correlated between the positions on both the right side (r=0.90) and the left (r= 0.91). These results demonstrated CSA measurements of the multifidus can be made in either the prone or side lying position with valid comparison of results.

Contribution of this Study

The literature review demonstrates the need to assess the structure and function of the multifidii muscles in order to fully understand LSI and to better delineate intervention approaches that can yield successful outcomes in patients with LBP. As previously discussed, EMG methods have deficiencies in their clinical applicability and/or the logistics of their use, namely cost, inconvenience, possible pain associated with the procedure, and training. With regard to clinical deficiencies of the surface EMG, detection of the muscle of interest is impossible, because the multifidii are situated within the deep musculature of the spine. When using the gold-standard indwelling electrodes, the accuracy and ability to detect activation of the muscle is indeed present. However, the majority of PTs are not certified to use this modality, so it is outside the scope of their clinical practice. Other barriers to widespread use of needle EMG by physical therapists include the facts that the equipment can be expensive and certification, which can be time-consuming and costly to obtain, is required.

The MPSLR test used in this study addressed each of the aforementioned problems associated with EMG. It requires no equipment, no major training, no added cost, and would also offer a physical therapist additional accuracy in diagnosing multifidii weakness as a causative factor to lumbar instability. Multifidus weakness, which contributes to lumbar instability, can be confirmed if the subject's pelvis drops during the straight-leg raise procedure. This finding has been confirmed in this study by RUSI. The use of RUSI does not require special certification, and although some training is needed in order to use this modality, it is less demanding than the training required to accurately perform EMG. RUSI is also a far less invasive procedure than EMG, and is within the scope of practice for a physical therapist for assessment of deep musculature, unlike the use of indwelling electrodes. Since a correlation exists between RUSI findings and the MPSLR, the use of this test has proven to be invaluable in detecting and confirming multifidus weakness in the lumbar spine and has eliminated the use of RUSI as a requirement, in the future, as part of the diagnostic testing procedure. Treatment plans can be tailored to the findings, which should provide for better outcomes, resulting in a more efficient and cost-effective delivery of care. Additionally, this study has explored the clinical relevance of test findings by investigating their relationship to disability measures and impact on quality of life, an aspect that has not been explored in

the existing literature. This information will also assist the therapist in optimizing patient management.

Other stakeholders that may benefit from the findings of this study include patients and third-party payers. Patients would benefit from less pain and less of the stress associated with a potentially painful testing procedure. They may also achieve improved outcomes based on the increased quality of information available to the therapist when designing a plan of care. Third-party payers could benefit from a moreaccurate, less-costly, and non-invasive test by experiencing a reduction of their payouts, including the price of the EMG, as well as the length of rehabilitation stays.

CHAPTER 3: METHODOLOGY

Subject Selection

After obtaining approval from the NSU Institutional Review Board (IRB), subject recruitment began by recruiting volunteers from local health clubs, recreational facilities, colleges, and the existing patient population of a private outpatient orthopaedic physical therapy clinic. Participants consisted of two groups of subjects with each group containing 30 to 36 subjects each. One group (n=30,) was comprised of both males (n=26) and females (n=4) in general good health, aged 18-55, without history of back pain. The second group (n=36) was comprised of both males (n=20) and females (n=16), aged 18-55, with a current history of low back pain or a past medical history of low back pain within the past 12 months.

Exclusion criteria included a history of lumbar surgery, lumbar radiculopathy, previous athletic training that would have resulted in hypertrophy of the multifidii muscle, neurological conditions resulting in muscle weakness that would affect their ability to complete the testing procedures, the inability to lie prone, or inability to understand English.

All participants were required to complete a brief medical history form (appendix D) screening for the aforementioned conditions. Once acceptable participants were identified, they were informed about the study and asked to sign consent forms (appendix C). The allocation of subjects into either of the two groups were made by an assistant researcher. This helped to ensure that the primary researcher, who was responsible for assessing the MPSLR maneuver, was blinded to group assignment.

Testing

All eligible subjects completed the Oswestry Disability Questionnaire (appendix F). After completing the questionnaire, there were two components to the experimental phase of this study; the MPSLR maneuver and the RUSI imaging segment.

For the MPSLR maneuver, subjects were instructed to lie prone. The examiner palpated the anterior superior iliac spines (ASIS) of the innominate bone bilaterally. The examiner instructed the subjects to extend one hip with their knee extended resulting in a posterior straight-leg raise. The choice of side tested first was randomized by a coin flip.

As the subject raised their lower extremity, the primary researcher monitored the anterior translation of the pelvis through: a) visual observation and b) increased pressure on the palpating finger between the ASIS and the treatment table on the ipsilateral side (Figure 1). The subject was instructed to return their leg to the original resting position. A negative test was defined as no visual and palpable translation of the pelvis from the transverse plane on the ipsilateral side of testing. Otherwise, the test was considered positive. Anterior pelvic translation and/or pressure increases on the palpating finger was recorded as a yes/no measurement.

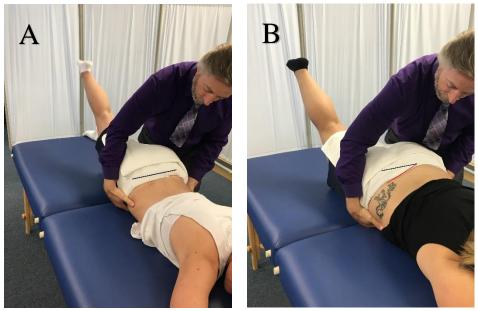


Figure 1. MPSLR test negative (A), Positive (B).

The testing process, as described in steps 2-4, was repeated on the contralateral side. Steps 1 and 3 was repeated with the addition of the RUSI. Many researchers have reported on the use of RUSI for measuring the multifidi muscles and have reported success using a B-mode with a 5-MHz, 60 mm curvilinear array.^{15,46-48,50} Subjects remained in the prone position. Coldron et. al. found no difference in CSA measurements of the multifidii muscles when measured in prone versus sidelying.⁴⁷ Images were obtained using a Mindray DP-50 portable ultrasonography unit (Mindray Medical International Limited, Shenzhen, China) using B mode. A 3.5–7.0 MHz curvilinear transducer was used on all the participants. Gain was adjusted for each image for optimal clarity. The Curvilinear probe was placed long axis just lateral to the spinous processes along the parasagittal plane. The probe was toggled to steer the beam medial back towards midline targeting the lumbar spinous processes. After the spinous processes were identified, the probe beam was toggled more laterally to identify the articular pillars. Once the articular pillars were identified, L4 was centered in the middle of the

screen. The probe was the toggled to identify the facet joints on the targeted side. At this point, the multifidi musculature would be identified. In order to take resting images, the multifidus needed to be differentiated from the longissimus. This was achieved through a contralateral leg lift of 5-7 inches from table and observing the contractile state of the multifidi.

After the multifidus was differentiated, a still image was taken of the contracted multifidus and the probe was translated medially until the contralateral multifidus was identified and the protocol was repeated. Finally, a CSA measurement was taken utilizing the trace feature of the ultrasound unit. The CSA's of the right and left multifidi at the L4 vertebral segment were recorded (Figure 2). A pillow was used at the discretion of the clinician to minimize lordosis and optimize imaging. Several researchers have identified the L4/L5 regions as being adequate for visualization.^{15,46,47,50} Sions et al reported excellent reliability for measuring thickness changes in the multifidii muscles during a prone straight leg raise maneuver (ICC = 0.93).⁴⁶ A reduced cross-sectional area compared to the norms, either in resting or while performing the straight-leg raise maneuver, would be indicative of weakness of the muscle. Stokes et al. reported on the normal CSA measurements of both males and females. They concluded that males had a mean CSA measurement of the multifidus muscle at the L4 and L5 levels of 7.87 and 8.91 cm² respectively while females had mean scores of 5.55 and 6.65 cm² for the same levels.48

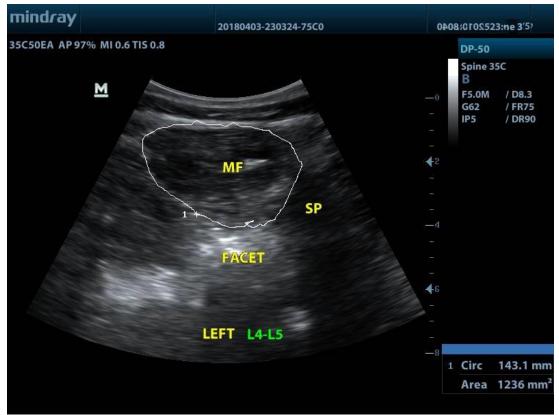


Figure 2. CSA measurement utilizing the trace feature of the ultrasound unit. MF, multifidus muscle, SP, Spinous process.

CHAPTER 4: RESULTS

Introduction

To address our research questions, we investigated (1) the proportional differences in positive MPSLR results in both symptomatic (LBP) and asymptomatic (no LBP) groups; (2) the existence of differences in the CSA of the multifidus muscle, as measured by RUSI, between the symptomatic and asymptomatic groups; (3) the correlation between a positive MPSLR test and the CSA of the multifidus muscle; and (4) the correlation between a positive MPSLR test and self-reported LBP as measured by the Oswestry Low Back Disability Questionnaire.

Data from the MPSLR test were recorded as either positive or negative, as described in chapter 3, step 4 of section 2. Data from RUSI were collected as described in chapter 3, step 7 of section 2, recorded as multifidi CSA measurements in cm², and compared to existing norms.

Functional assessment was recorded by self-reporting using the Oswestry Disability Questionnaire, which was filled out prior to testing. The Oswestry Disability Questionnaire is considered to be the gold standard of low back functional outcome tools.²⁰ It has also been reported to have sufficient reliability and scale width to be applied in an ambulatory clinical population with low back problems.²⁰

Collected data were de-identified and assigned a record number to protect patient privacy. Basic demographic information, including gender and age, was used for descriptive statistics of the two groups participating in the study. Data analysis included comparison between the asymptomatic and symptomatic groups in terms of MPSLR results, RUSI measurements, and Oswestry Disability Questionnaire scores. Statistical significance was set at alpha = 0.05. A regression model was created with MPSLR results (dichotomous) and CSA measured by RUSI (ratio) as predictor variables and Oswestry percent scores as the dependent variable (ratio computed from an ordinal scale, as validated in the literature). This model described whether the presence of symptoms can be predicted by MPLR and RUSI results, indicating the clinical relevance of the assessments. Additionally, we tested for significant differences between groups (p < .05) in MPSLR results, CSA by RUSI, and Oswestry percent scores using two-way ANOVA for ratio variables and chi-square testing for MPSLR.

In this chapter we provide a discussion of the results of these investigations. This chapter also provides a detailed description of the subjects and groups utilized in this study. Sixty-six participants, male and female, completed the study. Their age range was 18-55 years. The subjects were assigned to one of two groups: individuals in general good health without history of back pain, and individuals with history of low back pain within the past 12 months. There were 30 subjects in the no LBP group and 36 subjects in the LBP group, with no significant difference in ages of the subjects between groups (p-value =.742).

Participant Characteristics

Following the screening process for inclusion/exclusion criteria, data were collected and analyzed for 66 subjects. The no LBP group (n = 30) comprised individuals in general good health, aged 18-55 years, without history of back pain. The LBP group (n = 36) comprised individuals aged 18-55 years, with history of low back pain within the past 12 months. Table 1 lists the descriptive characteristics of each group. Table 2

contains the results of a t-test which demonstrates no difference in age between groups.

Figure 1 is a graphic representation of the results provided in Table 2.

| Group | Sex | Ν | Age (years) | Height (in) | Weight (lbs) | Oswestry (%) | CSA-L | CSA-R |
|-------|-----|----|-----------------|----------------|------------------|---------------|----------|----------|
| | | | | | | | (cm^2) | (cm^2) |
| No | Μ | 26 | 39.7 ± 11.9 | 71.8 ± 2.4 | 198.4 ± 21.9 | 2.5 ± 5.7 | 5.1 ± | 4.9 ± |
| LBP | | | | | | | 1.9 | 2.0 |
| | F | 4 | 38.3 ± 21.2 | 62.8 ± 1.3 | 149.5 ± 24.9 | 0.5 ± 1.0 | 4.3 ± | 3.9 ± |
| | | | | | | | 2.8 | 1.6 |
| LBP | Μ | 20 | 39.7 ± 11.3 | 70.0 ± 2.1 | 190.7 ± 32.3 | 16.3 ± 13.5 | 5.3 ± | 4.9 ± |
| | | | | | | | 2.0 | 2.1 |
| | F | 16 | 36.9 ± 13.3 | 63.9 ± 2.9 | 131.7 ± 23.3 | 22.6 ± 17.2 | 4.7 ± | 4.6± |
| | | | | | | | 1.4 | 1.3 |

Table 1. Descriptive characteristics of each group

Values expressed as mean \pm SE. No LBP, No Low Back Pain, LBP, Low Back Pain, CSA–L, Cross Sectional Area–Left, CSA-R, Cross Sectional Area Left.

 Table 2. t-test results demonstrating no significant differences in mean age between groups.

| Group | Ν | Age (years) | Estimate of difference | 95% CI for difference | <i>t</i> -test of difference <i>p</i> -value |
|--------|----|-----------------|------------------------|-----------------------|--|
| No LBP | 30 | 39.5 ± 13.0 | 1.03 | (-5.2, 7.3) | .742 |
| LBP | 36 | 38.5 ± 12.1 | | | |

Values expressed as mean <u>+</u> SE. No LBP, No Low Back Pain, LBP, Low Back Pain

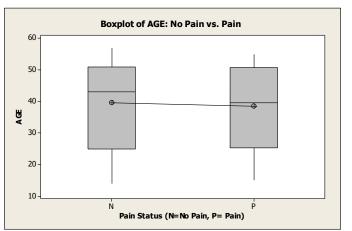


Figure 3 – no significant differences in mean age between groups

The asymptomatic group contained a lower proportion of females (13%) versus the symptomatic group (44%), and a *t*-test revealed a significant difference (*p*-value =

.008). This difference could be due to lower pain tolerances in females versus males

(Table 3).

| 1 abic 5 - | <i>i</i> -icst for j | propord | on or reman | ts m cach gi | Jup | | |
|--------------|----------------------|---------|-------------|--------------|------------|-----------------|----------|
| Group | Female | n | Sample | Estimate | 95% CI | z-test of | Fisher's |
| | | | proportion | of | for | difference | exact |
| | | | female | difference | difference | <i>p</i> -value | test p- |
| | | | | | | | value |
| No LBP | 4 | 30 | .13 | 31 | (51,11) | .003 | .008 |
| LBP | 16 | 36 | .44 | | | | |

Table 3 – *t*-test for proportion of females in each group

Because of the inequitable proportion of females to males in each group (z-test p =

.003), means for both height (no LBP, 70.6 \pm 3.9; LBP 67.3 \pm 3.9) and weight (no LBP,

191.8 \pm 27.6; LBP, 164.4 \pm 41.0) also differed significantly between the groups (*p*-value =

.001) and in the expected direction of men typically being taller and heavier than women

(Table 4; Figure 2).

| I doite i dif | Table 4 – unterences in neight and weight between groups | | | | | | |
|---------------|--|----------------|-------------|--------------|------------------------------|--|--|
| Group | n | Height (in) | Estimate of | 95% CI for | <i>t</i> -test of difference | | |
| | | | difference | difference | <i>p</i> -value | | |
| No LBP | 30 | 70.6 ± 3.9 | 3.36 | (1.44, 5.28) | .001 | | |
| LBP | 36 | 67.3 ± 3.9 | | | | | |
| | | | | | | | |
| | | | | | | | |
| Group | n | Weight (lbs) | Estimate of | 95% CI for | <i>t</i> -test of difference | | |
| | | | difference | difference | <i>p</i> -value | | |
| No LBP | 30 | 191.8 ± 27.6 | 27.4 | (10.4, 44.4) | .002 | | |
| LBP | 36 | 164.4 ± 41.0 | | | | | |
| | | | | | | | |

Table 4 – differences in height and weight between groups

Values expressed as mean \pm SE.

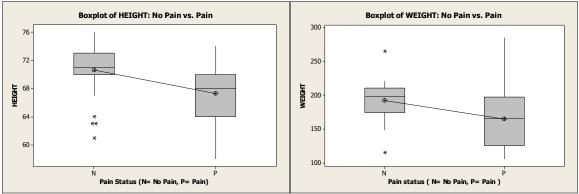


Figure 4 – differences in height and weight between groups

There were no significant differences between average CSA values for pain and/or sex groups. In the no LBP group, the average CSA for males was 5.04 cm² with a standard deviation of 1.87 cm² and for females, 4.10 cm² with a standard deviation of 2.13 cm². For the LBP group, the average CSA value for males was 5.11 cm² with a standard deviation of 1.96 cm², and for females 4.66 cm² with a standard deviation of 1.21 cm².(Table 5)

| | | 8 | r 8 | r |
|---|--------|----|--------|-----------------------------|
| 0 | Group | n | Sex | CSA AVER (cm ²) |
| Ν | No LBP | 26 | Male | 5.04±1.87 |
| | | 4 | Female | 4.10±2.13 |
| Ι | LBP | 20 | Male | 5.11±1.96 |
| | | 16 | Female | 4.66±1.21 |

Table 5 – average CSA per group and sex

Values expressed as mean <u>+</u> SE. CSA AVER, Cross Sectional Average

A *t*-test on the difference between male CSA averages and female CSA averages grouped by sex only was performed and revealed a slight, but not significant, difference. This difference is most likely due to morphology (*p*-value =.216; table 6). The results are tentative because of the small samples and the imbalance in the sexes. The results of an ANOVA show that the male groups (n=46) is normal distributed (*p*-value of .097). For the female groups (N=20) the results show a p-value even higher at .583 and again not significantly different from a normal distribution. Figure 3 illustrates the probability plot.

| I dole o | | | | | | | | |
|----------|----|---------------------------|-------------|--------------|-------------------|--|--|--|
| Group | n | Average CSA | Estimate of | 95% CI for | <i>t</i> -test of | | | |
| | | values (cm ²) | difference | difference | difference | | | |
| | | | | | <i>p</i> -value | | | |
| Male | 46 | 5.07 ± 1.89 | 0.53 | (316, 1.361) | .216 | | | |
| Female | 20 | 4.55 ± 1.39 | | | | | | |

Table 6 – results of *t*-test of differences in CSA between sexes

Values expressed as mean \pm SE.

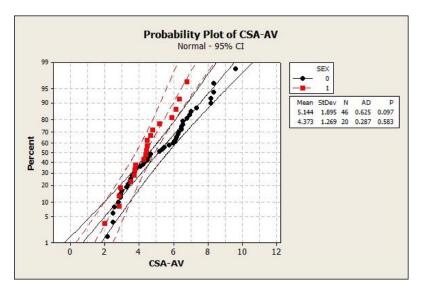


Figure 5. Probability plot of CSA AV by sex

A *t*-test was conducted to identify differences in the average CSA between groups as opposed to individual CSA or symmetry within subjects. Testing revealed no

differences between groups regarding CSA averages (p = .983; Table 7).

| Group | n | Average CSA values(cm ²) | Estimate of difference | 95% CI for difference | <i>t</i> -test of difference <i>p</i> -value |
|---------|----|--------------------------------------|------------------------|--------------------------|--|
| No pain | 30 | 4.92 ± 1.89 | 0.01 | (876, 0.896) | .983 |
| Pain | 36 | 4.91 ± 1.66 | | | |

Table 7 – results of a t-test of no differences in CSA between groups

Values expressed as mean \pm SE.

There were no significant differences between CSA left and CSA right observed for the 66 pairs of measurements (Table 8). CSA left and CSA right were strongly positively linearly correlated (PPMC, r = .845, p-value < .001), indicating that when the right CSA was decreased, the left CSA was as well, and vice versa (Figure 4).

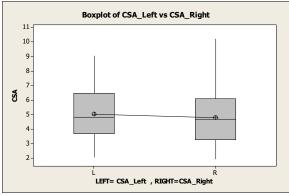


Figure 6 – differences in CSA between left and right sides

| 1 able $\delta - \alpha$ | Table 8 – differences in left vs right CSA | | | | | | |
|--------------------------|--|---------------------------------------|------------------------|-----------------------|------------------------------|--|--|
| CSA | n | Average CSA values (cm ²) | Estimate of difference | 95% CI for difference | <i>t</i> -test of difference | | |
| | | | | | <i>p</i> -value | | |
| Left | 66 | 5.03 ± 1.84 | 0.236 | (394, 0.865) | .46 | | |
| Right | 66 | 4.79 ± 1.82 | | | | | |
| | | | | | | | |

 Table 8 – differences in left vs right CSA

Values expressed as mean \pm SE.

An average of CSA left and CSA right was used for each subject to compare

groups and to avoid dependent measures in the analysis. However, individual CSA left

and CSA right values were used to measure asymmetry in each subject.

Specific Aim 1:

The first aim was to determine whether there were any significant differences in

the proportion of positive MPSLR results between the symptomatic (LBP) and

asymptomatic (no LBP) groups.

Analysis and Results of Specific Aim 1:

A chi-square analysis was performed to identify this association: Pearson's chisquare = 15.3, p-value < .001, Fisher's exact test p-value < .001, kappa = .47, test of

concordance, p-value < .001, odds ratio = 9.3.

Data from the MPSLR test were recorded as either positive or negative, as

described in chapter 3, step 4 of section 2. The chi-square test of association between

pain and the MPSLR test revealed a significant association between a positive MPSLR and the presence of pain (Table 9). The results also revealed the MPSLR had a sensitivity of 86% in its ability to predict pain and a specificity of 60%.

| | | 8 1 | |
|---------|-----------|-----------|--------|
| | MPSLR (-) | MPSLR (+) | Totals |
| No pain | 18 | 12 | 30 |
| Pain | 5 | 31 | 36 |
| Total | 23 | 43 | 66 |

Table 9 – association between (+) and (-) MPSLR between groups

Specific Aim 2:

The second aim was to determine if there were significant differences in the multifidus cross-sectional area, as measured by RUSI, when comparing the symptomatic (LBP) and asymptomatic (no LBP) groups.

Analysis and Results of Specific Aim 2:

We recoded the data to look at differences between the right and left multifidi muscle within each subject to identify whether asymmetry was present, and how that would associate with the MPSLR. Rather than looking at whether a MPSLR test was positive and associating those findings with the corresponding multifidi based on sides, a dichotomous variable was computed from CSA left and CSA right, and was evaluated using the MPSLR test result and published norms for CSA for males (mean 7.87 cm², SD 1.85 cm²) and females (mean 5.55 cm², SD 1.28 cm²) as follows: We coded the data to identify whether there was a CSA difference in either side, regardless of which side tested positive. Therefore, if the MPSLR tested positive on the left and the CSA on the right was less than that of the left, we coded it as positive. If the MPSLR tested positive on the right and the CSA on the left was less than that of the right, we coded it as positive. If the MPSLR tested positive on both sides and the CSA on either the right or left was less than the published norms for that sex, we coded it as positive, and if the MPSLR tested negative on each side and the difference in the CSA between the sides was greater than the lowest standard deviation of the expected norm, we coded it as positive (Tables 11 and 12). When the CSA of the multifidi muscles was analyzed bilaterally within subjects using a Pearson's chi-square test = 24.09, and the binary coding of positive or negative looking for asymmetry, the data revealed a significant relationship between asymmetry of multifidi CSA, relative atrophy, a positive MPSLR, and pain (MPSLR *p*-value < .001, pain *p* = .001, OR 27.12). Sensitivity and specificity were calculated and revealed a sensitivity of 94% and a specificity of 63% in the ability of the MPSLR test to detect asymmetry of the multifidus muscle within subjects.

The results of this study also revealed that the cross-sectional area of the multifidi muscles was not significantly different in the LBP versus the no LBP group (ANOVA p-value = .676) (table 10, figure 5); however, the CSA averages were significantly different from the published norms of 7.87 ± 1.85 for male CSA (*t*-test, p < .001) and 5.55 ± 1.28 for female CSA (*t*-test, p = .007). To assure that the groups were normally distributed, an ANOVA was performed and revealed that the male groups (n=46, p-value of .097) and the female groups (n=20, p-value .583) were both acceptably normal.

| Group | | n | Sex | Avera | ge CSA v | values (cm ²) | | |
|---------|----|----|--------|-----------|----------|---------------------------|---------|----------|
| No Pain | | 26 | Male | 5.04±1.87 | | | | |
| | | 4 | Female | 4.10± | 2.13 | | | |
| Pain | | 20 | Male | 5.11±1.96 | | | | |
| | 16 | | Female | 4.66±1.21 | | | | |
| Source | Dł | 7 | SS | MS | 5 | F | P-value | Adjusted |
| | | | | | | | | R-square |
| Groups | 3 | | 4.83 | 1.6 | 1 | 0.51 | .676 | 0 |
| Error | 62 | | 195.66 | 3.1 | 6 | | | |
| Total | 65 | | 200.49 | | | | | |

Table 10 – CSA differences between groups

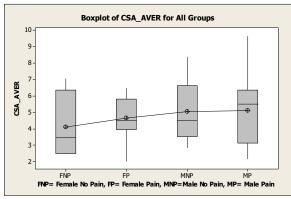


Figure 7– CSA differences between groups

| MPSLR result | Coding criterion for asymmetry |
|--------------|--------------------------------|
| | of CSA |
| L | CSA-R < CSA-L |
| R | CSA-L < CSA-R |
| В | CSA-L or CSA-R < norm |
| N | CSA-L-CSA-R > 1.28 |

L, Left, R, Right, B, Bilateral, N, Neither, CSA, Cross Sectional Area, Norm, Published Normal Values

| | MPSLR (-) | MPSLR (+) | TOTALS | | | |
|------------------|-----------|-----------|--------|--|--|--|
| CSA_symmetrical | 21 | 12 | 33 | | | |
| CSA_asymmetrical | 2 | 31 | 33 | | | |
| Total | 23 | 43 | 66 | | | |

Table 12 – totals of symmetrical vs asymmetrical CSA per MPSLR results

Specific Aim 3:

The third aim of this study was to determine whether the findings from the

MPSLR test correlated with CSA measurements of the multifidus muscle as shown by

RUSI.

Analysis and Results of Specific Aim 3:

A Pearson linear correlation was conducted to test the association between the MPSLR test results and the CSA measurements of the multifidus muscle. We coded the MPSLR as being either positive of negative, and correlated those results with the averages of the CSA of the multifidus muscle. We chose to use the CSA averages over individual left and right measurements to prevent dependencies in the variables. In addition, we chose to use the CSA averages as the results of a *t*-test revealed no differences between the left and right measurements within subjects (p = .46).

The linear model failed to show a linear correlation between a positive MPSLR and moderate reduced CSA average, as verified by a MANOVA (p = .835) (r = .049, ppmc test p = .696). However, as stated earlier, there was an association between a positive MPSLR and asymmetry of the multifidi between the left and the right.

Table 13 – correlation between MPSLR and CSA

| | Oswestry | MPSLR |
|----------|---------------------|---------------------|
| MPSLR | .222 (P-value=.074) | |
| CSA_AVER | 013 (P-value=.917) | .049 (P-value=.696) |

Specific Aim 4:

The fourth aim of this study was to determine if the findings from the MPSLR test correlated with patient self-report of disability due to low back pain as measured by the Oswestry Low Back Disability Questionnaire.

Analysis and Results of Specific Aim 4:

A Pearson linear correlation was used to test the association between the test results of the MPSLR and self-reported disability as measured by the Oswestry Low Back Disability Questionnaire. In addition, a chi-square test was employed to test for an association between Oswestry scores and a positive MPSLR test.

A weak linear correlation between the MPSLR and Oswestry test scores was observed at the 10% level; however, it did not reach significance at the 5% level (PPMC, r = .222, p = .074) (table 13). Additionally, a chi-square test for association between Oswestry score and a positive MPSLR test confirmed no significance (p = .106, Kappa = .18, OR = 2.39). Oswestry test scores (medial cut) were significantly associated with pain status (p < .001). A logistic regression model was employed as the optimal method to investigate the MPSLR and Oswestry scores as predictors of pain status. The independence of MPSLR and Oswestry score (as covariate) was confirmed by a binary logistic regression model to predict pain status (model p < .001; MPSLR p = .005, OR = 38.2; Oswestry p = .001, OR = 1.27) (Table 14 and Figure 6).

| Predictor | Coefficient | SE coeff | Ζ | <i>p</i> -value | ŌR | 95% CĪ | 95% CI |
|-----------|-------------|-----------|-------|-----------------|------|--------|--------|
| | | | | | | lower | upper |
| Constant | -4.03815 | 1.3567 | -2.98 | .003 | | | |
| MPSLR | 3.64291 | 1.3048 | 2.79 | .005 | 38.2 | 2.96 | 492.88 |
| Oswestry | 0.239979 | 0.0721715 | 3.33 | .001 | 1.27 | 1.1 | 1.46 |

Table 14 - odds ratio of the MPSLR and Oswestry score as predictors of pain

The probability equation is (Equation 1):

 $Pr(Pain) = \frac{e^{-4.03815+3.64291(MPSLR)+0.239979(Oswestry)}}{1+e^{-4.03815+3.64291(MPSLR)+0.239979(Oswestry)}}$

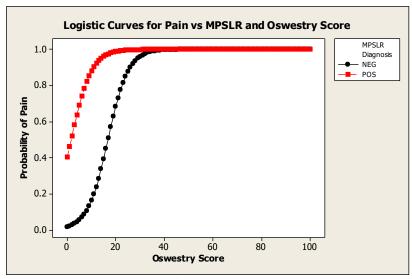


Figure 8 – logistic curve for pain probability

A positive MPSLR was a strong indicator of pain, and a positive MPSLR combined with a high Oswestry score of 25-30 further reinforced the probability of pain. The wide odds ratio was identified and most likely explained by a small sample of subjects. The model was significant (*p*-value < .001) and can be used to predict the probability of a patient having pain using the Oswestry and the MPSLR. For each point scored with the Oswestry the odds of having pain increase by a factor of 1.27. For a positive MPSLR test the odds of having pain increase by an estimated factor of 38.2. For both logistic curves shown in the graph, the odds and probabilities for each leftmost point can be calculated with Equation 1. The model has a baseline probability of approximately 1.7% of having pain with a negative MPSLR and an Oswestry score of zero, and a baseline odds in favor of having pain of approximately 9:500, or about 0.018. This is the leftmost point of the negative (black) curve. Given a positive MPSLR and an Oswestry score of 0, the probability of having pain increases to 40.2% with an odds in favor of having pain increasing to approximately 337: 500, or about 0.674. This is the leftmost point of the positive (red) curve.

Summary

The MPSLR test was examined for its ability to detect weakness within the multifidus muscle when compared to RUSI. Weakness was identified by a positive MPSLR test and a decrease in the CSA averages of the multifidus muscle when compared to the normal CSA values. The results of this study demonstrated that a positive MPSLR test was significantly associated with pain (p-value = <.001). The MPSLR test also proved to have a sensitivity of 86% in its ability to predict pain. Although a linear model failed to demonstrate a linear correlation between a positive MPSLR test and a moderate reduction in the CSA averages of the multifidus (*p*-value = .696), there was an association between a positive MPSLR test and asymmetry of the multifidus muscle between the left and right sides within subjects (p-value < .001). Sensitivity and specificity were calculated and revealed a sensitivity of 94% and a specificity of 63% in the ability of the MPSLR test to detect asymmetry of the multifidus muscle within subjects. A logistic regression model was also employed as the optimal method to investigate the MPSLR and Oswestry scores as predictors of pain status. The independence of MPSLR and Oswestry score (as covariate) was confirmed by a binary logistic regression model to predict pain status (model p < .001; MPSLR p = .005, OR = 38.2; Oswestry p = .001, OR = 1.27). As previously mentioned, a positive MPSLR was a strong indicator of pain, however, when combined with a high Oswestry score of 25-30, the probability of pain was further reinforced.

CHAPTER 5: DISCUSSION

Introduction

The focus of this chapter will be on the interpretation of the findings of this study while associating them to the current literature. We will discuss each of the specific aims of the study and provide, where applicable, clinical relevance of the findings with current clinical practice. This chapter will also discuss the limitations and delimitations of the study while providing recommendations for follow-up studies.

Specific Aim 1

One of the purposes of this study was to determine whether there were any significant differences in the proportion of positive MPSLR results between the symptomatic (LBP) and asymptomatic (no LBP) groups. We hypothesized that the proportion of individuals with positive MPSLR results will be significantly higher (p<0.05) in the symptomatic group. The results of this study revealed a significant (pvalue<.001) proportion of positive MPSLR tests in the LBP group. Several authors^{29, 39} have demonstrated that, in the prone position, the multifidus muscle was highly active with hip extension movements in healthy adults. Hides et al^{32} studied the multifidus muscle in subjects with acute episode of LBP and concluded that multifidus not only shut down with LBP, but did not demonstrate spontaneous recovery following a remission of painful symptoms. Given the results of the aforementioned studies, and concluding that the multifidus not only serves in a stabilizing role of the lumbar area with prone hip extension, it will also assume a diminished role in stabilizing following an episode of LBP. In our study, we observed a positive MPSLR test in the proportion of LBP subjects versus the non-symptomatic group. We concluded that the inability of the multifidus to

stabilize the lumbar area in the presence of LBP was identified with the administration of a MPSLR test. Nelson-Wong et al,³⁴ investigated the frontal plane displacement of the pelvic girdle during side-lying active hip abduction to predict the risk of low back pain in individuals who perform prolonged standing activities. Data collected included visual observations of pelvic displacement, as well as self-report levels of difficulty maintaining a level pelvis. Correlations between low back pain development and anterior pelvic displacement during the active abduction test were made. The results of their study revealed that the active hip abduction test was a "promising" clinical tool to predict individuals who may be at risk for low back pain development.³⁴ The authors concluded that a lack of trunk muscular stability contributed to the frontal displacement of the pelvis during unsupported lower extremity hip abduction.

In our study, we opted to challenge the frontal displacement of the pelvis using the MPSLR maneuver. Like Wong et al, we utilized a visual observation of pelvic displacement and also included palpation of the ASIS to further detect the degree of anterior pelvic displacement. By utilizing palpation of the ASIS, we were able to detect a unilateral anterior displacement of the pelvis during an ipsilateral MPSLR maneuver. The inability of the pelvis to maintain frontal plane stability during a unilateral contralateral prone SLR is consistent with the findings of McDonald et al.¹⁶ In the study by MacDonald, the multifidus was observed as having a greater percent change in thickness when a prone contralateral SLR was performed. When a subject in our study performed a MPSLR maneuver and the ipsilateral pelvis was observed to displace anteriorly and there was increased pressure on the palpating finger on the ipsilateral ASIS, it can be concluded that weakness in the contralateral multifidus muscle was the cause for the

displacement. Our conclusion is consistent with Wong et al's conclusion that a lack of trunk muscular stability was the reason for the anterior pelvic displacement. These findings could provide a clinician with a simple, non-invasive, diagnostic tool in detecting lumbar spinal instability with a root cause of multifidus involvement, and subsequently, aid in tailoring a more focused treatment regimen.

In addition to observing the high proportion of positive MPSLR test in the LBP group, we were able to assess the MPSLR test's ability to screen for the presence of LBP. Based on the results of our study, the MPSLR test had a sensitivity of 86% in its ability to predict LBP while demonstrating a weaker specificity of 60%. Calculating the odds ratio of predicting pain, a positive MPSLR increased the odds of having pain 38.2 times over baseline odds. Despite the very wide confidence interval, the odds ratio for MPSLR is still very high and very significant. Using larger sample sizes will make the denominators larger in the estimate for the standard error. Using larger samples will help narrow down the confidence interval so that a better estimate of the odds ratio can be found. From this preliminary study, the MPSLR looks to be a very powerful indicator of pain and deserves further study.

Our study is in agreement with many studies previously mentioned^{9,10,16,28,29,33,37,38} that the multifidi's ability to control spinal motions in the horizontal plane indicate that the MPSLR maneuver may serve as a valid clinical diagnosis tool that can be utilized by clinicians to detect weakness of the multifidi muscles.

Specific Aim 2

The second aim was to determine if there were significant differences in the multifidus cross-sectional area, as measured by RUSI, when comparing the symptomatic

(LBP) and asymptomatic (no LBP) groups. Although our study failed to demonstrate a significant difference in the cross-sectional area of the multifidi muscles in the LBP versus the no LBP group (ANOVA p-value = .676), we were able to demonstrate a difference in the CSA of the multifidus muscle within subjects. Previous studies^{15,42,4,46} have investigated the CSA of the multifidus muscle in a variety of subjects and compared the findings to both non-symptomatic and symptomatic populations, and have general agreement that the side of pain has been correlated to the side of a decreased CSA. It is unclear however, as to whether any of these studies investigated the differences in the CSA of the multifidus muscles within subjects, and if any differences in size existed in non-symptomatic sides. As described in chapter 4, we coded the data to identify whether there was a CSA difference in either side, regardless of which side tested positive. Therefore, if the MPSLR tested positive on the left and the CSA on the right was less than that of the left, we coded it as positive. If the MPSLR tested positive on the right and the CSA on the left was less than that of the right, we coded it as positive. If the MPSLR tested positive on both sides and the CSA on either the right or left was less than the other we coded it as positive, and if the MPSLR tested negative on each side and the difference in the CSA between the sides was greater than the lowest standard deviation of the expected norm, we coded it as positive. Sensitivity and specificity were calculated and revealed a sensitivity of 94% and a specificity of 63% in the ability of the MPSLR test to detect asymmetry of the multifidus muscle within subjects. Our study demonstrates that there is an association between asymmetry found in the CSA of the multifidus muscle (relative atrophy), a positive MPSLR test, and pain (MPSLR p-value < .001, pain p =.001, OR 27.12) regardless of which side tested positive. These results indicate that pain

symptoms in the lumbar spine region are associated with a relative decrease in CSA of the multifidus muscle, on either side comparing left to right, which, most likely, contributes to the loss of spinal stability. These findings are also consistent with the findings of Nelson-Wong et al in that lack of stunk stability resulting from muscle weakness is associated with LBP symptoms. Stokes et al⁴⁸ reported the average CSA of the multifidus muscle in both males (mean 7.87cm², SD 1.85cm²) and females (mean 5.55cm², SD 1.28cm²) without LBP. These reported numbers were slightly elevated from a previous study by Hides et al⁵¹. Unlike our study, Stokes et al measured the resting CSA of the multifidus while we measured the contracted CSA of the muscle. Also of note, Stokes performed an ipsilateral leg lift to identify the margins of the multifidus while we utilized a contralateral leg lift, as per previously mentioned studies.^{45,46,51} In our study, the CSA measurements of the multifidi muscles were slightly less for males (mean 5.04cm², SD 1.87cm²) and females (4.10cm², SD 2.13cm²) without LBP than those previously report. Our study was limited to 66 subjects, while in the Stokes article 120 subjects were utilized. Differences in the methods used to activate the multifidus, measuring the resting state versus the contracted state of the multifidus and having a smaller sample size in our study may be the reasons for the differences between our CSA measurements and those reported by Stokes et al. Regardless, even though the average CSA of the multifidi muscles for both male and female subjects in our study differed significantly from those norms published by Stokes et al, we feel that these differences were insignificant because our aim was not to validate the published norms.

Of note was the finding of age as a factor affecting the CSA averages. Stokes et al reported that age played no role in the CSA measurement of the multifidus muscle in

either males or females in their study. They did, however, report that the quality of the muscle may have been altered due to trophic changes, such as fatty infiltration or fibrous changes within the muscle, as seen in the aging process. Our study revealed a significant change in CSA averages with an advanced age of the subject (p < .001). As the age of the subject increased, the CSA average of the multifidus muscle decreased. This finding may be due to the normal decline in muscle mass as part of the aging process. The infiltration of fatty tissue was observed with RUSI along the medial and anterior borders of the multifidus along the lamina groove in many of our subjects. It is possible that other researchers have included those borders when tracing around the margins of the multifidus. We traced only the fibers that appeared dark during a contraction on the image as RUSI displays muscle fiber as a darker tone than the whitish appearance of the fatty tissue. The manner in which we traced the around the multifidus may also contribute to the differences in our measurements from those previously published. To our knowledge, there are no true protocols established for measuring gender specific CSA of the multifidus and future research should investigate establishing said protocols. It should also be noted that the proportion of females in the no-LBP group (n=4) compared to males (n=26) was significantly less than females (n=16) vs. the males (n=20) in the LBP group. The data revealed no difference in the CSA of the multifidus muscle of either sex within groups however, this may be a result of pain tolerance differences between males and females. If the females in the no LBP group had a higher pain tolerance than the males, their CSA measurements may have been reduced, but not contributing to the association with LBP and decreased CSA.

Although we were not successful in detecting a difference in the CSA of the multifidus muscle between the LBP and no-LBP groups and make a correlation to the positive or negative MPSLR test, we were able to uncover an association between a positive MPSLR test and asymmetry of the CSA of the multifidus muscle within subjects. These findings may provide a deeper insight into the role and functional anatomy of the multifidus muscle when diagnosing LBP pathology. Our study demonstrated an association between LBP and asymmetry of the multifidus muscle when compared between left and right sides. Since the multifidus muscle is responsible to the transverse stability of the spinal column, our study may have uncovered that any disturbance in the structural integrity of the spinal column could result in positive testing procedures such as the MPSLR test. Perhaps a compensatory firing pattern is adapted in those with LBP symptoms, thus presenting with unconventional patterns of functioning that differ from those that are expected to be observed with testing procedures. Regardless of the rationale, an association between the asymmetry and LBP symptoms was observed in our study and further investigation into this relationship is warranted.

Specific Aim 3

The third aim of this study was to determine whether the findings from the MPSLR test correlated with CSA measurements of the multifidus muscle as shown by RUSI. The linear model failed to show a linear correlation between a positive MPSLR and moderate reduced CSA average of the multifidus (p = .696) as compared to the group who tested negative with the MPSLR test. However, as stated earlier, there was an association between a positive MPSLR and asymmetry of the multifidi between the left and the right multifidus muscle within the subjects who tested positive. This indicates

that a relationship exists between a positive MPSLR test and a relative decrease in the CSA of the multifidus muscle within subjects. This difference was not seen when compared to the group who tested negative, as other studies have reported.⁴⁴ This may be due to the fact that we used a smaller sample size than the other previously reported studies, but we believe this association is unique to the group who tested positive.

Our results demonstrated a strong positive linear correlation between the CSA of each left and right measurement of the multifidus muscle (p=.001). If the subjected tested positive during the MPSLR test and a decrease in the CSA of the multifidus muscle on either side was visualized on RUSI, a relative decrease in the CSA was also seen on the contralateral side. We expected to observe a significant difference between the left and right CSA measurement in those who tested positive on the MPSLR test; however, what we observed was a relative decrease in both sides of the multifidus muscle with a positive test. This indicates that the multifidus muscle may be affected in a more general, symmetrical pattern of atrophy rather than specifically to the side of injury as previous research has shown.^{42,52} Hodges et al demonstrated that an injury to the lumbar intervertebral disc induced multifidus atrophy ipsilaterally, however, studies such as those conducted by Gildea et al⁴⁴ demonstrated that ballet dancers with LBP only, as compared to those who had LBP and hip pain, had a more symmetrical pattern of multifidus atrophy when compare to those dancers who had LBP and hip pain combined. They concluded that the changes in the CSA of the multifidus were not related to the side of the pain symptoms. Our results are more consistent with the findings of Gildea et al in that general, bilateral atrophy was observed in our subjects. In the study conducted by Hodges et al, their subjects underwent an acute injury to either the intervertebral disc or

the spinal nerve root, as compared to the study by Gildea et al, where subjects included a history of LBP, but not necessarily of an acute nature. In our study, the subjects presented with a history of LBP, not exceeding a 12 month period, and none were of an acute nature. A possible explanation of why we observed a bilateral pattern of atrophic changes in the multifidus, as opposed to the findings of Hodges et al, may be the differences in the acute LBP subject versus the chronic LBP subject. In a study conducted by Macdonald et al¹⁶ they demonstrated that subjects with reoccurring LBP had a greater percent thickness change of the multifidus muscle during the prone straight leg raise task when compared to a healthy group and concluded that, during symptom remission, subjects with recurrent low back pain may have greater activity in at least some portion of the lumbar multifidus. Our study included subjects with a history of LBP within the past 12 months and did not differentiate between the various lengths of time a participant experienced symptoms within the past 12 months. Therefore, those individuals with symptoms of a more chronic nature may have demonstrated a greater percent change in the CSA of the multifidus when compared to those subjects who presented with symptoms of a shorter duration.

The chronicity of the LBP symptoms requires further investigation and may explain why, in our study, we did not observe a purely ipsilateral atrophic change in the CSA of the multifidus, but rather a bilateral relative CSA change.

Specific Aim 4

The fourth, and final, aim of this study was to determine if the findings from the MPSLR test correlated with patient self-report of disability as measured by the Oswestry Low Back Disability Questionnaire. The results of this study demonstrated that an association exists between asymmetry in the CSA of the multifidus within subjects and

higher scores on the Oswestry questionnaire. This significant relationship was also seen when comparing asymmetry of multifidi CSA, relative atrophy, a positive MPSLR, and pain (MPSLR *p*-value < .001, pain p = .001, OR 27.12). Since data from the results of this study had already revealed a significant association between the MPSLR test and pain, and a significant association between asymmetry in the multifidus within subjects (relative atrophy) and a positive MPSLR test, it is logical to expect to observe an association between the MPSLR test and the Oswestry. Our results demonstrated that the lower a subject scored on the Oswestry, the more symmetrical the CSA of their multifidus. Conversely, the higher a subject scored on the Oswestry, the more asymmetry of the multifidus. Since the Oswestry measures disability levels based on pain, these findings are consistent with the data that demonstrated a strong association between a positive MPSLR test and pain. Therefore, the MPSLR appears to be a very good predictor of pain, as demonstrated with the logistic regression model, which may predict self-reported disability levels. Both the Oswestry and the MPSLR test contributed an independent assessment of pain status and are also valuable independent indicators of pain, with an odds ratio of 38.2, in the model. The odds ratio is important because it states how much the odds change given a positive MPSLR or an increase in Oswestry score. That is to say that a positive MPSLR test increases the odds of having pain 38.2 times over baseline odds. For each one point increase in Oswestry score, the odds of having pain induced disability increases by a factor of 1.27. The standard errors were computed using the sample sizes, and the large standard error for MPSLR of 1.30 appears to be the reason that a wide range in estimates for the 95% confidence interval exists. (2.96, 492.75).

Despite the very wide confidence interval, the odds ratio for MPSLR is still very high and very significant. Using larger sample sizes will make the denominators larger in the estimate for the standard error. Using larger samples will also help narrow down the confidence interval so that a better estimate of the odds ratio can be found. From this preliminary study, the MPSLR looks to be a very powerful indicator of pain and deserves further study.

Based on the model, when the Oswestry score are >25, the MPSLR can be predicted as being positive. When the MPSLR test is positive, it can serve as a predictor of pain, independent of the Oswestry questionnaire however, the Oswestry can be used to reinforce the degree of self-reported disability. The MPSLR test also demonstrated a sensitivity of 86% in identifying the presence of LBP and may be a useful tool to identify those patients who may present with LBP symptoms on an inorganic nature. Given that a positive MPSLR test is strongly associated with pain and asymmetry of the multifidus, and the Oswestry is strongly associated disability due to pain, it can be deduced that scores > 25 on the Oswestry can be used to predict the likelihood of having asymmetry of the multifidus.

Both the Oswestry and the MPSLR test are easy assessment tools to administer in the clinical setting. The MPSLR test is extremely cost-effective as it requires no forms or equipment and can be performed very quickly during a routine examination to verify reported pain and could be refined for a wider application.

LIMITATIONS

There are several limitations to our study that necessitate attention. Our sample of subjects included only 66 participants. In previous studies that investigated the CSA of the multifidus, as many as 120 subjects were used⁴⁸. We believe that the smaller number of participants in our study contributed to a very large confidence interval when assessing the relationship between the Oswestry Low Back Disability Questionnaire and the results of the MPSLR test. The smaller number of participants further limited our study by way of a disproportionate distribution between males and females. Our study consisted of 46 males but only 20 females. More importantly, the no LBP group contained only 4 females, as compared to 26 males in the same group. This may have skewed the association between a MPSLR test and self-reported pain as this small group of females may have had a lower pain tolerance than their counterparts. Future studies that include a larger sample size and more homogeneity of the groups should reduce the confidence interval and provide more accurate results.

In our study, the BMI of each subject played no major role in the findings however, we did not differentiate between waist circumference sizes between subjects. BMI measurements can be misleading and should not be used as an indicator of waist size as muscle tends to be denser than adipose tissue. A cubic inch of muscle tissue would weigh more than a cubic inch of adipose tissue, resulting in any two subjects of the same height weighing differently with exact waist sizes. This may have explained why BMI played no role in our findings. Waist size, however, may play a more significant role in the testing procedure than BMI alone. We did not investigate the association between waist circumference and the MPSLR test. It can be hypothesized that with a

larger waist circumference, the excursion of pelvic drop during the MPSLR test may be decreased as the pelvis could potentially be supported by the larger abdominal region. This may have led to a small number of positive MPSLR test and a larger number of false negative tests. Future studies are warranted to investigate this potential relationship.

We acknowledge that our testing protocol may have contained measurement error when recording the CSA of the multifidus as we did not standardize the height in which each participant lifted their lower extremity during the MPSLR test. We are unsure as to how height of the leg lift affected the quality of the muscle contraction of the multifidus. In our experience, the anterior translation of the pelvis is observed and palpated immediately upon unweighting the limb from the surface of the table however, we cannot be certain that the force production or motor recruitment of the multifidus is not altered in any manner due to the height of the limb lift. Future studies involving a standardized limb lift height is warranted.

Another limitation of this study is the experience level of the investigator in the use of RUSI. The investigator of this study is a novice sonographer, with only a few weeks of experience in the use of RUSI. The investigator was trained to visualize and measure the multifidus muscle by an experienced sonographer with greater than one year of experience however, the practice hours were limited due to time constraints and a limited number of practice participants. We acknowledge that the margins of our measurements may not be as precise as possible and therefore, measurement error was likely to occur. Combining a small sample size with the limited experience in sonography of the investigator may explain why our CSA averages differed from the published norms.

The inclusion criteria for the symptomatic group in our study included LBP symptoms within the past 12 months. We did not identify or factor in the length of time of the LBP symptoms of each participant, therefore we are unsure of how chronicity of symptoms affected the results of our study. Some authors describe a reduced activation of the multifidus in the acute stage while others have reported an increase in, at least, some fibers of the multifidus in chronic or reoccurring LBP symptoms. Not factoring in the length of LBP symptoms may have limited the result of this study and future studies are required to investigate the relationship between the chronicity of the LBP symptoms and unilateral versus bilateral atrophy of the multifidus.

Finally, the low average of all Oswestry scores in the LBP group may have also contributed negatively to our study. The average disability score amongst all subjects was 19.45%, (Males 16.1%, Females 22.6%) indicating only a minimal level of disability. We are unsure as to whether or not subjects with a higher severity of disability rating would perform differently. Further investigation into the use of the MPSLR test with moderate to severely disabled subjects is warranted.

DELIMITATIONS

The CSA of the multifidus muscle can be affected by many variables. Athletic training regimens such as those requiring lumbar extension activities may result in a hypertrophy of the multifidus muscle.³⁶ Conversely, certain pathological process, such as lumbar radiculopathy, neurological conditions affecting the central nervous system, and surgical procedures that have altered the normal anatomical structure and/or the physiological functions of the multifidus could hinder the subject's ability to perform or complete the required tasks of this study.^{37,41} These factors were accounted for by the exclusion criteria, giving assurance that there was no history of recent specific muscle strength training, surgery or neurological conditions amongst our subjects.

Age related atrophy could also have an effect on the CSA and function on the multifidus, as well as having a history of chronic pain greater than 1 year.⁵³ Our inclusion criteria limited the participants to no older than 55 years and history of chronic LBP no greater than 12 months.

CLINICAL RELEVANCE

The MPSLR test appears to be a good, cost-effective assessment tool, which can be used to identify patients who not only present with asymmetry of the multifidus muscle, but who are at risk for LBP symptoms due to asymmetrical changes in the lumbar multifidus muscle. The MPSLR test requires no major training, no equipment, and can be administered quickly and safely to patients presenting with LBP symptoms. The MPSLR test can also be used to aid in directing an appropriate rehabilitation approach to those patients in need of specific multifidus exercise prescription.

SUMMARY

Many cases of low back pain (LBP) are associated with lumbar segmental instability (LSI), yet there is no single test that all clinicians can rely on to confirm the instability while identifying a causative factor, such as muscle weakness. The definition of LSI has evolved over the past several decades, but the most widely accepted description was proposed by Panjabi in 1992.² His model gave way to the definition of LSI as being "a significant decrease in the capacity of the stabilizing system of the spine to maintain the intervertebral neutral zones within the physiological limits so that there is no neurological dysfunction, no major deformity, and no incapacitating pain."³ The challenge, then, is for the clinician to identify the exact subsystem at fault.

LSI is typically diagnosed by assessing the retrodisplacement (anterior-toposterior translation) of lumbar vertebrae on lateral radiographs taken at end range spinal flexion and extension.^{4,5} Many researchers have described clinical tests for the detection of LSI,^{2,6-8} the most routinely employed tests are the passive lumbar extension test (PLE) and the prone instability (PI) test. Both of these tests have not only demonstrated a limited ability to detect LSI,^{8,9} they are unable to identify which of the subsystems, as described by Panjabi, is the causative factor that results in a positive test.

Electromyography (EMG) can be used to detect the level of activity of a contracting muscle and is currently considered the gold standard for assessing a suspected case of LSI due to multifidus weakness however, surface electrodes are capable to record muscle activity in superficial muscle and require indwelling needles to reach the deeper musculature. Therefore, EMG is invasive, costly, and considered inappropriate in routine physical therapy clinical practice.¹⁰

Rehabilitative Ultrasound Imaging (RUSI) has emerged as a clinical tool that physical therapists can use to detect the alterations in neuromuscular control. Research has shown that RUSI is a valid discriminative tool for measuring deep trunk muscular contraction in subjects with LBP,¹¹ but most studies that target the multifidus using RUSI fail to make a correlation

In motions that require lumbar extension, for example, the activity level of the multifidus (78%) is greater than that of the iliocostalis lumborum muscle (65%).¹⁴ Given the fact that lumbar extension activates the multifidus muscle, it can be concluded that sagittal plane motions of the extremities that intersect the coronal plane will also activate the multifidus, as seen in activities such as the prone straight-leg raise. Therefore, it can be hypothesized that if a subject performed a prone straight-leg raise maneuver and the ipsilateral pelvis were unable to maintain its orientation in the transverse plane, the contralateral multifidus can be identified as the weak muscle contributing to pelvic displacement. The prone straight-leg raise (PSLR) maneuver may serve as a valid clinical tool that can be utilized by clinicians to detect weakness of the multifidii muscles.

The aim of this study was to seek a relationship between the results of a modified prone straight-leg raise test (MPSLR) and RUSI to identify patients that present with LSI due to a decrease in multifidus cross sectional area (CSA). We further investigated the clinical relevance of the MPSLR test and changes in the CSA of the multifidus muscle (which were measured using RUSI), as well as correlating MPSLR and RUSI findings with the presence of low back pain symptoms that interfere with regular daily activities. Self-reported functional limitations were assessed using the Oswestry Low Back Pain Questionnaire.^{19,20}

Participants consisted of two groups of subjects. One group (N=30) comprised individuals in general good health, aged 18-55, without history of back pain. The second group (N=36) comprised individuals aged 18-55, with history of low back pain within the past 12 months. Subjects performed a MPSLR test to identify multifidus weakness. All subjects, regardless of testing results, repeated the same test with concurrent RUSI to visualize the muscle and measure its CSA.

Functional assessment was recorded by self-reporting using the Oswestry Disability Questionnaire. Data analysis tested for significant differences between groups (p<0.05) in MPSLR results, CSA by RUSI, and Oswestry percent scores using two-way ANOVA for ratio variables and Chi-square testing for MPSLR. A regression model was created with MPSLR results (dichotomous) and CSA measured by RUSI (ratio) as predictor variables and Oswestry percent scores as the dependent variable (ratio computed from an ordinal scale, as validated in the literature).

A chi-square test of association between pain and the MPSLR test revealed a significant association between a positive MPSLR and the presence of pain. A sensitivity of 86% and a specificity of 60% was also discovered in the ability of the MPSLR test to predict pain.

The results of this study also revealed that the cross-sectional area of the multifidi muscles was not significantly different in the LBP versus the no LBP group (ANOVA *p*-value = .676) however, the CSA averages were significantly different from the published norms of 7.87 \pm 1.85 for male CSA (*t*-test, *p* < .001) and 5.55 \pm 1.28 for female CSA (*t*-test, *p* = .007).

The linear model failed to show a linear correlation between a positive MPSLR and moderate reduced CSA average, as verified by a MANOVA (p = .835) (r = .049, ppmc test p = .696). However, there was an association between a positive MPSLR and asymmetry of the multifidi between the left and the right side between subjects. Sensitivity and specificity were calculated and revealed a sensitivity of 94% and a specificity of 63% in the ability of the MPSLR test to detect asymmetry of the multifidus muscle within subjects.

A weak linear correlation between the MPSLR and Oswestry test scores was observed at the 10% level; however, it did not reach significance at the 5% level (PPMC, r = .222, p = .074). Additionally, a chi-square test for association between Oswestry score and a positive MPSLR test confirmed no significance (p = .106, Kappa = .18, OR = 2.39). Oswestry test scores (medial cut) were significantly associated with pain status (p <.001). The independence of MPSLR and Oswestry score (as covariate) was confirmed by a binary logistic regression model to predict pain status (model p < .001; MPSLR p =.005, OR = 38.2; Oswestry p = .001, OR = 1.27). A positive MPSLR was a strong indicator of pain, and a positive MPSLR combined with a high Oswestry score of 25-30 further reinforced the probability of pain. The model was significant (p-value < .001) and can be used to predict the probability of a patient having pain using the Oswestry and the MPSLR. Given that a positive MPSLR test is strongly associated with pain and asymmetry of the multifidus, and the Oswestry is strongly associated with pain, it can be deduced that scores > 25 on the Oswestry can be used to predict the likelihood of having asymmetry of the multifidus.

Although we did not demonstrate that a correlation existed between a positive MPSLR test and a decrease in multifidus CSA in the LBP group, compared to the no-LBP group, the MPSLR test appears to be a valid tool to predict and verify pain symptoms arising from the lumbar region. The MPSLR test also demonstrated a strong association between a positive test and asymmetry of the multifidus muscle within subjects. These findings may serve to assist a clinician in determining a rehabilitation plan of care that targets the multifidus muscle without the use of expensive, training dependent, equipment such as RUSI.

RECOMMENDATIONS

Based on the results of this study, as well as its limitations, the following recommendations are made:

Our study included only 66 participants, with an extremely small number of females in the no LBP group (n=4). Using larger samples and more homogeneity of the groups will help narrow down the confidence interval so that a better estimate of the odds ratio can be found while providing more accurate results.

There appears to be an association between the asymmetry of the multifidus within subjects and LBP symptoms. Future studies are required to establish the relationship between chronicity of the LBP and ipsilateral versus bilateral CSA change. As well, waist circumference may have an impact on the MPSLR test's ability to differentiate between a positive and negative test. Future studies are required to identify if a relationship exists between the MPSLR test and waist circumference and whether that relationship is associated with function. In our study, the LBP subjects were identified by the Oswestry Low Back Disability Questionnaire as having minimal disability. Further investigation into the use of the MPSLR test in subjects with moderate to severe disability is warranted.

Finally, well-established protocols are needed for measuring gender-specific CSA of the multifidus, while at rest and during contraction, in both symptomatic and asymptomatic subjects.

APPENDIX A

NOVA SOUTHEASTERN UNIVERSITY IRB APPROVAL



MEMORANDUM

| To: | Mitchell T Maione, DPT, PhD(c) College of Health Care Sciences |
|-------|--|
| From: | Rose Colon, PhD, Center Representative, Institutional Review Board |
| Date: | July 27, 2016 |
| Re: | IRB #: 2016-314; Title, "The Correlation between Rehabilitative Ultrasound Imaging and the Prone Straight Leg Raise Test to Identify Multifidus Weakness." |

I have reviewed the above-referenced research protocol at the center level. Based on the information provided, I have determined that this study is exempt from further IRB review under **45 CFR 46.101(b)** (**Exempt Category 2)**. You may proceed with your study as described to the IRB. As principal investigator, you must adhere to the following requirements:

- 1) CONSENT: If recruitment procedures include consent forms, they must be obtained in such a manner that they are clearly understood by the subjects and the process affords subjects the opportunity to ask questions, obtain detailed answers from those directly involved in the research, and have sufficient time to consider their participation after they have been provided this information. The subjects must be given a copy of the signed consent document, and a copy must be placed in a secure file separate from de-identified participant information. Record of informed consent must be retained for a minimum of three years from the conclusion of the study.
- 2) ADVERSE EVENTS/UNANTICIPATED PROBLEMS: The principal investigator is required to notify the IRB chair and me (954-262-5369 and Rose Colon, PhD, respectively) of any adverse reactions or unanticipated events that may develop as a result of this study. Reactions or events may include, but are not limited to, injury, depression as a result of participation in the study, lifethreatening situation, death, or loss of confidentiality/anonymity of subject. Approval may be withdrawn if the problem is serious.
- 3) AMENDMENTS: Any changes in the study (e.g., procedures, number or types of subjects, consent forms, investigators, etc.) must be approved by the IRB prior to implementation. Please be advised that changes in a study may require further review depending on the nature of the change. Please contact me with any questions regarding amendments or changes to your study.

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: Alicia Fernandez-Fernandez, PT, DPT, Ph.D.

APPENDIX B

STAATS PHYSICAL THERAPY APPROVAL LETTER



July 20, 2016

Nova Southeastern University 3301 College Avenue Fort Lauderdale, FL 33314-7796

Subject: Site Approval Letter

To whom it may concern:

This letter acknowledges that I have received and reviewed a request by Mitchell T. Maione, PT. DPT, PhD(c), OCS, MTC, CFC to conduct a research project entitled "The Correlation between Rehabilitative Ultrasound Imaging and the Prone Straight Leg Raise Test to Identify Multifidus Weakness." at Staats Physical Therapy and I approve of this research to be conducted at our facility.

When the researcher receives approval for his/her research project from the Nova Southeastern University's Institutional Review Board/NSU IRB, I agree to provide access for the approved research project. If we have any concerns or need additional information, we will contact the Nova Southeastern University's IRB at (954) 262-5369 or irb@nova.edu.

Sincerely,

Daniel Staats, PT, DPT, OCS, MTC Owner staatsphysicaltherapy@yahoo.com

staatsphysicaltherapy@yahoo.com

www.stnatspt.com

APPENDIX C

SUBJECT CONSENT TO PARTICIPATE FORM

Consent Form for Participation in the Research Study Entitled: The Correlation between Rehabilitative Ultrasound Imaging and the Prone Straight Leg Raise Test to Identify Multifidus Weakness.

Funding Source: None.

IRB protocol #:

| Principal investigator(s) | Co-Investigator: | |
|--|---|--|
| Mitchell T. Maione, PT, DPT, OCS, MTC, CFC | Alicia Fernandez-Fernandez, PT, DPT, PhD | |
| 501 Juniper Spring Ct | Associate Professor, Physical Therapy Dept. | |
| Saint Augustine, FL 32092 | Nova Southeastern University | |
| Phone: 732-245-0632 | 3200 S. University Dr., Fort Lauderdale, FL 33328 | |
| | Phone: (954) 262 1653 | |

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

Study site: Staats Physical Therapy 489 Brick Boulevard Brick, NJ 08723

What is the study about?

The proposed study seeks to identify weakness of the back muscles using a quick test called the modified prone straight-leg raise test (MPSLR). The results of this test will be compared to images of the muscles obtained using ultrasound. One goal of the study is to determine if the MPSLR test results can help identify patients with muscle weakness, and whether these results are consistent with the information from ultrasound measurements. We also want to learn more about the relationship between muscle weakness and low back instability.

Why are you asking me?

We are inviting you to participate because the research study involves the assessment of lumbar muscle strength in approximately 60 individuals between the ages of 18 to 55, with or without a history of back pain.

Initials _____ Date____

Page 1 of 3

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

You will enter a treatment room where an investigator will conduct an initial medical history screening and provide you with a standardized low back pain disability questionnaire. Upon completion of the initial medical screening, you will be asked to lie face down on a treatment table and will be instructed in performing a MPSLR test. The test requires you to lay face down and lift one leg at a time towards the ceiling when instructed, while the investigator has a hand positioned on your pelvis. The results of the test will be documented by the investigator. You will then be asked to continue to lie face down and will undergo an ultrasound imaging assessment of the muscles of your low back. While in this position you will be asked to perform the MPSLR test again. The imaging results will also be documented. Your total participation time in the study will take approximately 30 minutes.

Is there any audio or video recording?

There are no audio or video recordings taking place in this study.

What are the dangers to me?

Risks to you are minimal, meaning they are not thought to be greater than other risks you experience every day. Ultrasound imaging is a non-invasive procedure and is routinely used to visualize the fetus in pregnant women. You will be screened for any contraindications for ultrasound use during the medical screening portion of the study. The performance of the MPSLR test is also a non-invasive maneuver which requires you to lay face down and lift one leg at a time towards the ceiling. This should not cause and harm or pose any dangers to you however, if you feel any discomfort at all during the procedure we will immediately halt your participation. If you have questions about the research please contact Mitchell Maione at 732-245-0632. You may also contact the IRB at the numbers indicated above with questions about your research rights.

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

Although we cannot claim that you will benefit from this study, there is the possibility that you may be identified as having weakness in your multifidus muscle and may receive free advice as to the prevention and/or management of low back pain.

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

There are no costs to you or payments made for participating in this study.

How will you keep my information private?

All study information that includes identifying information such as your name including this signed consent form will be kept in a secure location. No identifying or other information about you will be disclosed within this study. This information may be analyzed in the future by other investigators. The other investigators will only be given your information identified by a study code. The medical history forms and disability questionnaires from this study will be destroyed 36 months after the study ends. All information obtained in this study is strictly confidential unless disclosure is required by law. The IRB, regulatory agencies, or research investigators may review research records. Initials _____ Date_____ Page 2 of 3

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.

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 "The Correlation between Rehabilitative Ultrasound Imaging and the Prone Straight Leg Raise Test to Identify Multifidus Weakness."

| Participant's Signature: | Date: |
|--|-------------|
| Participant's Name: | Date: |
| Signature of Person Obtaining Consent: | |
| Date: | |
| Initials Date | Page 3 of 3 |

APPENDIX D

MEDICAL HISTORY AND DATA COLLECTION FORM

Medical history form for inclusion/exclusion of the following research project:

The Correlation between Rehabilitative Ultrasound Imaging and the Prone Straight Leg Raise Test to Identify Multifidus Weakness.

Sex: M F

Age: _____

Inclusion Criteria:

Have you ever had low back pain ? Y N If Yes, have you experienced pain within the past 12 months? Y N

Exclusion Criteria:

Do you ever been diagnosed with, or have had in the past, any of the following:

- Y N History of lumbar surgery
- Y N Lumbar radiculopathy
- Y N Previous athletic training that would have resulted in hypertrophy of the multifidii muscle
- Y N Neurological conditions resulting in muscle weakness that would affect their ability to complete the testing procedures
- Y N The inability to lie prone (on Belly)
- Y N The inability to understand English

Data Collection:

| Pain: | Right (+) | (-) | Left (+) | (-) |
|-------------|-----------|-----|----------|-----|
| MPSLR Test: | Right (+) | (-) | Left (+) | (-) |

RUSI:Right _____cmLeft ____cm

APPENDIX E

RESEARCH FLYER

RESEARCH PARTICIPANTS NEEDED

PURPOSE: To examine the relationship between lumbar spine muscle strength and low back pain, using a clinical test and ultrasound imaging. **ELIGIBILITY:** We are looking for males and females aged 18-55. We would like to have some participants who HAVE NOT had low back pain in the past 12 months; as well as some participants who HAVE had low back pain in the past 12 months. Either group may volunteer as long as they are within the age range. **REQUIREMENTS**: Participating in the study would require you to lie face down for approximately 15 minutes. Also, we are looking for participants who do not have a history of low back surgery and other medical issues. If you volunteer, you will complete a screening questionnaire about your medical history to ensure that you are eligible to participate. **BENEFITS:** It is unlikely that you will gain any direct benefits or significant risk by participating in this study. The primary benefit is to gain new knowledge. If you take part in this study, you may be helping others in the future! **CONTACT:** If you, or anyone you know, might be interested in participating in this study, please contact Dr. Maione. Mitchell T. Maione, PT, DPT, PhD(c), OCS, MTC, CFC Primary Investigator Director, Physical Therapist Assistant Program Keiser University, Jacksonville mmaione@keiseruniversity.edu 904-296-3440

APPENDIX F

OSWESTRY LOW BACK PAIN DISABILITY QUESTIONNAIRE Oswestry Low Back Pain Disability Questionnaire

Sources: Fairbank JCT & Pynsent, PB (2000) The Oswestry Disability Index. Spine, 25(22):2940-2953.

Davidson M & Keating J (2001) A comparison of five low back disability questionnaires: reliability and responsiveness. *Physical Therapy* 2002;82:8-24.

The Oswestry Disability Index (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test is considered the 'gold standard' of low back functional outcome tools ^[1].

Scoring instructions

For each section the total possible score is 5: if the first statement is marked the section score = 0; if the last statement is marked, it = 5. If all 10 sections are completed the score is calculated as follows:

Example: 16 (total scored)

50 (total possible score) x 100 = 32%

If one section is missed or not applicable the score is calculated:

16 (total scored)

45 (total possible score) x 100 = 35.5%

Minimum detectable change (90% confidence): 10% points (change of less than this may be attributable to error in the measurement)

Interpretation of scores

| 0% to 20%: minimal disability: | The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise. | |
|--------------------------------|---|--|
| 21%-40%: moderate disability: | The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means. | |
| 41%-60%: severe disability: | Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation. | |
| 61%-80%: crippled: | Back pain impinges on all aspects of the patient's life. Positive intervention is required. | |
| 81%-100%: | These patients are either bed-bound or exaggerating their symptoms. | |
| | | |

Oswestry Low Back Pain Disability Questionnaire

Instructions

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem.

Section 1 - Pain intensity

- I have no pain at the moment
- The pain is very mild at the moment
- The pain is moderate at the moment
- The pain is fairly severe at the moment
- The pain is very severe at the moment
- The pain is the worst imaginable at the moment

Section 2 - Personal care (washing, dressing etc)

- I can look after myself normally without causing extra pain
- I can look after myself normally but it causes extra pain
- It is painful to look after myself and I am slow and careful
- I need some help but manage most of my personal care
- I need help every day in most aspects of self-care
- I do not get dressed, I wash with difficulty and stay in bed

Section 3 - Lifting

- I can lift heavy weights without extra pain
- I can lift heavy weights but it gives extra pain
- Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eq. on a table
- Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- I can lift very light weights
- I cannot lift or carry anything at all

Section 4 – Walking*

- Pain does not prevent me walking any distance
- Pain prevents me from walking more than 2 kilometres
- Pain prevents me from walking more than 1 kilometre
- Pain prevents me from walking more than 500 metres
- I can only walk using a stick or crutches
- I am in bed most of the time

Section 5 - Sitting

- I can sit in any chair as long as I like
- I can only sit in my favourite chair as long as I like
- Pain prevents me sitting more than one hour
- Pain prevents me from sitting more than 30 minutes
- Pain prevents me from sitting more than 10 minutes
- Pain prevents me from sitting at all

Section 6 - Standing

- I can stand as long as I want without extra pain
- I can stand as long as I want but it gives me extra pain
- Pain prevents me from standing for more than 1 hour
- Pain prevents me from standing for more than 3 minutes
- Pain prevents me from standing for more than 10 minutes
- Pain prevents me from standing at all

Section 7 - Sleeping

- My sleep is never disturbed by pain
- My sleep is occasionally disturbed by pain
- Because of pain I have less than 6 hours sleep
- Because of pain I have less than 4 hours sleep
- Because of pain I have less than 2 hours sleep
- Pain prevents me from sleeping at all

Section 8 - Sex life (if applicable)

- My sex life is normal and causes no extra pain
- My sex life is normal but causes some extra pain
- My sex life is nearly normal but is very painful
- My sex life is severely restricted by pain
- My sex life is nearly absent because of pain
- Pain prevents any sex life at all

Section 9 - Social life

- My social life is normal and gives me no extra pain
- My social life is normal but increases the degree of pain
- Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport
- Pain has restricted my social life and I do not go out as often
- Pain has restricted my social life to my home
- I have no social life because of pain

Section 10 - Travelling

- I can travel anywhere without pain
- I can travel anywhere but it gives me extra pain
- Pain is bad but I manage journeys over two hours
- Pain restricts me to journeys of less than one hour
- Pain restricts me to short necessary journeys under 30 minutes
- Pain prevents me from travelling except to receive treatment

*Note: Distances of 1 mile, ½ mile and 100 yards have been replaced by metric distances in the Walking section

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