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EMG analysis of latissimus dorsi, erector spinae, and middle trapezius muscle activity during spinal rotation: a pilot study

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EMG ANALYSIS OF LATISSIMUS DORSI, ERECTOR SPINAE, AND MIDDLE TRAPEZIUS MUSCLE ACTIVITY DURING SPINAL ROTATION: A PILOT STUDY

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In partial fulfillment of the requirements
For the degree of

Doctor of Physical Therapy

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This Scholarly Project, submitted by Hunter Huberty, Jacob Klingbeil, Michael Miller, and Michael Utt, in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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Title          EMG Analysis of Latissimus Dorsi, Erector Spinae, and Middle Trapezius
               Muscle Activity during Spinal Rotation: A Pilot Study

Department     Physical Therapy

Degree         Doctor of Physical Therapy

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Date          October 23, 2017
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ABSTRACT

Purpose/Hypothesis: Rotation of the spine is a common movement used for completing daily activities and participating in sports. As a contributing factor to back injuries, the performance of spine rotation is an important consideration for the rehabilitation and prevention of future back injury. Muscles involved in spine rotation have been researched, though limited findings exist for one of the largest back muscles: Latissimus Dorsi (LD). The LD muscle contributes to many movements of the trunk and limbs given its multiple attachment sites including the pelvis, scapula, ribs and humerus. Influence of the LD on spine rotation, however, has not been thoroughly researched. The purpose of this study was to increase understanding and compare muscle activity of LD during open and closed kinetic chain activities to other back muscles.

Materials/Methods: Latissimus dorsi muscle activity was recorded using surface electrodes while subject performed left and right rotation in both standing and quadruped positions. Four spinal rotation test positions (standing rotation right/left, quadruped rotation right/left) were initiated by movement of the pelvis. Using Maximal Voluntary Contraction (MVC) to normalize muscle activity of the LD, findings were analyzed for significance at $\alpha=.05$.

Results: In fixed positioning, the LD activity was significantly greater than the L middle trapezius (MT) and L erector spinae (ES) during right rotation. In non-fixed positioning, the ES activity was significantly greater than the MT and LD for both right and left rotation and both right and left sides. No other significant differences were found in either positions.

Discussion/Conclusions: Our findings suggest the LD significantly contributes to fixed position contralateral spinal rotation when compared to MT and ES. In fixed positioning, the LD may be
mechanically advantaged to contribute to spinal rotation, whereas in non-fixed positioning, the LD may be mechanically disadvantaged to contribute to spinal rotation compared to the ES.

**Clinical Relevance:** Our findings suggest clinicians should consider the LD as significant contributors to spinal rotation. Treatment of patients with back pain should involve thorough examination and specific interventions addressing LD strength and mobility.
CHAPTER I
INTRODUCTION

Low back pain is one of the most common reasons patients visited physicians in the United States. About two-thirds of people in the United States experienced low back pain at least once in their life. Direct medical costs of low back pain in 2010 were estimated at $34 billion. The effects of low back pain have more than just an economic impact; an individual's quality of life and functional level were diminished by low back pain as well. When polled to classify their level of back pain, 23% of patients with low back pain used the term "disabling" to describe their symptoms. Lifting injuries in the workplace presented a significant risk factor in acquiring low back pain; 30% of workers were found to lift in a manner that is harmful to their back. Improper lifting with spinal rotation contributed to risk of developing low back pain, with 60% of low back injuries having involved a spinal rotation component.

Interventions by physical therapists for treatment of low back pain included therapeutic exercise targeting muscles of the pelvic floor, transversus abdominis, oblique abdominals, and quadratus lumborum. While targeting these muscles has been shown to improve symptoms of low back pain, interventions addressing the latissimus dorsi (LD) for the treatment of low back pain is less understood by the medical profession.

Problem Statement

The proximal attachments of the LD are the following: spinous processes of T7 to L5 vertebrae, sacrum, iliac crest, lower three or four ribs, inferior angle of scapula, and thoracolumbar fascia (TF). The distal attachment of the LD is the floor of the intertubercular groove of the humerus. Primary actions of the LD are recognized as shoulder adduction, shoulder medial rotation, and shoulder extension. Research regarding the LD has primarily focused on
upper extremity movements with limited research on the LD's influence during spinal rotation.

The erector spinae (ES) muscle group is commonly recognized as the primary agonist of spinal rotation, its attachments on the spinous processes and angle of pull is ideal for spinal rotation. Latissimus dorsi also has attachments on the spinous processes of T7 to L5 vertebrae. These attachments potentially allow the LD to contribute to spinal rotation in a way similar to ES. Therefore, understanding the magnitude of LD muscle activity during spinal rotation may impact the types of rehabilitative interventions for patients with spinal pathology.

Purpose of Study

The purpose of this study was to analyze muscle activity of back muscles (ES, LD, and middle trapezius (MT)) while subjects performed spinal rotation in positions with and without fixation of the upper extremities. Evidence from this study is valuable in defining the extent of LD activity in spinal rotation which may lead to improved interventions for clients with low back pain.

Significance of Study

The field of physical therapy would benefit from a greater understanding of the contribution LD makes in spinal rotation. Standard interventions for back pain address muscular imbalances which contribute to excessive stress and strain on tissues and structures of the spine. The findings of this study will help physical therapists better understand the contributions of LD, ES, and middle trap (MT) to spinal rotation. Based on the findings of study, future research may be appropriate investigating muscle activity in patients with low back pain.

Research Questions

1.) Will LD activation during fixed upper extremity spinal rotation differ significantly than non-fixed upper extremity spinal rotation?

2.) Will LD activity significantly differ than ipsilateral MT and ES activity during fixed upper extremity spinal rotation?
3.) Will LD activity significantly differ than ipsilateral MT and ES activity during non-fixed upper extremity spinal rotation?

Null Hypothesis

1.) There is no significant difference in LD EMG activity (%MVC) between fixed and non-fixed spinal rotation.

2.) There is no significant difference in LD activation compared to the ipsilateral MT and ES during fixed upper extremity spinal rotation.

3.) There is no significant difference in LD activation compared to the ipsilateral MT and ES during non-fixed upper extremity spinal rotation.

Alternative Hypothesis

1.) There is significant difference in LD EMG activity (%MVC) between fixed and non-fixed spinal rotation.

2.) There is significant difference in LD activation compared to the ipsilateral MT and ES during fixed upper extremity spinal rotation.

3.) There is significant difference in LD activation compared to the ipsilateral MT and ES during non-fixed upper extremity spinal rotation.
CHAPTER II
LITERATURE REVIEW

The numerous muscular and ligamentous attachments of the spine often make diagnosing and treating spinal pathologies quite difficult. In order to properly rehabilitate and prevent future injuries, the spinal anatomy, function, and biomechanics must be examined closely.

The LD is a trunk muscle whose effect on spinal rotation is often forgotten or unappreciated in the therapy setting. The role the LD muscle plays at its insertion, the humerus, is usually given more consideration than its action on the spine. Though its largest connection is with thick TF, the fascia attaches to the spinous processes of the lumbar spine. Therefore, the LD not only has direct attachment to the T7-T12 spinous processes, but also an indirect attachment to the lumbar spinous processes through the TF. Given these attachments to the spinous processes, axial rotation is definitely a feasible action the LD can have on the spine.

Research studies and published textbooks lack significant information as to the action the LD has on the spine.\textsuperscript{7-11} Currently there is limited published research that definitively determines the role of the LD with spinal rotations; therefore, this study was completed to investigate the role of the LD in regards to spinal rotation in fixed and non-fixed upper extremity positions.

Posterior Trunk Anatomy

The LD is the broadest of all the back muscles, with a wide array of origin attachment points as it makes its way to the intertubercular groove of the humerus. The superior iliac crest, lumbar fascia, spinous processes of T7-T12, ribs 9-12 (blending with the external oblique muscle)
and the inferior angle of the scapula are all the points of origin of the LD. Fibers are
differentiated throughout the muscle by their alignment. Inferior muscles fibers are more
vertically orientated, but as one moves more superiorly the fibers are more horizontal as they
come off the thoracic vertebrae. Innervation of the LD is supplied by the thoracodorsal nerve
(nerve roots C6-8) which is a branch of the posterior cord of the brachial plexus. The LD is
responsible for numerous actions of the humerus including: extension, medial rotation, and
adduction. With the humerus fixed, the LD can be more efficient in its actions on the spine and
scapula such as: depressing the shoulder girdle, downwardly rotating the scapula, elevation of the
pelvis, elevation of the trunk when the shoulders are flexed overhead, bilateral extension of the
trunk, ipsilateral trunk lateral flexion, and contralateral rotation of the trunk in theory. The
LD’s most powerful actions occur in activities with the arms overhead, such adducting a raised
arm against resistance, and elevation of the trunk as seen with a pull up. It has also been found
that the LD can be used as an accessory respiratory muscle, when the humerus is fixed, for forced
expiration during high intensity activity.

With the LD’s origin in the lumbopelvic region as well as its insertion on the proximal
humerus, it is clear that it has the largest anatomic moment arm acting on the spine. A majority
of the force generation of the LD comes from the large portion of the muscle fibers residing over
the lumbopelvic region despite also spanning a vast portion of the lower thoracic region: 64%
compared to 36%. The LD muscle is capable of more efficiently influencing lumbopelvic
movement, due to the long lever arm and the vast origin source. The LD’s potential to impact
spinal motion comes from a tensile force applied to the thoracolumbar fascia which is maximized
by the distance between its origin and insertion.

The LD muscle works to extend, medially rotate, and adduct the humerus. When these
actions are performed bilaterally during bending and lifting tasks, as an object is lifted closer to
the body, the already activated bilateral LD muscles work together to extend the lumbar spine. When there is not proper engagement of the LD, the upper extremities are allowed to move passively. This lack of LD activation causes increased strain on the extensor muscles of the spine due to their need for over activation to make up for the lack of LD assistance. During lifting tasks utilizing both upper extremities, the LD's activation allows equal distribution of forces on the lumbar spine. This information can be utilized to help prevent unnecessary stress on the tissues of the lumbopelvic region thereby reducing spinal pathology.

Because of the LD's powerful influence on the spine, it is important to review specific spinal anatomy to know what structures may be under abnormal stress if the LD does not properly function. The foundation of the body is the axial skeleton, consisting of the skull, spine, ribs, pelvis, and sternum. There are five divisions of the spinal column: 7 cervical vertebrae, 12 thoracic vertebrae each of which as a corresponding rib, 5 lumbar vertebrae, 5 sacral vertebrae, and 4 coccygeal vertebrae (sacral and coccygeal segments are usually fused in the adult skeleton). Each vertebrae is abbreviated alphanumerically cranially to caudally, C1-Co4. Intervertebral discs provide shock absorption and distribution of forces and are present between each vertebra throughout the non-fused portion of the spinal column except between the levels of the occiput and C1 and C1-C2. The axial skeleton is connected to appendicular skeleton by only 4 joints, one on each side of the body both superiorly and inferiorly, the sternoclavicular joints superiorly and the sacroiliac joints inferiorly.

A typical vertebral segment is divided into three divisions: a body, pedicles, and the laminae. Weight bearing throughout the spinal column is supplied by the vertebral body. The vertebral bodies become progressively larger as they move caudally, this increases their weight bearing capacity. The vertebral canal lies posterior to the vertebral body; its function is to protect the spinal cord. The posterior portion of the vertebrae is comprised of the spinous and transverse
processes, laminae, and articular processes. The spinous and transverse processes are the location of attachment for various muscular and ligamentous structures. The lamina forms the bridge between the spinous and transverse processes, whereas the anterior and posterior structures of the vertebrae are connected by the pedicles and exist to distribute muscle forces.

Inferior to the cervical vertebrae are the thoracic vertebrae. Thoracic vertebrae have transverse processes which are larger in size than lumbar and cervical vertebrae (excluding C1); these transverse processes provide support for the rib cage due to their articulation with the ribs. The thoracic vertebrae have spinous processes which are angled inferiorly into the transverse plane of the vertebra below and pedicles that are pointed directly posterior.

Wide vertebral bodies are required in the lumbar region to form a strong base of support and support the weight of the upper body. The short and thick pedicles and lamina create a sturdy posterior wall of the vertebral canal in the lumbar region. Lumbar transverse processes project laterally whereas the broad, rectangular shaped lumbar spinous processes project straight posteriorly. At the base of the spinal cord is a collection of nerve roots called the cauda equina which is housed within the spinal canal. The cauda equina begins around the level of L2 and extends into the triangular sacral canal which provides the protection the nerve roots require to remain functional.

The sacral portion of the spinal column follows the lumbar region. A typical sacrum is fused and composed of five vertebral segments; its main purpose is to distribute weight to the structures of the pelvis from the vertebral column. The superior sacrum which displays a large broad surface area articulates with the L5 vertebra. The pedicles of the sacrum are thick and extend laterally which allows them to increase support and stability in the region. Several muscles and connective tissue structures attach to the vertebrae and sacrum to provide additional stability and movement.
The zygapophyseal joint, intervertebral joints, and sacroiliac joints are the main joints located the lumbopelvic region. The structures share a common function of allowing the body weight, frictional, and ground reaction forces to be transferred throughout the entire lumbar spine. Assisting the joints to distribute forces as well as provide shock absorption are the important structures of the intervertebral discs. The discs contain the nucleus pulposus which is the viscous center portion and is surrounded the dense, protective annulus fibrosus which functions to contain the nucleus pulposus within the intervertebral disc. The nucleus pulposus shifts when weight is distributed to the intervertebral disc and adjusts to allow for better distribution of the forces acting on the body.

Due to the amount of bodily support supplied by the lumbosacral spine, increased stabilization is required in this region. This increased stabilization is proved by an aponeurotic connective tissue structure called the TF which is the main component of the fascial structures that surround the erector spinae muscles to provide additional stability and support for the lower spinal segments. The TF also play an important role in the stability of the bilateral sacroiliac joints through the attachments of the LD and gluteus maximus into the TF. The LD take origin from the TF, which attaches to the lumbar spinous processes, therefore giving the LD an indirect articulation with the lumbar spinous processes. The TF also attaches to the ilium near the posterior superior iliac spine as well as the sacrum. The TF provides a cover to the posterior surface of the ES. There may be many factors contributing to stiffness and tension of the TF due to the multiple insertions into this broad connective tissue structure. Stiffness and tension of the TF often leads to pain and limited range of motion of the lumbar spine.

The MT, ES, and multifidus are other important musculature that may contribute to spinal rotation in the posterior trunk. Similar muscle alignment to the superior portion of the LD can be found in the MT. The trapezius is comprised of upper, middle, and lower fibers. The
middle fibers run laterally from the T1-5 spinous processes and supraspinous ligaments, the origin, to its insertion on the superior lip of the crest on the spine of the scapula and the medial acromial margin. Cranial nerve XI (spinal accessory nerve) provides motor innervation to the MT which is active during scapular retraction, scapular stabilization.13

From lateral to medial, the iliocostalis, longissimus, and spinalis make up the three muscles of the ES group. All of the ES muscles originate from the TF and broad tendon which attaches itself to the sacrum, sacroiliac ligaments, sacral and inferior lumbar spinous processes, posterior iliac crest, as well as supraspinous ligaments. Inspection of the insertion of the iliocostalis by spinal section is: the angle of ribs 7-12 serve as the insertion for the lumborum portion, the angle of ribs 1-6 and transverse process of C7 serve as the insertion for the thoracic portion, and the transverse processes of C4-C6 serve as the insertion for the cervical portion. Inspection of the insertion of the longissimus muscle by spinal section is: the transverse processes and ribs in the thoracic region serve as the insertion for the thoracic portion, the transverse processes in the cervical region serve as the insertion for the cervical portion, and the mastoid process serves as the insertion for the capitis portion. Finally, the spinous processes of the middle to upper thoracic spine serve as the insertion for the thoracis and cervicis portion of the spinalis muscle and the capitis portion blends with the semispinalis capitis. These muscles will be referred to as a group called the ES for the purpose of this study.6

The ES group has been found to be the most prominent stabilizer of the lumbar spine when the muscles contract isometrically.19 The ES works bilaterally to extend the head, neck, and trunk. The entire muscle group also works eccentrically to control the descent of the trunk when bending forward. When working unilaterally, the ES laterally flexes and ipsilaterally rotates the spine. While deeper musculature aid in anchoring the lumbar vertebrae to the ilium, the ES aides in rotation of the lumbar spine through its prominent lever arm from its centrally located origin to
its laterally located insertion. The ES muscles have a posterior direction of pull to reduce anterior shearing forces that may occur between lumbar vertebrae and the sacrum. The ability to check rotary forces and increase compressive forces between various vertebral segments are added functions of the deep ES muscles in the lumbar region. Figure 1 shows the posterior surface anatomy of the LD, MT, and ES.

![Figure 1. The posterior surface anatomy of LD, MT, and ES](image)

**Biomechanics**

The most mechanically stable region of the spine is the thoracic region due to the ribs which attach posteriorly to the vertebrae of the thoracic spine, and anteriorly to the sternum. The amount of rotation the thoracic vertebral body can perform is limited by its articulation with the rib cage; however, the thoracic region contains more gross rotation than the lumbar region due to the larger number of segments. Intervertebral discs are thin in this region and orientation of articular facets are in the frontal plane. Thoracic vertebrae begin to change their shape as one transitions from the thoracic region to the lumbar region, starting to resemble more of a lumbar vertebra with articular facets facing the sagittal plane around T9. Table 1 lists the normal range of motion values for the lumbar and thoracic regions.
Table 1. Normal Range of Motion Values for Lumbar and Thoracic Spine

<table>
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<tr>
<th>Motion</th>
<th>Lumbar Spine (in degrees)</th>
<th>Thoracic Spine (in degrees)</th>
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<tr>
<td>Flexion</td>
<td>40-60</td>
<td>20-45</td>
</tr>
<tr>
<td>Extension</td>
<td>20-35</td>
<td>20-45</td>
</tr>
<tr>
<td>Lateral Flexion</td>
<td>15-20</td>
<td>20-40</td>
</tr>
<tr>
<td>Rotation</td>
<td>3-18</td>
<td>35-50</td>
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</table>

The focus of this study is the motion of spinal rotation and what muscles are most active during rotation. The orientation of the facet surfaces in the sagittal plane is the reason for greater flexion and extension movement than that of lateral flexion. During standing posture, a typical lumbar lordosis is 25-30 degrees. Spinal rotation is limited due to joint compression contralateral to the side of rotation stemming from the orientation of the apophyseal joints in the sagittal plane. The sacroiliac joint and multifidi muscles work together to stabilize the lumbar spine during rotation, while compression of the articular cartilage is produced with movement.

The sacrum can have an impact on movement as well, it is important not to neglect this impact. A 40 degree angle is present between the horizontal plane and the superior aspect of the sacrum, this angle is known as the sacro-horizontal angle. An anterior shear force results on the L5-S1 junction especially during extension due to the orientation of the sacrum (inclined anteriorly and inferiorly), equaling as much as 64% of body weight. This anterior shear force is counteracted in part by the following structures: the anterior longitudinal ligament, L5-S1 facet surfaces with a frontal plane orientation, iliolumbar ligament, and fibers from the quadratus lumborum muscle. Surface electromyography (SEMG) has been used to monitor these structures to know when and to what degree these structures are active.
Surface Electromyography

The energy production of a muscle is monitored using SEMG. Muscles elicit electrical activity which is detected by the SEMG electrodes that are placed over a muscle. An action potential, or a series of depolarizations and repolarizations, is produced when that muscle contracts. Action potentials initiate movement when they are sent from the alpha motor neuron to the central nervous system and back. The action potentials are detected by the electrodes, and the SEMG instrument amplifies the electrical signals from the action potentials. If a greater number of motor units are recruited, a larger electrical signal will be produced by the muscle. This will cause an increase in the volume of the conducted signal on the SEMG instrument. It is important to remember that SEMG only measures the amount of electrical activity that muscles elicit during a contraction. The force of strength of a muscle contraction is not measured by SEMG.

In order to minimize any unwanted transfer of signals from other proximal muscles that could be picked up between communication channels, it is crucial to have concise electrode placement. The area with the smallest amount of tissue between the muscle and the skin is the ideal placement for the electrode. Any hair should be removed from this area. The electrodes should be aligned parallel to the muscle fibers in order to have maximum sensitivity and selectivity. Anatomical landmarks are used to ensure proper placement of the electrodes. The electrodes monitoring LD function are placed over the muscle belly at the T12 level along a line connecting the most superior point of the posterior axillary fold and the S2 spinous process. The electrodes monitoring MT function are placed 4 cm lateral to T3 spinous process. The electrodes monitoring ES function are placed horizontal with the L3-4 interspace, 4 cm lateral to midline.
Skin impedance is another factor that must be taken into account. Skin impedance is defined as the resistance the skin has to direct current applied to it. Skin impedance can be affected by the following factors: skin oil content, skin moisture, hair, the density of the dead-cell layer, and adipose tissue. Research has indicated that impedance should be less than 10 kOhms at each electrode site. Making sure skin impedance is as low as possible is important to get the most accurate reading from the SEMG electrodes. The skin should be abraded using fine grit sandpaper, followed by cleaning with alcohol to reduce impedance for electrode placement. The area may have to be shaved of all hair prior to skin abrasion. Recording of muscle contraction can begin once skin impedance is within acceptable levels.\textsuperscript{14}

Maximal Voluntary Contraction

Maximal voluntary contraction (MVC) is the greatest amount of force that a muscle is able to create. The International Society of Electrophysiology and Kinesiology set the standards for documenting the force created by a muscle. A subject should practice creating a MVC before collecting MVC data. Research has shown that there is a 20-30\% decrease in MVC performance without proper training. Without proper training, results may not represent the subject's true MVC. Feedback, such as verbal and visual, have been found to impact MVC, therefore, should be an attempt to minimize negative effects of feedback on MVC so that data collection is accurate.\textsuperscript{1,2}-\textsuperscript{3,4}

Manual muscle testing (MMT) is not the same as MVC. Collecting an MVC requires the subject's maximal effort with a certain motion. Manual Muscle testing is not as reliable since the subject only has to produce a force that is equal to the resistance being given by the examiner. It does not represent the maximal effort that is capable by the subject.\textsuperscript{5} Different from the traditional MMT position for the LD, the best test position for LD activation is in the prone position with the upper extremities in extension. Researchers found the average MVC was
92.62% in this position whereas other positions averaged much less. The researchers of the cited study concluded that these findings were relevant and appropriate to include in the study.36

Testing the MVC of the ES utilizes the traditional MMT position. The subject is prone with hands at the side. The researchers stabilize at the ankles and the pelvis. The subject lifts their trunk off the table by extension of the lumbar spine as far as they possibly can approaching the subject's umbilicus clearing the table.27 Testing the MVC of the MT is done by using the traditional MMT position. The subject is prone with upper extremities abducted to 90 degrees and resistance is given at the distal arm. The opposite side of the trunk is stabilized during the movement.

Muscle Function

The low back is an area of the body that is very susceptible to injury. It's of great importance to be mindful of the ways that different muscles function and how they can lead to common pathologies. It's important to know which forces are acting during movement on different areas of the body to determine where a dysfunction is originating. Knowledge of how a muscle functions will allow for advanced and specific strengthening to the muscles.

Muscle are able to contract in three different ways. Those include: concentrically, eccentrically, and isometrically. When the muscle shortens against a force and the distal segment moves towards the proximal segment, it's considered a concentric force. An eccentric force is the opposite. The muscle is lengthened against a force as the distal segment moves away from the proximal segment. An isometric contraction is when the muscle creates a force where proximal and distal segments do not move relative to each other.

Muscles function in open chain or closed chain movements. Open chain movements occur when the kinetic chain is unfixed to the ground or any other object that is unable to move. Closed chain movements occur when the kinetic chain is fixed to the ground or other object that
is unable to move. An example of a closed chain movement would be a push up. Both hands are fixed on the ground while you extend at the elbows. This causes the body to move upward against gravity.

Testing Positions

The ability of muscles to function in both open and closed chains effects how a muscle can operate. The LD originates at the trunk and inserts on the upper extremity. The LD is in a closed chain position when the upper extremities are fixed and the trunk is free to move. The LD will be isolated while the subject is in quadruped. The subject will lift one of the lower extremities while bearing weight through both hands and the opposite lower extremity. This will rotate the spine. For example, if the left lower extremity is raised off the table, the spine will rotate right, relative to the pelvis.

Right Fixed Position: The subject is in the quadruped position. The subject then lifts their right knee off of the surface so that the thigh hovers perpendicular to the surface. This causes left spinal rotation with initiation from the pelvis.

Left Fixed Position: The subject is in the quadruped position. The subject then lifts their left knee off of the surface so that the thigh hovers perpendicular to the surface. This causes right spinal rotation with initiation from the pelvis.

Open chain position is achieved by standing spinal rotation. The trunk is fixed while the upper extremities are free. Terms to define this are “right non-fixed position” and “left non-fixed position.”

Right Non-Fixed Position: The subject is in the standing position with their feet shoulder-width apart. The subject then moves the right side of their pelvis posteriorly in the horizontal plane to initiate left spinal rotation. The subject’s feet remain planted while completing this motion.
Left Non-Fixed Position: The subject is in the standing position with their feet shoulder-width apart. The subject then moves the left side of their pelvis posteriorly in the horizontal plane to initiate right spinal rotation. The subject's feet remain planted while completing this motion.
CHAPTER III
METHODS
Subjects

This study was approved by the University of North Dakota Institutional Review Board, and Research Development and Compliance (IRB-201504-329). Inclusion criteria consisted of subjects between the ages of 20-40, dominance of the right hand, and the ability to tolerate prone and quadruped positioning for 20 minutes each. Exclusion criteria consisted of current or previous pathology of the shoulder or spine requiring medical attention, pregnancy, and allergies to latex or isopropyl alcohol.

Twelve healthy subjects (8 female, 4 male) volunteered to participate in the study (Table 2). Subjects were recruited by placement of fliers throughout the University of North Dakota School of Medicine and Health Sciences during the months of April-May 2017. All subjects were aware of the experimental procedure, purpose of the study, and any possible risks of the study. Subjects were asked to complete a demographic questionnaire (Appendix A) and sign a consent form (Appendix B) prior to participation in this study. A copy of the consent form was provided to the subject if they desired one.

<table>
<thead>
<tr>
<th>Table 2. Subject Demographics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean</strong></td>
</tr>
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</tr>
<tr>
<td>Height (Inches)</td>
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<td>Weight (Pounds)</td>
</tr>
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</table>
Instrumentation

Instrumentation used for this study was wireless electromyography hardware and software (Noraxon, USA, Scottsdale, AZ). The LD, MT, and ES were studied using self-adhesive, pre-surfaced EMG electrodes. Silver/Aluminum adult electrodes with a 3.3 cm inter-electrode distance were utilized for this study (Ambu/Medicotest A/S, Denmark). Data analysis for the raw EMG data was performed using Noraxon MyoResearchXP software (Noraxon, USA, Scottsdale, AZ).

Electromyography

Prior to the beginning of this study, the research team set up and tested the EMG equipment to ensure proper signal reception and transmission. The research testing was conducted in a private room in Grand Forks, North Dakota at the University of North Dakota School of Medicine and Health Sciences. This was done to ensure privacy and confidentiality for each participant involved in the study. Prior to the study, participants were given a verbal explanation of the study and were allowed to ask any questions about the procedure or express any concerns. Each participant completed the testing session in approximately one hour. All participants were asked to wear shorts to the session. Female subjects were asked to wear a tank top, and male subjects were asked to remove their shirt to allow for direct skin contact of each electrode. The SENIAM group guidelines for preparation and placement of electrodes was followed by the researchers (SENIAM Group, Enschede, Netherlands). Electromyography (EMG) procedure required electrode site preparation, electrode placement, and proper application of equipment for collection of EMG data. Electrode site preparation was prepared in a standardized manner for all applications. The skin preparation consisted of the removal of excess hair (if necessary) using an electric razor, wiping the skin surface with 400 grit sandpaper, and then followed by wiping with isopropyl alcohol.
The same researcher measured and applied each electrode to the participants in order to increase reliability of the study. Electrodes were placed over the LD, MT, and ES muscles parallel to the muscle fibers (Fig. 2). For the LD, the electrodes were placed over the muscle belly at T12 level and along a line connecting the most superior point of the posterior axillary fold and S2 spinous process. For the MT, the electrodes were placed 4 cm lateral to the spinous process of T3. For the ES, the electrodes were horizontally aligned with the L3-4 interspaces, 4 cm lateral to midline. A Noraxon impedance analyzer (Noraxon USA, Inc., Scottsdale, AZ) was placed over each pair of electrodes in order to measure impedance. Skin impedance was assessed to be less than 10 kOhm. The electrodes were connected to the Telemyo 900 transmitter which were attached to the subject’s skin using double sided tape. The EMG signals were transmitted to the Telemyo 900 transmitter and stored on a laptop computer for later analysis (Hewlett Packard, Palo Alto, CA).

Figure 2. Electrode placement for MT, LD, and ES.

Reflective markers were placed bilaterally over the anterior superior iliac spine (ASIS) and bilateral acromion processes to measure rotation. The testing positions were video recorded to analyze motion. Using a meter stick attached perpendicular to a six inch wooden box, a vertical
point of reference was developed for the study. The meter stick was used as the point of reference to determine the amount of spinal rotation for the video recording. After the electrode placement was completed, maximal voluntary contraction was collected for each muscle with a randomized order. The EMG data was used to analyze the amount of muscle activity during spinal rotation at different points of the video recording.

Maximal Voluntary Contraction

An MVC was obtained for each muscle of all subjects. Testing the MVCs began by positioning the participant in prone with the head resting in neutral. Participants were instructed to exert their maximal force against the dynamometer (microFET2) (Hoggan Health Industries, West Jordan, UT, USA) during each MVC trial. The same researcher utilized the microFET2 for the participant each time to ensure consistency. A metronome was set to a speed of 60 beats per minute for consistent timing. Each participant had one second to move into the appropriate MVC testing position, hold the MVC for three seconds, and return to the starting position in one second. Each participant was allowed to practice the MVC testing positions until feeling comfortable.

Three trials were performed for each MVC testing position with a 30 second rest in-between each trial. Subjects were instructed to give their best effort during each trial. After each trial, participants were informed of their resistance values in order to encourage full MVC. No additional encouragement was given to the participant during the actual contraction. The participants were reminded to contract slowly and fully, without jerking, in order to produce the best results.\(^1\) MicroFET2 values were recorded in each testing position for reliability. All trials were required to be within a 5 point interval. If a trial fell outside the 5 point interval, it was repeated until there were three trials recorded that fell within 5 point interval of each other for each testing position. A computer randomized the MVC testing position for each participant.
Latissimus Dorsi (Fig. 3): The tested side was aligned with the edge of the plinth, with the shoulder and upper extremity placed off the plinth. The participant was then asked to flex their elbow to 90 degrees and extend their elbow to be parallel with the trunk. The researcher, using the microFET2, applied resistance to the distal humerus during upper extremity adduction and extension. Stabilization was applied to the ipsilateral scapula and contralateral pelvic.

![Testing position for the maximal voluntary contraction of LD.](image)

Middle Trapezius (Fig. 4): The participant’s upper extremity was placed in 90 degrees of abduction, neutral rotation, and 90 degrees of elbow flexion. The same researcher, using the microFET2, applied resistance to the distal humerus during scapular adduction. Stabilization was applied to the contralateral scapula and ipsilateral pelvis.

Erector Spinae (Fig. 5): The participant’s arms were placed at their sides. The pelvis and lower extremities were stabilized using the velcro belts attached to the plinth. Additional stabilization was applied to the participant’s ankles by a researcher. The participant was instructed to lift their chest off the plinth into trunk extension through full range of motion while...
maintaining a neutral head position. No external resistance was applied. Consistent effort was measured by assessing full range of motion prior to testing and ensuring full range of motion was achieved during each trial.

Figure 4. Testing position for the maximal voluntary contraction of MT.

Figure 5. Testing position for the maximal voluntary contraction of BS.
Experimental Testing

The experimental testing was performed after completion of all MVC testing. A computer randomly generated the sequence of testing conditions for each participant to eliminate bias of selection. Before beginning the first testing condition, one to two minutes of rest was allowed for the participant. One to two minutes of rest was also allowed between each experimental testing condition. Participants were able to practice each testing motion until comfortable. A 30 second rest period was given before performing the first trial. Each movement was paced to a metronome set to a speed of 92 beats per minute.

Following the beat of the metronome, participants were instructed to move three counts into their full range of rotation followed by three counts back to neutral position. A researcher verbally cued to the participant during the motion to the beat of the metronome, saying, “Back, Two, Three. Forward, Two, Three...” The participant completed three trials of five repetitions for each movement. There was a rest period of 30 seconds between each trial. A six-inch wooden block with a meter stick attached perpendicular to the testing surface was placed on the testing side to measure spinal rotation.

Standing (Fig. 6): Participants were asked to stand with feet flat on the floor, shoulder-width apart, and arms crossed over their chest. A researcher stabilized the participant’s shoulders to avoid movement of the upper trunk. The participants were instructed to rotate their pelvis by bringing their right ASIS posteriorly and left ASIS anteriorly (Left Spinal Rotation). This was repeated by in the opposite direction bringing the left ASIS posteriorly and right ASIS anteriorly (Right Spinal Rotation). The rotation was performed keeping their feet in contact with the floor and knees straight. The video camera was placed on the side rotating posterior with a clear view of the reflective markers. The camera lens was placed at the height of the participant’s ASIS for consistency.
Figure 6. Standing spinal rotation (non-fixed) testing position. (A) Starting position of standing test position. (B) Maximal rotation before returning to starting position.

Quadruped (Fig. 7): For this testing position, participants were in quadruped with knees and hands shoulder-width apart. The six-inch wooden box was placed adjacent to the participant’s knee on the testing side. A towel was placed between the box and the participant’s leg for greater ease of movement. The participants were asked to lift their knee off the plinth while maintaining contact with the box to prevent abduction of the thigh and to promote spinal rotation.

Data was collected during the entire cycle for each MVC and three trials of each testing position and stored in separate files. Once all data collection was completed, the electrodes and motion analysis reflectors were removed from the subject and the skin was cleaned with isopropyl alcohol.

Data Analysis

Data analysis occurred using the MyoResearch XP software. The collected EMG data was transported, rectified, and normalized to the MVC for each muscle by the Noraxon MyoResearchXP software (NoraxonUSA, Inc., Scottsdale, AZ). The EMG data was recorded in 5-count intervals during every muscle contraction for the MVC’s. The EMG data was recorded in 3 count intervals forward and back for testing positions. Data from
seconds 2-4 was used for data analysis in order to find the most precise data representation within the 5-count interval. Once these values were obtained, all data was transferred to the Statistical Package for Social Sciences (SPSS) spreadsheet. To determine a significant effect of each muscle
In a fixed and non-fixed position on the EMG activity, a repeated measures ANOVA was used (alpha < 0.05). A Scheffe post hoc test was utilized to find significant differences between muscles.
CHAPTER IV
RESULTS

An ANOVA or repeated measures t-test was used to research each of the questions presented to analyze significant differences in EMG activity for specific muscles under the previously explained conditions (Table 3). A least significant difference (Scheffe) post hoc test was used to compare the planned pairwise comparisons to determine if an ANOVA was found to be significant.

The right and left LD EMG function was compared under differing conditions of movement and degree of upper extremity fixation. This was done to investigate our first research question. All four RM t-tests were found to be significant (Table 3). During left fixed spinal rotation, the right LD was found to be most active. Additionally, during right spinal rotation, the left LD was found to be most active. For all conditions, LD fixed was statically more active than non-fixed.

The second and third research questions compared the EMG activity of the LD, ES, and the MT in the following positions: right and left spinal rotation in a fixed quadruped position (Table 4) as well as right and left spinal rotation in a non-fixed standing position (Table 5). Differences in the LD and ipsilateral ES, as well as the LD and the ipsilateral MT were addressed using a Two-Way Repeated Measures Analysis of Variance to compile specific pair-wise comparisons.

The Repeated Measures Analysis demonstrated the difference in normalized EMG activity between the muscles under the conditions of left and right spinal rotation while the upper extremities are fixed, pertaining to research question number two. The right LD was
Table 3: Repeated Measures T-test: The difference of EMG activity in fixed and non-fixed positions for movement R and movement L for the right and left latissimus dorsi (LD)

<table>
<thead>
<tr>
<th>Muscle</th>
<th>Movement direction</th>
<th>Position</th>
<th>N</th>
<th>Mean (%MVC)</th>
<th>SD</th>
<th>T</th>
<th>Df (Degrees of Freedom)</th>
<th>P</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Non-Fixed</td>
<td>12</td>
<td>4.535</td>
<td>2.228</td>
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<tr>
<td></td>
<td>Left</td>
<td>Fixed</td>
<td>12</td>
<td>17.553</td>
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<td>.001</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
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<td>18.884</td>
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<td>11</td>
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*Movement Direction: Right Direction = Left Spinal Rotation, Left Direction = Right Spinal Rotation*
Table 4: Repeated ANOVA post hoc analyses: The difference in EMG activity between the right and left LD, MT, and ER under condition of fixed upper extremities and movement right and movement left

<table>
<thead>
<tr>
<th>Position</th>
<th>Movement Direction</th>
<th>Muscle</th>
<th>N</th>
<th>Mean (%MVC)</th>
<th>SD</th>
<th>F</th>
<th>df (Degrees of Freedom)</th>
<th>p</th>
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<td></td>
<td></td>
<td>R MT</td>
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<td>6.233</td>
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<td>.276</td>
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<tr>
<td></td>
<td></td>
<td>R ES</td>
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<tr>
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<td>Left</td>
<td>R LD</td>
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<td></td>
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<td>R MT</td>
<td>12</td>
<td>8.099</td>
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<td>1.583</td>
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<td>Right *</td>
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*Significant difference found between the L LD and L MT, L LD and L ES. p=.001, p=.001
Table 5: Repeated ANOVA post hoc analyses: The difference in EMG activity between the right and left LD, MT, and ER under condition of non-fixed upper extremities and movement right and movement left

<table>
<thead>
<tr>
<th>Direction</th>
<th>Movement direction</th>
<th>Muscle</th>
<th>N</th>
<th>Mean (%MVC)</th>
<th>SD</th>
<th>F</th>
<th>df (Degrees of Freedom)</th>
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<td>Non-Fixed</td>
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*Significant difference found between the R ES and R MT, R ES and R LD. p<.001, p<.001
◊Significant difference found between the R ES and R MT, R ES and R LD. p=.01, p=.01
□Significant difference found between the L ES and L LD, L ES and L MT. p=.040, p=.040
<Significant difference found between the L ES and L LD, L ES and L MT. p=.001, p=.001
slightly more active than the right ES during right fixed rotation, and both right LD and right ES were more active than right MT. Also, the right LD was more active than the right MT and right ES in left fixed rotation. However, the p values of these findings determined the difference was not statistically significant. The left LD was more active than the left MT and left ES during right fixed rotation which was shown to be statistically significant. During left fixed rotation, the left ES was slightly more active than the left LD, and both left ES and left LD were more active than the left MT which were found to be not significant. Refer to Table 4 for significant p values, and the specific numerical differences between the muscle groups.

Repeated Measures Analysis was used to assess standing rotation, or non-fixed spinal rotation, this demonstrated a significant difference in normalized EMG activity when comparing the muscles under the conditions of non-fixed right and left spinal rotation. The only significant difference found in muscular groups during non-fixed rotation are listed (Table 5).
CHAPTER V
DISCUSSION and CONCLUSION

Discussion

This study’s purpose was to analyze EMG activity during spinal rotation with and without upper extremity fixation of the LD, MT, ES muscles. The results of this study indicated a statistically significant increase in LD EMG activity during fixed position (quadruped) when compared to the non-fixed position, supporting hypothesis one. While past research has shown the LD does not play a significant role in spinal rotation, our findings support the previous two pilot studies stating the LD does in fact contribute to contralateral spinal rotation when in the quadruped position.

In the fixed position right rotation, the left LD was significantly more active than the left ES and left MT. The significantly greater left LD activation during fixed right rotation correlates with the previous pilot study, however, left MT activation was not significantly greater as was found during previous pilot studies. The findings of greater left LD activation in fixed right rotation suggest contralateral LD does in fact contribute significantly to fixed spinal rotation, but may not consistently be the prime mover. The findings may be attributed to the position of the humerus in fixed compared to non-fixed positioning. With the humerus fixed, movement at the insertion was prevented, which caused the concentric shortening to take place from origin to insertion of the LD (closed chain). This contraction resulted in contralateral spinal rotation. The fixed position places the lumbar spine in a flexed posture with flexion of the hips, favoring the LD as a contralateral spinal rotator in comparison to the ES and MT.
In the fixed position, no significant differences were found between the right MT, LD, and ES in either right or left spinal rotation. Given the significantly different activation of left LD compared to left ES and left MT during right fixed rotation, we would expect similar findings in respect to right LD in comparison to R MT and R ES during fixed left rotation. The inconsistencies between the right and left LD in the fixed position cannot be explained from the current set of data.

Consistent with a previous study conducted by Kumar et al.\(^1\), the LD muscle has significant influence on spinal rotation in the fixed (quadruped) position. While Kumar et al.\(^1\) focused on isometric rotation of LD during lifting activities; our study examined LD influence on rotation in positions more closely related to exercise and functional movement practiced in a physical therapy setting, improving the clinical applicability of our findings.

When evaluating the left side musculature in the non-fixed position, the ES had significantly more EMG activity than either the LD or MT in both left and right rotation on both left and right sides. The LD and MT did not significantly differ in both left and right rotation on both left and right sides. The lack of significantly greater activation of the LD compared to ES and MT in non-fixed positioning suggests the LD is unfavorably positioned to contribute torque during non-fixed spinal rotation. The non-fixed spinal rotation testing position may also allow for greater compensatory movement via lumbar extension, placing the ES in a favorable position to activate in comparison to LD. Subjects activating different musculature throughout the prescribed movement patterns may account for differences in EMG activity.

In this study, several limitations were present. First, there was a small sample size of only 12 individuals. The demographics of these 12 individuals were also fairly similar, ranging in ages of 22-31 and rather than being members of the general public, they were healthy, active physical therapy students. Each individual displayed a different body type, postural alignment, level of muscular development of the muscles tested, as well as coordination level and awareness of body
movements. Secondly, other confounding variables which researchers were not aware may have influenced the experimental procedure. Such conditions include decreased practice time of tested movements, researcher discrepancy when providing stabilization, and the inability for the researcher to consistently apply pressure into the dynamometer.

Suggested future research could include a more specific degree of rotation at which the LD is active, assessment for hand dominance, variance in age of population as well as fitness level. These suggestions would increase statistical significance and allow results to be more generalizable. Eventually, performing LD specific exercises with LBP patients in physical therapy and their outcomes would be beneficial to expand the knowledge of low back pathologies and available treatments for healthcare professionals.

Conclusion

In conclusion, the LD was found to be more active during contralateral spinal rotation during fixed positional movements. The MT and ES were found to have a greater function on spinal rotation during standing, non-fixed rotation. The ES muscles have a greater effect than the LD due to their increased activity in lumbar extension during standing. In standing, non-fixed rotation, the MT is also more active than the LD. Greater initiation of spinal rotation in the cervical and upper thoracic spine, versus only the lumbar spine which isolates more specific LD activity, may explain the increased MT activity with rotation to the opposite side.

The contributions of the LD muscle in spinal rotation is highlighted in this study and the previous two pilot studies. It is a part of ongoing research concerning rotational movement strategies which the LD may play a role in with individuals with and without LBP. Many activities of daily living require spinal rotation with upper extremities fixed; meaning properly functioning LD muscles are required for increased quality of life. Rehabilitation for LBP often includes both standing and quadruped exercises. In the future, the LD should be evaluated when assessing spinal rotation in a client with LBP.
Patient Questionnaire

Name ____________________________________________

Date of Birth ___________ Height ___________ Weight ___________

Dominant Arm ___________

Sensitivity to: Latex Y N Isopropyl Alcohol skin sensitivity Y N

If yes, please explain ____________________________________________

Do you have any history of shoulder pain/pathology? Y N

If yes, please explain ____________________________________________

Do you have any history of back or spinal disc/pathology? Y N

If yes, please explain ____________________________________________

Are you pregnant? Y N

Do you have any condition for which lying on your stomach would be a problem? Y N

If yes, please explain ____________________________________________

All the information provided in this questionnaire has been answered accurately and to the best of my knowledge.

Signature of participant: ___________________________ Date ___________
THE UNIVERSITY OF NORTH DAKOTA
CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Electromyographic Analysis of Latissimus Dorsi, Erector Spinae and Middle Trapezius Muscle Activity During Trunk Rotation

PROJECT DIRECTOR: Susan H N Jeno, PT, PhD

PHONE #: 701 777-3662

DEPARTMENT: Physical Therapy

STATEMENT OF RESEARCH
A person who is to participate in the research must give his or her informed consent to such participation. This consent must be based on an understanding of the nature and risks of the research. This document provides information that is important for this understanding. Research projects include only subjects who choose to take part. Please take your time in making your decision as to whether to participate. If you have questions at any time, please ask.

WHAT IS THE PURPOSE OF THIS STUDY?
You are invited to be in a research study about muscle activity during trunk rotation because you are a student in the UND School of Medicine and Health Sciences.

The purpose of this study is to determine the level of muscle activity of several back muscles including latissimus dorsi, middle trapezius, and erector spinae muscles with trunk rotation with and without fixation of the upper extremities. The conclusions drawn from this study will allow practicing clinicians to better develop the exercise programs provided to their clients with back or upper extremity pathology.

HOW MANY PEOPLE WILL PARTICIPATE?
Approximately 50 people will take part in this study at the University of North Dakota.

HOW LONG WILL I BE IN THIS STUDY?
Your participation in the study will last approximately 60 minutes. You will need to visit the Department of Physical Therapy 1 time to participate in this study.

WHAT WILL HAPPEN DURING THIS STUDY?
After you agree to participate in this study, you will be asked to complete a questionnaire pertaining to information about you. You are free to skip any question that you would prefer not to answer. This study will involve the collection of electrical activity of some of the muscles in your back while you perform trunk rotation activities while standing upright and while on your hands and knees. In order to access the muscles on your back and for comfort during the test.
procedures, female subjects will be asked to wear shorts and a swimsuit top or sports bra to expose the appropriate areas of your back for placement of the electrodes. For male subjects, you will be asked to wear shorts and remove your shirt to expose your back. You will be asked to lie on your stomach on a padded table and marks will be placed on your skin where the electrodes will be placed over the muscles on both sides of your back (see attached diagram). Pre-gelled, self-adhesive electrodes placed over the muscles will collect the electrical signal the muscles produce when they contract. In order to obtain the best signal from the muscles, the skin where the electrodes will be placed will be prepared in standard fashion which includes clipping any excess hair with an electric razor, lightly rubbing the skin with fine grit sandpaper followed by cleaning the area with rubbing alcohol wipes. This process is intended to reduce the resistance of the skin to allow of better signal collection by the electrodes. A device to measure the amount of rotation will be placed along the spine in the low back area. The data collecting devices will be attached by lead wires to a transmitter which will be attached around your waist by a belt. Electrical signals are sent from the transmitter to a computer for recording and analysis.

Once the electrodes are in place, you will be asked lie on your stomach and to perform a maximal voluntary contraction (MVC) – a full effort contraction – of each of the muscles which will be used for comparison of muscle activity. A hand-held device will be used to record the amount of force created by each contraction. For each MVC, you will be asked to push against a fixed device as hard as you can for 5 seconds. This will be repeated 3 times for each muscle with 30-60 seconds rest between trials. You will be allowed to practice the testing procedure before data collection.

Following the collection of the MVC data, you will be asked to perform a series of trunk rotations both to the right and to the left from a standing position and from a position on your hands and knees. Each rotation will be timed with a metronome for a 3 count motion to obtain full rotation and a 3 count motion to return to a resting position. You will be allowed to practice to be sure the timing of the motions is clear. The rotation measurements will be randomized with you selecting a card to determine the order of the activities. You will perform 5 repetitions of each rotation timed by a metronome for each trial. You will be given 30-60 seconds rest between each trial. The rotational motions will be recorded on the computer for use in analyzing the data.

WHAT ARE THE RISKS OF THE STUDY?
Although there is some degree of risk involved in physical activity testing, the researchers believe the risk of injury and discomfort is minimal; however, minor muscle soreness may occur following repeated activity. The use of a spotter will minimize any risk from loss of balance during the activity. Reddening of the skin in the areas where the electrodes are placed is possible due to the adhesive material. The EMG equipment will only monitor muscle activity and the equipment will not cause discomfort. If at any time you experience pain, discomfort, fatigue, or any other uncomfortable symptoms, you may stop your participation in this study.

Approval Date: JAN 1 1 2017
Expiration Date: JAN 1 0 2018
University of North Dakota IRB
WHAT ARE THE BENEFITS OF THIS STUDY?
You may not benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study and these benefits include but are not limited to 1) gaining a better understanding of the muscle activity in the back muscles with trunk rotation and 2) increasing the current level of knowledge of muscle activity and motion patterns of these muscles during this activity. This will begin to provide more information on how to design treatment programs that include these muscles.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?
You will not be paid for being in this research study.

WHO IS FUNDING THE STUDY?
The University of North Dakota and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

CONFIDENTIALITY
The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, you will not be identified. Your study record may be reviewed by Government agencies, the UND Research Development and Compliance office, and the University of North Dakota Institutional Review Board.

Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained as each subject will be given a randomly selected identification number at the beginning of the study, which will be known by the researchers only. All information involving the research study, digital and hard copy, along with a hard copy of the statistically analyzed data, will be secured in a locked cabinet inside the Department of Physical Therapy at the University of North Dakota. Unless the data is required for future studies, the information will be destroyed via shredding three years after the study has been completed.

If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified.

EMG data and digital recordings of the motions performed as part of this research study will be coded in the same manner as the information form. Your name will not be associated with the digital file. All digital information will be stored separately from the consent forms in a secure location in the Department of Physical Therapy. After a period of 3 years from the completion
of the study, the digital data will be deleted from all disks/drives. You are free to look at the digital recordings of your muscle activity at the conclusion of the data collection period.

COMPENSATION FOR INJURY
In the event that this research activity results in an injury, treatment will be available including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (such as health insurance, Medicare, etc.) No funds have been set aside to compensate you in the event of injury. Also, the study staff cannot be responsible if you knowingly and willingly disregard the directions they give you.

IS THIS STUDY VOLUNTARY?
Your participation is voluntary. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your current or future relations with the University of North Dakota.

The investigators or you may stop the experiment at any time if you are experiencing discomfort, pain, fatigue, or any other symptoms that may be detrimental to your health. If you agree to participate, you will be allowed to stop your participation in this study at any time without prejudice or jeopardizing any future relationships with the UND Department of Physical Therapy.

CONTACTS AND QUESTIONS?
The researcher conducting this study is Susan H. N. Jeno, PT, PhD. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Susan Jeno at 701 777-2831 during the day.

If you have questions regarding your rights as a research subject, you may contact The University of North Dakota Institutional Review Board at (701) 777-4279.

- You may also call this number about any problems, complaints, or concerns you have about this research study.
- You may also call this number if you cannot reach research staff, or you wish to talk with someone who is independent of the research team.
- General information about being a research subject can be found by clicking “Information for Research Participants” on the web site: http://und.edu/research/resources/human-subjects/research-participants.cfm

I give consent to be videotaped during this study.

Please initial:   Yes   No

Approval Date: JAN 11 2017
Expiration Date: JAN 10 2018
University of North Dakota IRB
Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subjects Name: ____________________________________________

Signature of Subject ___________________________ Date ____________

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative.

Signature of Person Who Obtained Consent ___________________________ Date ____________

Approval Date: JAN 1 1 2017
Expiration Date: JAN 1 0 2018
University of North Dakota IRB

Date ___________________________ Subject Initials: _______
Location of electrodes on your back. Electrodes are placed on both sides of the back (small circles). The large bar indicates the position of the joint angle measurement tool.
Appendix C
PROTOCOL CHANGE FORM
UNIVERSITY OF NORTHERN DAKOTA INSTITUTIONAL REVIEW BOARD

Please complete this form and attach revised research documents for any proposed change to your protocol, consent forms, or any supportive materials (such as advertisements, questionnaires, surveys, etc.). All changes must be highlighted. Any proposed change in protocol affecting human participants must be reviewed and approved by the IRB prior to implementation, except where an immediate change is necessary to eliminate a hazard to the participant.

Principal Investigator: Susan H Jeno
Telephone: 777-3662 E-mail Address: Sue.jeno@med.und.edu
Complete Mailing Address: 401 N Columbia Rd Stop 9037 Grand Forks, ND 58202-9037
School/College: SMHS Department: Physical Therapy

Project Title: EMG Analysis of Latissimus Dorsi, Erector Spinae and Middle Trapezius Muscle Activity During Trunk Rotation
Proposal Number: IRB-201504-329 Approval Date: 3-4-16

THE CURRENT STATUS OF THE PROJECT IS (Check one)

- Project currently in progress. Number of subjects enrolled is: __________
- x Project not yet started. No subjects enrolled.
- Project closed to subject entry.

1. Briefly describe and explain the reason for the revision or amendment and the justification for the change. Include a copy of affected protocol pages and consent form with specific changes highlighted.

Change in the graduate students assisting with data collection.

2. Does the change affect the study or subject participation (procedures, risks, costs, etc.)? _______ Yes x No
   Please explain:

3. Does the change affect the consent document? _______ Yes x No
   If yes, include the revised consent form(s) with the changes highlighted, and a clean copy of the revised consent form(s).

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signatures:

Principal Investigator Date: __________
Student Adviser (if applicable) Date: __________

Revised 5/1/66
Protocol Summary  EMG Analysis of Latissimus Dorsi, Erector Spinae and Middle Trapezius Muscle Activity During Trunk Rotation

Rotation of the trunk is a complex movement that has yet to be fully understood but that occurs regularly in activities of daily living and sport performance. Rotation (twisting) of the spine is a major contributing factor in low back pain pathology and by reports has been associated with up to 60% of all back injuries. Unfortunately, one of the largest muscles of the back, the latissimus dorsi (LD), is rarely included in research relative to axial rotation or rehabilitation programs for patients with low back pain. As the only muscle to attach to the spine, pelvis, ribs, scapula, and humerus, LD has the potential to impact the spine during many different activities. To date, there have been 26 subjects evaluated so far as part of this ongoing study. Results to date indicate that there is a significant difference in the activation of the contralateral latissimus dorsi with trunk rotation in the quadruped position but insufficient sample size to determine the effects of the motion in other positions or the other muscles.

There have been no complaints about the research nor changes to the protocol. Continuation of this study will provide a larger number of subjects and appropriate power for data analysis.
University of North Dakota Human Subjects Review Form
January 2015 Version

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University’s policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the “IRB Checklist” for additional guidance.

Please provide the information requested below. Handwritten forms are not accepted – responses must be typed on the form.

Principal Investigator: Susan H N Jeno, PT, PhD
Telephone: 777-3662  E-mail Address: sue.jeno@med.und.edu
Complete Mailing Address: 501 North Columbia Road Stop 9037 Grand Forks, ND 58202-9037
School/College: SMHS  Department: PT

Student Advisor (if applicable):
Telephone:  E-mail Address:
Address or Box #:
School/College:  Department:

***All IRB applications must include a Key Personnel Listing.

Project Title: EMG Analysis of Latissimus Dorsi, Erector Spinae and Middle Trapezius Muscle Activity During Trunk Rotation

Proposed Project Dates: Beginning Date: April 15, 2015  Completion Date: April 15, 2016
(including data analysis)

Funding agencies supporting this research: N/A

Did the contract with the funding entity go through UND Grants and Contracts Administration?  □ YES or □ NO
Attach a copy of the contract. Do not include any budgetary information. The IRB will not be able to review the study without a copy of the contract with the funding agency.

Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

□ YES or □ NO

Will any research participants be obtained from another organization outside the University of North Dakota (e.g., hospitals, schools, public agencies, American Indian tribes/reservations)?

□ YES or □ NO

Will any data be collected at or obtained from another organization outside the University of North Dakota?

□ YES or □ NO

If yes to either of the previous two questions, list all organizations:
Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands its involvement and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on an organizational letterhead.

Does any external site where the research will be conducted have its own IRB? □ YES □ NO □ N/A

If yes, does the external site plan to rely on UND’s IRB for approval of this study? □ YES □ NO □ N/A

(If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

_________________ Date submitted: _________ Status: □ Approved □ Pending

_________________ Date submitted: _________ Status: □ Approved □ Pending

(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

Type of Project: Check “Yes” or “No” for each of the following.

☑ YES or □ NO New Project

☐ YES or ☑ NO Continuation/Renewal

☐ YES or ☑ NO Student Research Project

☐ YES or ☑ NO Dissertation/Thesis/Independent Study

☐ YES or ☑ NO Is this a Protocol Change for previously approved project? If yes, submit a signed Protocol Change Form, along with a signed copy of this form with the changes bolded or highlighted.

☐ YES or ☑ NO Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.

☐ YES or ☑ NO Does your project include Genetic Research?

Subject Classification: This study will involve subjects who are in the following special populations: Check all that apply.

□ Children (< 18 years)

☑ UND Students

□ Prisons

□ Pregnant Women/Fetuses

☑ Cognitively impaired persons or persons unable to consent

□ Other

Please use appropriate checklist when children, prisoners, pregnant women, or people who are unable to consent will be involved in the research.

This study will involve:

☐ Deception (Attach Waiver or Alteration of Informed ConsentRequirements)

□ Stem Cells

□ Radiation

□ Discarded Tissue

☑ New Drugs (IND) IND # _______ Attach Approval

□ Fetal Tissue

☑ Investigational Device Exemption (IDE) # _______ Attach Approval

□ Human Blood or Fluids

☑ Non-approved Use of Drug(s)

☑ Other ______

☐ None of the above will be involved in this study

I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

To date, the research concerning the activation of the latissimus dorsi muscle focuses on its contribution to upper extremity movement. With attachments on spinous processes, the latissimus dorsi as well as the middle trapezius has the potential to impact spinal rotation. Without proper identification of these muscles’ contribution to spinal rotation, proper rehabilitation of a patient with upper extremity or spinal pathology would be impossible. This pilot project is intended to analyze the activation of the latissimus dorsi, middle trapezius and for comparison, the erector spinae muscles during spinal rotation to identify the muscles’ contribution to this biomechanical movement.

II. Protocol Description
Please provide a thorough description of the procedures to be used by addressing the instructions under each of the following categories.

1. Subject Selection.
   a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects. Investigators will voluntarily recruit subjects through fliers posted throughout the SMHS during the months of April-June 2015. No incentives will be provided to participants in this study. See attached flyer. (See attached)
   b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the “Subject Classification” section above. Subjects will be between the ages of 20-40, have no history of shoulder or spine pathology. They will also be able to lay in a prone position for a maximum of 20 minutes and maintain a 4-point quadruped position for approximately 15 minutes during the testing procedure. Subjects from the SMHS will be recruited as a sample of convenience.
   c) Describe your exclusionary criteria and provide a rationale for excluding subject categories. Exclusion criteria include pathology to the shoulder or spine that required medical attention, if the subject is pregnant, or has allergies to latex or isopropyl alcohol. Any of these criteria would pose a risk for the subject to participate in the research study. Exclusion criteria for this study include: 1) history of shoulder or spine pathology - differences in electrical activity and functional movements associated with pathology could alter the patterns demonstrated during the testing procedure and subjects will be asked to perform an isometric contraction of the shoulder extensors, scapular retractors and trunk extensors which may exacerbate previous pathologies; 2) age of subjects less than 20 years or greater than 40 years. Differences in muscle physiology in younger and older individuals could enhance variability between subjects; 3) sensitivity to isopropyl alcohol or latex - electrodes used during the procedure may contain trace amounts of latex; skin is cleaned with isopropyl alcohol; in an effort to avoid adverse reactions, individuals with these sensitivities will be excluded from participation in this study.
   d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects. It is anticipated that a maximum of 50 healthy UND students will be recruited for this study to reduce the risk of research error associated with smaller sample sizes.
   e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method. Valid results are anticipated with a sample size of up to 50 subjects and randomization of the order of the testing position during the data collection protocol to minimize the error associated with training effects or fatigue.

2. Description of Methodology.
   a) Describe the procedures used to obtain informed consent. Informed consent will be obtained from each subject through the information and consent form (see attached form). All individuals participating in this study will be capable of independent decision making and will sign a consent form stating their understanding and willingness to participate in this study. A copy of the consent form will be provided for each subject.
   b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research. All data collection will occur within a private room in the UND Department of Physical Therapy within the SMHS. EMG equipment owned by the Department will be utilized for all data collection.
   c) Indicate who will carry out the research procedures. Research will be carried out by Dr. Sue Jeno and Year 2 Graduate Physical Therapy Students.
   d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.
Electromyographic (EMG) activity of the muscles will be monitored during standing trunk rotation and trunk rotation in a 4-point quadruped position with the use of pre-gelled, self-adhesive electrodes placed over motor points of the relevant muscles in the back. Muscles to be monitored include the latissimus dorsi, middle trapezius, erector spinae muscles on both sides of the body. Precise electrode placement will be determined by standard electrode placement charts and previously published research. Female subjects will be asked to wear shorts and bathing suit top and male subjects will be asked to wear shorts to facilitate access to the muscles and protect modesty. Prior to electrode placement, the skin will be prepared in standardized fashion and skin impedance will be measured to ensure adequate electrical conduction at each site. Preparation of the skin includes removing excess hair in the area where the electrodes will be positioned with an electric razor, the skin slightly abraded with sandpaper and then cleaned with alcohol wipes. A goniometer attachment will be placed along the lumbar spinous processes to record trunk rotation. The electrodes and goniometer will be connected to a transmitter which will be placed in a belt around the subject’s waist. The EMG signals will be transmitted to a receiver and then to a computer. Raw EMG data will be obtained for analysis.

Once the electrodes are in place, each subject will perform a maximal voluntary contraction (MVC) of each of the muscles on both sides of the body for muscle activity comparison. A hand-held device will be utilized to record the amount of force generated by each contraction in addition to the EMG data. Each exercise will be performed 3 times, held for 5 seconds with 30-60 sec rest between trials. The MVC testing position for all muscles is a prone position; latissimus dorsi (LD) - resistance to arm extension from a neutral position will be used to record the MVC; middle trapezius (MT) - the arm will be abducted to 90 degrees with the elbow bent to 90 degrees and scapular retraction will be resisted at the proximal humerus; erector spinae (ES) muscles - trunk extension with the arms at sides with resistance provided across the upper back. Subjects will be allowed to practice the testing and rotation activities prior to data collection to ensure understanding of the motions and appropriate speed of motion. Following the data collection of the MVC, a series of trunk rotations both to the right and to the left from a standing position and from a 4-point quadruped position will be performed with the order randomized to avoid research bias or error. Each rotation will be timed with a metronome for a 3 count motion to obtain full rotation and a 3 count motion to return to a neutral position. Subjects will be asked to perform 5 continuous repetitions of each rotation paced by a metronome for each trial. A rest of 30-60 seconds will be provided between each trial. The rotational motions will be digitally video recorded for use in analyzing the EMG data.

e) Describe audio/visual procedures and proper disposal of tapes.
   Video recording is directly linked to the computer and EMG data for analysis. No actual audio recordings are made of the subjects. Video recordings will be utilized in the data analysis process, saved and stored in similar fashion as the EMG data and destroyed simultaneously. No separate tapes are created in this process.

f) Describe the qualifications of the individuals conducting all procedures used in the study.
   The primary investigator for this study is a faculty member in the Department of Physical Therapy who will be assisted by Year 2 Graduate Physical Therapy students all of whom are trained in the use of EMG equipment.

g) Describe compensation procedures (payment or class credit for the subjects, etc.).
   There will be no compensation given to subjects involved in this study.

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

   a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.
   The potential physical risks associated with this study are minimal. The EMG electrode placement and analysis is a non-invasive procedure utilized in clinical practice. During the performance of the
MVC contractions and trunk rotation activities, there is a slight chance the subject may lose balance or experience shoulder or back pain. This potential risk will be minimized by the presence of a spotter during the activity. Minor skin irritation from the skin preparation and EMG electrodes is possible. Subjects may experience slight fatigue or muscle soreness following participation in this study but it is anticipated that this would not be any worse than that experienced during minimal physical exercise. All subjects will be healthy with no history of shoulder or spine pathology so these risks are minimized by inclusion/exclusion criteria.

b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.

Subject’s names will not be used in any reports of the results of this study. Each participant will be assigned an identification number, known only by the investigators, which will be the only association between consent forms and data collected by EMG. Any information that is obtained in connection with this study and that can be identified with the subject will remain confidential and will be disclosed only with permission from the subject. At the completion of the study, the research data and the consent forms will be stored in separate locked locations in the Department of Physical Therapy for 3 years at which point the forms will be shredded and electronic data deleted. Data will be reported in aggregate form only to protect the confidentiality of all subjects.

c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.

d) If the PI will be the lead-investigator for a multi-center study, or if the PI’s organization will be the lead site in a multi-center study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.

4. Subject Protection.

a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).

Selection of the subject pool utilizing the exclusion criteria will minimize the risks associated with this study. Limiting the trunk rotation to what the subject can complete comfortably will also limit potential risks of back pain associated with trunk rotation. Muscle soreness will be minimized by limiting the number of repetitions in each position. The possibility of skin irritation will be minimized by proper skin preparation and subject screening prior to participation. To protect confidentiality and modesty, all data collection will occur in a private room. The investigators or participant may stop the experiment at any time if the participant is experiencing discomfort, pain, fatigue, or any other symptoms that may be detrimental to his/her health. All subjects will be allowed to terminate their participation in this study at any time without prejudice.

b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.

Subject and result information will not be linked to the consent form in order to protect the confidentiality of the subjects. Names will not be associated with data collection forms. Subjects will be assigned a confidential, unique number which will be used for identification purposes. To protect confidentiality and modesty, all data collection will occur in a private room.

c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.
Prior to participation in this study, each subject will read and sign a consent form. Participants in this study will all be capable of independent decision making and will sign a consent form stating their understanding and willingness to participate in this study. Participants will be encouraged to ask any questions regarding the consent form to ensure their understanding of the document. Each participant will be given a copy of the signed consent form for their records.

d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study. Describe: 1) the storage location of the research data (separate from consent forms and subject personal data) 2) who will have access to the data 3) how the data will be destroyed 4) the storage location of consent forms and personal data (separate from research data) 5) how the consent forms will be destroyed

Participant consent forms and data collection sheets/computerized files will be stored separately and secured in separate locked locations in the Department of Physical Therapy. Only the investigators will have access to this information. After a period of 3 years from the completion of the study, the consent forms and data collection sheets will be shredded for final disposition and computerized data will be deleted from all disks/drives.

e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.). The investigators or participant may stop the experiment at any time if the participant is experiencing discomfort, pain, fatigue, or any other symptoms that may be detrimental to his/her health. If subjects consent to participate they will be allowed to terminate their participation in this study at any time without prejudice or jeopardizing any future relationships with the UND Department of Physical Therapy. All investigators are CPR trained. Medical treatment will be provided to each subject as needed, including first aid, CPR, and follow-up care as that provided to a member of the general public in a similar circumstance.

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

In the event an adverse event occurs during participation in this study, the subject will be prompted to seek immediate medical attention. All incurred medical expenses will be the responsibility of the subject or the subject's third-party payer.

III. Benefits of the Study
Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). Please note: extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

Possible benefits of this study include but are not limited to: 1) gaining a better understanding of the muscle activity in the back muscles with trunk rotation and 2) increasing the current level of knowledge of muscle activity and motion patterns of these muscles during this activity; 3) further research may be stimulated; and 4) improved understanding of the kinematics of trunk rotation to aid in the teaching of this activity to students enrolled in the professional physical therapy curriculum. There will be neither cost associated with nor any compensation to any subject who participates in this study.

IV. Consent Form
Clearly describe the consent process below and be sure to include the following information in your description (Note: Simply stating 'see attached consent form' is not sufficient. The items listed below must be addressed on this form.):

1) The person who will conduct the consent interview
2) The person who will provide consent or permission
3) Any waiting period between informing the prospective participant and obtaining consent
4) Steps taken to minimize the possibility of coercion or undue influence
5) The language to be used by those obtaining consent
6) The language understood by the prospective participant or the legally authorized representative
7) The information to be communicated to the prospective participant or the legally authorized representative

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1. The person who will conduct the consent interview will be the primary investigator or a second year PT graduate student. Consent interview will be done in a private location within the PT Department in the SMHS.
2. The person who will provide consent or permission will be the subject in the study. Only those subjects who understand written and verbal explanation of the test protocol in English and who are able to provide consent will be subjects in this study.
3. There will be no waiting period between informing the participant and obtaining consent.
4. All subjects will gain access to the study through voluntarily contacting the researcher for an opportunity to participate. During the consenting process, it will be explained to the potential subjects that the process is entirely voluntary and that they are free to withdraw at any point in the process. Withdrawal from the study will not alter their relationship with the Department of Physical Therapy in any way.
5. English will be the language used to obtain consent. Medical jargon will not be utilized to ensure subject understanding of the research protocol.
6. English will be the language understood by the participant.
7. All risks and benefits, test procedures, and consent document will be explained to each prospective subject.

See Attached form.

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects, and complete the Application for Waiver or Alteration of Informed Consent Requirements. Refer to Form IC 701-A, Informed Consent Checklist, and make sure that all the required elements are included. Please note: All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. The consent form should be written at no higher than an 8th grade reading level, and it is recommended that it be written in the third person (please see the example on the RD&C website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

Necessary attachments:

- Signed Student Consent to Release of Educational Record Form (students and medical residents only);
- Investigator Letter of Assurance of Compliance; (all researchers)
- Consent form, or Waiver or Alteration of Informed Consent Requirements (Form IC 702-B)
- Key Personnel Listing
- Surveys, interview questions, etc. (if applicable);
- Printed web screens (if survey is over the Internet); and
- Advertisements (flyer, social media postings, email/letters, etc.).

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signatures:

(Principal Investigator) Date: ________________________________

(Student Advisor) Date: ________________________________

**All students and medical residents must list a faculty member as a student advisor on the first page of the application and must have that person sign the application.**

Requirements for submitting proposal:
Additional information can be found on the IRB website at: [http://und.edu/research/resources/human-subjects/index.cfm](http://und.edu/research/resources/human-subjects/index.cfm)
Original, signed proposals and all attachments, along with the necessary number of copies (see below), should be submitted to: Institutional Review Board, 264 Centennial Drive Stop 7134, Grand Forks, ND 58202-7134, or brought to Room 106, Twamley Hall.

**Required Number of Copies:**
- Expedited Review: Submit the signed original and 1 copy of the entire proposal.
- Full Board Review: Submit the signed original and 22 copies of the entire proposal by the deadline listed on the IRB website: [http://und.edu/research/resources/human-subjects/meeting-schedule.cfm](http://und.edu/research/resources/human-subjects/meeting-schedule.cfm)
- Clinical Medical Subcommittee and Full Board Review: Submit the signed original and 24 copies of the entire proposal by the deadline listed on the IRB website: [http://und.edu/research/resources/human-subjects/meeting-schedule.cfm](http://und.edu/research/resources/human-subjects/meeting-schedule.cfm)

Prior to receiving IRB approval, researchers must complete the required IRB human subjects’ education. Please go to: [http://und.edu/research/resources/human-subjects/human-subjects-education.cfm](http://und.edu/research/resources/human-subjects/human-subjects-education.cfm)

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the IRB website regarding required copies and IRB review categories, or you may call the IRB office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 5 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 5 copies of the company’s protocol must be provided.
1. The person who will conduct the consent interview will be the primary investigator or a second year PT graduate student. Consent interview will be done in a private location within the PT Department in the SMHS.
2. The person who will provide consent or permission will be the subject in the study. Only those subjects who understand written and verbal explanation of the test protocol in English and who are able to provide consent will be subjects in this study.
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7. All risks and benefits, test procedures, and consent document will be explained to each prospective subject.

See Attached form.
REFERENCES


