LUMBAR SPINE MOBILIZATION: MEASUREMENT AND EFFECTS

BY

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Submitted to the graduate degree program in Rehabilitation Science and the Graduate Faculty of the University of Kansas in partial fulfillment of the requirements for the degree of Doctor of Philosophy

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Abstract

Low Back Pain (LBP) is the second most common cause of disability in the United States, and it is associated with abnormal high activity of Erector Spinae (ES) and low activity of Lumbar Multifidus (LM) muscles. This abnormal activity of muscles has shown to be associated with pain and dysfunction in people with LBP. Lumbar mobilization is a common physical therapy intervention for LBP. Yet, there is a lack of knowledge about the effects of lumbar mobilization on the activity of back muscles in both healthy subjects and in people with LBP. Investigating such effect of mobilization on the activity of back muscles may lead to a better understanding of the physiological effects of mobilization, and a better application of mobilization to normalize the abnormal activity of back muscles in LBP. This may improve the intervention outcomes and decrease the disability in people with LBP.

Furthermore, there is a need to measure lumbar mobilization in clinical settings due to the inconsistency in applying mobilization, which may affect the intervention outcomes. Current laboratory methods like Optotrak and force plate to measure mobilization are expensive and not portable. Inertial Measurement Unit (IMU) is a potential device to measure the clinician's hand movement during mobilization. IMU is inexpensive and portable. However, the validity and reliability of IMU in measuring mobilization need to be determined before its application is considered in clinical and research settings.

In chapters two and three, the effect of mobilization on the activity/contraction of back muscle was investigated. Ultrasound imaging and surface electromyogram (EMG) were used to measure LM contraction and activity of ES respectively at low isometric contraction (arm lift task).

In chapter two, the effect of lumbar mobilization on both LM and ES muscles in healthy subjects was investigated. Healthy subjects received three intervention sessions (no intervention, placebo, and grade IV mobilization) on different days. Contraction of LM and the EMG amplitude of ES activity were measured at two time points (before and immediately after the intervention) in each session. The only significant effect of lumbar mobilization was found on LM contraction compared to the placebo effect (the mobilization increased the LM contraction), whereas there was no significant effect of mobilization on LM contraction compared to no intervention.

In chapter three, the effect of lumbar mobilization on both LM and ES muscles in people with LBP was investigated. LBP subjects were randomly assigned into two groups (grade III mobilization or placebo/light touch group). Subjects received intervention based on their assigned group and for two sessions. Contraction of LM, the activity amplitude and the activity onset of ES were measured at two time points (before and immediately after the intervention) in each session. Compared to the placebo group, there were significant effects of lumbar mobilization on the activity amplitude and the activity onset of ES, and on LM contraction. The mobilization decreased both activity amplitude and activity onset of ES, and increased the contraction of LM. The findings support the use of lumbar mobilization to decrease the activation impairment of back muscles and decrease the disability in people with LBP

In chapter four, the validity and reliability of IMU in measuring clinician's hand displacement during mobilization were investigated. Healthy subjects received four different amplitudes of lumbar mobilization by two clinicians in two sessions. The validity of IMU was tested by comparing the IMU measurements (displacement) to the measurements of Optotrak (displacement), and calculating the correlation between IMU measurements (displacement) and

the force plate measurement (force). The reliability of IMU was tested by comparing the IMU measurements between two clinicians (inter-rater reliability) and between two sessions (intra-rater reliability). Our results showed that IMU had high agreement with Optotrak and high correlation with force plate. Therefore, IMU was found to be a valid device to measure the amplitude of displacement of clinicians' hand during lumbar mobilization. The reliability of IMU was moderate (both inter-reliability and intra-reliability), which can be due to inconsistency in applying mobilization between sessions and between clinicians.

The findings suggest that lumbar mobilization may change the activity/contraction of back muscle in people with LBP but not in healthy subjects during the arm lift task used to collect outcomes. That might be because healthy subjects do not have impairment in activity/ contraction of back muscle to be corrected by mobilization. Therefore, the findings further support the use of mobilization as an integral intervention for people with LBP, and emphasize a new therapeutic effect of lumbar mobilization to normalize back muscle impairment in LBP. Though IMU was found as a valid device to measure lumbar mobilization, the reliability of IMU needs to be tested with more accurate methods of replicating the mobilization between sessions and between clinicians.

Acknowledgements

I would like to express my sincere gratitude to my mentor, Neena Sharma, PhD who has given me a great learning experience. Throughout my study, she has provided guidance, encouragement, advice, and support. She was patient and helpful as I was improving my writing skills and was always accessible to provide support whenever needed.

This project was possible because of the assistance from the rest of my dissertation committee: Dr. Sara Wilson, Dr. Marcio Santos, Dr. Vincent Staggs, Dr. Stephen Jernigan, and to my comprehensive exam committee member, Dr. Sharon Henry. Dr. Wilson was always there to help with technical difficulties in data collection and analysis, Dr. Santos provided his guidance regarding using Electromyography in this project, Dr. Staggs statistical expertise were essential to analyze and interpret the data, Dr. Jernigan helped in reviewing the aims of the dissertation, and Dr. Henry expertise regarding Ultrasound Imaging were critical for this project.

I would particularly like to thank Dr. Theresa Spitznagle for providing the Ultrasound imaging training needed to accomplish this project, and Dr. Irina Smirnova, the director of our PhD program, for her guidance and encouragement throughout my PhD program.

My sincere thanks also to the faculty members, administrative staff at the Department of Physical Therapy and Rehabilitation Science (PTRS) who provided encouragement, advice, and help to accomplish my PhD project. Furthermore, the department has supported me through many GTA and GRA positions during my study.

I would like to thanks students at the Department of Physical Therapy and Rehabilitation Science (PTRS) for their friendship, encouragement, advice, and help to accomplish my PhD project. Furthermore, many of them have helped in data collection: Kosaku Aoyagi, Kasey Miller, Ethan Gechter, Ally Burden, Brooke Schmidt, Jessica Cottrell, and Zaid Mansour while

Kathryn Mena helped in editing my scientific writing. Moreover, I would like to thank the visiting scholars and the students from outside the department: Asha Mathew, and Jarius Jones who helped in data collection while Anita Jeyakumar helped in improving my writing skills.

My deepest appreciation goes to Tim Craig, PhD and Krista Cyr, MS for their help in designing the LabVIEW programs which were used to collect the data in my studies, and the staff of Hoglund Brain Imaging Center at the University of Kansas Medical Center for providing the Ultrasound machine and the space to conduct these studies.

My gratitude is also extended to Norton-Ringle Health Professions Scholarship and Dean's Diversity Scholarship for financially supporting my PhD study.

On personal level, I owe a very special thanks to my parents, wife, and kids, and other family members for their endless love, support, and patient throughout my journey in PhD program. They were always there to help when I felt overwhelmed and stressed.

Last, I must also thank the participants in my project.

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Chapter 1: Introduction

1.1 Low back pain prevalence and sources:

Low back pain (LBP) is a common disorder that affects approximately 80% of the population at some point in their lives [1]. The recurrences of LBP is also common; about 25% of people who recover from an acute episode of LBP experience another episode of LBP within one year after recovery [2]. LBP is the fifth most common cause for seeking a physician care in the United States [3]. Therefore, LBP is associated with significant costs and disability. It costs our society about $100 billion each year as a result of medical care, absenteeism from work, and reduced productivity [4,5].

LBP is defined as an unpleasant sensation located in the area between the costal margin and the inferior gluteal folds [6] from tissue damage or described in terms of such damage [7]. LBP can be classified according to the source of pain and stages of healing. About 90% of LBP is diagnosed as non-specific LBP [8], suggesting no specific source of symptoms can be identified. Degenerative changes of spinal discs or facet joints found in spine imaging are common findings present in patients even without LBP symptoms [9]. In most cases LBP resolves within the first three months of onset. However, about 20% of people with back pain develop chronic LBP [10], which is defined as pain greater than three months from the initial onset of injury or spontaneous episode of pain [11,12]. Once in the chronic stage, LBP becomes a complex disorder with many associated symptoms besides pain. These symptoms include hyperalgesia [13], dysfunction in trunk muscles [14-20], and cognitive and psychological symptoms (fear of movement, distress, anxiety, depression, and somatization) [21,22]. Thus, investigating various dysfunctions and treatment effects of chronic LBP are important.

The economic burden and disability associated with chronic LBP is even higher. The prevalence of chronic LBP was found to be approximately 20% in people between 20 and 59

years of age [23]. Compared to people with other health conditions, people with chronic LBP have 2-12 times more comorbidity i.e. anxiety, depression, and sleep disorders, use 2-12 times more prescription pain medications, and account for more number of visits to health care professionals (i.e. 5 times more visits to physical therapists and 20 times more visits to chiropractors) [24].

There are two conceptual models regarding the source of LBP and pain in general, the end-organ dysfunction and the altered nervous system processing models [25]. The dysfunction model suggests the source of LBP symptoms are structural abnormalities/ dysfunctions in related tissues and structures [25]. Local spinal tissues and structures such as intervertebral disc, facet joints, muscles, tendons, and ligaments can be a source of LBP [9]. Furthermore, internal organ dysfunctions or abdominal aortic aneurism can present sources of LBP [9]. However, the altered nervous system processing model suggests dysfunction in the nervous system either in encoding or processing of sensory information within the peripheral and the central nervous systems rather than dysfunction in spinal tissues and structures [25]. At the peripheral nervous system, a sustained injury can cause changes in the excitability of the afferents to external stimuli, which can lead to hyperalgesia (increased sensitivity to a painful stimulus). In addition, sustained injury can cause changes in the resting membrane properties of the afferents, leading to spontaneous action potentials and pain perception in the absence of external stimuli [25]. Furthermore, within the central nervous system, plasticity and dysfunction of pain processing might occur within the dorsal horns of the spinal cord and in various regions within the brain [25], leading to allodynia (abnormal sensation of pain with a nonpainful stimulus).

The economic burden and disability associated with chronic LBP demand for a better understanding of current intervention strategies, which may improve outcomes of pain and disability and may also be cost saving. This dissertation investigates the effects of a commonly

used physical therapy intervention, lumbar mobilization, on the activity of the impaired back muscles in people with chronic LBP.

1.2 Low back pain and lumbar stability:

LBP can also be due to lack of lumbar stability [26]. The stability of lumbar spine, which is defined as the ability to control the intervertebral movement, is important for pain free performance of activities of daily life. The lumbar stability is achieved through three components: passive, active, and neural components [26]. The passive component consists of the bony and the ligamentous structures that resist the movement at the end range of movement [35]; the active component consists of the muscles that provide stability through contractions [35]; the neural component consists of the mechanical receptors (muscle spindles and Golgi tendon organs) and the nervous system [35] that controls and coordinates muscle activities at different levels. For example, at the spinal level, proprioceptive input from the mechanical receptors is used to regulate α-motor neurons activity while at the brainstem level, different position inputs (vestibular, visual, and proprioception) are coordinated and then used to regulate muscle activity. Moreover, the central nervous system uses the stored motor commands to adjust muscle contractions as in the anticipatory postural response [27], in which trunk muscles contract before the limb movement to stabilize the spine and to compensate for perturbations in posture. Dysfunction in any of the three components of spinal stability can lead to abnormally large intervertebral movements, which may stress the articular and neural structures that consists nociceptors and cause LBP.

1.3 Role of trunk muscles in lumbar stability:

All muscles of the lumbar spine contribute to stability and movement of lumbar spine. These muscles can be classified into global and local (intrinsic) muscles. The global muscles (e.g.

erector spinae) connect the thoracic cage to the pelvis, and are responsible for producing gross movements of the spine and providing general stability. The local (intrinsic) muscles (e.g. lumbar multifidus) are connected to individual segments of the lumbar spine and thus provide segmental stability by controlling intervertebral movement [28]. Lumbar Multifidus (LM) muscle consists of both superficial and deep fibers. The deep fibers stabilize the lumbar spine by fine-adjusting the intervertebral motion, while the superficial fibers primarily extend and rotate the lumbar spine [29]. Although not directly connected to the vertebrae, transversus abdominis (TA) and internal oblique (IO) muscles are attached to the lumbar vertebrae indirectly through the thoracolumbar fascia and therefore play a role in stabilizing the lumbar spine. TA increases the stiffness and stability of the spine by increasing the intra-abdominal pressure [30]. Studies found that both TA and deep fibers of LM muscles contract in the anticipatory postural responses to stabilize the spine before the arm movement [31]. Normal contraction timing and strength of trunk muscles is important to maintain stability of the lumbar spine and to avoid LBP.

1.4 Assessment of back muscle contraction and activity:

Electromyography (EMG) is the gold standard measurement for measuring skeletal muscle activation. The EMG signal can be analyzed three ways (amplitude, timing, and spectral analyses). The amplitude of the rectified EMG signal provides information about the strength of muscle contraction as the signal amplitude is highly correlated with the muscle force; the higher the muscle forces, the higher the EMG signal amplitude [32]. The timing analysis of EMG signals provides information about the time of muscle activation and order of muscle recruitment (the onset and the end of muscle contraction), while the spectral analysis provides information about the frequencies of EMG signal in relation to time, and is mostly used to study muscle fatigue [33].

EMG is conducted by placing surface electrodes on the skin (surface EMG) or by inserting needle/fine-wire electrodes into a deep muscle tissue (intramuscular/needle EMG). In contrast to the superficial back muscles, a reliable signal of LM activation can only be detected by intramuscular EMG [34]. However, intramuscular EMG is an invasive method that is not always feasible and desirable; it might cause pain, bleeding, or infection [35].

Ultrasound (US) imaging of LM is an alternative non-invasive measure to needle EMG and has been extensively used to visualize thickness of LM. Muscle thickness measurements have been shown to indirectly quantify muscle contraction at low level of contraction. Although the conventional US imaging method has the limitation of displaying only two dimensions of muscle thickness [36], changes in muscle thickness of LM as measured by US imaging was found to be highly correlated with EMG amplitude of LM at low level of contraction (less than 35% of maximum voluntary contraction of LM) [37]. Thus, US imaging is considered a valid alternative method to measure LM muscle contraction strength at low level of muscle activity. In this dissertation, we used the amplitude and timing analysis of EMG signals to measure the activity and activity onset of a superficial muscle (Erector Spinae; ES), and muscle thickness measurements from US imaging to measure the contraction of the deep muscle of LM.

1.5 Trunk muscle dysfunction in low back pain:

Imbalance and dysfunction in the activity of ES have been reported in LBP. According to a meta-analytic review [38], the following dysfunctions have been reported in ES muscles: delayed muscle onset, muscle imbalance between the left and the right sides, faster muscle fatigue, lack of flexion relaxation phenomenon (absence of ES muscle relaxation at the end of flexion), and abnormal amplitude of EMG signals. The abnormal amplitude of EMG signals was found as high EMG activity at low level isometric contractions like standing [39-41], and low EMG activity

at moderate and maximum levels of isometric contractions [42-44]. Furthermore, higher co-contraction of superficial trunk muscles (ES and abdominal muscles) was found in people with LBP [45]. Dysfunctions in the major stabilizing deep muscles of the lumbar spine have been also reported in LBP such as less activity, atrophy, and delayed muscle onset of LM. The delayed muscle onset of TA [14-20]and LM was associated with recurrent LBP [46]. Furthermore, the improvement in LBP does not necessarily result in returning of normal function of LM [16,46].

Although the increased muscle activity of ES and the co-contraction of trunk muscles increase the stability of the spine, it may mechanically add stresses to the articulating structures, resulting in further micro trauma, limiting the patient's flexibility and function, and leading to further pain and disability [45]. Therefore, it is important to decrease the activity of ES, while attempting to increase the stability of the spine via increasing the activation of deep back muscles (e. g. LM). In this dissertation, we investigated whether lumbar mobilization intervention can restore the normal activity of LM and ES muscles in people with chronic LBP (Chapter three). Restoring the normal muscle activation may prevent further damage and pain and increase functional abilities in people with LBP.

1.6 Possible mechanisms of pain on muscle activity and motor control:

Vicious cycle model (pain-spasm-pain) and pain adaptation model are the two main theories explaining the effects of pain on motor control in LBP [47]. The vicious cycle model proposes that pain signals at the spinal cord level stimulate alpha motor neurons, which induce muscle reflexes in form of hyperactivity (spasm or contraction) around the painful site. The hyperactivity of the muscles attempts to protect and support the injured tissue. However, this hyperactivity can cause further loading of the facet and intervertebral joints and lead to more pain, which stimulates alpha motor neurons again; thus, continuing the cycle of pain–spasm-

pain. The pain adaptation model [48] suggests that pain decreases the activity of agonist muscles (the muscles that contract to create the painful movement) and increases the activity of antagonist muscles (the muscles that contract to resist and control the painful movement) in order to limit the range and the velocity of the movement, thereby reducing further injury and pain. According to the pain adaptation model, pain afferent signals can excite or inhibit the alpha motor neuron by excitatory or inhibitory interneurons, and the motor command from the brain determines which output (the inhibitory or the excitatory interneurons) dominate.

However, the changes in the motor control in people with chronic LBP are complex and cannot be fully explained by the previous two models alone. Hodges et al. hypothesized that the central nervous system may interpret the increased stiffness of the painful spine (via co-contraction of ES and superficial trunk muscles) as a less need for the deep spinal muscles to fine-adjust the intervertebral motion, which in turn leads to decreased activity of LM; he suggested multiple mechanisms for pain and motor control. The mechanisms include changes in motor neuron activity at the spinal and cortical levels, altered proprioception, and effects of other symptoms, such as stress and fear, on motor control[49]. Therefore, it is important to capture these symptoms in LBP studies to be able to interpret and compare results between studies. In this dissertation, we used standard questionnaires to capture activity level, fear avoidance, depression, and disability of chronic LBP subjects.

1.7 Role of manual therapy in treating trunk muscle dysfunction in low back pain:

Physical therapy interventions for LBP include physical modalities, therapeutic exercises, patient education and manual therapy. Spinal manipulation and skilled motor training were found to restore the normal activation pattern of low back muscles to certain extent [50-52]. Skilled motor training refers to use of cognitive attention to activate LM muscles with minimal or no activity of

ES muscles. Lumbar mobilization is another example of manual therapy treatment that is commonly used to decrease pain and stiffness in LBP. However, the effect of lumbar mobilization on the activity of back muscles is not known. Investigating the effect of mobilization on the activity of back muscles may lead to a better understanding of lumbar mobilization and its appropriate application for LBP. Chapter three investigated such effect of lumbar mobilization on the activity of back muscles in people with chronic LBP.

1.8 Mobilization versus manipulation for low back pain:

Lumbar mobilization and manipulation are common treatments for LBP in physical therapy practice to decrease pain and stiffness in back, and both interventions are recommended in the clinical guidelines for managing LBP [53]. Both interventions have low risks. However, very rare complications after manipulation of lumbar spine have been reported [54].

Several differences exist between the two interventions. First, during lumbar mobilization, the clinician's hands press on the patient's back, and apply oscillatory (back and forth) movements at a specific grade (grade I to grade IV) within the available accessory range of motion (AAROM). On the other hand, during manipulation the clinician applies a single quick thrust movement beyond the AAROM. Second, during manipulation and in contrast to mobilization, patient is unable to control or prevent the movement. Clinicians usually select mobilization intervention over manipulation when manipulation is contraindicated or patient condition is too irritable [55]. Furthermore, manipulation is more skillful technique and often used by experienced clinicians who are trained in manipulation; thus lumbar mobilization is more commonly used technique over manipulation among physical therapists [55].

There are four grades of mobilization (grade I to grade IV) based on the amount of oscillatory movement (amplitude) and the portion of the AAROM in which the oscillation is

applied (Figure 1.1). Grade I consists of small amplitude movements near the beginning of the AAROM, grade II consists of large amplitude movements through the mid-range of the AAROM, grade III consists of large amplitude movements near the end of the AAROM, and grade IV consists of small amplitude movements near the end of the AAROM. The amplitude represents the oscillatory movements as shown in Figure 1.2.

The underlying mechanisms for both spinal mobilization and manipulation interventions are poorly understood. Bialosky et al. suggested a theoretical model (Figure 1.3) explaining how mechanical stimuli from these interventions could lead to neurophysiological effects at the peripheral, spinal, and/or brain levels. These neurophysiological effects include changes in muscle activity, hypoalgesia, and autonomic responses (e.g. changes in heart rate and skin conduction) [56]. Regarding changes in muscles activity, both manipulation and higher grades of mobilization have shown to change the cervical and lumbar spine muscle activity [50,57-60]. Studies suggest that mobilization and manipulation stimulate a brain stem region (periaqueductal gray) that controls sensory input from the spinal cord and the brain, leading to combined analgesia, sympathetic excitation, and motor effects [56]. It has also been proposed that these interventions can stimulate the mechanoreceptors within the joints and muscles which changes the α-motor neurons excitability [61]. In cats, manipulation increased the discharge frequency of the mechanoreceptors (muscle spindles and Golgi tendon organs) in LM and longissimus (a part of ES) muscles [62-66]. It is also possible that the effects of mobilization and manipulation on muscle activity are mediated by the hypoalgesic effect of these interventions [67]. However, several studies reported changes in muscle activities in healthy subjects without pain [68-70]. Thus, it is probable that all of the above mechanisms contribute to change the muscle activity after mobilization.

1.9 Effects of mobilization and manipulation on the activity/recruitment of spinal muscles:

It is unclear if mobilization and manipulation can change the spinal muscle activity in absence of pain. Studies in healthy subjects have shown increased trapezius muscle strength after both grade IV thoracic mobilization [70] and thoracic manipulation [68], and decreased activity of ES muscles after grade IV lumbar mobilization [69]. In contrast, one study reported no change in the activity of sternocleidomastoid muscle after grade III cervical mobilization in healthy subjects [67].

In people with neck pain, both mobilization and manipulation were found to change the cervical muscle activity. Both cervical manipulation and grade IV mobilization increased the contraction of the deep cervical flexors [71]. Furthermore, Grade III cervical mobilization has shown to increase the contraction of deep cervical flexors and decrease the contraction of superficial cervical flexors muscles [72].

In people with LBP, manipulation has shown to change the activity of ES. However, the direction of the change in ES activity depended on the type and intensity of muscle contraction. These studies are summarized in Table 1.1. Manipulation decreased the activity of ES muscles at static and low isometric contraction conditions [50,51,57], and increased the activity of ES at maximum isometric contraction in people with LBP [60]. Only one study demonstrated no effect of manipulation on ES muscles activity in quite standing [73]; although the study had a small sample size of 12 subjects, and was not a randomized control trial.

Manipulation has also shown to increase the activity of LM in people with LBP. In a large study (78 LBP subjects), small but significant increase (2%) in the muscle thickness of LM was found during an arm lift task (submaximal isometric contraction) [51]. However, it is unknown if mobilization, has similar effects on back muscles in presence or absence of pain.

This dissertation investigated the effect of lumbar mobilization on back muscles (ES and LM) activity during a task that requires low isometric contraction in healthy subjects (Chapter two) as well as in people with chronic LBP (Chapter three). We hypothesized that lumbar mobilization will lead to changes in the activity of back muscles similar to the reported changes in the previous manipulation and cervical mobilization studies. Those changes were increase in the contraction of the deep muscles and decrease in the contraction of the superficial muscles. Both higher grades of mobilization and manipulation have shown to change the cervical and thoracic spine muscle activity in healthy subjects and in people with neck pain [68,70-72] as discussed earlier. Furthermore, both cervical and lumbar regions have similar anatomy and neurophysiology.

1.10 Quantifying lumbar mobilization:

The four grades of mobilization are defined by displacement, which represents the distance moved during the mobilization as a result of the applied forces, and has two measures, the amplitude and the magnitude (Figure 1.2). The amplitude represents the distance moved during the oscillatory (back and forth) movements of mobilization. The magnitude represents the part of AAROM in which the amplitude/oscillatory movement is applied, or how deep/far the clinician pushes into the AAROM before applying the oscillatory movements. Both amplitude and magnitude are subjectively assessed by clinicians, and clinicians rely on "sensing" the amplitude and magnitude of displacement to apply various grades of mobilization. This has resulted in high variability of applying grades of mobilization. Studies have found poor intra- and inter-reliability of applying mobilization forces within and across mobilization sessions [74]. For example, clinicians with more than three years of experience, applied force magnitude that ranged from 63 to 347 N during grade IV lumbar mobilization [74]. This inconsistency may result

in inconsistent patient outcomes. For example, without quantifying mobilization force and displacement, the mobilization may be either too small to produce the desired clinical effect or too extreme, leading to adverse effects such as increased pain. Thus, measuring force or displacement of mobilization may improve reliability and clinical outcomes.

Current force measure instruments such as force plate or motion capture systems are not available during clinical practice. Therefore, there is a need for alternative devices that can measure mobilization forces or displacement in clinical settings. There is a linear relationship between forces applied at the lumbar spine and displacement, for forces higher than 30 N [75]. However, the displacement is affected by factors other than the force such as the rate/frequency of mobilization, the angle of the clinician's hand, the point of force application, the patient's body mass index, and most importantly the stiffness of the spine [76]. For examples, for the same amount of force application, the displacement is greater in a person with a flexible spine than in a person with a stiff spine. Spinal stiffness is less at lower mobilization frequency [77]; therefore, for the same amount of applied force, more displacement is expected when mobilization is applied at a frequency of 0.5 Hz than at 2 Hz.

To date, there has been no described method to measure mobilization displacement in clinical setting. The displacement can be measured in clinical setting as the movement of the therapist's hand during mobilization. Optortrak motion capture system has high reliability and accuracy in measuring small displacement. It has an accuracy of 0.1 mm and resolution of 0.01 mm [78]. However, Optotrak is a large, heavy, and expensive device to be used in clinical settings and requires engineering knowledge for its operation. Therefore, there is a need to develop a new method/device that can be applied to quantify displacement during mobilization that can potentially be used in clinical setting.

Inertial Measurement Unit (IMU) is a small size, inexpensive, and portable device that has the potential to measure clinician's hand displacement during mobilization. The unit usually includes both an accelerometer and gyroscope and sometimes magnetometer (compass). Accelerometer measures acceleration while gyroscope measures angular velocity. The acceleration and angular velocity of the clinician's hand movements during mobilization can be captured by IMU, and then used to calculate the amplitude of the vertical displacement of the clinician's hand.

Many factors may affect the accuracy of IMU in measuring the amplitude of vertical displacement such as errors of estimating orientation/angles, accelerometer and gyroscope drifts, the integration errors, and the speed of the movement. Accelerometer had an error of measurement less than 7% when used to measure 1.25 mm displacement of vibrational movements at 20 Hz of frequency [79]. However, IMU has less accuracy when used to measure movements that are both slower and larger than vibrational movements. When used to measure vertical toe displacement (around 15 cm) during walking, the error of measurement was found to be approximately 20% [80]. The mobilization movements are faster than walking but slower than the vibrational movements. Mobilization is usually applied at a frequency of 1 Hz, and the amplitude of mobilization is few millimeters. Therefore, the validity and reliability of IMU in measuring mobilization displacement need to be tested before its application can be considered for research or clinical use.

In this dissertation, we investigated the validity and reliability of IMU in measuring the amplitude of clinician's hand displacement during mobilization (Chapter four). We hypothesized that IMU would have shown validity and high reliability in measuring the amplitude of lumbar mobilization.

1.11 Significance of the study:

The findings of our studies make significant contribution toward our knowledge about lumbar mobilization and its application in clinical practice. First, the results may lead to a better understanding of lumbar mobilization and its underlying mechanism. Lumbar mobilization is a commonly used treatment for LBP; approximately 70-90% of physical therapists use lumbar mobilization for management of LBP [81,82]. Yet the underlying mechanisms of lumbar mobilization are poorly understood. Our study is the first to investigate the effects of lumbar mobilization on both deep (LM) and superficial (ES) back muscles in healthy subjects. Determining such effects will improve our knowledge if mobilization can change muscle activity in absence of pain.

Secondly, to our knowledge, there are no published studies about the effects of spinal mobilization on the activity of the back muscles in people with chronic LBP. The dysfunction of ES and LM muscles may add to the disability and recurrent pain experiences in chronic LBP. Normalizing the abnormal activity of back muscles may decrease pain and functional disability in people with LBP. The findings from a previous study suggested that the improvements in LM contraction after manipulation mediated disability level in people with LBP [83]. Determining the effects of lumbar mobilization on back muscles in people with LBP may support the current use of mobilization with the physiological rational of restoring normal muscle activity.

Thirdly, the findings of this dissertation may lead to a better measuring method of mobilization, which may subsequently decrease the variability in application of mobilization in clinical practice and in research settings and improve patient outcomes. Current methods to quantify mobilization are limited to laboratory settings because they are not feasible to be used in

clinical settings. Our study is the first step to develop a friendly used device that can potentially be used in clinical and educational settings to measure mobilization.

1.12. Specific Aims and Statement of Hypotheses:

LBP is the second most common cause of disability in the United States [84] and is associated with increased activity of ES and decreased activity of LM [16,17,85,86]. This abnormal activity of back muscles may lead to muscular pain and limitations in function [87]. Lumbar mobilization is a common intervention for LBP to decrease pain and stiffness. However, the underlying mechanism of mobilization is still unclear, and there is a lack of understanding about the effect of lumbar mobilization on back muscle activity in healthy subjects and in people with LBP. Furthermore, there is inconsistency in application of mobilization, and this inconsistency may result in inconsistent patient outcomes following mobilization. Therefore, there is a need for devices that can be used in clinical settings to measure mobilization and decrease the inconsistency in applying mobilization.

The purpose of this work was to investigate the effects of lumbar mobilization on the activities of back muscles in both healthy subjects and people with LBP, and to investigate the validity and reliability of an IMU in measuring lumbar mobilization. The findings from previous spinal mobilization and manipulation studies guided us to conduct our studies.

Our rationale for this project was that investigating the effects of lumbar mobilization on activity of back muscles may lead to a better understanding of lumbar mobilization in targeting muscle dysfunction in people with LBP and may further support the use of mobilization in people with LBP. Furthermore, validating IMU is the first step toward its use in clinical settings to increase the consistency of mobilization application. The specific aims and hypothesis of this study are:

Aim 1: To determine the effects of grade IV lumbar mobilization on back muscles in healthy subjects.

We hypothesized that compared to both placebo and no intervention, grade IV mobilization would decrease the activity of ES (H1) and increase LM contraction (H2).

Healthy subjects will receive three intervention sessions (no intervention, placebo, and grade IV mobilization) on different days. Contraction of LM and the activity of ES will be measured with an arm lift task requiring low isometric contraction of back muscles, at two time points (before and immediately after the intervention) in each session. Ultrasound imaging and surface electromyogram (EMG) will be used to measure LM contraction and activity of ES respectively.

Aim 2: To determine the effects of grade III lumbar mobilization on back muscles in people with chronic LBP.

We hypothesized that compared to placebo, grade III mobilization will decrease the amount of activity (H3a) and activity onset (H3b) of ES, and increase LM contraction (H4).

LBP subjects will be randomly assigned into two groups (grade III mobilization or placebo/light touch group). Subjects will receive intervention based on their assigned group and for two sessions. Contraction of LM and the activity of ES will be measured with low isometric contraction (arm lift task) at two time points (before and immediately after the intervention) in each session. Ultrasound imaging and surface electromyogram (EMG) will be used to measure LM contraction and activity of ES respectively.

Aim 3: To determine the validity and reliability of IMU in measuring the amplitude of displacement of the clinician's hand during lumbar mobilization on healthy subjects.

We hypothesized that IMU measurements will have high agreement with Optotrak (H5a) and high correlation with force plate (H5b) measurements, and that IMU willhave high inter-rater (H6a) and intra-rater (H6b) reliability in measuring the amplitude of displacement.

Each healthy subject will receive four different amplitudes of lumbar mobilization – that is equivalent to grades III and IV of mobilization – by two clinicians in two sessions. The validity of IMU will be tested by comparing the IMU measurements (displacement) to the measurements of Optotrak (displacement) and by examining the correlation between IMU measurements (displacement) and the force plate measurement (force). The reliability of IMU will be tested by comparing the IMU measurements between two clinicians (inter-rater reliability) and between two sessions (intra-rater reliability).

The findings of our studies will add to the current knowledge about the physiological effects of lumbar mobilization and may support the use of lumbar mobilization to normalize abnormal back muscle activity found in people with LBP. Furthermore, based on our findings we conclude that IMU can be used as a valid instrument in measuring the amplitude of clinician's hand displacement during lumbar mobilization. Eventually, the IMU can serve as a user-friendly device in clinical settings to increase the consistency of application of mobilization and can be used in future mobilization studies.

1.13 Tables

Table 1.1: Previous studies about the effect of manipulation on back muscles activity/contraction in people with LBP

Study	Design (number of subjects)	Testing task	Results	Time of observed findings
Bicalho (2010) [50]	Randomized controlled trail (40)	From standing, dynamic flexion, static full flexion and then dynamic extension	No changes during dynamic flexion ↓ EMG activity of ES during both static full flexion and dynamic extension	Immediately after the manipulation
DeVocht et.al. (2005) [57]	Pre and post study design (16)	Resting in prone position	↓ EMG activity of ES	Immediately after the manipulation
Keller et.al. (2000) [60]	Non-randomized control trial (40)	Maximum voluntary contraction from prone position	↑ EMG activity of ES	Immediately after the manipulation
Lehman et.al. (2001) [73]	Pre and post study design (14)	Quite standing , dynamic flexion, lateral bending and axial twist	No consistent changes in EMG activity of ES or abdominal muscles	Immediately after the manipulation
Koppenhaver et.al. (2011) [51]	Prospective case series (81)	Low isometric contraction LM: arm lift task. Abdominal muscles: straight leg raise and abdominal draw in maneuver	↑ contraction of LM ↓ contraction of abdominal muscles	3-4 days after the manipulation Immediately after the manipulation
EMG: Electromyography, ES: Erector Spinae muscle, LM: Lumbar Multifidus muscle ↑: increased ↓: decreased				

1.14. Figures

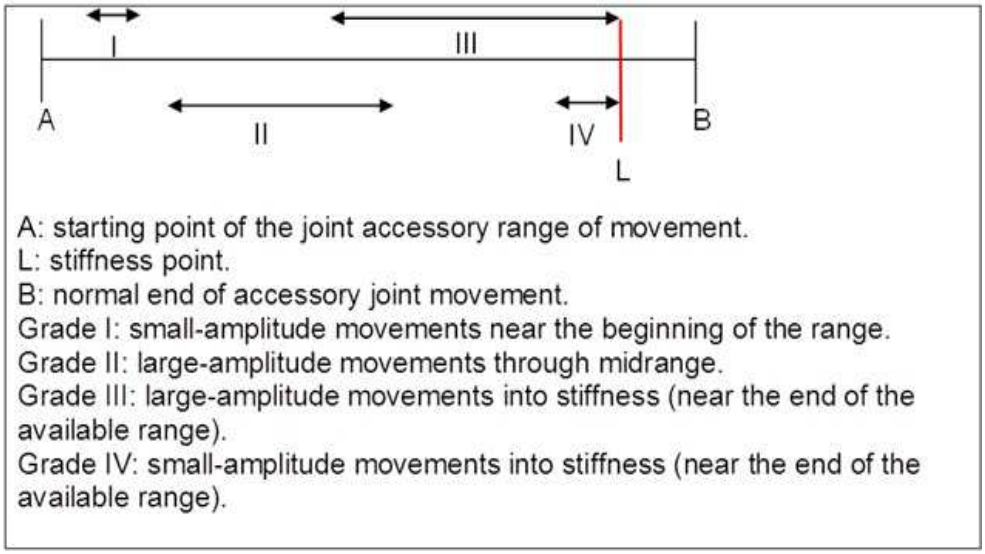


Figure 1.1: Grades of Mobilization [88].

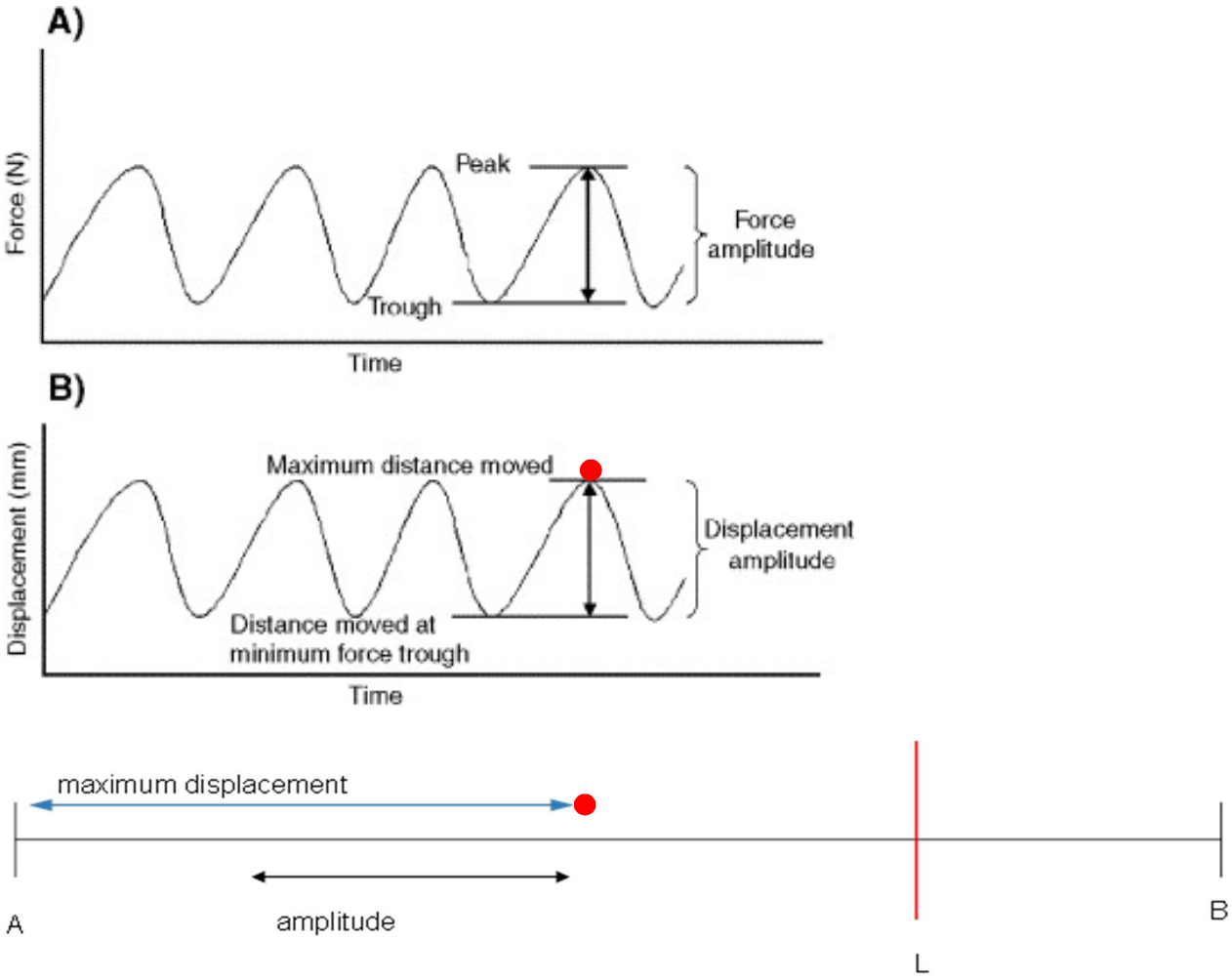
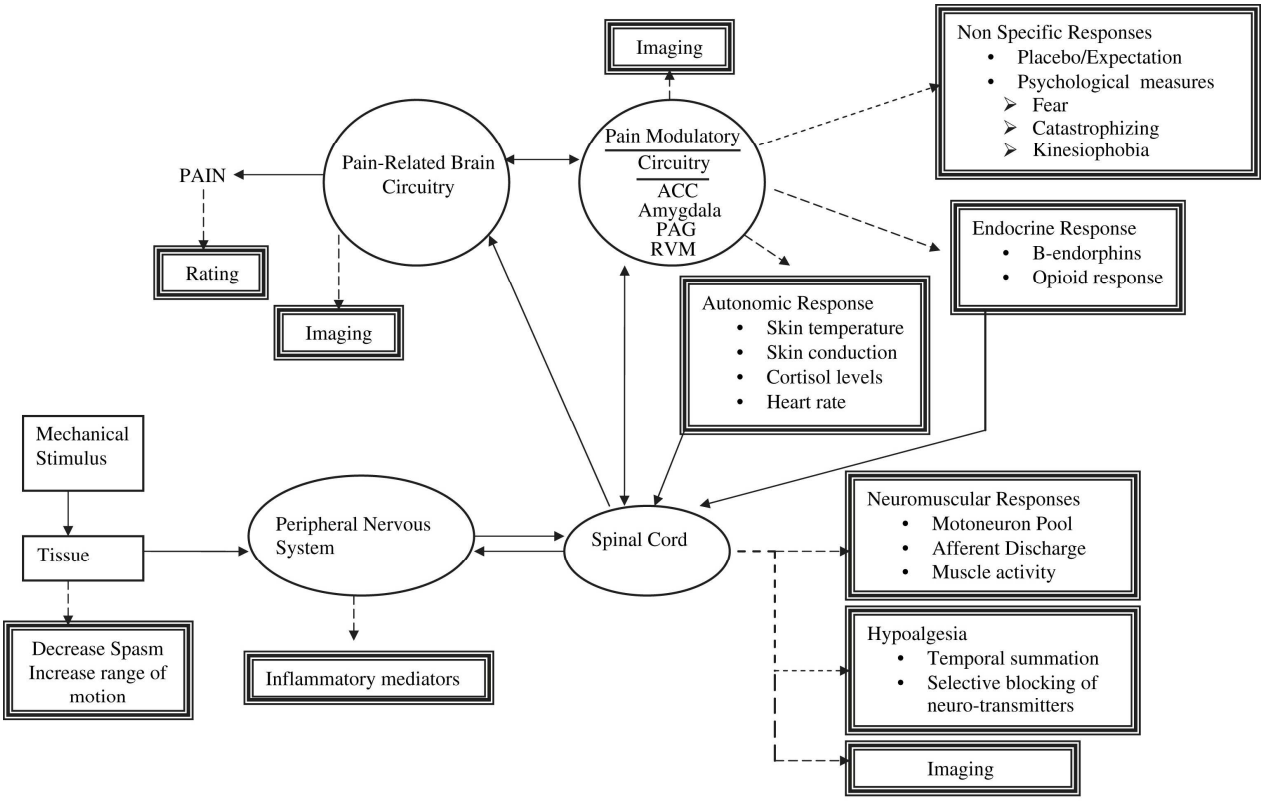


Figure 1.2: Up: Measures of force (A) and displacement (B) [76]. Down: blue line represents the magnitude; black line represents grade II mobilization amplitude as an example. Red dots on up and down figures represent magnitude



ACC = anterior cingular cortex; PAG = periaqueductal gray; RVM = rostral ventromedial medulla

Figure 1.3: The theoretical model of Bialosky et al. explaining the underlying effects of manual therapy including mobilization and manipulation[56].

Chapter 2: Effect of lumbar mobilization on back muscle in healthy subjects

2.1 Abstract:

Objectives: Lumbar mobilization is a standard assessment and treatment method for the lower back. Only few studies have investigated the effect of lumbar mobilization on the activity of back muscles in healthy people. This study investigated the effect of grade IV lumbar mobilization on erector spinae (ES) and lumbar multifidus (LM) muscles in healthy people.

Methods: A randomized, repeated measures design was used. Sixteen healthy subjects attended three testing sessions with different intervention in each session (no-intervention, grade IV central lumbar mobilization at L4, and placebo/light touch). Lying in prone position, subjects lifted a light weight with their right arm. During the arm lift task, ultrasound (US) images of LM and surface Electromyography (EMG) signals of ES were captured before and immediately after the application of the intervention in each session. The contraction of LM was calculated from US images, and the Root Mean Square (RMS) was calculated from the EMG signals and used as outcome measures.

Results: A significant difference was found in LM contraction between the placebo and mobilization intervention (difference =0.04, $p=0.02$). There was no significant difference for the RMS of EMG signals between the interventions.

Conclusion: The significant difference in LM contraction was small, and may not have a clinical significance. Lumbar mobilization did not change the activity of ES in healthy people. Future studies with larger sample size are needed to confirm these findings and to investigate the effect of mobilization on the back muscles in people with low back pain.

2.2 Introduction:

Lumbar mobilization is a common manual therapy technique used to decrease low back pain (LBP) and increase lumbar spine range of motion [88]. During mobilization, the clinician's

hands produce oscillatory movements of a specific grade (grade I- IV) to a single vertebra of the lumbar spine [88]. The underlying mechanisms of joint mobilization are still unclear. Joint mobilization may induce several physiological responses including pain reduction, hypoalgesia, and change in muscle activity [56]. Joint mobilization has been proposed to stimulate mechanoreceptors in the joints and muscles, which may alter the muscle activity through stimulating α-motor neurons at the spinal level [61] and the neurons of the periaqueductal gray in the midbrain [56].

The effect of joint mobilization on muscle activity in healthy subjects is still controversial. a few studies have shown increased strength of hip muscles after grade IV hip mobilization [89,90], increased trapezius muscle strength after grade IV thoracic mobilization [70], and decreased activity of erector spinae (ES) muscles after grade IV lumbar mobilization [69]in healthy subjects. In contrast, one study reported no change in the activity of superficial neck flexor muscles after grade III cervical mobilization in healthy subjects [67]. On the other hand, in people with neck pain, grade III cervical mobilization increased the activation of deep cervical muscles but decreased the activation of superficial cervical muscles [72], and grade IV cervical mobilization increased the motor performance of the deep cervical flexors muscles [71]. From the previous findings, it is unclear if mobilization can change the muscle activity in absence of pain.

The purpose of this study is to further investigate the effect of lumbar mobilization on back muscle activity in healthy subjects. This study examines the effect of lumbar mobilization on both superficial muscles of ES and deep muscles of lumbar multifidus (LM). Studying the effect of lumbar mobilization on the activity of back muscles in healthy subjects may lead to a better understanding of the underlying mechanism of mobilization. We hypothesized that lumbar

mobilization would increase the activity of the LM and decrease the activity of the ES. This hypothesis was based on findings from the previous studies in people with neck pain [71,72].

2.3 Methods:

Subjects between the age of 18 and 50 years with no history of LBP in the last six months were included in the study. Subjects with body mass index larger than 30 kg/m^2, any reported bony or joint pathology affecting lumbar spine (e.g., osteoporosis), lumbar/sacral deformities (e.g., spondylolisthesis), spinal surgery, and pregnancy were excluded. Before initiating the study, approval was obtained from the internal review board at University of Kansas Medical Center. All subjects consented prior to the testing. The subjects' physical activity was assessed using the long version of the International Physical Activity Questionnaire (IPAQ) [91].

Each subject attended three sessions, which were 3-4 days apart. During the first session, no-intervention was applied, which served as control intervention. During the second and third sessions, grade IV central lumbar mobilization and placebo (light touch) interventions were applied to lumbar segment 4 (L4) in a random order. In each session, the subject lifted a light weight (1.5-2 lb.) with the right arm before and immediately after each intervention (no-intervention, placebo, or mobilization). Ultrasound (US) images of LM and surface Electromyography (EMG) signals of ES were captured during the arm lift task. Muscle contraction from US images and Root Mean Square (RMS) of EMG signals were calculated and used as the outcome measures.

The arm lift task: Subjects laid in prone position with lower back exposed and legs shoulder-width apart. An inclinometer was used to measure the lumbo-sacral angle. If the angle was greater than 10 degrees, one or two pillows were used under the abdomen to flatten the lumbar curve to less than 10 degrees. Subjects' right elbow was flexed to approximately 90

degrees and right shoulder was abducted to approximately 120 degrees. A goniometer was used to measure the elbow and shoulder angles. Then subjects were asked to lift a specific amount of weight (1.5 to 2 Lb.) with their right hand to elicit 30% of the maximal voluntary contraction of LM [37]. Subjects lifted the weight by raising their arm up until their right elbow touched a horizontal head piece of stadiometer (at 5 cm height), and held their arms at that height, to induce isometric contraction, for three seconds. Subjects were instructed to keep their elbow and wrist at the same horizontal level during the arm lift. The subjects repeated the arm lift task three times before and immediately after each intervention.

The US imaging: A Logiq P5 US (GE Healthcare, Milwaukee, WI) with a 60 mm curvilinear array transducer, and a frequency of 5 MHz was used to capture the US images. The images of LM were taken from left side of lower back at the L4-L5 level. The spinous process of L4 was palpated and marked. The US transducer was placed in sagittal orientation just lateral to the spinous process and angled medially to clearly visualize the sacrum and the left L4-L5 facet joint in the image. US images were captured immediately before the arm lift task and during the isometric contraction of the arm lift task.

The EMG: Bagnoli™ Desktop EMG System was used. The system collects EMG signals at a bandwidth of 20-450 Hz. The EMG electrodes had 10 mm contact spacing and 100mm² detection area. The EMG procedures were performed by the same experimenter and followed SENIAM standards [92]. The skin of each subject's back was cleaned with alcohol and allowed to dry before placing the EMG electrodes. These electrodes were placed 3.5 cm lateral from the lumbar spine spinous processes [69]. Two electrodes were placed at the level of the first lumbar vertebra (L1) on each side (ES_L1_Left, ES_L1_Right), and one electrode was placed at the level of the fourth lumbar vertebra (L4) at the right side (ES_L4_Right). The reference

electrode was placed on the sacrum[93]. To collect and save the data from the EMG system, a data acquisition program was used (Labview 2012®; NI, Austin, USA). The EMG data was collected at frequency of 1000 Hz.

For normalization purpose, EMG signals were collected during a back-lift task that induced submaximal contraction of ES. At the beginning of each session, the subjects lifted their back from prone position until the spine of their scapulae touched the horizontal piece of the stadiometer (approximately 5cm away from their thorax) and held their back at that height for three seconds. The EMG signals from both tasks (the back lift and the arm lift tasks) were recorded from rest until the end of the contraction.

The interventions (no-intervention, placebo, and mobilization): All interventions were applied for 5 minutes. During the first session (no-intervention), no contact was made with the subject's back. During the second and third sessions, placebo and grade IV lumbar mobilization interventions were applied in a random order. The placebo (light touch) was performed by placing the therapist's hand at L4 vertebra. The light touch that we used was an appropriate placebo intervention. To our knowledge, there are no previous studies that investigated the effect of touch/light pressure placebo on the muscles activity. However, Kinesio tape, which is another type of light contact pressure, was found to have no effect on muscle strength/activity [94].

The mobilization included grade IV mobilization using the pisiform grip, and was applied four times, each with 60 seconds oscillation and 20 seconds rest in between. A force plate (Bertec Force Plate ®, Columbus, OH, USA) was used to standardize the amount of force by providing live visual feedback to the therapist about the amount of mobilization force applied. The therapist stood on the force plate and applied mobilization oscillating forces from 150 to 180

N at a frequency of 1Hz. The mobilization was applied consistently at 1 Hz frequency using a metronome. The sampling frequency of the force plate was 100 Hz. The collection, display, and storage of the force plate data were implemented by using a second Lab view program (Labview 2012®; NI, Austin, USA).

Data analysis:

LM muscle thickness from the US images was measured with Image J software [95]. The thickness of LM was measured as the distance between the most posterior portion of the facet joint and the fascial plane as visualized by the hyper-echoic line between the muscle and subcutaneous tissue [96](**Figure 2.1**). The contraction (percent thickness change) of LM was calculated using the following equation[37]:

$$\text{Contraction of LM} = \frac{\text{LMthickness}_{\text{activity}} - \text{LMthickness}_{\text{rest}}}{\text{LMthickness}_{\text{rest}}} \qquad \text{eq. 2.1}$$

A Matlab program was used to analyze the EMG signals from both the back lift and arm lift tasks. First, the EMG signals were filtered using a band pass filter of 30-400 Hz (Butterworth, 2nd order). Second, the signals were filtered with a notch filter (Butterworth) at frequencies of 60, 120 and 180 Hz to eliminate electrical noise. Third, the signals were smoothed using RMS with an RMS window size of 20 ms. Fourth, the contraction onset was identified only for ES_L1_Right electrode. The contraction onset was considered as the time point when the signal exceeded a threshold of the mean plus two standard deviations away from its baseline for more than 25 consecutive samples[97]. Fifth, the RMS for the EMG signals was selected for the middle second of the 3-second isometric contraction (one second after the onset of muscle contraction). Finally, the RMS from the arm lift task were normalized to the RMS from the back-lift task and used for statistical analysis.

Statistical analysis:

The normalized RMS of ES and the contraction of LM were averaged across the three trials of the arm lift task in each session. Then, the averaged values for ES at L1 on both sides (left and right) were averaged. As a result, three outcomes emerged, the normalized RMS at L1, the normalized RMS at L4, and the contraction of LM. The change in the outcomes (the outcome at the end of the session – the outcome at the beginning of the session) within the session was used in the final analysis.

SAS statistics software was used for statistical analysis. Wilcoxon signed-rank tests were carried out for the three outcomes to test the null hypothesis of zero median difference. Due to the pilot nature of the study, no correction was made for conducting Wilcoxon tests several times.

2.4 Results:

16 subjects (9 males and 7 females, age =26.8±4.8, BMI= 23.4±3.2) participated in the study. Most subjects had a high activity level as measured by the IPAQ (12 high, 3 moderate, and one low activity level). The EMG system has broken and failed to collect data for one subject.

The mean and standard deviation for each outcome is presented in Table 2.1. Median differences between placebo and baseline for ES L1, ES L4, and LM US were 0.029, 0.061, and 0.041, respectively. In terms of standard deviations (SDs, computed from placebo measurements), these median differences represent increases of 0.39, 0.58, and 1.05 SDs. Wilcoxon signed-rank tests revealed that effects on the activity of ES at L1 and L4 were not statistically significant ($p = .45$ and .28, respectively), whereas the effect on LM contraction was

(p = .02). We also tested differences between the non-intervention and mobilization conditions, and none was statistically significant.

2.5 Discussion:

The purpose of the study was to investigate the effect of grade IV lumbar mobilization on back muscle activity in healthy people. US imaging of LM muscle and EMG of ES muscles were used to investigate this effect. A significant difference was found in LM contraction between the placebo and the mobilization.

This is the first study to investigate the effects of lumbar mobilization on both deep (LM) and superficial (ES) back muscles in healthy subjects. No significant differences were found in the EMG activity between the three interventions in healthy subjects. This finding lines with the finding of Soon et al [67], who found no significant changes in EMG activity of cervical muscles after grade III cervical mobilization in subjects with no neck pain. However, this result contradicts other previous studies reporting effects of hip, thoracic, and lumbar mobilization on subjects with no pain [69,70,89,90]. These studies suggested that mobilization can alter the firing of mechanoreceptors, which can change the muscle activity through arthrokinetic reflex [70,89,90]. The discrepancy in findings may be explained by the differences in the protocols and the tested joints. Most of the previous studies [70,89,90] tested the maximum torque /strength of the muscles, while our study tested the activity of the muscles at submaximal contraction. The submaximal contraction used in this study might not be challenging enough to the muscles, and therefore no change in the muscle activity was observed after mobilization.

Only one previous study [69] detected significant changes in EMG activity of ES muscle at submaximal contraction in healthy subjects after lumbar mobilization. In the study [69], the ES muscle activity was tested at quiet standing (standing still with no movement). The discrepancy

of the findings between the previous study and our study might come from the different site of mobilization application and different testing tasks. The previous study [69] found that the mobilization effect on muscle activity is larger at the mobilized segment than other segments of lumbar spine. It is possible that changes in EMG at L1 level were not detected in this study because L1 is far from the mobilized segment (L4), and it might be that a change could not be detected at L4 level due to both small sample size (9 subjects) and the low activity level of the task. Furthermore, the testing task in previous study [69] was quiet standing while in our study we used the arm lift while the subject was lying prone. The quiet standing task is a slow postural task while the arm lift task in our study is a faster active task. The different testing positions and tasks might have contributed to the discrepancy in the findings between the two studies.

A statistically significant difference between placebo and mobilization sessions was found in LM contraction. However, the difference was very small; only a 4% median difference was found. Such a small difference may not have a clinical significance. Despite the fact that US imaging is a reliable method to indirectly measure LM contraction, the relative minimal detectable change (MDC) of US imaging for LM muscle contraction has been reported to be 11-13% [96,98].

There was no significant difference in the LM contraction between the no-intervention and mobilization. This result is consistent with a dissertation project conducted by Lim [99], in which neither mobilization nor manipulation changed the LM contraction in healthy subjects. Several factors could have contributed to the negative findings. First, the subjects did not have LBP, and 15 out of 16 subjects had moderate to high physical activity level. Unlike people with LBP, healthy subjects do not have muscle inhibition from pain or weakness in their LM muscle [14-18]. It might be that the effect of mobilization on the activity/contraction of back muscles is not

possible when the motor function is intact or in absence of pain. Second, US imaging may not be sensitive enough to detect small changes in LM contraction due to the large MDC of US imaging. Third, a single session of mobilization may not be enough to elicit changes in the activity of back muscles in a healthy population.

Limitations:

This study has few limitations. The arm lift task that was used in this study may have not sufficiently challenged the subjects' back muscles. However, the arm lift task is considered the standard task and consistently been used in previous US imaging for examination of LM. Furthermore, US imaging may not be sensitive enough to detect small changes in LM contraction due to relatively large MDC of US imaging for LM.

Future studies may investigate the effect of lumbar mobilization on back muscles at maximal isometric contraction in healthy people, and at either maximal or submaximal contraction in people with LBP. Furthermore, future studies may investigate the effect of several sessions of mobilizations on the activity of back muscles. Needle EMG has higher sensitivity than US imaging and may be used in order to detect the activity of LM muscle.

2.7 Conclusion:

This study concludes that lumbar mobilization may not result in clinically significant changes in the activity of back muscles at submaximal contractions in healthy people. Future studies may consider more sensitive methods to detect the activity of back muscles or exertions that require higher submaximal or maximal contractions.

2.8 Tables:

Table 2.1: The differences in the outcomes in each session (Mean ± SD)

	EMG_L1 (n=15)			**EMG_L4** (n=15)			**LM contraction** (n=16)		
	baseli-ne	After interv-ention	Δ	baseli-ne	After interv-ention	Δ	baseli-ne	After interv-ention	Δ
No-treatment (control)	59% ± 20%	60% ± 23%	1% ± 6%	58% ± 26%	61% ± 30%	3% ± 7%	17% ± 6%	18% ± 8%	1% ± 5%
Placebo	65% ± 38%	66% ± 36%	1% ± 7%	63% ± 49%	63% ± 48%	<1% ± 11%	19% ± 8%	16% ± 7%	-3% ± 6%
Mobilization	65% ± 33%	65% ± 33%	<1% ± 18%	57% ± 33%	58% ± 37%	61% ± 16%	16% ± 6%	17% ± 8%	1% ± 5%

The EMG outcomes represent the normalized RMS of the EMG signals (normalized to submaximal contraction). The LM contraction represents the % change in muscle thickness between rest and contraction states. Δ represents the difference in the outcome between baseline and after the intervention.

2.9 Figures:

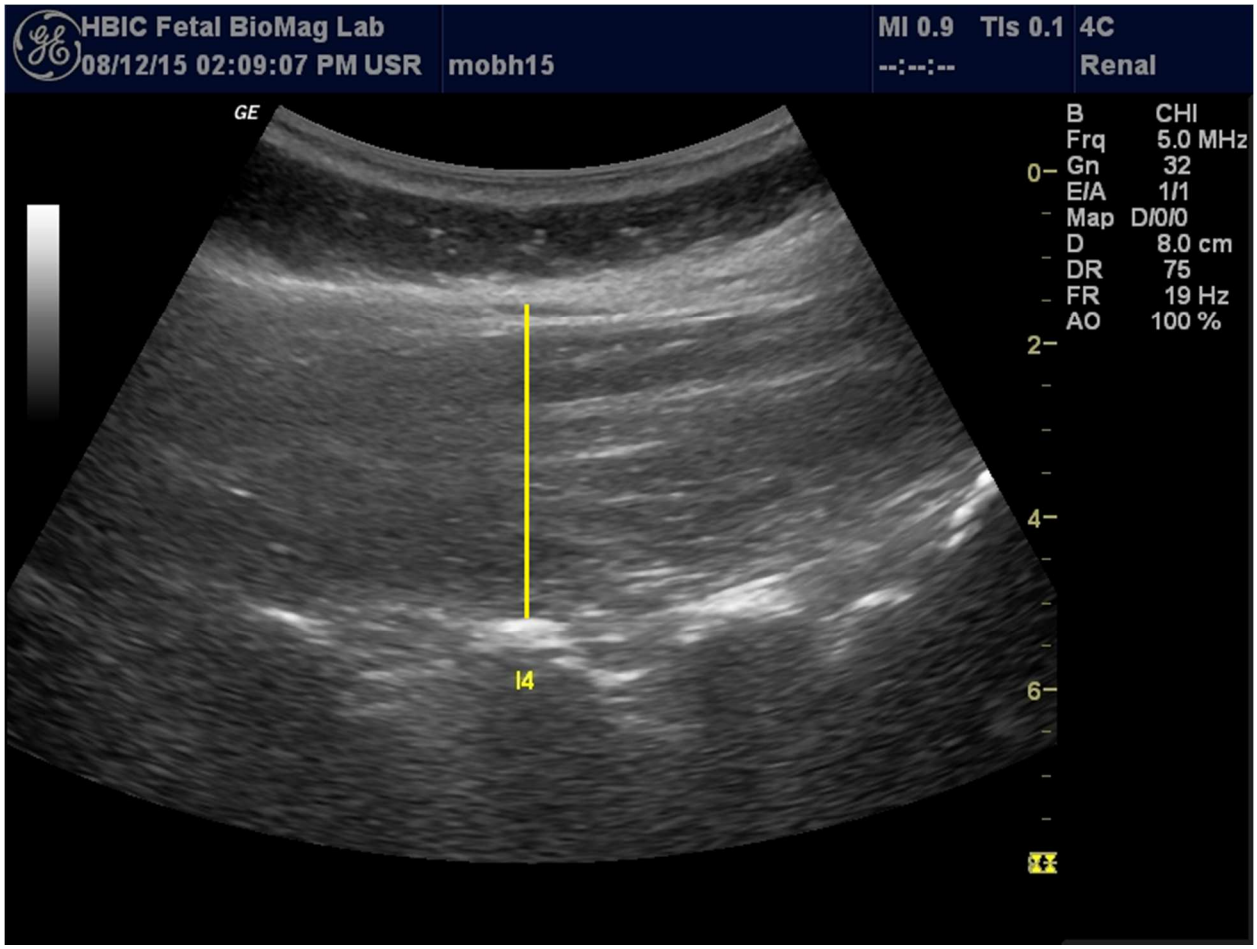


Figure 2.1: Measurement of LM muscle thickness from US images

The yellow line represents the measurement (LM muscle thickness) from the US image. LM: Lumbar multifidus, L4: facet joint of fourth lumbar vertebrae

Chapter 3: Effect of lumbar mobilization on back muscle activity in people with low back pain

3.1 Abstract:

Background: Lumbar mobilization is a standard treatment method for lower back pain (LBP). However, its effect on the activity of back muscles is not well known.

Objectives: To investigate the effects of grade III lumbar mobilization on the activity/contraction of erector spinae (ES) and lumbar multifidus (LM) muscles in people with LBP.

Design: randomized control study.

Methods: Twenty-one subjects with LBP received either grade III central lumbar mobilization or placebo (light touch) intervention on lumbar segment level 4 (L4). Surface Electromyography (EMG) signals of ES and ultrasound (US) images of LM were captured with an arm-lift task in prone position before and after the intervention. The contraction of LM was calculated from US images at L4 level. The normalized amplitude of EMG signals (nEMG) and activity onset of ES were calculated from the EMG signals at both L1 and L4 levels.

Results: Significant differences were found between the mobilization and placebo group in LM contraction ($p=0.03$), nEMG of ES at levels L1 ($p =0.01$) and L4 ($p= 0.05$), and activity onset of ES at the level of L1 ($p=0.02$).

Conclusion: Lumbar mobilization decreased both the activity amplitude and the activity onset of ES in people with LBP. However, the significant difference in LM contraction was small and may not have clinical significance. Future studies with larger sample size are needed to confirm these findings.

3.2 Introduction:

Low back pain (LBP) is the second most common cause of disability in the United States [84]. LBP is associated with increased activity of superficial back muscle erector spinae (ES) and

decreased activity of deep back muscle lumbar multifidus (LM) [16,17,85,86]. This abnormal activity of superficial and deep muscles in LBP may lead to further pain and limitations in function [87].

Lumbar Mobilization and manipulation are manual therapy interventions that are recommended in the clinical guidelines for managing LBP [53]. There are few differences between lumbar mobilization and manipulation. During mobilization, clinicians target a single lumbar spine vertebra using their hands to apply oscillatory movements within the available range of movement, and with a predetermined grade (grade I, II, III, or IV). On the other hand, during manipulation, the clinicians apply a single quick thrust movement beyond the available range of movement. Further, in contrast to mobilization, during manipulation the patient is unable to control or prevent the movement. Both interventions are commonly used for LBP. However, therapists most often select lumbar mobilization over manipulation when manipulation is contraindicated or patient condition is too irritable [55].

Manual therapy interventions may reduce pain, lead to hypoalgesia, and change the activity of muscles [56]. Manipulation studies found that manipulation decreased the activity of ES and increased the activity of LM in people with LBP [50,51], and previous mobilization studies found that grade III cervical mobilization decreased the activity of superficial neck muscles and increased the activity of deep neck muscles in people with neck pain [71,72]. Yet, the effect of lumbar mobilization on the activity of back muscles in people with LBP is not known.

To our knowledge, this is the first study to investigate the immediate effects of lumbar mobilization on both deep (LM) and superficial (ES) back muscles in people with LBP. Investigating this effect may lead to a better understanding of lumbar mobilization and its appropriate application for management of LBP, and may lead to use of lumbar mobilization to correct muscle dysfunction in LBP.

3.3 Methods:

Subjects between the ages of 18 and 55 years with chronic LBP, defined as pain for more than half the days in the past six months [100] were recruited. Subjects were included if they had: 1) pain localized between the 12th rib and the inferior gluteal folds, 2) pain greater than 3 out of 10 on 0-10 numerical rating pain scale where 0=no pain, 10=worse pain imagined, and 3) left side or bilateral LBP (since US measurement was conducted on the left side only). Subjects were excluded if they had symptoms radiating below the knee, body mass index (BMI) larger than 30 kg/m^2, presence of neuromuscular diseases such as stroke, lumbosacral conditions/pathology such as severe osteoporosis, pregnancy, inability to perform the arm lifting or back lifting tasks of the study, and inability to tolerate prone position for one hour. Finally, subjects were excluded if they had night pain, progressive neurological deficit, unexplained weight loss, or if they were involved in LBP intervention program or spinal mobilization/manipulation within the month prior to the start of the study.

Ethical Approval Statement:

The Human Subjects Committee at University of Kansas Medical Center approved the study before subjects were recruited. All subjects consented prior to the testing.

Following the consent, the pain level of the subjects was assessed using 0-10 numeric pain rating scale; the subjects' activity level was assessed using the long form of the International Physical Activity Questionnaire (IPAQ); disability level was measured with the modified Oswestry Back Pain Disability Questionnaire (MOSQ); severity of depression was tested using the Beck Depression Inventory (BDI-II); and pain avoidance behavior was tested using the Fear-Avoidance Beliefs Questionnaire (FABQ). These questionnaires are standard,

valid and reliable [101-104]. These questionnaires were used to address the multidimensional (psychological and physical) aspects of chronic LBP.

A randomized controlled design was used with a convenience sample of 21 subjects with LBP. Subjects were randomized either to mobilization (10 subjects) or to placebo group (11 subjects) using a randomized block design to ensure approximately equal percentages of males and females in each group. The researcher completed the randomization allocation online using Graph Pad for each gender separately [49].

Each subject attended two sessions 2-4 days apart. At the beginning of each session, subjects practiced a back-lift task (a normalization task described below) twice before performing it two times for measurement and then practiced an arm-lift task and Pressure Pain Threshold (PPT) testing (described below) thrice, before performing it three times for measurement. Next the researcher applied the intervention of placebo or mobilization. Immediately after the intervention subjects repeated the arm-lift task and PPT testing three times. Pressure pain threshold was always tested after the arm lift. The researcher captured ES surface EMG signals and ultrasound (US) LM images during the arm-lift task and used these measures as outcomes (described below). PPT was tested to understand the relationship between pain reduction (as measured by percent changes in PPT) and the outcome measures.

The Back-lift task: The back-lift task induced submaximal contraction of ES and was used to normalize the EMG signals of the arm-lift task. The subjects raised their back from prone position until the spine of their scapula touched a horizontal piece of the stadiometer (approximately 5 cm up), then held their back at that height (to induce isometric contraction) for three seconds [105]. EMG data were captured during two repetitions of the back-lift task only at the beginning of each session.

The arm-lift task: Subjects carried out an arm-lift task from the prone position with their legs shoulder-width apart [106]. The researcher used an inclinometer to measure the lumbar curve and placed 1-2 pillows under the subject's abdomen, if necessary, to ensure the curve was less than 10 degrees [106]. The subject's right arm was placed at approximately 90 degrees of elbow flexion and 120 degrees of shoulder abduction using a goniometer. Next, using the right hand the subject lifted a weight of 1.5 to 2 lbs. to achieve 30% of maximal voluntary contraction of LM [37], keeping the wrist and elbow level. The subject stopped the lifting motion when the elbow reached a 5 cm-high horizontal piece of the stadiometer and held the weight for three seconds. EMG signals and US images were captured during the three repetitions of the task before and immediately after the intervention.

The ultrasound imaging: US images were captured with a Logiq P5 ultrasound (GE Healthcare, Milwaukee, WI) with 60-mm curvilinear array transducer at 5-MHz frequency. After palpating and marking the spinous process of L4, the researcher placed the US transducer to the left of the L4 spinous process, angling it medially until the sacrum and left L4-L5 facet joint were visible [107]. The researcher captured the US images both at rest and during activity (the 3-second isometric arm contraction).

The EMG: EMG signals were collected at 1000 Hz using the Bagnoli™ Desktop EMG System which has an internal band-pass filter bandwidth of 20-450 Hz; electrodes had contact spacing and detection area of 10mm and 100mm^2, respectively. Skin was cleaned and the electrodes were placed at L1 and L4 levels. To determine L1 and L4 levels, two methods were used, US imaging of facet joints and sacrum, and palpation of spinous processes of lumbar spine. The examiner started US imaging by using the sacrum as a landmark in the US image and then moved the US transducer cephalically to clearly visualize the facet joint at the middle of the US

image. Palpation of lumbar spine was completed using two landmarks, the iliac crest for identification of L4 spinous process, and the 12th rib for identification of L1 spinous process.

The researcher placed three electrodes 3.5 cm lateral from the lumbar spine spinous processes at L1 level (one electrode on each side, L1_Left and L1_Right) [69] and at L4 level (only electrode on the right side, L4_Right). One electrode was placed over the posterior deltoid muscle of the right arm. The reference electrode was placed over the sacrum [93]. Data acquisition box (USB-6218 BNC, NI, Austin, USA) and LabVIEW program (2012®; NI, Austin, USA) were used for EMG data acquisition. The EMG signals of the back-lift and the arm-lift tasks were recorded from rest until the end of the contraction.

Pressure Pain Threshold (PPT): Algometer PPT is a valid and reliable way to quantify pain [108]. An algometer with a one centimeter square tip was applied at L2-L3 level between the EMG electrodes on the right side (3.5 cm lateral from the lumbar spinous processes). The testing point (L2-L3) was marked with a marker to ensure reliable and rapid location during the experimental procedure. The pressure from the algometer tip was applied at the rate of one kg per second (kg/s) using visual feedback on a computer screen provided by the LabVIEW program. Subjects were provided with a computer mouse and instructed to click the mouse button once they began to feel a change in the sensation from pressure to mild pain. The readings of the algometer were captured when the subject clicked the mouse button. The PPT testing was repeated three times with 10 seconds rest between each repetition [109] immediately after the arm-lift task, before and after the intervention.

Intervention (Placebo or mobilization): The intervention was applied for five minutes as either placebo intervention (light touch) or grade III mobilization. The researcher applied light touch with the hand at the L4 vertebra and applied grade III mobilization using the pisiform grip

for four bouts of 60 seconds each with rest time of 20 seconds between bouts. To provide live visual feedback to the therapist about the applied mobilization forces, a force plate (Bertec Force Plate ®, Columbus, OH, USA) was used with a sampling frequency of 100 Hz. The therapist stood on the force plate and tested the maximum force that the subject could tolerate without having pain. Then the mobilization was applied with oscillating forces from 50% to 100% of the maximum force. A metronome was used to apply mobilization at the frequency at 1 Hz. The collection, display, and storage of the force plate data were implemented by a LabVIEW program (LabVIEW 2012®; NI, Austin, USA).

Data analysis:

IPAQ and Beck depression scores were transformed to categorical variables according to their corresponding guidelines. Furthermore, pain scores less than five (i.e., 3 or 4) were categorized as moderate pain, whereas pain scores of five or more were categorized as severe pain [110].

LM muscle thickness from the US images was measured with Image J software [95]. The thickness at both rest and activity was measured as the distance between the posterior part of the facet joint and the fascial plane (Figure 2.1). The contraction of LM was calculated using the following equation [37]:

$$\text{LMcontraction} = \frac{\text{LMthickness}_{\text{activity}}\text{-LMthickness}_{\text{rest}}}{\text{LMthickness}_{\text{rest}}} \qquad \text{eq. 3.1}$$

To analyze the EMG signals from the back-lift and arm-lift tasks, the MATLAB program was used. First, the EMG signals were filtered twice, with a second order Butterworth band pass filter (30-400 Hz), and with a Butterworth notch filters (60, 120 and 180 Hz). These filters were performed both forward and reverse to eliminate temporal effects of the filter. The notch filters were used to remove electrical noise. Second, the signals were rectified and integrated using

root-mean-square (RMS, 20 ms window size). Third, the activity onset was determined for the posterior deltoid muscle. The activity onset was defined as the time point when the signal exceeded a threshold of the mean plus two standard deviations away from its baseline for more than 25 consecutive samples [97]. Fourth, the RMS values during the middle second of the contraction (second two after the onset) were selected for the three ES electrodes locations (L1_Left, L1_Right, and L4_Right). Finally, the normalized amplitudes of EMG (nEMG) were calculated by dividing the RMS values from the arm-lift task by the RMS values from the back-lift task; the nEMG values were used for statistical analysis.

The activity onsets from the three ES electrodes were calculated the same way as the activity onset of the posterior deltoid muscle. Then, the relative activity onsets from the three ES electrodes were calculated by subtracting the deltoid activity onset.

The contraction of LM, nEMG of ES, and the activity onsets of ES were averaged across the three trials of the arm-lift task in each session. The averaged nEMG at L1 on both sides (L1_Right and L1_Left) were summed. The change in each outcome (the outcome at the end of the session minus the outcome at the beginning of the session) was modeled as the outcome variable in the final analysis. As a result, there were six such outcomes: the change in contraction of LM, the change in nEMG L1, the change in nEMG L4, and the change in ES activity onset s at the three electrodes locations (activity onsets at L1_Left, L1_Right, and L4_Right).

For PPT, the three values were averaged at each time point (before and after the intervention), and the percent (%) change of PPT was calculated using the following equation:

$$\%\text{change of PPT} = \frac{\text{PPT}_{\text{afterintervention}} - \text{PPT}_{\text{baseline}}}{\text{PPT}_{\text{baseline}}} \qquad \text{eq. 3.2}$$

Statistical analysis:

SAS statistical software (SAS 9.4) was used for statistical analysis.

Each model included a random subject intercept to adjust for within-subject correlation. The base model included only group (placebo or mobilization) and pain category (moderate or severe) as predictors. A second model included group, pain category, and session; and a third model included group, pain category, and group × pain category interaction. The full model included session, group, pain category, and group × pain category interaction. After model selection, we re-fitted the final model for each outcome using "sandwich" variance estimators for robustness against non-normality. In addition, Spearman correlations were computed to investigate the relationship between % change of PPT and any significant changes in the outcomes.

3.4 Results:

Table 3.1 describes subject characteristics and clinical outcomes at base line. subjects were recruited between November 2015 and June 2016. Two subjects in the placebo group withdrew after the first session due to testing time conflict, and one subject in the mobilization group did not complete the IPAQ, MOSQ, BDI-II, and FABQ questionnaires. The available data from the 21 subjects were analyzed. Most subjects had moderate or high physical activity level (n=6 moderate, n=12 high, and n=2 low) and experienced moderate pain intensity (n=13 moderate and n=8 high). Most subjects had minimum to moderate disability (n=12 minimal disability, and n=8 moderate disability) and did not report depression (n=16 had normal score on BDI-II, n=3 had mild mood disturbance, and n=1 had borderline depression). The mean and standard deviation for the maximum mobilization force that was applied in the mobilization group was 108 N ± 35 N.

For three outcomes (changes in LM contraction, nEMG L1, and nEMG L4) the statistical model including group, pain category, and group × pain category interaction was selected as best-fitting. The interaction was statistically significant for all three outcomes (p = 0.01, 0.03,

and 0.03 respectively). We carried out post hoc tests of group effect by pain category. For the changes in LM contraction, the group effect was significant only for subjects with moderate pain (P =0.03), suggesting mobilization led to more LM contraction compared to the placebo group in subjects with moderate pain. For the changes in nEMG L1 and the changes in nEMG L4, the group effect was significant only for subjects with severe pain (p = 0.01 and 0.05 respectively), suggesting that mobilization led to less EMG activity compared to the placebo group in subjects with severe pain. All three of these effects were large, corresponding to an estimated between-group difference exceeding 1 SD (see Table 3.2).

For all three activity onset of ES outcomes, the best-fitting model was the base model (with only group and pain category as predictors). There were statistically significant effects of group in the onset of ES at L1_Left and L1_Right locations. Under placebo the average onset time increased after intervention, whereas the applied mobilization force led to a decrease in the average onset time. The estimated between-group differences for L1 Left and Right, respectively, were 49 ms (p=0.02) and 86 ms (p=0.05), equivalent to differences of 0.63 and 0.72 SDs.

There were no statistically significant effects for the activity onset of ES at L4 location, although the effect for group was in the same direction as for the L1 locations (estimated between-group difference = 79 ms, equivalent to 0.61 SDs, p=0.08).

For the relationship between the significant changes in the outcomes and the % change in PPT, there were weak to moderate but insignificant correlations (Table 3.3).

3.5 Discussion:

The purpose of the study was to investigate the effect of grade III lumbar mobilization on back muscle activity in people with chronic LBP. US imaging of LM muscle and EMG of ES

muscles were used to investigate this effect. A significant difference was found in the changes of LM contraction, nEMG of ES, and activity onset of ES between the placebo and the mobilization groups. These results suggest that grade III mobilization can influence muscle activity of deep and superficial back muscles, which is reported to be altered in chronic LBP and may be beneficial for normalizing muscle activation in managing chronic LBP.

There was a significant difference in changes of EMG amplitude, nEMG, between the mobilization and placebo group. Our findings line with the findings from previous studies in people with neck pain. In people with neck pain, grade III cervical mobilization was found to immediately decrease the activity of superficial muscles and increase the activity of deep muscles [71,72]. In the absence of similar mobilization studies on people with LBP, our results can be compared with the results from manipulation studies, as both manipulation and high grades of mobilization (grades III and IV) apply mechanical force that stretches the joint capsule and the surrounding muscles. In addition, both mobilization and manipulation have shown to change the cervical and thoracic spine muscle activity [68,70-72]. Previous manipulation studies had shown contrary findings regarding the direction of change in EMG activity of ES after manipulation in people with LBP [50,60]. A study by Bicalho et al. found that manipulation immediately decreased the EMG activity of ES during dynamic extension in people with chronic LBP [50]. Whereas Keller et al. found that manipulation immediately increased the maximum voluntary contraction of ES [60]. The contrast between these studies might be due to the different level of ES contraction tested. Both our study and the study by Bicalho et al. (2010) used a task that required low contraction of ES. In our study, we used the arm-lift task in which ES stabilize the spine during the task, and Bicalho et al. (2010) used dynamic extension with no resistance. However, the study by Keller et al. (2000) used a task that requires maximum contraction of ES. The decreased

activity of EMG in our study reflects positive effect of mobilization toward rectifying the muscle activity since people with LBP have high EMG activity of ES at low level isometric contractions like standing [39-41].

The significant difference in nEMG of ES in our study was only in people with severe pain. No statistically significant changes were found in people with moderate pain. This may be because back muscle dysfunction in people with LBP is associated with pain severity [111,112]. People with moderate back pain in our study may have had too little impairment in muscle activity to be rectified by the mobilization.

There was a significant difference in the ES activity onset between groups. Mobilization decreased the time of ES activity onset. These results line with the findings of a previous study by Ferreira et al. (2007) in which the activity onset of the Oblique Internus muscle during rapid arm-lift task decreased after grade IV unilateral mobilization [113]. Both ES muscles in our study and the Oblique Internus muscle in the Ferreira et al. (2007) study contracted to stabilize the trunk during arm movement. However, the activity of the Oblique Internus muscle was found to occur before the activity of the deltoid muscle, while in our study the activity of ES was found to occur after the deltoid activity. The different timing of activity (before or after deltoid) is probably due to differences in the task between the two studies. The arm-lift task was performed in standing position in Ferrera et al. (2007) study, which perturbed balance in antero-posterior direction [114], therefore the central nervous system used anticipatory postural adjustments to counteract the forthcoming postural perturbation [115]. Therefore, the abdominal muscle contracted before the deltoid muscle (arm movement) to stabilize the trunk in an anticipatory postural adjustments [114,116-118]. In our study, the arm-lift task was performed in prone position; hence, there was no need for using anticipatory postural adjustments since the balance was not

threatened. The ES muscle activity following the deltoid activity in our study was probably a consequence of contractions in a group of muscles (muscle chain) that synergically work to generate a proper functional movement [119], which was clearing the arm from the bed. The change in ES activity onset found in our study might represent better synergic activity of the muscle chain involving the ES and posterior deltoid as a result of mobilization. The change in ES activity onset found in our study might have clinical significance as a previous study has shown that people with LBP have delayed onset of ES activity [120].

There was small but statistically significant difference in LM contraction between the two groups. Our findings line up with the results of Koppenhaver et al. in which manipulation was shown to increase (approximately 2%) the muscle thickness of LM during the arm-lift task (submaximal isometric contraction) in people with LBP [51]. In our study, the changes in LM contraction were found only in people with moderate pain but not severe pain. That may be due to the individualization of mobilization force according to subjects' tolerance. It might be that people with severe back pain had more stiffness in their back and less tolerance for the mobilization forces, thus the individualized mobilization forces might not be sufficient enough to stretch the deep LM muscle and the facet joint capsule, therefore causing no detectable change in LM in people with severe pain.

The correlations were insignificant between the % changes in PPT and the changes in randomized RMS, ES activity onset, and LM contraction. Although there was insufficient evidence to conclude that observed changes in muscle activity are associated with change in the pressure pain threshold, the pressure pain threshold was tested after the arm-lift task, and some studies reported increased pressure threshold (pain reduction) after isometric contraction [121-123]. Therefore, it might be that the isometric contraction of the arm-lift task affected the observed

PPT values, and therefore we could not find a significant correlation between the calculated % changes in PPT and the outcome measures.

The changes in the back muscles activity/contraction found in this study might result from potential mechanical and neurological effects of mobilization. Joint mobilization has been proposed to stimulate mechanoreceptors in the joints and muscles, which may alter the muscle activity through stimulating α-motor neurons at the spinal level [61] and the periaqueductal gray area in the midbrain [56].

This study has some limitations. First, the minimum detectable change for contraction of LM muscles measured by US imaging has been reported to be 11-13% [96,98]. Therefore, the small change (approximately 3%) in LM contraction that was found in this study may not have clinical significance. A more sensitive measure, such as needle EMG, is needed in future studies to further investigate the effect of mobilization on deep back muscle activity. Second, the mobilization technique applied in this study was applied at a consistent lumbar segment, L4, which is unlikely to be the most symptomatic lumbar segment in all individuals. Thus, more changes in outcomes might have been induced if mobilization was applied at the most symptomatic segment of the lumbar spine or multiple segments. It should also be noted that because the sample size provided limited statistical power we did not adjust for multiple testing, so the overall false positive rate may exceed 0.05. Study findings should be independently validated in future research.

3.6 Conclusion:

This study concludes that lumbar mobilization may decrease both the EMG activity amplitude and onset of superficial back muscles (ES) while increase the contraction of deep back muscles (LM) in people with LBP. The findings contribute to the growing knowledge about

underlying physiologic mechanisms of mobilization. Future studies with larger sample size are needed to confirm these findings. Future studies may consider more sensitive methods than US imaging to measure the activity/contraction of deep back muscles.

3.7 Tables:

Table 3.1: The Characteristics of the two groups

	Placebo (n=11)	**Mobilization** (n=10)	***P* value**
Gender (number of males)	5	4	0.58
Age (year)	25 (24-42)	24.5 (20-37)	0.25
BMI	22.5 (19.8-25.5)	25.4 (21.0-26.9)	0.19
IPAQ physical activity category: mild (n) moderate (n) high (n)	 2 2 7	 0 4 5	0.45
Pain intensity (0-10)	3 (3-4)	5 (4-5)	**0.02***
MOSQ	14 (10-26)	24 (13-29)	0.20
FABQ physical subscale	11 (6-12)	16 (12.5-17.5)	**0.01***
FABQ work subscale	9 (6-14)	11 (5-14)	0.65
BDI-II: Normal (n) Mild mood disturbance (n) Borderline depression (n)	 10 1 0	 6 2 1	0.36

BMI: body mass index, IPAQ: the International Physical Activity Questionnaire, MOSQ: modified Oswestry Back Pain Disability Questionnaire, FABQ: Fear-Avoidance Beliefs Questionnaire, BDI-II: Beck Depression Inventory.

Values are in median (25^{th} - 75^{th} percentiles) format unless otherwise indicated

Fisher's exact test was used to compare the categorical variables, and Mann-Whitney U test to compare the continuous variables between the two groups.

*Significant difference between the two groups (*P* value<0.05)

Table 3.2: The changes in LM contraction and nEMG of ES

Pain category	**Outcomes**	**Placebo group** Mean (SD)	**Mobilization group** Mean (SD)	**Estimated difference between groups** (SDs)	***P* value**
Moderate pain	nEMGL1	-0.04 (0.16)	0.02 (0.24)	0.39	0.53
	nEMG L4	-0.02 (0.06)	0.01 (0.09)	0.49	0.26
	LM contraction	-0.01 (0.04)	0.03 (0.03)	1.04	**0.03***
Severe pain	nEMG L1	0.20 (0.16)	-0.04 (0.08)	-1.39	**< 0.01***
	nEMG L4	0.08 (0.10)	-0.04 (0.05)	-1.76	**0.05***
	LM contraction	0.02 (0.02)	<0.01 (0.03)	-0.53	0.20

LM: Lumbar multifidus muscle; nEMG: normalized EMG amplitude; ES: Erector spinae muscle; L: erector spinae muscle at the specified level (L1 or L4).

A positive mean value indicates increased activity/contraction after the intervention, while negative values indicate decreased activity/contraction.

Table 3.3: The correlation between % changes in PPT and the outcomes.

	nEMGL1	**nEMG L4**	**LM contraction**	**Activity onset of ES L1_left**	**Activity onset of ES L1_Right**
Correlation coefficient	0.42	0.28	0.10	0.21	0.35
***P* value**	0.06	0.24	0.68	0.39	0.13

PPT: Pressure pain threshold; LM: Lumbar multifidus muscle; nEMG: normalized EMG amplitude; ES: Erector spinae muscle; L: lumbar vertebrae level; L: erector spinae muscle at the specified level (L1 or L4).

Chapter 4: The validity and reliability of IMU in measuring mobilization

4.1 Abstract:

Background: Lumbar mobilization is a standard intervention for management of low back pain, yet ways to quantify lumbar mobilization are limited. Inertial Measurement Unit (IMU) is a small, inexpensive device that can be used to measure the amplitude of displacement (oscillation) of clinician's hand during mobilization as an indirect way of quantifying lumbar mobilization.

Objectives: To determine the validity and reliability of an IMU in measuring amplitude of displacement of clinician's hand movement during oscillatory lumbar mobilization.

Design: Agreement and Reliability study.

Methods: To determine validity and reliability of IMU, an IMU unit was secured on the right hand of the clinician during mobilization force application at L4 segment of 16 healthy subjects. The amplitude of the clinician's hand displacement was calculated from the IMU's acceleration and angular velocity using integration methods and geometric equations. The validity of the IMU was tested against common laboratory methods of measurements (forceplate and Optotrak). The reliability of the IMU measurements was determined between two clinicians (inter-rater) and between two sessions (intra-rater).

Results: The IMU had high correlation with forceplate ($r_s = 0.94$) and good agreement with Optotrak, having small percent measurement error and narrow limits of agreement. Inter-rater and intra-rater reliability of IMU measurements was moderate.

Conclusion: IMU was found as a valid device to measure the amplitude of clinician's hand movement as an indirect measure of lumbar mobilization. The moderate reliability found in this study does not reflect poor reliability of the IMU but suggests inconsistency in re-application of lumbar mobilization.

4.2 Introduction:

Lumbar mobilization is a common manual therapy treatment used to decrease pain and stiffness in people with low back pain (LBP). During mobilization, clinicians use their hands to apply forces, and to induce oscillatory movements on the patients' back. The mobilization movements have both amplitude (oscillation) and magnitude (depth) of displacement (FIGUR 4.1). There are four grades of mobilization that differ in the amplitude and the magnitude. For example, grade IV is defined as mobilization with small amplitude and large magnitude of displacement within the available range of motion.

Clinicians rely on "sensing" the amount of mobilization movements (amplitude and magnitude of displacement) to apply various grades of mobilization. This has resulted in high variability of applying grades of mobilization. Studies have found poor intra- and inter-reliability of mobilization forces within and across mobilization sessions [74] by clinicians. This inconsistency may result in inconsistent patient outcomes. Thus, measuring forces of mobilization or displacement of mobilization movements may improve reliability and clinical outcomes.

Methods to measure mobilization in clinic settings are lacking. Studies have used force measuring devices like force plates to measure the forces [74,124-128] applied during mobilization, and to our knowledge, only one study [129] has used motion capture system to measure the displacement of the clinician's thumbs during lumbar mobilization. The force plate and motion capture system are limited to research laboratory settings and are expensive. A practical, inexpensive, and indirect method of measuring mobilization in clinical practice is to measure the clinician's hand motion during mobilization. Inertial Measurement Unit (IMU) is an inexpensive, small, portable device that consists of a triaxial Accelerometer and triaxial Gyroscope and can

measure acceleration and angular velocity. By placing the IMU on the clinician's hand, the amplitude of vertical displacement of the clinician's hand can be measured during various grades of mobilization. Current applications of IMU in rehabilitation include measurements of physical activity [130] (e.g. Fitbit®) and postural sway/balance [131]. Furthermore, previous studies have used IMUs in measuring the displacement of the center of mass [132], and vertical toe displacement during walking [80]. However, no study to our knowledge has used IMU device to measure displacement of lumbar mobilization movements.

The purpose of this study was to investigate the validity and reliability of IMU in measuring the amplitude of vertical displacement of the clinician's hand during mobilization. In particular, we determined the validity of the IMU against the current laboratory measures of both an Optotrak motion capture system and a floor mounted force plate. We also measured the reliability between two clinicians (inter-rater reliability) and between two sessions (intra-rater reliability) of IMU. Validating the use of IMU to measure lumbar mobilization is the first step toward its clinical application in improving patients' outcomes.

4.3 Methods:

Participants:

A convenience sample of faculty and students were recruited from University of Kansas Medical Center. Subjects were 18-55 years old without history of LBP within the past six months. Exclusion criteria were any reported bony or joint pathology (e.g., osteoporosis, rheumatoid arthritis), lumbar/sacral deformities (e.g., spondylolisthesis, spina bifida), spinal surgery, and pregnancy.

Ethical Approval Statement:

The study was approved by the Institutional Review Board at University of Kansas Medical Center, and all participants singed informed consent prior to testing. The rights of the subjects were protected.

Application of lumbar mobilization:

The participants attended two sessions of lumbar mobilization that were 2-3 days apart. In each session, two clinicians (physical therapists) used pisiform grip to apply central lumbar mobilization to the fourth lumbar vertebrae (L4) while the participants were lying prone. One clinician had two years of clinical experience whereas the second clinician had eight years of experience.

The clinicians applied the mobilization forces while standing on a force plate (AMTI ® model MSA-6; AMTI, Watertown, USA). In previous research, the force plate was found to have a measurement error of 3% in measuring the mobilization forces [127]. A data acquisition program (LabView 2012®; NI, Austin, USA) was used to provide live feedback on a computer screen about the amount of forces being delivered by the clinician. The data from the force plate were collected at a frequency of 120 Hz. To represent grade III and IV mobilization, we selected four ranges of forces as follows: 170-200 N, 140-200 N, 110-200 N and 80-200 N. These forces represent the magnitude of 200 N and four amplitudes of forces: 30, 60, 90, and 120 N (Figure 4.2). Each of the force amplitudes was applied three times with each trial lasting 80 seconds. A three-minute rest break was provided after each amplitude of force application. The clinician used a pisiform grip and maintained hand contact on the subject's back during the first and the last 20 seconds, and applied the oscillatory movements of mobilization in the middle 40 seconds of each 80 second trial. Furthermore, the clinicians applied the mobilization using metronome beats at a frequency of 1HZ.

After the first clinician completed application of all four amplitudes of forces (12 trials), the participant walked on a treadmill for 10 minutes, to eliminate the effect of mobilization, before the second clinician applied the mobilization in the same order. The sequence of the clinicians in each session was the same for each subject but randomized between subjects.

Measurement of the amplitude of displacement:

The clinician's hand movement during the mobilization was recorded using both the IMU (PhidgetSpatial Precision 3/3/3 2g®; Phidgets company, Calgary, Canada) and an Optical motion capture system (Optotrak Cyrtus position sensor®; NDI company, Waterloo, Canada). The IMU has a tri-axial accelerometer with acceleration measurement resolution of 76 μg and a gyroscope with angular velocity resolution of 0.02°/s. The Optotrak Cyrtus has an accuracy of 0.1 mm and resolution of 0.01mm [78].

The IMU data were collected at a frequency of 120Hz and the Optotrak data were collected at a frequency of 100 Hz. The IMU was secured over the dorsal aspect of the clinician's hand over an elastic band that was wrapped around the hand and wrist. Specifically the IMU was placed at the base of the third metacarpal (Figure 4.3). A self-adherent wrap was used to further secure the IMU, and one Optotrak marker was fixed over the IMU. The data from the IMU and force plate were synchronized using a DAQ board (NI USB-6210®; NI Company, Austin, USA). The pisiform carpal bone remained uncovered for skin contact with the subject.

Data analysis:

Matlab software program was used to analyze the data from the IMU, force plate, and Optotrak. The IMU data was filtered several times with band pass and high pass filters. The force plate and Optotrak data were filtered only once with band pass filters. All filters used were fourth

order filters. The lower cut off point of the filters was 0.5 Hz and the higher cut off point was 30Hz.

First, the tilting angles of the IMU relative to the ground (Figure 4.4) at 20 seconds into the trial (the end of the baseline) were calculated from the acceleration signals using the following equations [133]:

$$\text{Tan } \theta_y \text{ at base line } = \frac{\text{baseline mean of ax}}{\text{baseline mean of az}} \qquad \text{eq.4.1}$$

$$\text{Tan } \theta_x \text{ at base line } = \frac{\text{baseline mean of ay}}{\text{baseline mean of az}} \qquad \text{eq.4.2}$$

Where ax, ay, and az represent the mean of IMU acceleration signals in x, y, z directions at 20 seconds into the trial.

Second, the gyroscope data for angular velocity were integrated and filtered (band pass filter) to determine the changes in the baseline angles ($\Delta\ \theta_y$ and $\Delta\ \theta_x$) for the remainder of the trial period. Then the tilting angles (θ_y and θ_x) for the remaining of the trial period were calculated using the following equations:

$$\theta_y = \theta_y \text{ at base line} + \Delta\ \theta_y \qquad \text{eq.4.3}$$

$$\theta_x = \theta_x \text{ at base line} + \Delta\ \theta_x \qquad \text{eq.4.4}$$

Third, the vertical acceleration relative to the ground (Az) was calculated using Euler transformation matrix using the tilting angles and acceleration in the X, Y and Z directions from the accelerometer according to the following equation[80]:

$$Az = a_x \sin\theta_y \cos\theta_x + a_y \sin\theta_x + a_z \cos\theta_y \cos\theta_x - g \qquad \text{eq.4.5}$$

Fourth, the vertical acceleration was double integrated (trapezoidal integration) and filtered to calculate the vertical displacement[79] (Figure 4.5).

Finally, the amplitudes of vertical displacement and forces from the IMU, Optotrak, and force plate were calculated. Only the last 30 seconds of the oscillatory movement data were used for the final results, as the two clinicians required an initial period to reach the desired magnitude of force. For each force amplitude (30, 60, 90, and 120N), the average displacement from the three trails was used for final statistical analysis.

Statistical analysis:

IBM SPSS statistics version 22 was used for statistical analysis. Spearman correlation coefficient (r_s) was used to measure the association between the amplitude of the displacement measured by the IMU and the amplitude of the applied forces. Furthermore, repeated measure ANOVA was used to determine if the IMU measurements during the four amplitudes of forces were statistically different. For post hoc analysis, Bonferroni adjustment was used for pairwise comparisons between the amplitudes of displacement. The significance threshold used in this study was 0.05.

Bland-Altman plots were used to display the differences in displacement measurements between the Optotrak and the IMU, and the differences in IMU displacement measurement between the two clinicians and between the sessions. We used averaged data for each of the comparisons (between devices, between clinicians, and between sessions). Because the differences in the measurements were proportional to the mean, the percent error of the measurement (%e) was plotted, and the mean and 95% Limits of Agreement (LOA) for %e were calculated [134,135].

The %e was calculated using the following equations:

$$\%e \text{ between the Optotrak and the IMU measurements} = \left(\frac{Opt}{IMU} - 1\right) \times 100 \qquad \text{eq.4.6}$$

$$\%e \text{ between the IMU measurements of the clinicians} = \left(\frac{Clinician1}{Clinician2} - 1\right) \times 100 \qquad \text{eq.4.7}$$

%e between the IMU measurements of the sessions= $\left(\frac{\text{Session1}}{\text{Session2}} - 1\right) \times 100$ eq.4.8

In order to understand the sources of error that affected the reliability of IMU measurements, we performed similar steps to calculate %e from the Optotrak measurements between the two clinicians and between the two sessions.

Because we used average scores to assess agreement between methods, between clinicians, and between sessions and because data were clustered (four intensities/amplitudes per subject), the usual limits of agreement for the Bland-Altman plots would be anticonservative. However, in clinical setting, there is usually one clinician and one intensity (amplitude) in a given session, and our interest is in the range of Optotrak-IMU differences we would expect to see in most cases. Similarly, we would like a sense of the expected variability in between-clinician IMU measurements for a single session, and in between-session IMU measurements for a single clinician.

To reflect real-life practice conditions more closely and to circumvent the clustering (non-independence) problem, we computed Bland-Altman limits of agreement using a non-parametric bootstrap estimate of the standard deviation (SD) of the difference of interest. In each of 20,000 iterations of the bootstrap we randomly selected 16 patients (sampled with replacement); one of the four intensities (amplitudes); one clinician-session combination (for comparing Optotrak with IMU measurements); one session (for comparing IMU measurements between clinicians and comparing Optotrak measurements between clinicians); and one clinician (for comparing IMU measurements between sessions and comparing Optotrak measurements between sessions). In each bootstrap sample the three differences of interest (between-measure, between-clinician, and between-session) were computed along with the SD of each. For each

difference of interest, the mean of its SDs across the 20,000 bootstrap samples was taken as its SD estimate for use in the limits of agreement formula.

Agreement was interpreted good when the mean %e was less than 10% (small mean) and the absolute values for LOA were less than 20% (narrow LOA) and moderate when mean %e was 10- 20% and the absolute values for LOA were 20-40% (wide LOA).

4.4 Results:

Sixteen healthy subjects (10 males, mean age = 32±5 years, body mass index =25 ±4) completed the study. The mean and the standard deviation for the force amplitudes applied during mobilization sessions are presented in table 4.1. Minor differences in force application were noted between the two clinicians (mean difference in force =1.5 ±1.7 N) and between the two sessions (mean difference in force =0.2 ± 2.2 N).

The correlation between the amplitude of displacement measured by the IMU and the amplitude of forces was found to be high (r_s= 0.94) (Figure 4.6). Furthermore, the repeated measure ANOVA and the post hoc tests revealed that the IMU measurements were statistically different between the four amplitudes of force (P<0.01; mean amplitude of displacement = 1.7±0.2, 3.3±0.5, 5.5±0.9, and 7.7±1.2 mm for the 30, 60, 90, and 120 N amplitudes of force respectively).

Bland-Altman plots showed small %e in the amplitude measurements between the IMU and the Optotrak (Figure 4.7 A), between the clinicians (Figure 4.7 B), and between the sessions (Figure 4.7 C). Table 4.2 indicates the mean %e for the measurements between the IMU and Optotrak, between clinicians, and between sessions; the mean was found to be 4%, 6%, and 1% respectively. However, the LOA for the differences in the IMU measurements between clinicians and between sessions were wide.

The mean %e in the Optotrak measurements between the two clinicians and between the two sessions was small (8% and 1% respectively).

4.5 Discussion:

The purpose of this study was to investigate validity and reliability of the IMU in measuring the amplitude of mobilization displacement. The results show that IMU is a valid device in measuring the amplitude of mobilization displacement as indicated by 1) high correlation between the amplitude of the displacement from the IMU and amplitude of mobilization forces, 2) ability of the IMU to differentiate between four different forces applied, and 3) good agreement criteria between the IMU and Optotrak measurement (%e had small mean, and narrow LOA). However, the IMU showed moderate inter-rater and intra-rater reliability as shown by wide LOA.

This is the first study investigating the validity of the IMU in measuring mobilization movements. We investigated the validity of IMU against two common laboratory measures, force plate and Optotrak to verify its application. Force plate is the most widely used device to measure mobilization, and optical motion capture systems such as Optotrak are the standard measure of displacement. Previous studies have investigated the validity of the IMU against optical motion capture systems in measuring other applications in human kinematics. Esser et al. [132] used IMU to measure the displacement of the center of mass during walking, and the measurement error was found to be less than 2%. Charry et al. [80] used IMU to measure vertical toe displacement during walking, and the measurement error was found to be approximately 3 cm (approximately 20%). The difference in the measurement error between the previous two studies may have resulted from the differences in the tested movements as well as differences in the sensitivity of the IMU components used. In the study by Esser et al. [132], the IMU was placed

on the trunk, and the tilt angles of the IMU were relatively steady during walking. In the study by Charry et al. [80], the IMU was placed on the distal end of the shoe, and the tilting angles were changing as the distal end of the shoe was moving during walking, resulting in large changes in the angles of the IMU. Errors in the IMU angles estimation may have increased the error of the measurements in the second study [80]. In our study, the clinicians attempted to avoid large changes in the angles of the IMU during the mobilization, which might have decreased the error in the estimation of IMU angles.

The moderate between-clinician and between-session reliability (wide LOA) found in this study may be partly attributed to factors unrelated to the reliability of the IMU. The wide LOA can be explained in part by the variability in forces applied by clinicians and in reapplying the mobilization between sessions. Secondly, the force plate used to provide biofeedback to the clinician has a measurement error of 3% in measuring the mobilization forces [127], which may have contributed to some degree of variability in the displacement between clinicians and between sessions. Finally, small differences in the position of both the IMU and Optotrak marker on the clinician's hand might have affected the displacement measurements. Collectively these issues reduced reliability for IMU even when the actual differences in force applications were small. These issues also affected the reliability of Optotrak measurements between clinicians and between sessions as indicated by the LOA of Optotrak measurements.

The findings of our study can be generalized to grade III- IV mobilization but not to grades I-II. The ranges of forces used in our study were 170-200 N, 140-200 N, 110-200 N and 80-200 N. These forces represent the amplitude and magnitude of grades III- IV. Grades III- IV mobilization were reported to have mean force magnitudes of 90-240 N[124-126,128] and mean force amplitudes of 102 N and 33 N[124] respectively. In addition, grades III- IV of mobilization are

usually applied using the pisiform grip used in our study, but grades I-II are applied using the thumbs. The location and the size of the IMU will need to be considered if it is targeted to measure grades I and II mobilizations.

The study has several limitations. The findings cannot be generalized to clinicians with various levels of experience, different patient populations, different hand positions for lumbar mobilization other than pisiform grip, or other ranges of forces and amplitudes. Future studies need to test the validity of the IMU in various patient populations, to establish reliability between clinicians with different levels of experience, and to use more precise methods of applying the mobilization forces.

Nevertheless, establishing the validity and reliability of IMU is the first step toward potential use of IMU to measure/quantify lumbar mobilization in clinical settings. Quantifying mobilization may decrease the inconsistency in applying mobilization and therefore may improve clinical outcomes. In addition, the clinician's hand displacement may be used with the force measures to calculate the stiffness of the spine. The stiffness is an objective measure and an outcome of clinical interest in people with LBP. Finally, future studies should validate the use of IMU in people with LBP (the population of the clinical interest), investigate the reliability of the clinicians mobilization application with IMU while receiving live visual feedback about their mobilization, investigate the potential use of IMU in measuring mobilization of other areas/joints and its broader application. Development of a user-friendly software for IMU application for clinicians with minimum technical knowledge/support would be an important contribution.

4.6 Conclusion:

The IMU can be a valid and inexpensive device to measure the lumbar mobilization displacement in healthy subjects for the following ranges of forces: 170-200 N, 140-200 N, 110-

200 N and 80-200 N, representing grade III-IV mobilization. Future studies with more precise methods of applying mobilization forces could further characterize the reliability of IMU in measuring lumbar mobilization displacement. The findings of our study are initial steps toward developing a user friendly application of IMU to measure mobilization in research and clinical settings.

Conflict of Interest Statement:

All authors affirm that they have no financial affiliation (including research funding) or involvement with any commercial organization that has a direct financial interest in any matter included in this manuscript. All authors do not have other conflict of interest (i. e. personal associations or involvement as a director, officer or expert witness).

4.7 Tables:

Table 4.1: Mean and standard deviation for the amplitudes of forces applied during mobilization trials.

	Session 1		**Session 2**	
Predetermined amplitudes	**Clinician 1** (N)	**Clinician 2** (N)	**Clinician 1** (N)	**Clinician 2** (N)
30 N	33.5 ± 1.5	31.7 ± 1.4	33.3 ± 1.4	31.6 ± 1.2
60 N	62.2 ± 2.4	61.0 ± 1.2	62.9 ± 2.5	61.5 ± 2.4
90 N	92.0 ± 2.1	90.6 ± 1.6	92.0 ± 2.8	90.5 ± 1.6
120 N	120.9 ± 3.1	118.8 ± 2.4	119.8 ± 3.4	118.6 ± 1.7

TABLE 4.2: The percent of error for the measurement comparisons.

	Mean	**Limits of agreement** (Lower LOA -Upper LOA)
%e for the measurements between the IMU and Optotrak %e=(IMU/Opt -1) X100	4%	-11% - 20%
%e for the IMU measurements		
Measurements between clinicians %e =(clinician1/clinician2 - 1) X100	6%	-25% - 37%
Measurements between sessions %e =(session1/session2 - 1) X100	-1%	-29% - 27%
%e for the Optotrak measurements		
Measurements between clinicians %e = (clinician1/clinician2 - 1) X100	-8%	-25% - 9%
Measurements between sessions %e =(session1/session2 - 1) X100	-1%	-18% - 17%

Abbreviations: %e: percent of error, LOA: limit of agreement.

4.8 Figures:

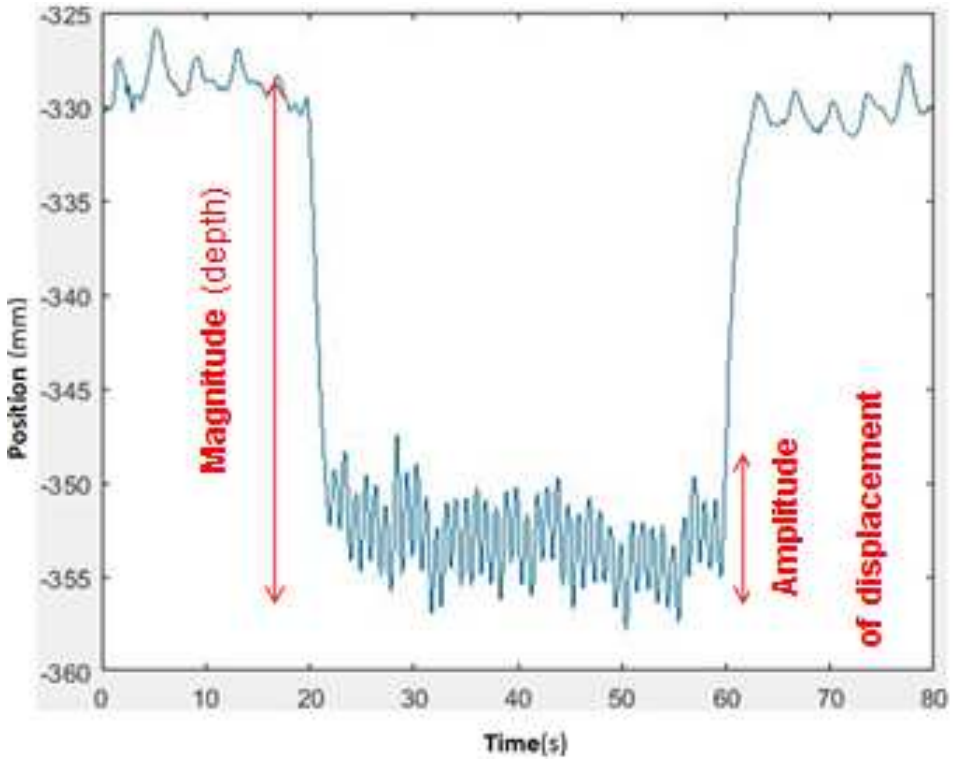


Figure 4.1: Mobilization recorded by Optical motion capture system, displaying the magnitude and amplitude of mobilization with red arrows.

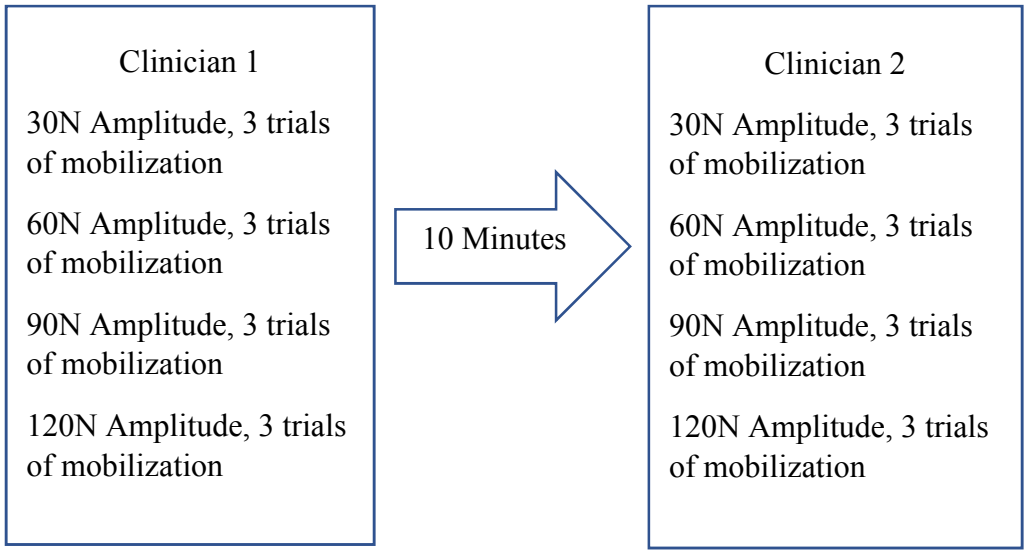


Figure 4.2: Study design showing 3 trials of four mobilization amplitudes by each clinician.

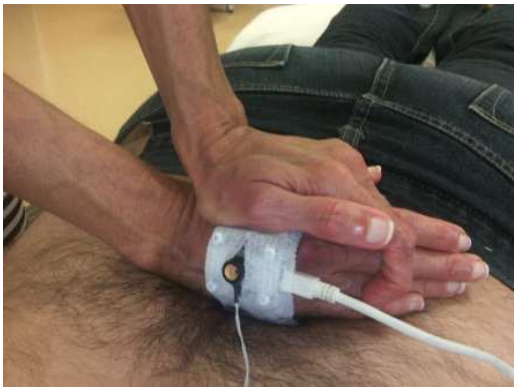


Figure 4.3: The placement of IMU and Optotrak marker and position of the clinician's hand during lumbar mobilization.

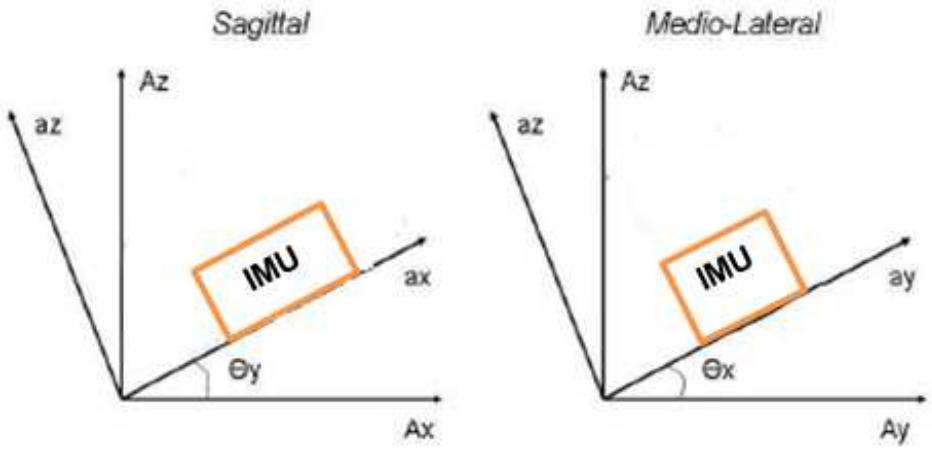


Figure 4.4: The IMU tilting angles relative to the ground (modified from Charry et.al[80]).

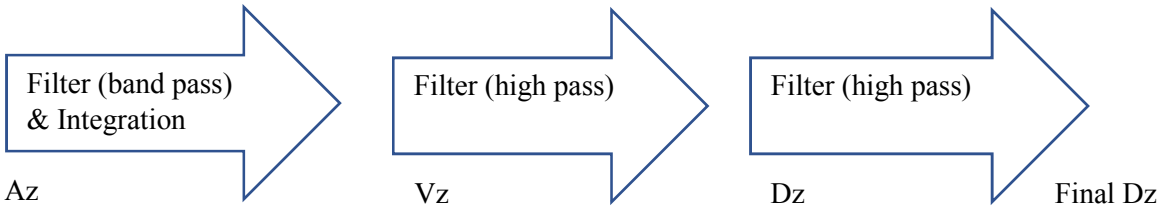


Figure 4.5: Double integration of vertical acceleration.

Abbreviations: Az, vertical acceleration; Vz, vertical velocity; Dz: vertical displacement.

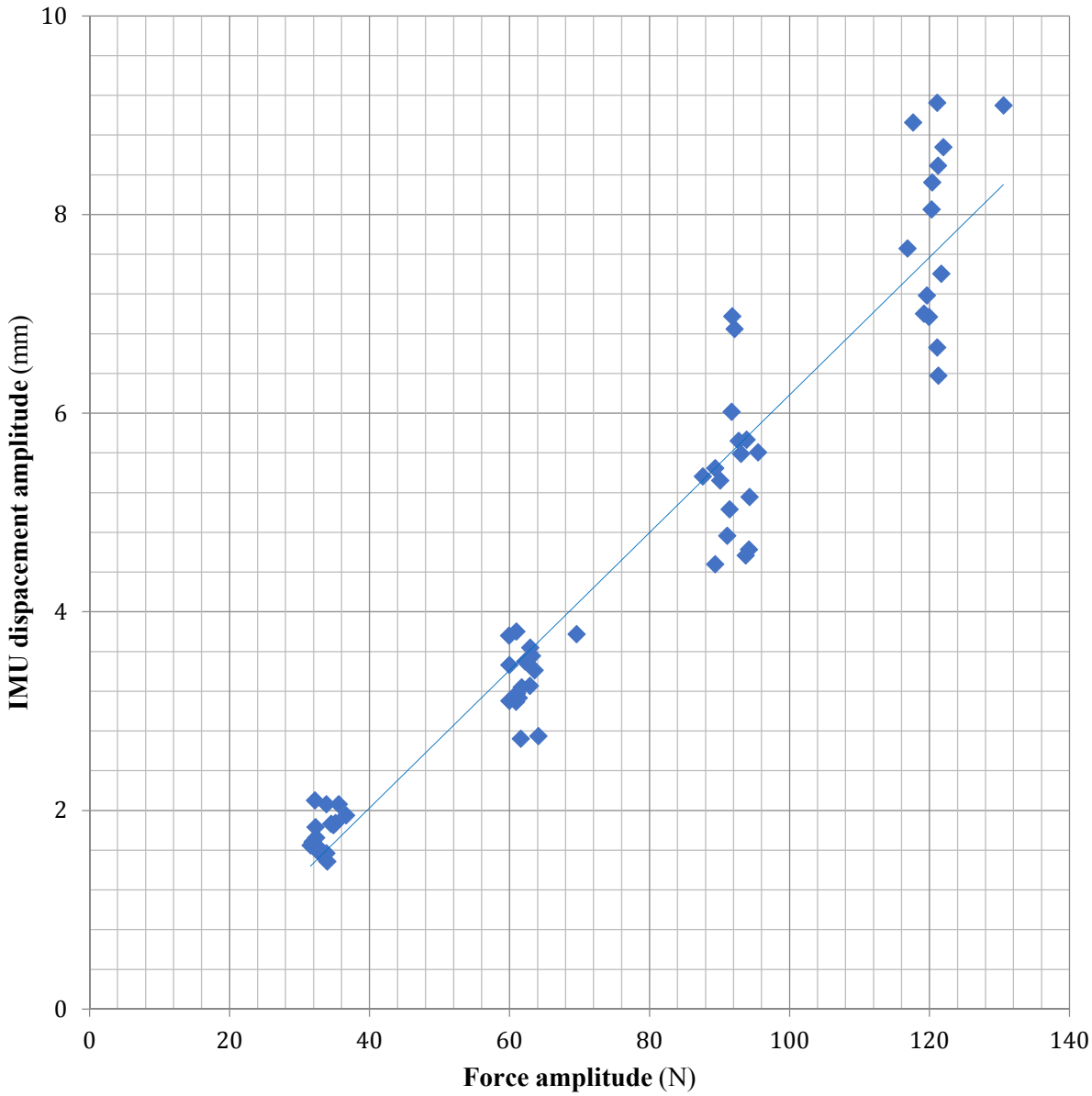


FIGURE 4.6: The correlation between amplitude of displacement measured by IMU, and the amplitude of force measured by force plate.

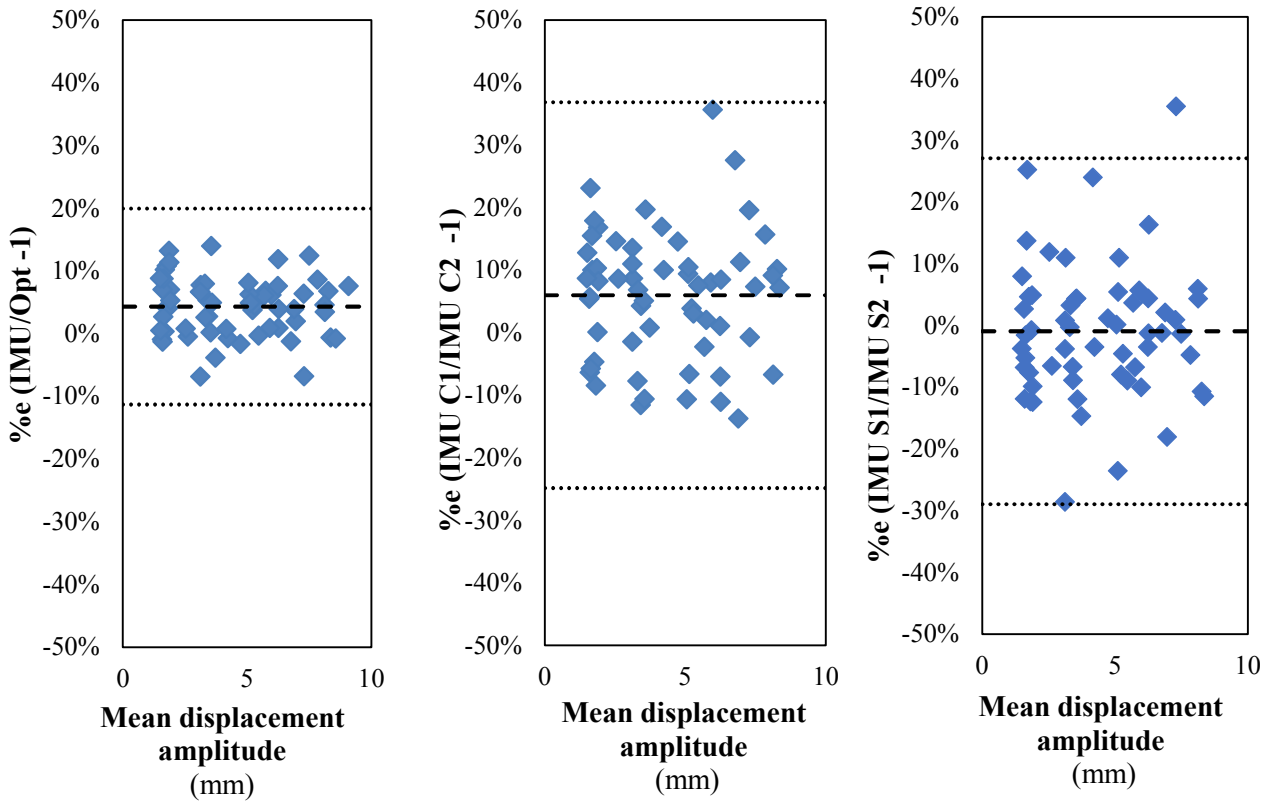


FIGURE 4.7: The Bland-Altman plots for the agreement of measurements:

between the IMU and Optotrak measurements.

between the two clinicians (IMU measurements).

between the two sessions (IMU measurements).

Abbreviations: %e, percent of error; Opt, Optotrak; C, clinician; S: session.

- - - Mean

……Upper and Lower LOA

Chapter 5: Conclusion

5.1 Overview:

We determined the effects of lumbar mobilization, a standard intervention used by physical therapists and chiropractors, on Lumbar Multifidus (LM) and Erector Spinae (ES) muscles in both healthy subjects and in people with low back pain (LBP). Furthermore, we investigated validity and reliability of an Inertial Measurement Unit (IMU) in measuring clinician's hand displacement during lumbar mobilization representing grades III and IV of mobilization.

LBP is the second most common cause of disability in the United States [84], it affect approximately 80% of the population at some point in their lives [1]. LBP is associated with abnormal high activity of ES and low activity of LM muscles [16,17,85,86], which has shown to be associated with pain and dysfunction in people with LBP. Lumbar mobilization a common treatment used by 70-90% of physical therapists in managing LBP [81,82]. Never the less, the underlying mechanism of lumbar mobilization is not well understood, and there is a lack of understanding about the effect of lumbar mobilization in normalizing the activity of muscle dysfunction seen in people with LBP. Previous studies suggested that mobilization can stimulate mechanoreceptors within the joints and muscles, which changes the α-motor neurons excitability [61]. Investigating such effect of mobilization on back muscle activity in both healthy subjects and people with LBP may lead to a better understanding of the physiological effects of mobilization, and a better application of mobilization to normalize the abnormal activity of back muscles in LBP; this in turn may improve the intervention outcomes and decrease the disability in people with LBP. To our knowledge, our studies were the first to investigate the effect of lumbar mobilization on both LM and ES muscles in healthy subjects and in people with LBP.

Despite the common use of mobilization for managing LBP, methods to quantify lumbar mobilization in clinical settings are lacking,; there is inconsistency in applying mobilization [74] which may affect the intervention outcomes. Current laboratory methods like Optotrak and force plate to measure mobilization displacement and forces are expensive and limited to laboratory settings. IMU is a potential device that can be used to measure the clinician's hand movement during mobilization. IMU is an inexpensive and portable device and thus, its use in clinical settings is feasible. However, the validity and reliability of IMU in measuring mobilization must be determined before its application can be considered in clinical and research settings. Our study was the first step to develop a friendly IMU-based method that can provide visual feedback to clinicians during mobilization; the live visual feedback could decrease the inconsistency in applying mobilization and therefore improve clinical outcomes.

The studies conducted are within the objectives of our Clinical Orthopedic and Rehabilitation Research (CORR) Laboratory at KUMC. The laboratory objectives are to understand the mechanisms of LBP and to determine the efficacy of physical therapy interventions to manage LBP and its associated symptoms.

5.2 Summery of findings:

Aim 1: To determine the effects of grade IV lumbar mobilization on back muscles in healthy subjects.

Healthy subjects received three intervention sessions (no intervention, placebo, and grade IV mobilization) on different days. Contraction of LM and the activity of ES were measured at low isometric contraction (arm lift task) at two time points (before and immediately after the intervention) in each session. Ultrasound imaging and surface electromyogram (EMG) were used to measure LM contraction and activity of ES respectively.

We hypothesized that compared to both placebo and no intervention, grade IV mobilization would decrease the activity of ES (H1) and increase contraction of LM (H2).

The only significant effect of lumbar mobilization was found on LM contraction compared to the placebo effect; the mobilization increased the LM contraction. There was no significant effect of mobilization on LM contraction compared to no intervention.

Aim 2: To determine the effects of grade III lumbar mobilization on back muscles in people with chronic LBP.

LBP subjects were randomly assigned into two groups (grade III mobilization or placebo/light touch group). Subjects received intervention based on their assigned group and for two sessions. Contraction of LM and the activity of ES were measured at low isometric contraction (arm lift task) at two time points (before and immediately after the intervention) in each session. Ultrasound imaging and surface electromyogram (EMG) were used to measure LM contraction and activity of ES respectively.

We hypothesized that compared to placebo, grade III mobilization would decrease the amplitude (H3a) and onset (H3b) of ES muscle activity, and increase LM contraction (H4).

Compared to placebo group, there were significant effects of lumbar mobilization on the amplitude and onset of ES muscle activity and on LM contraction. The mobilization decreased both activity amplitude and activity onset of ES, and increased contraction of LM. Furthermore, the observed changes in ES and LM were not associated with the changes in pressure pain threshold (PPT), suggesting the underlying physiological effect of mobilization on ES and LM was independent of perceived pain threshold.

Aim 3: To determine the validity and reliability of IMU in measuring the amplitude of displacement of the clinician's hand during lumbar mobilization on healthy subjects.

Each healthy subject received four different amplitudes of lumbar mobilization by two clinicians in two sessions. The validity of IMU was tested by comparing the IMU measurements (displacement) to the measurements of Optotrak (displacement), and by calculating the correlation between IMU measurements (displacement) and the force plate measurement (force). The reliability of IMU was tested by comparing the IMU measurements between two clinicians (inter-rater reliability) and between two sessions (intra-rater reliability).

We hypothesized that IMU measurements would have high agreement with Optotrak (H5a) and high correlation with force plate (H5b) measurements, and that IMU would have high inter-rater (H6a) and intra-rater (H6b) reliability in measuring the amplitude of displacement.

Our results showed that IMU had high agreement with Optotrak and high correlation with force plate. Therefore, IMU was found to be a valid device to measure the amplitude of displacement of clinicians' hand during lumbar mobilization. The reliability of IMU was moderate with both inter-and intra-reliability, which can be due to inconsistency in applying mobilization between sessions and between clinicians.

5.3 Clinical implications:

People with LBP have high activity amplitude and activity onset of ES during low load muscle activities, and atrophy in LM muscle [16,17,85,86]. The impairment in activity/contraction of ES and LM may lead to further pain and functional limitations in people with LBP. Clinicians should try to assess and address the back muscles impairments associated with LBP. Clinical guidelines for LBP published by the American Physical Therapy Association - Orthopedic Section recommend addressing the trunk muscle coordination and weakness impairments in LBP [136].

There is a gap in our knowledge about the effects of lumbar mobilization on back muscles in both healthy subjects and people with LBP. Our study findings contribute to fill in this gap in our knowledge. The findings from this dissertation suggest that lumbar mobilization may correct the abnormal activity in back muscles in LBP by decreasing the activity amplitude and onset of ES and by increasing the contraction of LM. Therefore, the findings emphasize a new therapeutic effect of lumbar mobilization and normalization of impairment of back muscles in LBP, and further support the use of mobilization as an integral intervention for people with LBP.

Establishing the validity and reliability of IMU is the first step toward using IMU to measure/quantify the clinicians' hand displacement during lumbar mobilization in clinical settings. There is an inconsistency in applying mobilization; studies have found poor intra- and inter-reliability of applying mobilization forces within and across mobilization sessions [74]. For example, physical clinicians with more than three years of experience, applied force magnitude that ranged from 63 to 347 N during grade IV lumbar mobilization [74]. This inconsistency may result in inconsistent patient outcomes. For example, without quantifying mobilization force and displacement, the mobilization may be either too small to produce the desired therapeutic effect or too extreme that could lead to adverse effects such as increased pain. Thus, measuring force or displacement of mobilization may improve reliability and clinical outcomes.

In addition, the clinician's hand displacement measured by IMU may be used with the force measures to calculate the stiffness of the spine. The stiffness is an objective measure and an outcome of clinical interest in people with LBP.

5.4 Limitations:

Effect of lumbar mobilization on back muscles activity in healthy subjects and in people with LBP:

The ultrasound imaging is a reliable method to measure LM muscle contraction during the arm lift task used in this study. However, the minimum detectable change of LM contraction measured by ultrasound is relatively high and the smaller detected changes in LM contraction in our study may not have clinical significant. Thus, the results should be used with caution.

The arm lift task in prone position used in these studies was selected because it is considered the standard task for ultrasound imaging of LM. However, the arm lift task in prone position is not a common functional task, and the findings cannot be generalized to other tasks that require different level of muscle demand or different muscle contraction patterns of back muscles.

We could not measure the activity onset of ES muscle in healthy subjects due to EMG device malfunction. Many channels of the EMG device at the time of data collection had malfunctioned, and we had to scarify the channel that tested deltoid muscle activity. Thus, there might have been an effect of lumbar mobilization on the activity onset of ES muscle in healthy subjects that was not captured in the current study.

PPT and the back-muscle activity could not be tested at the same time. The PPT was tested after the isometric contraction of the arm lift task, which might have affected the PPT values. Therefore, it is still possible that the observed changes in back muscles activity/contraction resulted from the hypoalgesic effect of mobilization even though we showed negative effects of mobilization on PPT.

The lumbar mobilization was applied consistently at L4 level, which is unlikely to be the most symptomatic lumbar segment in all subjects with LBP. Thus, more changes in outcomes in people with LBP might have been induced if mobilization was applied at the most symptomatic segment or multiple segments of the lumbar spine.

Our study only tested the immediate effect of lumbar mobilization on back muscles. This study would have been better if a follow up for the subjects was done to test short-term and long-term effects of mobilization. The short- and long-term follow up of our subjects would have provided us with better understanding for the lasting effects of mobilization; this additional information might have helped clinicians in determining the frequency (sessions per week) of mobilization needed to maintain such effects.

The findings cannot be generalized to other mobilization techniques, or other areas of the spine (cervical or thoracic). Other mobilization techniques may lead to less or more effects of mobilization on back muscle activity. Although, the cervical and thoracic spine have common anatomy and physiology with lumbar spine, the small anatomical and physiological differences in these areas may lead to different effects of mobilization.

The sample size used for the studies was small, which could increase a probability of type two error (false negative). In addition, the small sample size did not allow us to correct the significant level for multiple comparisons, which may have increased the probability of type one error (false positive). Therefore, the studies are considered preliminary and further investigation with a larger sample size is needed.

Measuring lumbar mobilization:

The findings cannot be generalized to clinicians with various levels of experience or in people with LBP. Clinicians with different level of experience might have higher or lower

reliability of IMU measurements. In addition, the study only investigated the reliability of IMU in healthy subjects. People with LBP might have changing pain level and stiffness between sessions, which might lead to different amplitude of displacement and therefore affect the reliability of IMU.

The study used a pisiform grip for applying the specific mobilization forces. Lumbar mobilization can be applied using the thumbs but that would have required different placement of the IMU on the clinicians' hand, which may affect the reliability of IMU. Furthermore, applying the mobilization with ranges of forces other than what used in the study might affect the reliability of IMU.

5.5 Future directions:

Future studies with larger sample size are needed to confirm the findings related to effects of mobilization on back muscles. Future studies should examine the effect of different grades (I, II, III, and IV), methods (unilateral V.S. central), and dosage of mobilization on the activity of back muscles, and should use more precise methods of measuring muscle activity (e.g. needle EMG) for deep back muscles (LM). Moreover, future studies should investigate the factors that might change the effect of mobilization on back muscles in people with LBP. Such factors might be related to the subjects (i.e. gender, symptoms, and duration of LBP) or to the lumbar mobilization itself (i.e. lumbar mobilization grade, dose, and frequency).

In our study, we analyzed the IMU data offline. Future studies could develop a software that can analyze the IMU data immediately and provide visual feedback to clinician about the displacement of their hands during mobilization. Furthermore, future studies need to test the validity of the IMU in people with LBP, to establish reliability between clinicians with different levels of experience, use more precise methods of applying the mobilization forces, and

investigate the reliability of the mobilization when clinicians receive live visual feedback from the IMU while applying mobilization.

Further, future studies may investigate the potential use of IMU in measuring mobilization of other areas/joints and its broader application. Development of a user-friendly software for IMU application for clinicians with minimum technical knowledge/support would be an important contribution to the field of manual and alternative therapies

Finally, the stiffness of the lumbar spine can be measured by dividing the amplitude of force during mobilization (as measured by force plate or other force measuring devices) by the amplitude of therapist hand displacement (measured by force plate). The stiffness of lumbar spine is an important clinical outcome measure that can be used in future studies.

5.6 Conclusions:

The findings show that lumbar mobilization decreased the abnormal high amplitude and onset of ES activity, and increased the LM contraction in people with LBP. These results add to the current literature about the physiological effects of lumbar mobilization on back muscles, and support the use of lumbar mobilization to decrease the dysfunction of back muscles in people with LBP.

IMU was found as a valid device to measure lumbar mobilization in the selected applied forces that represent grades III-IV of mobilization. The findings support the use of IMU to measure the amplitude of lumbar mobilization, which may lead to more consistent application of lumbar mobilization in clinical setting. Future studies should develop a user friendly IMU that can provide live visual feedback to the clinician during mobilization.

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Appendixes:

Appendix 1: Fear Avoidance Beliefs Questionnaire

FEAR AVOIDA NCE BELIEFS QUESTIONNAIRE (FABQ)

Name: _____ Date: _____

Here are some of the things which other patients have told us about their pain. For each statement please circle any number from 0 to 6 to say how much physical activities such as bending, lifting, walking or driving affect or would affect your back pain.

	COMPLETELY DISAGREE			UNSURE			COMPLETELY AGREE
1. My pain was caused by physical activity	0	1	2	3	4	5	6
2. Physical activity makes my pain worse	0	1	2	3	4	5	6
3. Physical activity might harm my back	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse	0	1	2	3	4	5	6

The following statements are about how your normal work affects or would affect your back pain.

	COMPLETELY DISAGREE			UNSURE			COMPLETELY AGREE
6. My pain was caused by my work or by an accident at work	0	1	2	3	4	5	6
7. My work aggravated my pain	0	1	2	3	4	5	6
8. I have a claim for compensation for my pain	0	1	2	3	4	5	6
9. My work is too heavy for me	0	1	2	3	4	5	6
10. My work makes or would make my pain worse	0	1	2	3	4	5	6
11. My work might harm my back	0	1	2	3	4	5	6
12. I should not do my normal work with my present pain	0	1	2	3	4	5	6
13. I cannot do my normal work with my present pain	0	1	2	3	4	5	6
14. I cannot do my normal work until my pain is treated	0	1	2	3	4	5	6
15. I do not think that I will be back to my normal work within 3 months	0	1	2	3	4	5	6
16. I do not think that I will ever be able to go back to that work	0	1	2	3	4	5	6

Appendix 2: Modified Oswestry Low Back Pain Questionnaire

MODIFIED OSWESTRY LOW BACK PAIN DISABILITY QUESTIONNAIRE

Section 1: To be completed by patient.

Name:_____ Age:_____ Date:_____

Occupation:_____ Number of days of back pain:_____(this episode)

Section 2: To be completed by patient.

This questionnaire has been designed to give your therapist information as to how your back pain has affected your ability to mange in every day life. Please answer every question by placing a mark on the line that best describes your condition today. We realize you may feel that two of the statements may describe your condition, but **please mark only the line which closely describes your current condition**.

Pain Intensity

_____The pain is mild and comes and goes.
_____The pain is mild and does not vary much.
_____The pain is moderate and comes and goes.
_____The pain is moderate and does not vary much.
_____The pain is severe and comes and goes.
_____The pain is severe and does not vary much.

Personal Care (Washing, Dressing, etc.)

_____I do not have to change the way I wash and dress myself to avoid pain.
_____I do not normally change the way I wash or dress myself even though it causes some pain.
_____Washing and dressing increases my pain, but I can do it without changing my way of doing it.
_____Washing and dressing increases my pain, and I find it necessary to change the way I do it.
_____Because of my pain I am partially unable to wash and dress without help.
_____Because of my pain I am completely unable to wash or dress without help.

Lifting

_____I can lift heavy weights without increased pain.
_____I can lift heavy weights but it causes increased pain.
_____Pain prevents me from lifting heavy weights off of the floor, but I can manage if they are conveniently positioned (ex. on a table, etc.).
_____Pain prevents me from lifting heavy weights off of the floor, but I can manage light to medium weights if they are conveniently positioned.
_____I can lift only very light weights.
_____I can not lift or carry anything at all.

Walking

_____I have no pain when walking.
_____I have pain when walking, but can still walk my required normal distances.
_____Pain prevents me from walking long distances.
_____Pain prevents me from walking intermediate distances.
_____Pain prevents me from walking even short distances.
_____Pain prevents me from walking at all.

Sitting

_____Sitting does not cause me any pain.
_____I can only sit as long as I like providing that I have my choice of seating surfaces.
_____Pain prevents me from sitting for more than 1 hour.
_____Pain prevents me from sitting for more than ½ hour.
_____Pain prevents me from sitting for more than 10 minutes.
_____Pain prevents me from sitting at all.

MODIFIED OSWESTRY LOW BACK PAIN DISABILITY QUESTIONNAIRE, p. 2

Section 2 (con't): To be completed by patient.

Standing

_____I can stand as long as I want without increased pain.
_____I can stand as along as I want but my pain increases with time.
_____Pain prevents me from standing more than 1 hour.
_____ Pain prevents me from standing for more than ½ hour.
_____Pain prevents me from standing for more than 10 minutes.
_____I avoid standing because it increases my pain right away.

Sleeping

_____I get no pain when I am in bed.
_____I get pain in bed, but it does not prevent me from sleeping well.
_____Because of my pain, my sleep is only ¾ of my normal amount.
_____Because of my pain, my sleep is only ½ of my normal amount.
_____Because of my pain, my sleep is only ¼ of my normal amount.
_____Pain prevents me from sleeping at all.

Social Life

_____My social life is normal and does not increase with pain.
_____My social life is normal, but it increases my level of pain.
_____Pain prevents me from participating in more energetic activities (ex. sports, dancing, etc.)
_____Pain prevents me from going out very often.
_____Pain has restricted my social life to my home.
_____I have hardly any social life because of my pain.

Traveling

_____I get no increased pain when traveling.
_____I get some pain while traveling, but none of my usual forms of travel make it any worse.
_____I get increased pain when traveling, but it does not cause me to seek alternative forms of travel.
_____I get increased pain when traveling, which causes me to seek alternative forms of travel.
_____My pain restricts all forms of travel except that which is done while I am lying down.
_____My pain restricts all forms of travel.

Employment/Homemaking

_____My normal job/homemaking activities do not cause pain.
_____My normal job/homemaking activities increase my pain, but I can still perform all that is required of me.
_____I can perform most of my job/homemaking duties, but pain prevents me from performing more physically stressful activities (ex. lifting, vacuuming, etc.)
_____Pain prevent me from doing anything but light duties.
_____Pain prevents me from doing even light duties.
_____Pain prevents me from performing any job or homemaking chores.

Section 3: To be completed by therapist/healthcare provider.

SCORE: Initial_____% **Subsequent_____%** Date_____ **Subsequent_____%** Date_____ **Discharge_____%** Date_____

Number of treatment sessions:_____

Diagnosis/ICD-9 Code:_____

Appendix 3: International Physical Activity Questionnaire

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (October 2002)

LONG LAST 7 DAYS SELF-ADMINISTERED FORMAT

FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS (15-69 years)

The International Physical Activity Questionnaires (IPAQ) comprises a set of 4 questionnaires. Long (5 activity domains asked independently) and short (4 generic items) versions for use by either telephone or self-administered methods are available. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health–related physical activity.

Background on IPAQ
The development of an international measure for physical activity commenced in Geneva in 1998 and was followed by extensive reliability and validity testing undertaken across 12 countries (14 sites) during 2000. The final results suggest that these measures have acceptable measurement properties for use in many settings and in different languages, and are suitable for national population-based prevalence studies of participation in physical activity.

Using IPAQ
Use of the IPAQ instruments for monitoring and research purposes is encouraged. It is recommended that no changes be made to the order or wording of the questions as this will affect the psychometric properties of the instruments.

Translation from English and Cultural Adaptation
Translation from English is encouraged to facilitate worldwide use of IPAQ. Information on the availability of IPAQ in different languages can be obtained at www.ipaq.ki.se. If a new translation is undertaken we highly recommend using the prescribed back translation methods available on the IPAQ website. If possible please consider making your translated version of IPAQ available to others by contributing it to the IPAQ website. Further details on translation and cultural adaptation can be downloaded from the website.

Further Developments of IPAQ
International collaboration on IPAQ is on-going and an ***International Physical Activity Prevalence Study*** is in progress. For further information see the IPAQ website.

More Information
More detailed information on the IPAQ process and the research methods used in the development of IPAQ instruments is available at www.ipaq.ki.se and Booth, M.L. (2000). *Assessment of Physical Activity: An International Perspective.* Research Quarterly for Exercise and Sport, 71 (2): s114-20. Other scientific publications and presentations on the use of IPAQ are summarized on the website.

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

   ☐ Yes

   ☐ No → ***Skip to PART 2: TRANSPORTATION***

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

   _____ **days per week**

   ☐ No vigorous job-related physical activity → ***Skip to question 4***

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

   _____ **hours per day**
   _____ **minutes per day**

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

   _____ **days per week**

   ☐ No moderate job-related physical activity → ***Skip to question 6***

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

_____ **hours per day**
_____ **minutes per day**

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

_____ **days per week**

☐ No job-related walking → ***Skip to PART 2: TRANSPORTATION***

7. How much time did you usually spend on one of those days **walking** as part of your work?

_____ **hours per day**
_____ **minutes per day**

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

_____ **days per week**

☐ No traveling in a motor vehicle → ***Skip to question 10***

9. How much time did you usually spend on one of those days **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

_____ **hours per day**
_____ **minutes per day**

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No bicycling from place to place → ***Skip to question 12***

11. How much time did you usually spend on one of those days to **bicycle** from place to place?

_____ **hours per day**
_____ **minutes per day**

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No walking from place to place → *Skip to PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY*

13. How much time did you usually spend on one of those days **walking** from place to place?

_____ **hours per day**
_____ **minutes per day**

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?

_____ **days per week**

☐ No vigorous activity in garden or yard → *Skip to question 16*

15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

_____ **hours per day**
_____ **minutes per day**

16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

_____ **days per week**

☐ No moderate activity in garden or yard → *Skip to question 18*

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

_____ **hours per day**
_____ **minutes per day**

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

_____ **days per week**

☐ No moderate activity inside home → *Skip to PART 4: RECREATION, SPORT AND LEISURE-TIME PHYSICAL ACTIVITY*

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

_____ **hours per day**
_____ **minutes per day**

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

_____ **days per week**

☐ No walking in leisure time → *Skip to question 22*

21. How much time did you usually spend on one of those days **walking** in your leisure time?

_____ **hours per day**
_____ **minutes per day**

22. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

_____ **days per week**

☐ No vigorous activity in leisure time → *Skip to question 24*

23. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

_____ **hours per day**
_____ **minutes per day**

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

_____ **days per week**

☐ No moderate activity in leisure time → *Skip to PART 5: TIME SPENT SITTING*

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?

_____ **hours per day**
_____ **minutes per day**

PART 5: TIME SPENT SITTING

The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

_____ **hours per day**
_____ **minutes per day**

27. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

_____ **hours per day**
_____ **minutes per day**

This is the end of the questionnaire, thank you for participating.

Appendix 4: Beck Depression Inventory

Roche

V 0477

Beck Depression Inventory

CRTN: _____ CRF number: _____

Page 14 patient inits: _____

Baseline

BDI-II

Date:

Name: _____ Marital Status: _____ Age: _____ Sex: _____

Occupation: _____ Education: _____

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness

0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time.
3 I am so sad or unhappy that I can't stand it.

2. Pessimism

0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure

0 I do not feel like a failure.
1 I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure

0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying

0 I don't cry anymore than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

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_____ Subtotal Page 1

Continued on Back

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11. Agitation

0 I am no more restless or wound up than usual.

1 I feel more restless or wound up than usual.

2 I am so restless or agitated that it's hard to stay still.

3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.

1 I am less interested in other people or things than before.

2 I have lost most of my interest in other people or things.

3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.

1 I find it more difficult to make decisions than usual.

2 I have much greater difficulty in making decisions than I used to.

3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.

1 I don't consider myself as worthwhile and useful as I used to.

2 I feel more worthless as compared to other people.

3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.

1 I have less energy than I used to have.

2 I don't have enough energy to do very much.

3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.

1a I sleep somewhat more than usual.

1b I sleep somewhat less than usual.

2a I sleep a lot more than usual.

2b I sleep a lot less than usual.

3a I sleep most of the day.

3b I wake up 1–2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.

1 I am more irritable than usual.

2 I am much more irritable than usual.

3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.

1a My appetite is somewhat less than usual.

1b My appetite is somewhat greater than usual.

2a My appetite is much less than before.

2b My appetite is much greater than usual.

3a I have no appetite at all.

3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.

1 I can't concentrate as well as usual.

2 It's hard to keep my mind on anything for very long.

3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.

1 I get more tired or fatigued more easily than usual.

2 I am too tired or fatigued to do a lot of the things I used to do.

3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.

1 I am less interested in sex than I used to be.

2 I am much less interested in sex now.

3 I have lost interest in sex completely.

3 4 5 6 7 8 9 10 11 12 A B C D E

_____ Subtotal Page 2

_____ Subtotal Page 1

_____ Total Score