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EFFECTS OF LUMBAR SPINAL FUSION ON LUMBOPELVIC RHYTHM DURING ACTIVITIES OF DAILY LIVING

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THESIS

A thesis submitted in partial fulfillment of the
requirements for the degree of Master of Science in
Biomedical Engineering in the College of Engineering
at the University of Kentucky

By

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Lexington, Kentucky

Director: Dr. Babak Bazrgari, Professor of Biomedical Engineering

Lexington, Kentucky

2018

ABSTRACT OF THESIS

EFFECTS OF LUMBAR SPINAL FUSION ON LUMBOPELVIC RHYTHM DURING ACTIVITIES OF DAILY LIVING

Abnormalities in lumbopelvic rhythm (LPR) play a role in occurrence/recurrence of low back pain (LBP). The LPR before spinal fusion surgery and its changes following the surgery are not understood. A repeated measure study was designed to investigate timing and magnitude aspects of LPR in a group of patients (n = 5) with LBP before and after a spinal fusion surgery. Participants completed a forward bending and backward return task at their preferred pace in the sagittal plane. The ranges of thoracic and pelvic rotations and lumbar flexion (as the magnitude aspects of LPR) as well as the mean absolute relative phase (MARP) and deviation phase (DP) between thoracic and pelvic rotations (as the timing aspects) were calculated. Thoracic, pelvic, and lumbar rotations/flexion were respectively 2.19° smaller, 17.69° larger, and 19.85° smaller after the surgery. Also, MARP and DP were smaller during both bending (MARP: 0.0159; DP 0.009) and return (MARP: 0.041; DP: 0.015) phases of the motion after surgery. The alterations in LPR after surgery can be the result of changes in lumbar spine structure due to vertebral fusion and/or new neuromuscular adaptations in response to the changes of lumbar spine structure. The effects of altered LPR on load sharing between passive and active components of lower back tissues and the resultant spinal loads should be further investigated in patients with spinal fusion surgery.

KEYWORDS: low back pain, lumbopelvic rhythm, lumbo-pelvic coordination, lumbar spinal fusion, activities of daily living, lumbar fixation

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April 19th, 2018

EFFECTS OF LUMBAR SPINAL FUSION ON LUMBOPELVIC RHYTHM DURING ACTIVITIES OF DAILY LIVING

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Chapter 1: Introduction

Roughly 80% of citizens in the United States suffer from low back pain (LBP) at one point in their life; furthermore, LBP is the leading cause of disability for those younger than 45 years of age and the third leading cause of impairment for those older than 45 years of age [26][11]. Fortunately, a good majority of people who suffer from LBP are able to respond to non-operative treatments ranging from simple stretching exercises to prescribed medications [20]. The natural process of spinal aging and disc degeneration within the body, however, can cause painful issues like spinal stenosis [20]. When the severity of degeneration becomes too painful to live with on a daily basis, operative intervention is often considered [3]. Surgical treatments such as spinal fusion procedure for treatment of LBP due to degenerative discs are increasing exponentially in regards to abundance as well as expense [26]. The increasing number of procedures, however, have not been met with improved outcomes in patient satisfaction as further complications have been reported post-surgery [26].

The disabling pain in patients with degenerative disc disease deals primarily with continued motion at one or more spinal motion segments. Stabilization of the problematic motion segments usually provides pain relief [3]. Spinal fusion surgery, essentially, is designed to do just this. The surgery involves placing small morsels of bone either in the front or back of the problematic motion segments in hopes to have the bones grow together, in turn fusing the targeted section [19]. Surgical rod and screw devices are utilized to provide stabilization of the given section of the spine. It should be noted that the spine is not actually fused during surgery, as the process takes anywhere from 3-18 months depending on which procedural level is performed [19]. While pain is usually relieved, the issues of spinal stiffness and altered mechanical loading become a major concern, especially when multilevel segments are fused. The elevated stiffness of fused segments post-surgery will often inhibit and impair various activities of daily living (ADL) for patients. Some of the common ADLs that are impaired due to increased stiffness of fused spinal motion segments include dressing independently, getting in or out of a chair, bending downwards, and bathing the lower

half of one's body [31]. It should be noted that all of these tasks require some degree of trunk flexion and extension.

Trunk flexion and extension is primarily achieved by contributions from lumbar and hip joints. Contributions of the lumbar and hip joints to trunk motion have been primarily investigated in literature using measures of lumbopelvic rhythm (LPR). LPR is a specific and organized pattern of coordination between the lumbar and hip regions in connection to the pelvis during trunk flexion and extension [17][23]. Abnormal LPR between trunk flexion and extension can lead to a greater spinal loading and ultimately an increased risk of low back pain or injury [42]. To elaborate, when pelvic posture deviates from the ideal posture, biomechanical compensation results in postural distortion patterns in the lumbar spine [23]. LPR has been reported to be different between patients with LBP and back healthy individuals. Specifically, the presence of LBP has been reported to cause a decrease in lumbar contribution (LC) during forward and backward return [39]. LBP is a complex and multifactorial problem, and as indicated before only a sub-group of patients with LBP will end up undergoing fusion surgery. Therefore, it remains unclear whether this sub-group of patients with LBP has a similar LPR to those reported in earlier studies. Further, the impact of structural changes in the lumbar spine due to fusion surgery on the LPR of patients is also unknown.

The objectives of the study are: 1) to characterize differences in LPR between patients who are candidates for spinal fusion and those with non-specific LBP, 2) to determine the effect of lumbar spinal fusion on LPR, and 3) to compare LPR of patients who have undergone spinal fusion with gender and age matched back healthy individuals. We hypothesized that compared to patients with non-specific LBP, LPR of candidate patients for spinal fusion involves smaller lumbar contribution. Additionally, we hypothesized that changes in LPR following spinal fusion surgery will depend on the number and location of fused levels and will include an increase in pelvis and decrease in lumbar contribution to trunk. Post-spinal fusion comparison of LPR with back healthy individuals was left as the exploratory objective of the project.

To enable testing our hypotheses, we extracted kinematics data collected from back healthy individuals and acute patients for fusion surgery from earlier studies of our lab [40].

Organization of thesis:

In the following chapters, a review of LBP significance and etiology as well as LPR characteristics for symptomatic and asymptomatic populations will be presented (Chapter 2). This review includes specific root causes for spinal fusion candidates. This chapter is succeeded by an in-depth explanation of study protocols and research methods (Chapter 3). A detailed description of results can be seen in Chapter 4, while a discussion of these results are followed immediately after in Chapter 5. Finally, Chapter 6 completes the thesis with a discussion on limitations within the research and aims of future work that the study can take.

Chapter 2: Background

2.1 Significance of Back Pain

Back pain is one of the most prevalent and costly problems seen in the medical field today. Roughly 4 out of 5 people in the United States suffer from LBP, while costs upwards of $50 billion a year are estimated to be spent on LBP issues [26][7]. Furthermore, it is the second leading cause of work absenteeism in the United States, ranking first in lost productivity among all medical conditions [5]. While LBP proves to be a major issue among people, the obstacles surrounding how to categorize and treat such issues become complicated. For one, the underlying source of majority of LBP cases is unknown. These cases are often referred to as non-specific cases. Secondly, when the underlying source can indeed be identified (i.e. specific LBP), the complimenting treatments are not always being met with patient satisfaction or comfort [26][11]. This can partly be attributed to both the complexities of the anatomical structure of the spine as well as the properties and function.

2.2 Low Back Pain Etiology

In principle, back pain can arise from any of the ligaments, muscles, joints or discs of the lumbar spine [11]. Further, strains, structural problems, and infections are among the common reasons for back pain, and some causes for pain are never found [11]. LBP is classified as pain which can be specified between the twelfth rib and inferior gluteal folds and can arise either with or without leg pain [11]. With this being said, it's vital that a firm understanding of the lumbar spine anatomy and physiology is understood to help explain potential root causes of specific LBP cases.

2.2.1 Anatomy of Lumbar Spine

The lumbar spine (Fig 2.1) is the third major region of the spine. The lumbar spine revolves around 5 moveable vertebrae, L1-L5. The segment L5 meets the sacrum vertebrae S1, which allows for rotation of the pelvis segment [23]. Any two neighboring vertebrae are stacked with an intervertebral disc (IVD) in between them. The IVD consists of a gelatinous nucleus pulposus and a tough but pliable outer annulus fibrosus

[4]. These IVDs act as force absorbers between the vertebrae, absorbing the various hydrostatic and tensile forces put on the spine during even the simplest activities of daily living. The vertebrae and discs are held together by ligaments and tendons which help stabilize and protect the spine from excessive movement in any one direction [6]. The lumbar spine also has finger-like facet joints, which link vertebrae together and help give the spine flexibility. These facet joints are located on the back side of the spinal column. In the center of the spinal column is the spinal canal. The spinal canal contains the spinal cord, which stems from the brain all the way to either the first or second lumbar vertebrae. Directly below the spinal cord comes the cauda equina, or the horse's tail, which goes through the spinal canal and branches off into various parts of the lower body. Both the spinal cord and cauda equina are part of the central nervous system, and help one move, feel and experience various sensations [6].

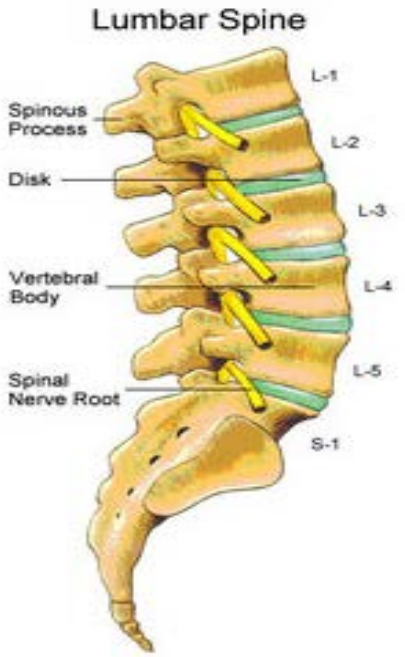


Figure 2.1: Anatomy of the Lumbar Spine

Image Reproduced from [10].

2.2.2 Potential Root Causes of LBP

Noticing the intricacies of the discs and nerves found in the lumbar spine, it is somewhat intuitive that various issues can arise to cause short to long-lasting pain.

Furthermore, LBP can be categorized into three subtypes: acute, sub-acute and chronic low back pain. These subtypes differentiate by length of the episode of LBP. Acute quantifies an episode of less than 6 weeks, while sub-acute quantifies between 6 and 12 weeks and chronic low back pain for 12 weeks and longer. Low back pain can also be classified further as non-specific or specific cases [7].

Non-Specific:

When discussing the root causes of LBP, it is important to reiterate that non-specific LBP has no recognizably known specific pathology and accompanies the majority of LBP cases at roughly 90% [24][5]. Non-specific LBP can be caused by traumatic injury, lumbar sprain or strain and/or postural strain. While many of these non-specific low back pain cases are self-limiting and can see pain relieved without treatment, the re-occurrence rate of LBP is at roughly 60% [24].

Specific:

Roughly 10% of all LBP patients present with specific root causes. Specific cases of LBP are diagnosed based on specific pathology [7]. Examples of these pathologies are scoliosis, spondylolisthesis, disc herniation and disc degeneration [4]. Disc degeneration is inevitable with age, but can also be seen as early as late teens as a result of trauma, surgery or poor genetics [2]. Furthermore, patients that present severe disc degeneration, categorized as degenerative disc disease (DDD) are often prime candidates for fusion surgery. It should be noted again, however, that fusion is a last resort option even for severe DDD cases.

2.3 Treatments for Disc Degeneration

A great majority of patients that present with degenerative disc disease (DDD) experience flare up periods of pain that come and leave in small periods of time. This pain originates from a combination of instability at the motion segment and inflammation at the given disc. These patients are generally able to combat the pain caused by DDD with non-operative solutions such as rehabilitation, stretching, weight

loss and prevention of stress using proper ergonomics [2]. With proper ergonomics and rehabilitation, the symptoms of DDD will sometimes subside. When the listed non-operative solutions cannot combat the pain successfully, pain medications such as acetaminophen, oral steroids or muscle relaxants may be used to complement the rehabilitation [6]. While these non-operative treatments are sometimes successful routes to solution, a small percentage of these specific LBP cases find that surgery is a right and necessary option after failed non-operative success and increased pain. The commonly used surgical treatment for DDD is spinal fusion surgery.

Fusion surgery for degenerative conditions is increasing exponentially in the United States. From 1990 to 2001, lumbar spinal fusion procedures had a 220% increase, rising from 32,701 operations to 122,316 operations [26]. Moreover, from 2001 to 2011, the Dartmouth Institute for Health Policy and Clinical Practice reported that there was a 67% increase in surgery [11]. With this being said, fusion surgery is also one of the most expensive surgical procedures today, with $4.8 billion spent on the procedure in 2001 in the United States alone. However, the increase in surgical rates and costs have not been met with improved outcomes and long-term disabilities, but have rather increased in regards to LBP disability associated with work loss, early retirement, and state benefits [26]. A study from 2011 found that patients who had no surgery to relieve pain were more likely to stop taking medication and return to work after two years [24]. In regards to why the commonly used surgical procedure for disc degeneration tends to still produce unsatisfactory results, a deeper understanding of how and why the procedure is performed should be understood.

Surgical procedure such as fusion is done to stop the motion between two neighboring vertebrae in hopes to decrease the associated pain. This motion is eliminated by utilizing bone graft substitute (Fig 2.2) to promote vertebral fusion [11]. Fusion procedure can happen at various levels needed. In other words, if there are more neighboring vertebrae that are causing pain and need to constrain their relative movements, multilevel fusion is performed. A single level fusion (Fig 2.3) is often the most effective option, noting that patients will likely notice very minimal limitations in

motion or stiffness after full recovery. Multilevel fusions (Fig 2.3), however, can become much more unlikely to provide complete relief in pain or stiffness as eliminating motion in three or more levels of the spine can often place too much stress on the remaining vertebrae [19].

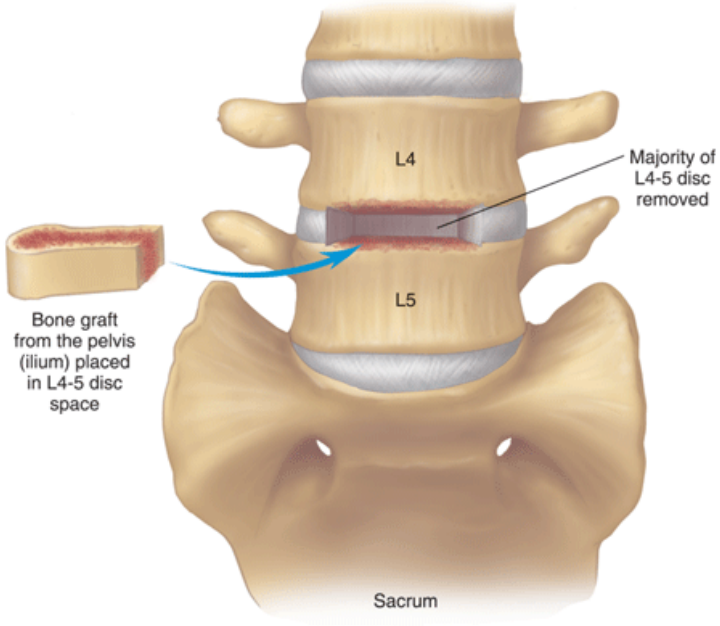


Figure 2.2: Bone graft substitute placement for intervertebral disc. Figure recreated by [12]

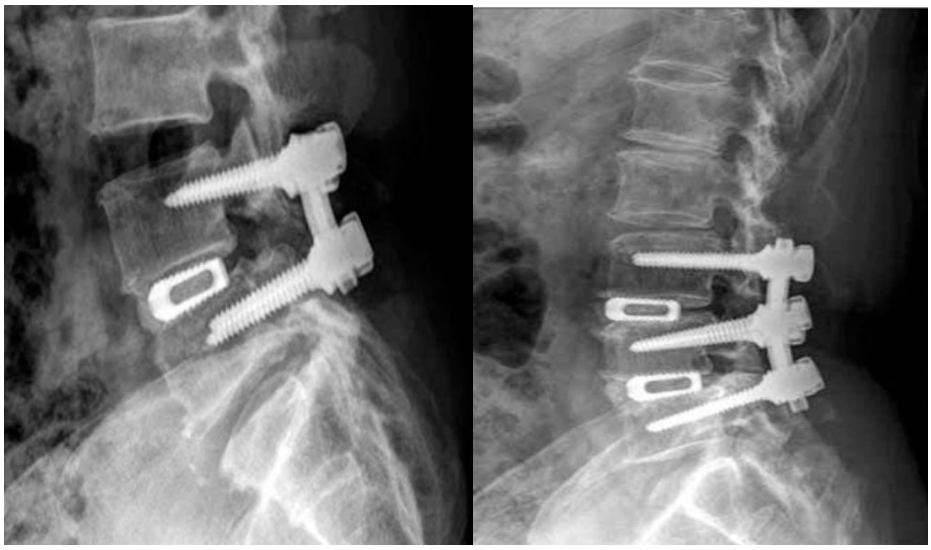


Figure 2.3: Medical Imaging of Single level fusion (Left) and Multi-level fusion (Right) – Recreated by [18]

2.4 LPR as Indirect Measure of Lower Back Mechanical Environment

Understanding that even single level fusions can cause limitations in motion and therefore alter the spine biomechanics of a patient, both researchers and clinicians have found great value in analyzing the lower back mechanical environment. It should be noted that direct in-vivo assessment of the lower back is currently not possible as there are both technical and ethical considerations associated with the current techniques available. However, indirect in-vivo measurements of the lower back mechanical environment are used heavily within the field as the ethical and technical issues are not a concern [33]. In particular, the indirect in-vivo kinematic measurements can serve as an alternative to direct mechanical loading techniques of the lumbar spine [40]. To elaborate, the way in which the lumbar spine moves is determined mainly by the kinematics of individual motion segments [13]. The biomechanics of the spine are affected by a correlation of three subsystems: 1) the passive tissues subsystem, 2) the active tissues subsystem, and 3) the neural subsystem. The passive tissues consist of vertebrae, discs, ligaments, and passive mechanical properties of muscles. The active tissues consist of spinal muscles and tendons. The neural subsystem consists of neural sensors and the control center. With this being noted, any change in the kinematics of motion is controlled by the nervous system, and results in an alteration of both the passive and active subsystems. This therefore leads to a change in loading on the passive and active tissues, resulting in a completely different load distribution on the lumbar spine. Moreover, any change in the kinematics of motion when performing a given task is directly related with a change in biomechanics of the lumbar spine [28][39][40].

The two lowest spinal segments of the lumbar spine, L4-L5 and L5-S1, respectively, bear the most weight and are therefore prone to more degradation and injury [22]. This region of the spine and pelvis, known as the lumbopelvic region, has a relative pattern of lumbar flexion/extension and pelvic rotation in the sagittal plane that can be utilized to differentiate between healthy and LBP individuals [39]. Any change in this relative pattern will be referred to as lumbopelvic rhythm (LPR). This LPR can often

be altered both while suffering from degenerative disc disease and after obtaining treatment, therefore changing biomechanics. Changes in kinematics of motion affect the major LPR components of timing and magnitude. In regards to abnormal LPR, lumbar and pelvic contributions in both forward bending and backward return have been noted to be measures of magnitude of LPR, while timing of motion is noted as the measure of timing [35]. The mean absolute relative phase (MARP) and deviation phase (DP) can measure and characterize the timing aspect of LPR [35]. A small MARP value signifies a more in-phase LPR, while a small DP means a more stable LPR.

2.5 LPR in Individuals with and Without LBP

LPR in Asymptomatic Individuals with No History of LBP:

In asymptomatic people with no history of LBP, the general observation is that lumbar contribution in forward bending is dominant in the early stage of trunk motion and then pelvic contribution becomes greater towards the end of the motion. Moreover, it was found that the early stage of backward return was done mainly by pelvic motion with the late portion of the movement being accomplished by the lumbar spine. In regards to the timing aspect, participants demonstrate a simultaneous lumbar and pelvic motion both in forward bending and backward return [39].

LPR in Individuals with a History of LBP:

Asymptomatic people with a history of LBP are susceptible to a recurrence of LBP. Previous studies show that participants with a history of LBP tend to have a smaller lumbar contribution than patients without a history of LBP in the middle stage of forward bending and a larger lumbar contribution in the early stage of backward return [39].

LPR in Patients with Current Episode of LBP:

In general, LBP patients tend to utilize less lumbar contribution in forward bending and backward return. In regards to timing, patients tend to utilize the same sequence as asymptomatic participants [39].

2.6: Research Gap

While there have been studies revolving around LPR of people with LBP and healthy controls, there are not many regarding LPR of patients who are candidates for spinal fusion or similarly related surgeries (Nguyen et al, 2015), (O'Shaughnessy et al, 2013). Furthermore, the information on the kinematic impact that fusion surgery has on LPR once a patient has recovered is unknown to the best of our knowledge. The absence of this information coupled with the insight that indirect mechanical measures can bring gives great reasoning towards researching this area and analyzing the differences in LPR. Furthermore, many clinical reports have been conducted on the long-term follow up of patients after spinal fusion with all reports showing evidence of accelerated deterioration of adjacent segments [8]. This complication known as adjacent segment disease (ASD) directly relates to the point made earlier regarding patient outcome not being satisfactorily satisfied, and moreover is just one of many complications that patients have been seen to deal with after surgery. Furthermore, complications such as ASD not only create physical pain and disability, but also pose as further burden in expense. Studying the changes in LPR before and after one has received spinal fusion may help give better understanding of the altered biomechanics and possibly help provide insight on why issues like accelerated deterioration of neighboring discs occur. A conceptual model (Fig 2.4) was used to rationalize our motive for the study.

Figure 2.4: Conceptual Model

Chapter 3: Methods

3.1: Study Design

A pre versus post repeated measure study design was used to investigate the effects of lumbar spinal fusion on a patient's LPR both pre and post-surgery using measures of magnitude and timing aspects of LPR. The study took place at the University of Kentucky Clinic, and University of Kentucky Good Samaritan Hospital. All participants completed an initial data collection session right before their fusion surgery followed by a twelve week follow up data collection session. During each data collection session, participants completed a trunk flexion/extension test. Each data collection session lasted approximately 15 to 20 minutes. Additionally, collected measures of fusion patient's LPR were compared with kinematic data collected previously from both back healthy individuals as well as acute LBP patients.

3.1.1: Participants and Participant Recruitment

Five lumbar spinal fusion patients participated in this study after completing a consenting process approved by the University of Kentucky Institutional Review Board. All patients recruited were between the ages of 20-80 years of age, and needed to have no previous back surgeries to meet inclusion criteria requirements. It is also worthy to note that in order to eliminate possible confounding factors, all patients included underwent either single level posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF). Both of these procedures are very similar in approach and comparable in technique, with the main difference being where the surgeon introduces the interbody cage. During a PLIF, the cage placement is directly posterior, while during a TLIF placement of the cage is posterolateral. Both approaches also have very similar construct of dual rods. Furthermore, all surgeons that performed fusion within the study used the same surgical instrumentation. All surgical instrumentation was of the EXPEDIUM 5.5 system designed and manufactured by DePuy Synthes, (Depuy Synthes, Raynham, MA) consisting of either titanium or polyether ether ketone (PEEK)

materials. A list of these materials from Depuy's Surgical Techniques Guide can be seen in Appendix A.

3.1.2: Acute LBP Patients Inclusion/Exclusion Criteria

The collected acute LBP patient's kinematics data were extracted from a case-control study design in which patients aged 40-70 years old with acute LBP (health care provider-diagnosed LBP ≤ 3 months) completed the trunk flexion/extension exercise that the fusion patients also completed. In regards to exclusion criteria, any acute LBP patients that had significant cognitive impairment, intention to harm themselves or others, or substance abuse were excluded from the study [32].

3.1.3: Back Healthy Individuals Inclusion/Exclusion Criteria

Kinematic data was extracted from a previous cross-sectional study in which asymptomatic individuals aged from 20-70 years old completed the trunk flexion/extension exercise. In regards to exclusion criteria, subjects were excluded from the study if they had one of the following: 1) back pain within the last year, 2) spinal deformity, abnormality or surgery in the trunk, 3) a history of work in physically demanding occupations, 4) BME <20 or >30 [37].

3.2: Coordination between Clinic and Study Personnel

When spinal fusion was determined necessary for patients within the inclusion criteria, the approved medical staff went through the consenting process in a detailed manner to seek patients who were willing to participate. Upon willingness, the approved medical staff then gave the patient ample time to ask any questions regarding the study. Only after properly consenting and giving time for questions did the approved medical staff give opportunity for the patient to sign for informed consent. Once the patient was properly consented and given time to ask questions, the approved medical staff then contacted the human musculoskeletal biomechanics laboratory (HMBL) at the University of Kentucky to give approved study personnel the opportunity to see the patient and collect data accordingly. Upon arrival of HMBL approved

personnel, the researchers again made sure to ask the patient if they are still able and willing to complete the exercises. Researchers made sure to let the respective patient know that if any discomfort arose, they should be notified to pause the data collection immediately.

3.3: Instrumentation and Experimental Procedure

A tri-axial Inertial Motion Sensor (Xsens Technologies, Enschede, Netherlands) system was used to measure the motion of participants' thorax and pelvis [40][41]. These motion sensors, otherwise known as accelerometers, were attached to the given body parts using straps with accelerometer clasps including: 1) on the participants back with the clasp at the T10 location of the spine and 2) on the participants pelvis with the clasp at the back side, centered and in line with the spine at location S1. The three-dimensional orientation of the accelerometers were collected at a sampling rate of 60Hz after a Kalman filter was utilized to minimize any possible effect of noise on the data [40]. The height from the ground to the top of all accelerometers were measured and recorded to ensure that similar placements were used in the post-surgery session. After placing accelerometers on trunk, participants were then directed to complete several basic movements and ADLs including: trunk flexion/extension, sit-to-stand and stand-to-sit, symmetric and asymmetric manual material handling, walking, and stair climbing. Upon completion of these tasks, the motion tracking accelerometers were taken off the participant in a careful manner to ensure no discomfort.

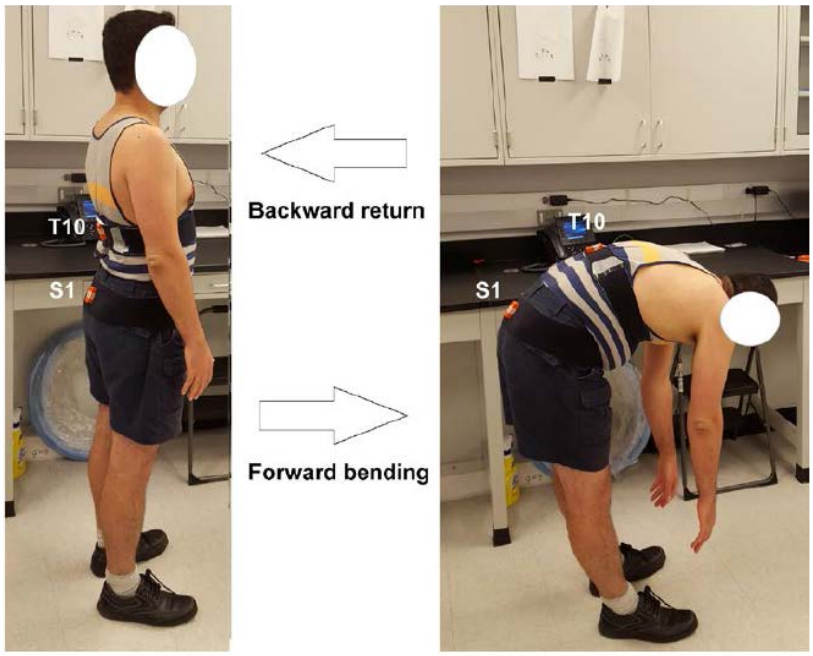


Figure 3.1: Accelerometers mounted correctly on participant at T10 and S1 levels of spine. Image recreated from [40]

3.3.1: Flexion/Extension Test

Given that all participants were not able to complete all ADLs, we only describe here the basic movement of forward bending and backward return that was successfully completed by all participants. Detailed description of all other tasks can be found in Appendix B. For the flexion/extension test, the participant was instructed to stand in an upright position for five seconds and then bend forward at the waist slowly until they reached their maximum but comfortable flexed posture. The participant was instructed not to stretch past this position, but rather stay flexed in the position for five seconds and return slowly back to the upright position. This sequence was repeated another two times during the test.

3.4 Data Analysis

In-house MATLAB scripts in addition to MT Manager, a processing program which exports stored accelerometer data were utilized to process the collected data for all tests.

3.4.1 Magnitude Aspect

Using the standing posture as a reference, the MTs' rotation matrices were utilized to calculate the thorax and pelvis rotations in the sagittal plane [40]. The range of motion values were calculated using the angles during bending movement of the thorax, lumbar and pelvis. The thoracic rotation was found using the accelerometer positioned at the T10 level and the pelvic rotation from the accelerometer located at the S1 spinal level. The range of motion (ROM) during each test was calculated as the difference in recorded rotation between starting and ending time points during the bending phase [40]. These starting and ending points can be described of being when the rotation was 5% and 95% of the maximum recorded rotation during each respective test [40]. Lumbar rotation was calculated for each instant of the task as the difference between corresponding thoracic and pelvic rotations at the same time instant. Lumbar range of flexion was subsequently calculated as the difference in thoracic and pelvic rotation between starting and ending time points during the bending phase. Further, the lumbar contribution (LC), which can be defined as total lumbar flexion/extension to total thoracic rotation, was found.

3.4.2 Timing Aspect

The timing aspect of LPR characterized using measures of continuous relative phase (CRP) between the thorax and pelvis. This data was calculated by first reformatting the thorax and pelvis rotations to set the median value as the new point of reference. The next step in the process required taking the phase angle for each of the rotations to calculate the tangent inverse of the Hilbert transformation. Once this was completed, the CRP was calculated by taking the difference of pelvic and thoracic phase angles at each instant of time per task. The MARP and DP were calculated from the CRP to give properties of timing of LPR [35]. MARP values represent the phase of coordination. Moreover, an MARP value that is closer to 0 represents a more in-phase LPR, whereas an MARP value closer to π represents a more out-of-phase LPR

coordination. The terms in-phase and out-of-phase are used in reference to the synchronization of the pelvis and thorax during LPR. In regards to DP, a value closer to 0 shows an LPR with less trial-to-trial variability giving a motion pattern with greater stability [35].

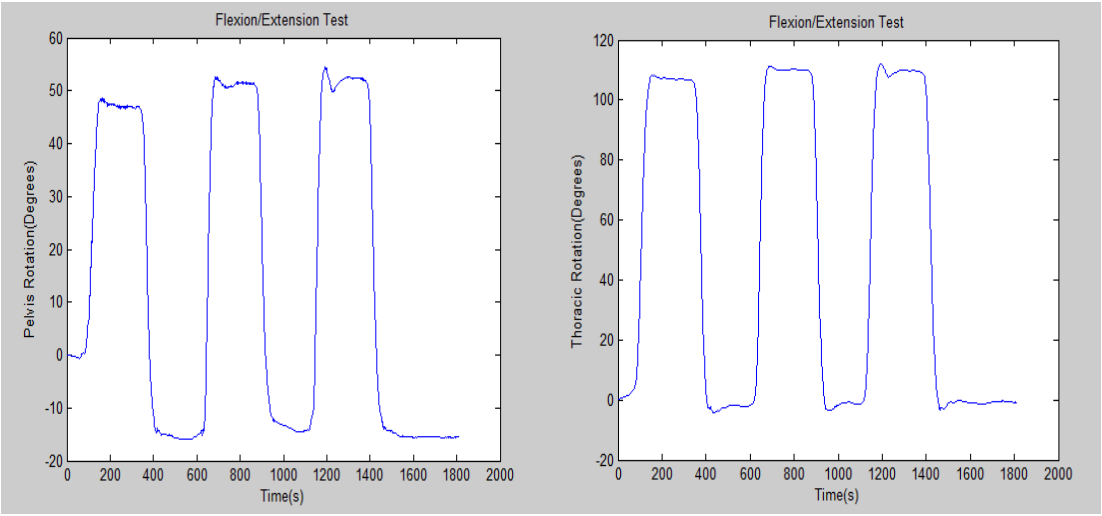


Figure 3.2: Pelvis and Thorax Rotation – Display of MATLAB output for angles of thorax and pelvis rotation during flexion and extension range of motion test. The maximum rotation during each bending movement is found as the average of each peak bending average.

3.5: Statistical Analysis

A repeated measures study design was conducted to investigate potential changes in LPR of patients following lumbar spinal fusion surgery. A paired samples t-test was conducted between pre-fusion and post-fusion patients. However, it should be noted that the pre-fusion and post-fusion patients are not equal, as some patients were not able to complete post-operation evaluation due to various circumstances. To further compare LPR of spinal fusion patients before and after surgery with other populations, analysis of variance (ANOVA) tests were conducted between pre-fusion, back-healthy individuals and acute LBP patients, as well as post-fusion, back-healthy individuals and acute LBP patients. Statistical analysis was conducted using SPSS (IBM SPSS

Statistics 23, Armonk, NY, USA) and in all cases a p value smaller than 0.05 was considered to be statistically significant.

Chapter 4: Results

4.1: Pre vs. Post Spinal Fusion Surgery

The ranges of pelvic, thoracic and lumbar rotation/flexion obtained from forward bending and backward return for spinal fusion patients pre-surgery were respectively 17.69° smaller, 2.19° larger and 19.85° larger than post-surgery. The MARP and DP values were smaller throughout the entire movement for patients post-surgery. More detailed analysis of the timing and magnitude values are summarized in Tables 4.1, 4.2, 4.3, 4.4 and 4.5.

4.2: Pre-Spinal Fusion Surgery vs. Acute LBP Patients

The ranges of pelvic, thoracic and lumbar rotation/flexion obtained from forward bending and backward return for age and gender matched acute LBP patients were respectively: 14.81° smaller, 7.89° smaller and 7.11° larger than spinal fusion patients pre-surgery. The MARP and DP values were smaller throughout the entire movement for patients pre-surgery.

4.3: Post-Spinal Fusion Surgery vs. Back-Healthy Individuals

The ranges of pelvic, thoracic and lumbar rotation/flexion obtained from forward bending and backward return for back-healthy individuals were respectively: 38.3° smaller, 11.8° smaller and 26.6° larger than spinal fusion patients post-surgery. The MARP value was smaller during the lowering portion of the movement and higher during the lifting movement post-surgery. The DP values were smaller throughout the entire movement for patients post-surgery.

4.4: Statistical Analysis

After conducting a paired samples t-test to analyze the changes in LPR magnitude and timing aspects, results show no statistical significance in differences pre vs. post-surgery at the 95% confidence level. In regards to the ANOVA tests, no values of statistical significance were found in the results for range of motion or continuous relative phase. It should be noted that based on the small sample size and insignificance, it is extremely difficult to generalize these findings.

Table 4.1: Mean (SD) of thoracic, pelvic and lumbar range of motion/flexion for pre-surgery patients, post-surgery patients, acute LBP patients, and back-healthy individuals

	Thoracic Rotation	Lumbar Flexion	Pelvic Rotation
Pre-Surgery	95.2°	35.9°	59.3°
Post-Surgery	93.1°	16°	76.9°
Acute LBP Patients	87.4°	43°	44.4°
Back-Healthy Individuals	81.3°	42.6°	38.6°

Table 4.2: Percentage contributions of motion/flexion for pre-surgery patients, post-surgery patients, acute LBP patients, and back-healthy individuals

	Lumbar Contribution	Pelvic Contribution
Pre-Surgery	38%	62%
Post-Surgery	17.40%	82.60%
Acute LBP Patients	49.20%	50.80%
Back-Healthy Individuals	52.40%	47.60%

Table 4.3: Timing results of Flexion/Extension Exercise for pre-surgery patients, post-surgery patients, acute LBP patients, and back-healthy individuals

	MARP Forward Bending	DP Forward Bending	MARP Backward Return	DP Backward Return
Pre-Surgery	0.0762	0.0747	0.1466	0.0432
Post-Surgery	0.0602	0.0657	0.1056	0.0281
Acute LBP Patients	0.1903	0.0786	0.1835	0.0549
Back-Healthy Individuals	0.2011	0.0628	0.1175	0.0475

Table 4.4: Summary of Statistics Results for Range of Motion. ANOVA: analysis of variance.

Magnitude of LPR						
ANOVA Results	**Pelvic Rotation**		**Thoracic Rotation**		**Lumbar Flexion**	
	F	p	F	p	F	p
Pre-Fusion (Group)	3.367	0.087	4.073	0.060	0.565	0.590
Post-Fusion (Group)	2.129	0.235	1.481	0.330	2.168	0.230

Table 4.5: Summary of Statistics Results for Timing. ANOVA: analysis of variance. MARP: mean absolute relative phase. DP: deviation phase.

Timing of LPR								
ANOVA Results	**MARP Lowering**		**DP Lowering**		**MARP Lifting**		**DP Lifting**	
	F	p	F	p	F	p	F	p
Pre-Fusion (Group)	1.679	0.246	0.44	0.657	1.07	0.388	0.40	0.683
Post-Fusion (Group)	5.67	0.068	1.159	0.401	5.047	0.081	1.025	0..437

Chapter 5: Discussion

5.1: Flexion/Extension Test:

5.1.1: Pre vs. Post Spinal Fusion

The main objective of this study was to investigate changes in magnitude and timing aspects of LPR between spinal fusion patients before and after surgery during forward bending and backward return. Patients showed to utilize more pelvic rotation and less thoracic and lumbar rotation after surgery. LPR was more in-phase (i.e., shown by smaller MARP values) and less variable (i.e., shown by smaller DP values) post-surgery as well. Further, the total lumbar contribution (LC) (i.e., total lumbar rotation/extension ÷ total thoracic rotation) shown for patients pre-surgery (0.38) was greater than the LC for patients post-surgery (0.17). These findings ultimately confirmed our initial hypothesis. The alterations observed in LPR after surgery may be a result of changes in the lumbar spine structure as a result of fusing. Another thought as to why such changes occurred is that new neuromuscular adaptations were utilized in response to changes in the lumbar spine structure.

To the best of our knowledge, few similar studies (Nguyen et al, 2015), (O'Shaughnessy et al, 2013) have been reported in relation to LPR alterations due to spinal fixation surgery. However, the findings from these results were able to be compared with previous kinematic data that was extracted from 1) a study that looked into timing and magnitude of LPR in patients with acute LBP, and 2) a study that looked into age-related differences of timing and magnitude of LPR in our lab and reported in previous publications [40].

5.1.2: Pre-Spinal Fusion Surgery vs. Acute LBP Patients

A secondary objective of the study was to investigate changes in magnitude and timing aspects of LPR between the spinal fusion patients before surgery and acute LBP patients. Upon analyzing it was shown that spinal fusion patients pre-surgery utilize more pelvic and thoracic rotation and less lumbar rotation during forward bending and backward return than the acute LBP patients. Further, the LPR was more in-phase and

less variable throughout for the spinal fusion patients. The total LC for spinal fusion patients (0.38) was less than the LC for acute LBP patients (0.49). This finding for total lumbar contribution confirmed our initial hypothesis.

The clinical significance of the kinematic results of pre-fusion patients when compared to acute LBP patients is something to look into. A smaller lumbar flexion/rotation reduces the passive contribution of lower back tissues in order to offset the task demand on the lower back. This LC alteration has been suggested to prevent painful deformation in the posterior elements of the spine [35]. Moreover, a more in-phase and less variable LPR (i.e. phase-locked coordination) is suggested to be a protective motor control strategy that reduces the likelihood of pain during dynamic tasks caused by spinal tissues. The biomechanical consequence of using such phase-locked coordination, however, is increased trunk muscle activation and co-activation which can cause increased spinal loads and muscle fatigue [35]. Patients who are going to receive spinal fusion procedure are often considered to have chronic LBP, whereas acute LBP patients can have pain that has lasted for a much shorter time span (i.e., acute LBP). The longer time span that a chronic LBP patient lives with discomfort gives greater chance for alterations in biomechanics such as phase-locked coordination to try and alleviate pain.

5.1.3: Post-Spinal Fusion Surgery vs. Back-Healthy Individuals

The final objective of the study was to investigate changes in magnitude and timing aspects of LPR between spinal fusion patients after surgery and back-healthy individuals. The spinal fusion patients post-surgery were shown to use more pelvic and thoracic rotation and less lumbar rotation than back-healthy individuals during forward bending and backward return. The total lumbar contribution (LC) for the patients post-surgery (0.17) was less than the LC for the back-healthy individuals (0.52). This objective of the study was left exploratory, and furthermore, a note-worthy component of discussion was found in the timing component of LPR of fusion patients post-surgery when compared with back-healthy individuals. The fusion patients were more in-phase

(MARP Lowering = 0.06019) during the lowering portion of the movement and then less in-phase (MARP Lifting = 0.1056) during the backward return portion of the movement than back-healthy individuals (MARP Lowering = 0.2010, MARP Lifting = 0.1174). Further, the patients post-surgery displayed a less variable LPR during the entire portion of the movement.

Better understanding changes in LPR during flexion/extension in individuals with LBP and back-healthy individuals can help provide insight. The differences in timing and magnitude when comparing post-fusion patients and back-healthy individuals are of clinical importance. Noting that a fusion patient post-surgery is overcompensating with pelvic and thoracic rotation and actually utilizing minimal lumbar rotation, this biomechanical alteration due to vertebral fusion can very well result in both short and long-term consequences ranging from stiffness to adjacent segment disease if even simple ADLs are not restrained and/or at the very least re-introduced with careful practice of proper mechanics.

5.2: Limitations

Limitations presented throughout the study should be considered when examining results. Firstly, the study utilized a small sample size (n = 5). Furthermore, all patients within the sample size underwent single level fusion surgery. Also, due to constraints from patients before undergoing surgery, limitations in ADL exercises were found in many cases. While flexion/extension test was found to provide great information, other exercises (i.e., Appendix A) could have given insight to more frequent ADLs. Finally, due to the feasibility of the study, we did not collect some important data such as pain level, potential musculoskeletal abnormalities, fear of movement due to LBP, and other various intrinsic patient factors.

In conclusion, it is well understood that fixation of the spine causes structural changes and alters mechanical loading, however, it has been less known what effect this fixation has on LPR measures of magnitude and timing. The large population of LBP patients who are affected by degenerative disc disease and seek spinal fusion procedure

to alleviate pain deal with both changes in magnitude and timing components of LPR that are likely to have adverse biomechanical consequences on spinal health. Adjacent segment disorder is a major negative outcome of spinal fusion surgery. Quantitative data on how LPR is affected after vertebral fixation can provide insight into how altering one's mechanics (i.e., rehabilitation techniques) may help prevent such future damage.

Chapter 6: Future Work

6.1: Future Work

Gaining base insight on the effect of spinal fixation on LPR magnitude and timing components is pivotal to the improvement of both patient's biomechanics as well as outcome of LBP satisfaction after surgery. The results provided within this pilot study can be used to potentially guide rehabilitation post-surgery to account for surgery related alterations in magnitude and timing components of LPR. With this being said, future studies are vital in order to gain a more well-rounded understanding on how these LPR components are altered upon spinal fixation.

Any future studies conducted revolving around this study should address the following: 1) sample size, 2) obtainment of more ADL movements 3) analyzation of the specific population to other LBP and healthy control groups 4) surveys that measure psychological factors that may come into play 5) similar studies dealing with other spine segments. Firstly, while the sample size of 5 patients was suitable to test the feasibility of this study, small alterations between participants can create very large alterations when a small sample size is utilized. Secondly, while the flexion/extension exercise captures the LPR components of magnitude and timing in all regards, obtainment of other exercises such as but not limited to the ones listed in Appendix A could very well provide new insight and/or help lessen the alteration gap in participants discussed earlier. Addressing this issue admittedly may be a challenge as spinal fusion patients can very often be limited in both duration and quantity of tasks that can be performed in a comfortable manner. Thirdly, while this study went on to analyze both spinal fusion patients before surgery compared to acute LBP patients and fusion patients after surgery compared to back-healthy individuals, there are various other populations that can be looked into. The benefits of doing such analysis can provide both further clinical and biomechanical significance such as what has been suggested in the current study. Fourth, we did not control for the effects of level of pain, history or presence of other musculoskeletal disorders, and psychosocial factors. These factors can affect LPR and should be considered in future studies. For example, it was discussed earlier that if a

patient understands that overcompensating with their pelvis while dealing with degenerative disc disease may help relieve pain, the repetitive movement may be remembered and utilized even after surgery when pain has been affectively relieved. This neuromuscular adaptation could potentially result in altered mechanical loading and create new damage of the lumbar spine. Future studies in regards to introducing/re-training correct neuromuscular pattern could be a very important line of research. Psychological surveys that focus and pin-point these types of concerns may be able to help assist when coupled with the results given in the study. Finally, another area for future work can revolve around similar studies of LPR measures for spinal fixation of the thoracic or even cervical spine. While the lumbar spine is well known to take majority of load baring and damage, insight on other segments of the spine could only provide a better overall understanding of spinal fixation to help guide rehabilitation.

Appendices

Appendix A: Depuy Synthes EXPEDIUM 5.5 Surgical Techniques Catalogue

EXPEDIUM 5,5 System

Implants - Screws

EXPEDIUM 5.5 Titanium

Monoaxial Screws	Cat. No	Description	Diameter	Length
	1797-02-425	Pedicle Screw, Monoaxial	4.35 mm	25 mm
	1797-02-430	Pedicle Screw, Monoaxial	4.35 mm	30 mm
	1797-02-435	Pedicle Screw, Monoaxial	4.35 mm	35 mm
	1797-02-440	Pedicle Screw, Monoaxial	4.35 mm	40 mm
	1797-02-445	Pedicle Screw, Monoaxial	4.35 mm	45 mm
	1797-02-525	Pedicle Screw, Monoaxial	5.00 mm	25 mm
	1797-02-530	Pedicle Screw, Monoaxial	5.00 mm	30 mm
	1797-02-535	Pedicle Screw, Monoaxial	5.00 mm	35 mm
	1797-02-540	Pedicle Screw, Monoaxial	5.00 mm	40 mm
	1797-02-545	Pedicle Screw, Monoaxial	5.00 mm	45 mm
	1797-02-550	Pedicle Screw, Monoaxial	5.00 mm	50 mm
	1797-02-625	Pedicle Screw, Monoaxial	6.00 mm	25 mm
	1797-02-630	Pedicle Screw, Monoaxial	6.00 mm	30 mm
	1797-02-635	Pedicle Screw, Monoaxial	6.00 mm	35 mm
	1797-02-640	Pedicle Screw, Monoaxial	6.00 mm	40 mm
	1797-02-645	Pedicle Screw, Monoaxial	6.00 mm	45 mm
	1797-02-650	Pedicle Screw, Monoaxial	6.00 mm	50 mm
	1797-02-655	Pedicle Screw, Monoaxial	6.00 mm	55 mm
	1797-02-735	Pedicle Screw, Monoaxial	7.00 mm	35 mm
	1797-02-740	Pedicle Screw, Monoaxial	7.00 mm	40 mm
	1797-02-745	Pedicle Screw, Monoaxial	7.00 mm	45 mm
	1797-02-750	Pedicle Screw, Monoaxial	7.00 mm	50 mm
	1797-02-755	Pedicle Screw, Monoaxial	7.00 mm	55 mm
	1797-02-760	Pedicle Screw, Monoaxial	7.00 mm	60 mm
	1797-02-765	Pedicle Screw, Monoaxial	7.00 mm	65 mm
	1797-02-780	Pedicle Screw, Monoaxial	7.00 mm	80 mm
	1797-02-840	Pedicle Screw, Monoaxial	8.00 mm	40 mm
	1797-02-845	Pedicle Screw, Monoaxial	8.00 mm	45 mm
	1797-02-850	Pedicle Screw, Monoaxial	8.00 mm	50 mm
	1797-02-855	Pedicle Screw, Monoaxial	8.00 mm	55 mm
	1797-02-865	Pedicle Screw, Monoaxial	8.00 mm	65 mm
	1797-02-000	EXPEDIUM 5.50 Ti X25 Set Screw		
	1797-10-100	Washer		
	1797-10-200	Split Washer		

Implants - Screws

EXPEDIUM 5.5 Titanium

Uniplanar Screws	Cat. No	Description	Diameter	Length
	1797-88-420	Uniplanar Screw	4.35 mm	20 mm
	1797-88-425	Uniplanar Screw	4.35 mm	25 mm
	1797-88-430	Uniplanar Screw	4.35 mm	30 mm
	1797-88-435	Uniplanar Screw	4.35 mm	35 mm
	1797-88-440	Uniplanar Screw	4.35 mm	40 mm
	1797-88-525	Uniplanar Screw	5.00 mm	25 mm
	1797-88-530	Uniplanar Screw	5.00 mm	30 mm
	1797-88-535	Uniplanar Screw	5.00 mm	35 mm
	1797-88-540	Uniplanar Screw	5.00 mm	40 mm
	1797-88-545	Uniplanar Screw	5.00 mm	45 mm
	1797-88-550	Uniplanar Screw	5.00 mm	50 mm
	1797-88-630	Uniplanar Screw	6.00 mm	30 mm
	1797-88-635	Uniplanar Screw	6.00 mm	35 mm
	1797-88-640	Uniplanar Screw	6.00 mm	40 mm
	1797-88-645	Uniplanar Screw	6.00 mm	45 mm
	1797-88-650	Uniplanar Screw	6.00 mm	50 mm
	1797-88-655	Uniplanar Screw	6.00 mm	55 mm
	1797-88-730	Uniplanar Screw	7.00 mm	30 mm
	1797-88-735	Uniplanar Screw	7.00 mm	35 mm
	1797-88-740	Uniplanar Screw	7.00 mm	40 mm
	1797-88-745	Uniplanar Screw	7.00 mm	45 mm
	1797-88-750	Uniplanar Screw	7.00 mm	50 mm

EXPEDIUM 5.5 Titanium

Single Innie Polyaxial Screw	Cat. No	Description	Diameter	Length
	1797-15-630	Single Innie Polyaxial Screw	6.50 mm	30 mm
	1797-15-635	Single Innie Polyaxial Screw	6.50 mm	35 mm
	1797-15-640	Single Innie Polyaxial Screw	6.50 mm	40 mm
	1797-15-645	Single Innie Polyaxial Screw	6.50 mm	45 mm
	1797-15-650	Single Innie Polyaxial Screw	6.50 mm	50 mm
	1797-15-655	Single Innie Polyaxial Screw	6.50 mm	55 mm
	1797-15-660	Single Innie Polyaxial Screw	6.50 mm	60 mm
	1797-12-730	Single Innie Polyaxial Screw	7.00 mm	30 mm
	1797-12-735	Single Innie Polyaxial Screw	7.00 mm	35 mm
	1797-12-740	Single Innie Polyaxial Screw	7.00 mm	40 mm
	1797-12-745	Single Innie Polyaxial Screw	7.00 mm	45 mm
	1797-12-750	Single Innie Polyaxial Screw	7.00 mm	50 mm
	1797-12-755	Single Innie Polyaxial Screw	7.00 mm	55 mm
	1797-12-765	Single Innie Polyaxial Screw	7.00 mm	65 mm
	1797-12-780	Single Innie Polyaxial Screw	7.00 mm	80 mm
	1797-12-030	Single Innie Polyaxial Screw	7.50 mm	30 mm
	1797-12-035	Single Innie Polyaxial Screw	7.50 mm	35 mm
	1797-12-040	Single Innie Polyaxial Screw	7.50 mm	40 mm
	1797-12-045	Single Innie Polyaxial Screw	7.50 mm	45 mm
	1797-12-050	Single Innie Polyaxial Screw	7.50 mm	50 mm
	1797-12-055	Single Innie Polyaxial Screw	7.50 mm	55 mm
	1797-12-050	Single Innie Polyaxial Screw	7.50 mm	60 mm
	1797-12-065	Single Innie Polyaxial Screw	7.50 mm	65 mm
	1797-12-070	Single Innie Polyaxial Screw	7.50 mm	70 mm
	1797-12-075	Single Innie Polyaxial Screw	7.50 mm	75 mm
	1797-12-080	Single Innie Polyaxial Screw	7.50 mm	80 mm
	1797-12-099	Single Innie Polyaxial Screw	7.50 mm	100 mm

Implants - Hooks

EXPEDIUM 5.5 Titanium

Hooks	Cat. No	Description	Length
	1797-52-000	Pedicle Hook	
	1797-52-002	Pedicle Hook	
	1797-52-005	Downsized Pedicle Hook (not pictured)	
	1797-52-045	Wide Blade Hook	5.0 mm
	1797-52-046	Wide Blade Hook	6.5 mm
	1797-52-048	Wide Blade Hook	8.0 mm
	1797-52-040	Wide Blade Hook	10.0 mm
	1797-52-042	Wide Blade Hook	12.0 mm
	1797-52-016	Reduced Distance Hook	6.5 mm
	1797-52-018	Reduced Distance Hook	8.0 mm
	1797-52-010	Reduced Distance Hook	10.0 mm
	1797-52-012	Reduced Distance Hook	12.0 mm
	1797-52-026	Angled Blade Hook	6.5 mm
	1797-52-028	Angled Blade Hook	8.0 mm
	1797-52-029	Angled Blade Hook	10.0 mm
	1797-52-020	Angled Blade Hook	12.0 mm
	1797-52-036	Narrow Blade Hook	6.5 mm
	1797-52-038	Narrow Blade Hook	8.0 mm
	1797-52-030	Narrow Blade Hook	10.0 mm
	1797-52-032	Narrow Blade Hook	12.0 mm

Implants - Hooks

EXPEDIUM 5.5 Titanium

Hooks	Cat. No	Description	Length
	1797-52-050	Extended Body Hook	10.0 mm
	1797-52-060	Right Angled Hook	
	1797-52-070	Left Angled Hook	
	1797-52-080	Right Offset Hook	
	1797-52-090	Left Offset Hook	
	1797-52-165	Side Tight Hook Left	6.5 mm
	1797-52-180	Side Tight Hook Left	8.0 mm
	1797-52-195	Side Tight Hook Left	9.5 mm
	1797-52-211	Side Tight Hook Right	11.0 mm
	1797-52-280	Side Tight Hook Right	8.0 mm
	1797-52-295	Side Tight Hook Right	9.5 mm
	1797-52-200	Ext. Tab Pedicle Hook	

EXPEDIUM 5.5

Straight Rod	Cat. No	Description	Length
	1797-62-030	Pre Cut Rod	30 mm
	1797-62-035	Pre Cut Rod	35 mm
	1797-62-040	Pre Cut Rod	40 mm
	1797-62-045	Pre Cut Rod	45 mm
	1797-62-050	Pre Cut Rod	50 mm
	1797-62-055	Pre Cut Rod	55 mm
	1797-62-060	Pre Cut Rod	60 mm
	1797-62-065	Pre Cut Rod	65 mm
	1797-62-070	Pre Cut Rod	70 mm
	1797-62-120	Pre Cut Rod	120 mm
	1797-62-300	Hex-end Rod	300 mm
	1797-62-480	Hex-end Rod	480 mm
	1797-77-300	Pre-Cut Commercially Pure Hex End Rod	300 mm
	1797-77-480	Pre-Cut Commercially Pure Hex End Rod	480 mm
	1797-77-600	Pre-Cut Commercially Pure Hex End Rod	600 mm

EXPEDIUM 5.5 Titanium

Pre-Lordosed Rods	Cat. No	Description	Length
	1797-72-035	Pre-lordosed Rod	35 mm
	1797-72-040	Pre-lordosed Rod	40 mm
	1797-72-045	Pre-lordosed Rod	45 mm
	1797-72-055	Pre-lordosed Rod	55 mm
	1797-72-065	Pre-lordosed Rod	65 mm
	1797-72-070	Pre-lordosed Rod	70 mm
	1797-72-075	Pre-lordosed Rod	75 mm
	1797-72-080	Pre-lordosed Rod	80 mm
	1797-72-085	Pre-lordosed Rod	85 mm
	1797-72-090	Pre-lordosed Rod	90 mm
	1797-72-095	Pre-lordosed Rod	95 mm

EXPEDIUM 5.5

Cobalt Chromium (CoCr)	Cat. No	Description	Length
	1967-89-120	CoCr Rods	120 mm
	1967-89-300	CoCr Rods	300 mm
	1967-89-480	CoCr Rods	480 mm
	1967-89-600	CoCr Rods	600 mm

EXPEDIUM 5.5

PEEK pre-lordosed rod	Cat. No	Description	Diameter	Length
	1867-82-030	PEEK Pre-lordosed Rod	5.5 mm	30 mm
	1867-82-035	PEEK Pre-lordosed Rod	5.5 mm	35 mm
	1867-82-040	PEEK Pre-lordosed Rod	5.5 mm	40 mm
	1867-82-045	PEEK Pre-lordosed Rod	5.5 mm	45 mm
	1867-82-050	PEEK Pre-lordosed Rod	5.5 mm	50 mm
	1867-82-055	PEEK Pre-lordosed Rod	5.5 mm	55 mm
	1867-82-060	PEEK Pre-lordosed Rod	5.5 mm	60 mm
	1867-82-065	PEEK Pre-lordosed Rod	5.5 mm	65 mm
	1867-82-070	PEEK Pre-lordosed Rod	5.5 mm	70 mm
	1867-82-075	PEEK Pre-lordosed Rod	5.5 mm	75 mm
	1867-82-080	PEEK Pre-lordosed Rod	5.5 mm	80 mm
	1867-82-085	PEEK Pre-lordosed Rod	5.5 mm	85 mm
	1867-82-090	PEEK Pre-lordosed Rod	5.5 mm	90 mm
	1867-82-095	PEEK Pre-lordosed Rod	5.5 mm	95 mm
	1867-82-105	PEEK Pre-lordosed Rod	5.5 mm	105 mm
	1867-82-120	PEEK Pre-lordosed Rod	5.5 mm	120 mm

EXPEDIUM 5.5

PEEK Set Screw	Cat. No	Description
	1867-82-000	PEEK Rod Set Screw

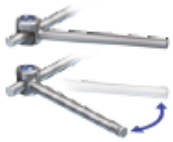
EXPEDIUM 5.5

Z Rod	Cat. No	Description	Length
	1797-98-300	Z Rod	300 mm

EXPEDIUM 5.5

Dual diameter	Cat. No	Description	Length
	1883-11-002	3.5mm - 5.5mm Dual diameter Rod	420 mm
	1883-11-012	3.5mm - 5.5mm Dual diameter Rod	600 mm

EXPEDIUM 5.5 Titanium
Sacral Pelvic Lateral Connectors

	Cat. No	Description	Diameter	Length
	1797-98-020	Closed Polyaxial Lateral Connector	5.5 mm	20 mm
	1797-98-040	Closed Polyaxial Lateral Connector	5.5 mm	40 mm
	1797-98-060	Closed Polyaxial Lateral Connector	5.5 mm	60 mm
	1797-98-100	Closed Polyaxial Lateral Connector	5.5 mm	100 mm
	1797-98-200	Closed Polyaxial Lateral Connector	5.5 mm	200 mm
	1797-97-020	Open Polyaxial Lateral Connector	5.5 mm	20 mm
	1797-97-040	Open Polyaxial Lateral Connector	5.5 mm	40 mm
	1797-97-060	Open Polyaxial Lateral Connector	5.5 mm	60 mm
	1797-97-150	Open Polyaxial Lateral Connector	5.5 mm	150 mm
	1797-97-200	Open Polyaxial Lateral Connector	5.5 mm	200 mm
	1797-93-020	Open Lateral Connector	5.5 mm	20 mm
	1797-93-050	Open Lateral Connector	5.5 mm	50 mm
	1797-93-150	Open Lateral Connector	5.5 mm	150 mm
	1774-40-040	Closed Lateral Connector	5.5 mm	40 mm
	1774-40-060	Closed Lateral Connector	5.5 mm	60 mm
	1774-40-125	Closed Lateral Connector	5.5 mm	125 mm

EXPEDIUM 5.5 Titanium
Sacral Pelvic Screws

	Cat. No	Description	Diameter	Length
	1797-12-765	Open Polyaxial Iliac Screw	7 mm	65 mm
	1797-12-780	Open Polyaxial Iliac Screw	7 mm	80 mm
	1797-12-065	Open Polyaxial Iliac Screw	7.5 mm	65 mm
	1797-12-080	Open Polyaxial Iliac Screw	7.5 mm	80 mm
	1797-12-865	Open Polyaxial Iliac Screw	8 mm	65 mm
	1797-12-880	Open Polyaxial Iliac Screw	8 mm	80 mm
	1797-12-965	Open Polyaxial Iliac Screw	9 mm	65 mm
	1797-12-980	Open Polyaxial Iliac Screw	9 mm	80 mm
	1797-12-165	Open Polyaxial Iliac Screw	10 mm	65 mm
	1797-12-180	Open Polyaxial Iliac Screw	10 mm	80 mm
	1797-12-765	Closed Polyaxial Iliac Screw	7 mm	65 mm
	1797-12-780	Closed Polyaxial Iliac Screw	7 mm	80 mm
	1797-12-065	Closed Polyaxial Iliac Screw	8 mm	65 mm
	1797-12-080	Closed Polyaxial Iliac Screw	8 mm	80 mm
	1797-12-865	Closed Polyaxial Iliac Screw	9 mm	65 mm
	1797-12-880	Closed Polyaxial Iliac Screw	9 mm	80 mm

EXPEDIUM 5.5 Titanium

Rod-to-Rod Connectors	Cat. No	Description	
	1774-92-020	Side-by-Side Connector	5.50 X 5.50 mm
	1774-92-060	End-to-End	5.50 X 5.50 mm
	1770-92-020	Wedding Band Connector	5.50X 6.35 mm
	1770-92-060	End to End Connector	5.50X 6.35 mm
	1797-47-155	Open Connector	4.75 X 5.50 mm
	1797-55-155	Conn Open/Closed	5.50 X 5.50 mm
	1797-55-163	Open Connector	5.50 X 6.35 mm
	1797-66-555	Side-by-Side Double Set-Screw Connectors	5.50 X 5.50 mm
	1797-66-655	Side-by-Side Double Set-Screw Connectors	5.50 X 6.35 mm
	1797-71-555	TOP NOTCH™ Connector	5.00 X 5.50 mm
	1797-71-655	TOP NOTCH Connector	6.35 X 5.50 mm
	1797-74-555	Variable Offset Connector	5.5-6.35 X 5.5 mm
	1797-76-555	Inline With Integrated Rod	5.5-6.35 X 5.5 mm
	1797-77-455	End-to-End Double Set-Screw Connectors	5.50 /4.75 mm
	1797-77-555	End-to-End Double Set-Screw Connectors	5.50 /5.5 mm
	1797-77-655	End-to-End Double Set-Screw Connectors	5.50 /6.35 mm
	1861-72-955	EXPEDIUM 4.5 Extended Side-by-Side Connector	4.50 x 5.50 mm
	1861-72-255	EXPEDIUM 4.5 End-to-End Connector	4.50 x 5.50 mm
	1861-72-355	EXPEDIUM 4.5 Open/Closed Connector	4.50 x 5.50 mm
	1883-11-302	Adjustable Wedding Band	3.5 mm - 5.5 mm
	1883-11-102	Axial Connector	3.5 mm - 5.5 mm
	1883-11-202	Wedding Band	3.5 mm - 5.5 mm
	1797-02-000	EXPEDIUM 5.5 Ti x25 set screw	

Appendix B: Summary of All ADL Exercises

The following ADLs listed below have been listed in the Appendix of the study because not all patients were able to complete the exercises before surgery for various reasons such as potential discomfort and lack of time. With this being said, all exercises can potentially provide important information clinically and kinematic data was retrieved from a portion of the patients.

Sit-To-Stand and Stand-To-Sit Test

An adjustable chair with no back and hand rest was used for the sit-to-stand and stand-to-sit test. Before data collection began, the stool was adjusted so that the patient's legs were roughly 90 degrees aligned with the seat and floor. The patient was then instructed to stand in an upright position in sitting distance from the chair with hands on hips for five seconds. The patient was then instructed to sit down on the chair while keeping hands on hips from the upright posture and hold the sitting position for five seconds before returning slowly back to the upright position with hands on hips. This sequence was repeated another two times during the test.

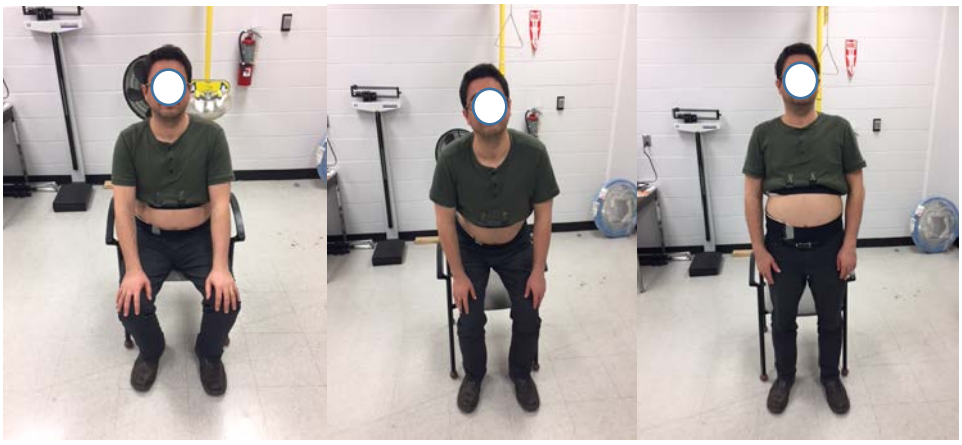


Figure A.1: Sit-To-Stand and Stand-To-Sit ADL Exercise

Symmetric and Asymmetric Manual Material Handling Tests

A designated 4.5 kg load and adjustable chair were used for the manual material handling tests. For the symmetric material handling test, the participant was asked to start standing in an upright position similar to the previous exercises, but also was within a specified distance of the adjustable chair which was adjusted to the participant's knee height. The person instructing the participant also held the 4.5 kg load at the start of the test. Once instructed, the participant was to stand in the upright position for five seconds, then take the 4.5 kg load from the person instructing at shoulder level and carefully flex down to place the load on the chair, pick it back up and return to upwards posture. This task was completed once per session.

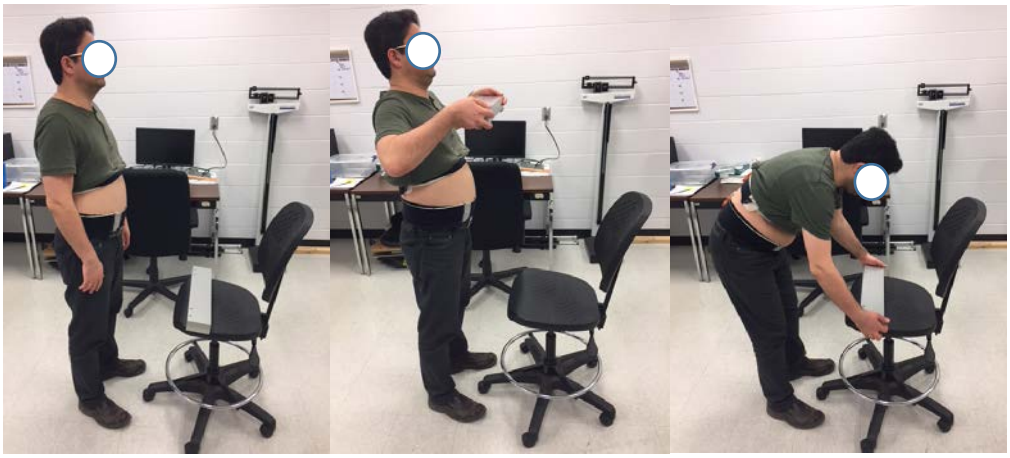


Figure A.2: Symmetric Manual Material Handling ADL Exercise

For the asymmetric material handling test, the participant was asked to stand in the same beginning upright posture with the chair adjusted in the same position. After five seconds, the participant was to carefully twist to their left to take the load from the person giving instructions at shoulder level, twist to the center to place the load on the chair, pick the load back up while carefully twisting to their right and handing the load back to the instructor at shoulder level. This task was completed once per session.

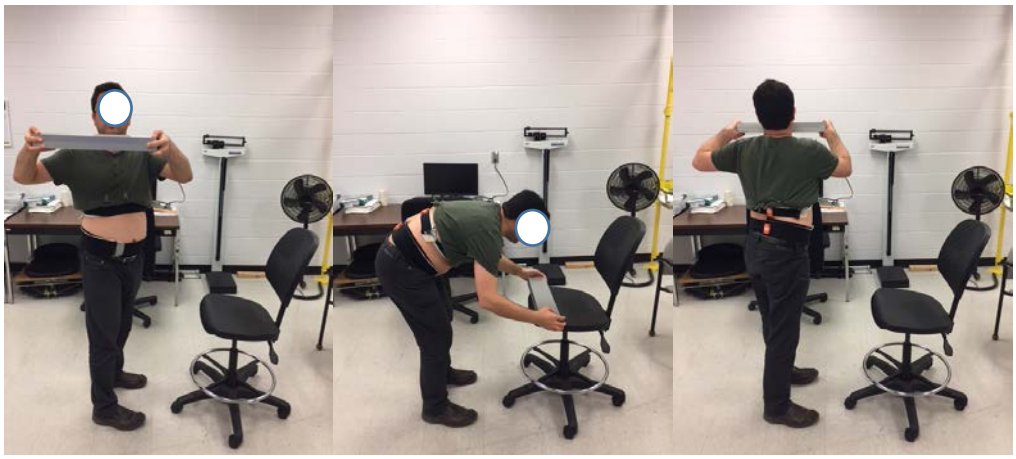


Figure A.3: Asymmetric Manual Material Handling ADL Exercise

Stair Climbing

For the stair climbing test, the participant was brought to the designated stairwell and asked to stand in a relaxed but upright position at the bottom of the stairwell until given the signal to start climbing. The participant was instructed to climb until reaching the top of the stairwell and stop until given signal to relax. Once completed, the participant was then to complete the exercise climbing down the stairs. Once again, the participant was instructed to stand in an upright but relaxed posture until given signal to start climbing down. Once making it to the bottom of the stairwell, the participant was instructed to stop until given signal to relax. This was done to ensure accuracy of the data.

Figure A.4: Stair Climbing ADL Exercise

Walking

For the walking test, the participant was brought to the designated hallway and asked to stand in a relaxed but upright position at the beginning of the hallway. The participant was instructed to walk at a normal and comfortable pace until reaching the end of the hallway and stop until given the signal to relax.

Upon completion of the ADL tests, the accelerometers and straps were removed from the participant.

Appendix C: Institutional Review Board Forms

Approval of IRB # 16-0706
Valid from 12/07/17 - 12/06/18

For ORI Use Only:

Consent to Participate in a Research Study

Effects of lumbar spinal fusion surgery on lumbo-pelvic rhythm

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about the effects of lumbar spinal fusion surgery on body parts during basic activities of daily life. You are being invited to take part in this research study because your age is between 20 and 70 years old and you are having either a spinal fusion procedure or you are part of the control group without any evidence of a musculoskeletal disorder. If you volunteer to take part in this study, you will be one of about 60 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Iman Shojaei, M.S., of University of Kentucky's Department of Biomedical Engineering. The Principal Investigator (PI) is a graduate student and he is being guided in this research by his advisor, Babak Bazrgari, PhD as well as Dr. Raul Vasquez, Dr. Stephen Grumpke, and Dr. Carter Cassidy. Other members of the research team will also be assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

We want to learn about changes in lumbo-pelvic rhythm in post lumbar fusion surgery patients and its impact in surgical outcomes. We would also like to see if it feasible to include biomechanical assessments in patients' outcome report inventory.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

If you have had any previous musculoskeletal and spinal surgeries, we will ask you not to participate in this study as the above mentioned condition will have their separate effects on our measures of interest and will prevent us from achieving our research goal.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the Human Musculoskeletal Lab which is located on the fifth floor of Robotic and Manufacturing Building at University of Kentucky. Data collection will also be done at the Kentucky Clinic, the PACU floor at the University hospital, or Good Samaritan Hospital. There will be two data collection sessions (before surgery, and the end of post-surgery rehabilitation program) and each session will take about 45 minutes.

WHAT WILL YOU BE ASKED TO DO?

We will attach several wireless motion sensors on your pelvis and trunk to measure your body posture and movement. You will be asked to perform a number of basic activities, like walking, stairs ascending, bending over, sitting to standing, and standing to sitting.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life. The risks of this study are minor. However, they may include some temporary muscle soreness that might occur after exercising. Subjects participating in physical conditioning may experience muscle soreness and/or musculoskeletal injury associated with inherent risks of cardiovascular, strength training and therapeutic exercise. To minimize these risks you will be asked to warm-up before the tasks and tell us if you are aware of any history of musculoskeletal injury, or cardiovascular limitations.

Although all necessary precautions are being taken there is still a potential risk of breach of confidentiality.

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from taking part in this study. However, by participating in this study, you will help to increase our understanding of the mechanics of the spine and musculoskeletal injury mechanisms of the lower back. We hope to make this research experience interesting and enjoyable for you where you may learn experimental procedures in biomechanical sciences.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

We will do our best to minimize any cost to you. Potential cost may include traveling and parking cost.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep private all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Signed consent forms and screening data

sheets will be kept in a designated cabinet in the Human Musculoskeletal Biomechanics Lab. Please note that only authorized people have access to this lab and only investigators of this application will be provided access keys to this cabinet. Collected data during experiments will be saved on lab computers and will be backed up on two portable hard drives (one will be kept in the PI's office and another in a distant location). Access password to these data will be only provided to investigators of present application.

All study personnel will have access to de-identified collected data, and data with any identifying information will be stored for six years after the end of study and will be deleted from hard drives and computers afterward.

We will keep private all research records that identify you to the extent allowed by law. However, there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court. Also, we may be required to show information which identifies you to people who need to be sure we have done the research correctly; these would be people from such organizations as the University of Kentucky.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to withdraw you from the study. This may occur if you are not able to follow the directions they give you or if they find that your being in the study is more risk than benefit to you.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Vasquez at 859-323-5661 immediately.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any monetary reward, but rather the reward of helping to serve humanity.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Iman Shojaei, M.S. at 859-539-6291 or his advisor Babak Bazrgari, PhD at 859-257-1379. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity between the business hours of 8am and 5pm EST, Mon-Fri at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

POTENTIAL FUTURE USE

Contacting Research Subjects for Future Studies

Do you give your permission to be contacted in the future by the principal investigator, Iman Shojaei, M.S. regarding your willingness to participate in future research studies about the biomechanics of lower back?

☐ Yes ☐ No _____Initials

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- The only information that will be sent to the other investigators by Dr. Vasquez will be the name and contact information of patient that will only be used for scheduling purposes. None of the investigators, except Dr. Vasquez who will be the primary surgeon of the patient and Paula Coffman certified Nurse Practitioner, will have access to patient data. Therefore, all investigators involved in biomechanical data collection and analyses will be blinded with respect to the patient group.

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.
- Law enforcement agencies when required by law.
- University of Kentucky representatives.
- UK Hospital

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.
You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect your:

- Current or future healthcare at the University of Kentucky
- Current or future payments to the University of Kentucky

- Ability to enroll in any health plans (if applicable)
- Eligibility for benefits (if applicable)

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Iman Shojaei to inform him of your decision. He can be reached at shojaei.iman@uky.edu.
- Researchers may use and release your health information already collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

.
The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.

You are the subject. You have read this information, and you will receive a copy of this form after it is signed.

_____ _____
Name of [authorized] person obtaining informed consent/HIPAA authorization Date

_____
Signature of Principal Investigator or Sub/Co-Investigator

_____ _____
Signature of person agreeing to take part in the study Date

_____
Printed name of person agreeing to take part in the study

_____ _____
Name of [authorized] person obtaining informed consent Date

_____
Signature of Principal Investigator or Sub/Co-Investigator

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