

**Validation of MRI-Derived Morphometric Estimations of Biomechanical Inputs to
Improve Low Back Pain Risk Assessment**

by

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Abstract

Low back pain (LBP) is one of the most common musculoskeletal disorders facing the working world. Previous LBP studies have focused on exposure to physical risk factors in the workplace such as lifting, pushing, pulling and awkward postures. Subject personal characteristics can vary significantly. Biomechanically relevant structures, such as internal low back geometry, impact biomechanics and resulting forces experienced by individuals. Most biomechanical models do not consider these important differences. Often, models rely on averages which may over- or underestimate forces and subsequent risk. This dissertation seeks to provide better inputs to these biomechanical models by first exploring methods to accurately measure and estimate these structures. Further, this dissertation seeks to demonstrate that the incorporation of such structural information into biomechanical models yields more predictive outcomes. Several studies have observed that personal characteristics such as age and gender are predictive of LBP. However, studies that focus on the impact of internal muscle and bone configuration, particularly those that utilize MRI-derived characteristics of the lumbar structure, are very rare. The aims of this research are to: 1) investigate relationships between gross anthropometric characteristics and internal low back geometry; 2) comprehensively evaluate the repeatability of MRI-based measures used to produce regression relationships for low back structures; 3) investigate novel approaches to quantifying lumbar endplate degeneration; and 4) improve the predictive ability of ergonomic models by incorporating subject specific characteristics.

This study uses Magnetic Resonance Imaging (MRI) scans to precisely measure low back geometry. This research consists of three different studies. The first study was conducted to assess reliability of MRI scans. Thirty-six (36) subjects (20 male, mean age = 24 years \pm 3.1; 16 female, mean age = 25 \pm 4.7) were scanned using a 3T scanner using a standardized T2 weighted protocol. Two operators who were blinded to subject identity and scan order performed the scanning procedures. The sagittal view and the axial view of the lumbar spine were

obtained from the subjects. Subject demographics (such as age, gender, height and weight) were also recorded.

Using OsiriX (v8.0.1, 2016, Antoine Rosset, Bernex, Switzerland), software, each examiner measured the anterior and posterior height of the vertebrae, superior and inferior length of vertebrae, concavity level of the intervertebral disc, anterior and posterior height of the intervertebral disc, vertebral body width and height, Pfirrmann Intervertebral Disc Grading (PIDG), vertebral angle, disc length and the sizes of the psoas and erector spinae muscles). Inter- and intra-rater reliabilities were investigated for all of these measures. In addition, reliability for the entire process was evaluated using a worst-case scenario comparing two distinct scans of the same subject with different researchers performing each MRI scan and different researchers performing the measurement of those scans using Osirix. Subsequent analyses were conducted to evaluate intra-rater reliabilities for researchers evaluating distinct scans including their own.

For the second study, T2-weighted MRI scans were obtained from fifty (50) subjects (25 females, mean age = 29 years \pm 5.8; 16 male, mean age = 32 \pm 4.7) who had no current low back pain or self-reported low back injury. The MRI scans contained the sagittal profile of the lumbar endplates (L2-S1). Each examiner measured the height and concavity level of each lumbar disc. These measures were used to calculate a novel metric: the Concavity Index (CI; concavity level divided by vertebral body height). CIs were compared to Pfirrmann IVD grading scores to evaluate their agreement and compare their respective inter-observer reliabilities. A linear relationship between average CI and corresponding Pfirrmann classification was observed. While overall agreement among Pfirrmann raters was high, 10% of ratings disagreed by two categories. There was never disagreement by more than two categories. CIs had an average coefficient of variation of 0.95% across all participants and lumbar regions. This presents an alternative method for quantifying intervertebral disc degeneration that appears to have advantages over the traditional Pfirrmann grading scale. Most notably, the objective, quantitative, and repeatable nature of the CI.

The third study details the feasibility of incorporating personal characteristics into existing ergonomic tools. The L5/S1 Intervertebral Disc (IVD) cross sectional area (estimated using regression relationship), age, gender, height and weight were explored as possible risk factors.

These factors were applied as multipliers to the Revised NIOSH lifting equation (RNLE) to determine if risk estimation could be improved. These multipliers were validated using a U.S. automotive manufacturer database with known health outcomes. The odds ratios and performance of the tool using only the traditional NIOSH lifting equation multipliers were compared to the new additional multipliers. This study showed that including these personal characteristics into the RNLE improved the odds ratios significantly.

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Chapter 1

INTRODUCTION

Musculoskeletal disorders (MSDs) are a major burden on individuals, health systems and social care systems. Indirect costs related to MSDs are predominant, prevalent and their impact is pervasive (Woolf and Pfleger, 2003). MSDs affects hundreds of millions of people around the World and the most common MSD is Low Back Pain (LBP) which is the leading cause of activity limitation and work absence (Lidgren, L. 2003).

There are many causes of low back pain including sprains, strains, intervertebral disc degeneration, herniated or ruptured disc degeneration, spinal disc problems, radiculopathy, sciatica, skeletal irregularities, spinal stenosis, traumatic injuries and spondylolisthesis (NINDS-NIH, 2014). One of the most common causes of low back pain is disc degeneration (NINDS-NIH, 2014). Discs are designed to absorb pressure and keep the spine flexible by acting as cushions during body movement. When a disc loses its cushion, the vertebrae may be unable to absorb stresses, and/or provide the movement necessary for bending and twisting. This is often the beginning of a degenerative process with progressive physiological changes that can be observed.

The impact of mechanical factors on low back pain has been studied (Atlas and Deyo, 2001; Gallagher et al., 2007). These studies clearly demonstrate that work-related factors for low back pain are lifting, bending, exposure to whole body vibration and prolonged postures (Riihimaki, H., 1991; Liira et al., 1996, Scientific Committee for Musculoskeletal Disorders of the International Commission on Occupational Health, 1996). The impact of individual variation on the estimation of these mechanical factors, however, is lacking. For this dissertation, MRI derived data from several studies were used to analyze the impact of personal

characteristics on ergonomic outcomes, consisting of three main thrusts: 1) evaluate the reliability of methods used to generate MRI-derived biomechanical factors; 2) propose an objective, quantitative measure for evaluating low back degeneration; and 3) modify existing ergonomic surveillance tools by considering subject specific anthropometry and evaluate the effectiveness of these modifications epidemiologically. This dissertation seeks to establish and validate a methodology for systemically collecting these parameters in a reliable and repeatable manner. Evaluating the veracity of the MRI-based parameter collection methods is a major contribution.

This work explores a variety of structures from multiple levels of the low back and torso ranging from the level of the second lumbar vertebrae (L2) to the sacrum (S1). The MRI scans contain sagittal and axial profiles of the lumbar endplates (L2-S1) and musculature of the low back and torso. Multiple examiners/observers who performed repeated morphological measurements (including anterior and posterior height of the vertebrae, superior and inferior length of vertebrae, Concavity level of the intervertebral disc, anterior and posterior height of the intervertebral disc, Vertebral body width and height, Pfirrmann Intervertebral Disc Grading, vertebral angle, and muscle sizes of Psoas, erector spinae and disc size).

This dissertation proposes a novel means for measuring disc and vertebral body degradation: the Concavity Index (CI). The objective was to develop a new mathematical method for quantifying vertebrae health rather than relying on a subjective scoring system. Specifically, we investigated the relationship between Pfirrmann score and morphological measurements as well as the inter-rater reliability of each method. The Pfirrmann score (Pfirrmann et al., 2001) is an ordinal scale ranking disc degeneration from 1 (normal disc height and having a healthy structure when compared with other levels) to 5 (the distinction between nucleus and annulus is completely lost, and the disc space has collapsed significantly). The Pfirrmann score was used as a comparator for the proposed CI. Results suggest that the Concavity Index values show promise for objectively quantifying low back health and predicting future low back pain. The measure also allows for relative comparisons because it is a continuous measure rather than an ordinal scale. Relating LBP to these measurements may also provide guidance for surgeons to describe end states for low back corrective surgery. These index values could be validated

directly with subject ratings of LBP and studied pre- and post- operation for surgical interventions. Ideally, the CI would be studied prospectively using a cohort of subjects with a variety of initial CIs and differing occupational exposures.

Accurate knowledge of normal and degenerative lumbar intervertebral discs is very important for both surgeons and radiologists. Using these measurements, medical professionals can potentially make more accurate diagnostic interpretations and, subsequently, more precise surgical interventions regarding the lumbar discs. The Pfirrmann grading system is considered a reliable method for evaluating the health of the lumbar discs and is an established method. However, Pfirrmann scores vary significantly among observers and the CI promises to improve both intra- and inter-rater reliability. In this regard, mathematical measurements/modeling may be an improved measure for reliably describing disc health.

Finally, this dissertation proposes modifications to existing ergonomic models to allow incorporation of subject-specific parameters into biomechanical calculations. Several regressions were performed to estimate internal biomechanical structures using a subjects gross anthropometric characteristics (e.g., height, weight, gender, etc.). Results are promising and suggest that ergonomic models can be improved with minor modifications that do not significantly complicate the models.

1.1 Definition of Low Back Pain (LBP)

Low back pain (LBP) represents one of the most costly and prevalent musculoskeletal disorders (MSDs). MSDs are the leading cause of disability in the United States and represent 48 percent of all self-reported chronic medical conditions (BMUS, 2011). In the mid-1980s, safety professionals and employers realized that MSDs (a common term used in the U.S. for such injuries) were an increasing issue and began implementing controls (Rostykus, Ip and Mallon, 2013).

Work-related musculoskeletal disorders (WMSDs), defined as a subset of musculoskeletal disorders (MSDs) that arise out of occupational exposures, may lead to work restriction, work-time loss, or consequently cause work leave (Forde et al., 2002). Work related MSDs, repetitive motion injuries, and soft-tissue injuries continue to be a major cause of loss in today's workplace

(Rostykus, Ip and Mallon, 2013). WMSDs were first defined in the early 18th century as workers in similar occupations developed similar injuries (Ramazzini, 2001). In 2010, WMSDs in the United States accounted for 29% of work-related injuries and illnesses and required a median of 10 days away from work; a percentage that has not changed much since 2005 (BLS, 2011).

According to the U.S. Department of Labor, Bureau of Labor Statistics, the overall incidence rate of nonfatal occupational injury and illness cases requiring days away from work to recuperate was 109.4 cases per 10,000 full-time workers in 2013 (BLS, 2014). Even though, the median days away from work for back injury cases (7 days) was the shortest duration compared to other body part injuries (shoulder, 21 days; abdomen, 20 days; arm, 15 days; wrist, 18 days; leg, 16 days; and multiple body parts, 15 days), the higher incidence and prevalence rate of back injuries makes them more severe compared to other body parts (Gungor, 2013).

Low back pain (LBP) is a common disorder that limits daily life activities. After headaches and tiredness, back pain is the third most common health problem reported by individuals (Waddell, 2004). Between 75% and 85% of the U.S. population will experience at least one episode of back pain during their lifetime (AAOS, 1999, Smith et al., 2014). LBP is a major health issue affecting millions of people worldwide (Pope et al., 2002; Brooks 2006; Woolf and Pfleger, 2003).

1.2 Prevalence of Low Back Pain

MSDs account for a significant proportion of the disease burden in the United States and have considerable economic implications (Summers et al., 2015). LBP is a common cause of lost workdays and disability (Ekman et al., 2001). The Department of Labor (1989), in a fact sheet citing the Bureau of Labor Statistics (BLS), states that preventing back injuries is a major workplace safety challenge (Pentikis, 2017). Studies of workers compensation data have suggested that LBP represents a significant portion of morbidity in working populations: data from a national insurer indicate that back related claims account for 16% of workers compensation claims and 33% of total claims costs [Meyer and Murtaner, 1999; Leigh and Robbins, 2004; NIOSH Publication No. 97-141, Chapter 6]. The annual prevalence of LBP in the United States

has been estimated at more than one-quarter of the U.S. population (Deyo et al., 2006). OSHA (2014) states it has been estimated that employers pay almost \$1 billion per week for direct workers compensation costs alone. In 2012, the National Health Interview Survey (NHIS) indicate that more than 50% of U.S. adults (125 million) had musculoskeletal disorders; 9.8% of adults had experienced sciatica, 14% had experienced neck pain, 17.5% had experienced non-arthritic joint pain or other joint conditions, 20.3% had experienced lower back pain (without sciatica), and 22.1% had experienced arthritic conditions (shown in Figure 1.1)

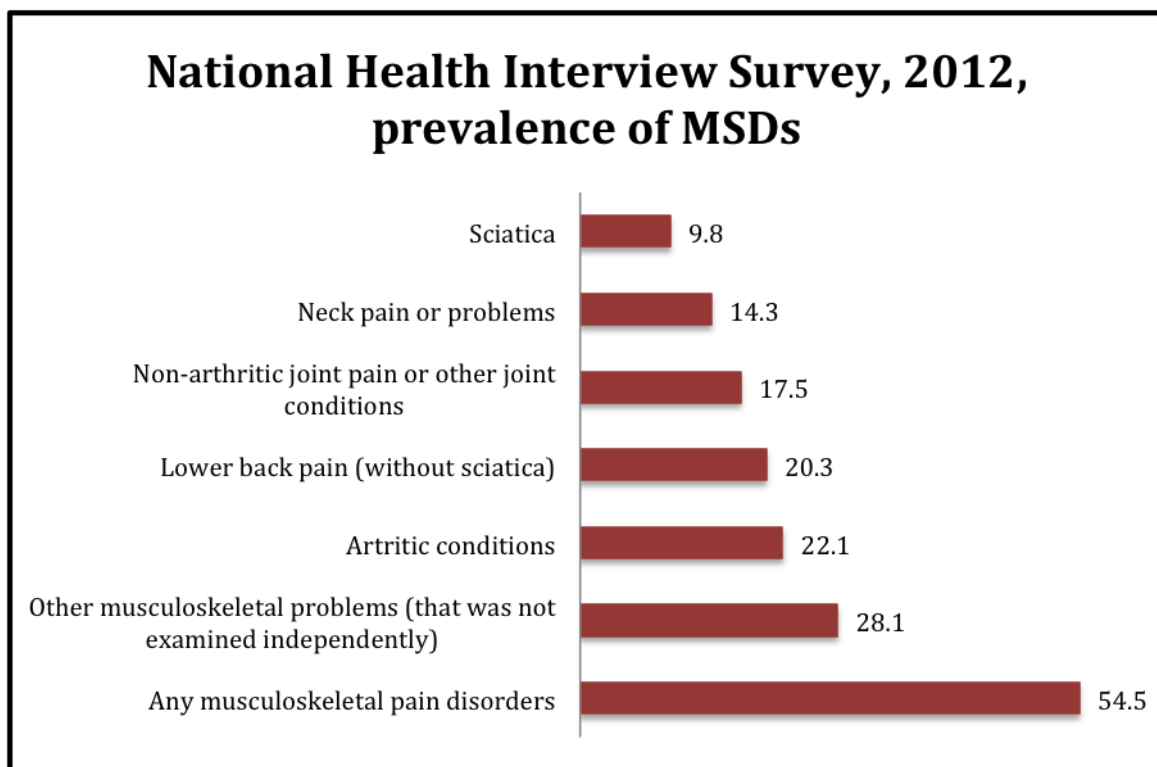


Figure 1.1: Prevalence of Musculoskeletal Pain Disorders among adults aged 18 and over, United States, 2012 - <https://www.cdc.gov/nchs/data/nhsr/nhsr098.pdf>.

Waterman et al (2012) conducted a study using data from the National Electronic Injury Surveillance System (NEISS), which included cases of low back pain reported to emergency departments between 2004 and 2008. Incidence rate ratios were calculated using demographic information such as age, gender and race and these ratios show that 2.06 million episodes of low back pain occurred among a population with 1.48 billion person-years yielding an incidence rate of 1.39 per 1,000 person-years in the United States (Waterman et al., 2012). BLS data (2014) represents four major body parts that are affected by MSDs: neck, trunk, upper

extremities and lower extremities. Back and spinal related MSDs were investigated under the trunk category. Results indicate that the body region most often injured is the trunk and low back (52%) and that 43% of trunk related injuries were related to low back pain. The remaining injured body parts from highest to the lowest are as follows: Upper extremities (31%), lower extremities (15%), and neck (2%) (shown in Figure 1.2).

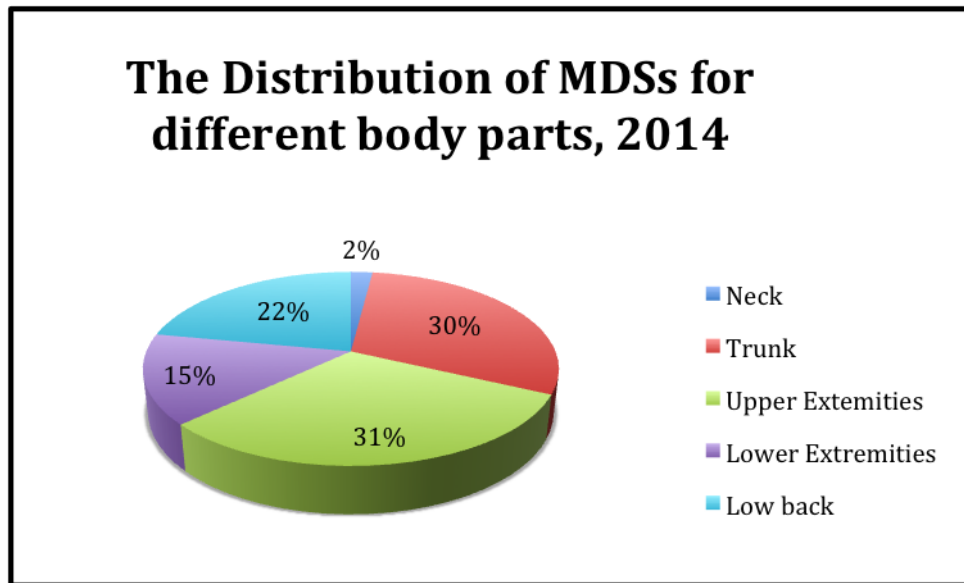


Figure 1.2: The distribution of MSDs for different body parts, Source by BLS, 2014 Neck (2%), Trunk (30%), Upper Extremities (31%), Lower Extremities (15%) and Low Back (22%)

Low back pain is costly to individuals, companies, and society as a whole because it requires medical treatment, complicates medical treatment for other conditions, and hinders peoples ability to work and function in society (Gaskin et al., 2011). The economic burden of LBP to society, due to the large number of workdays lost by the subset of patients with chronic LBP, expensive medical costs, and productivity losses is enormous (Maetzel and Li, 2002). According to the National Research Council (2001), WMSDs require more days away from work than any other group of occupational diseases. The annual cost of WMSDs as measured by compensation costs, lost wages, and lost productivity, is between \$45 and \$54 billion annually (Dunning et al., 2010). In addition, workers compensation systems cover 127 million U.S. workers (Green-McKenzie, 2005) and the estimated annual cost for back pain is \$20 billion to \$50 billion (Pai and Sundaram, 2004). Liberty Mutual Research Institute for

Safety (2013) claimed that overexertion (including lifting, pushing, pulling, holding, carrying, or throwing) costs \$13.61 billion dollars to US businesses in direct costs alone.

There are approximately 149 million lost work days per year with 68.5% of them work-related (Maetzel and Li, 2002) and more than 44.4 million health care visits due to back pain annually (BMUS, 2011). The annual productivity losses resulting from lost workdays are estimated to be \$28 billion (Maetzel and Li, 2002).

1.3 Occupational LBP

WMSDs constitute an important public health problem in the active work population (Cole et al., 2005; Eatough et al., 2012; Wind et al., 2005; Silva et al., 2016) and LBP is a frequent consequence of injuries at work in the United States. Of the 1.18 million nonfatal occupational injuries and illnesses in the United States requiring days away from work in 2011, 13.6% involved the back (BLS, 2013; Lee et al., 2016).

Studies of physical risk factors at work often involve indirect measurement tools through self-reported questionnaires rather than direct measurement of exposure (Paudyal et al., 2013, Rohrllich et al., 2014, Al-Otaibi, 2015). Most of the studies indicated that heavy lifting, driving, whole-body vibration, bending, twisting are highly associated with LBP (Al-Otaibi, 2015, Virtanen et al., 2007, Da Costa et al., 2012, Grotle et al., 2010, Tubach et al., 2004).

The World health organization (WHO) treats occupational and work-related disease separately, and occupational LBP is included as a work-related disease (WHO, 2001). WHO defines that occupational diseases are adverse health conditions in a human being, the occurrence or severity of which is related to exposure to factors on the job or in the work environment, and reports that such factors can be physical, chemical, biological, ergonomic, psychosocial and mechanical stressors. According to BLS (2014), overexertion is the leading exposure in occupational injuries or illnesses for all ownership, and the highest incidence rate and days away from work belongs to laborers, janitors and cleaners, and heavy truck and tractor-trailer drivers. According to OSHA (2014), mining and quarrying, manufacturing and construction are the sectors with the highest relative rate of MSD cases (960 new cases per 100,000 workers). In

addition to them, registered nurses and nursing assistants where lifting patients is obligatory have high MSD incidence rates.

1.4 Risk Factors for LBP

Not all musculoskeletal disorders are solely related to work injuries. They are also related to other biomechanical hazards, physical workload, morphological disadvantages, genetic predisposition, as well as personal traits and habits (Vieira, Kumar, Narayan, 2008) (shown in Figure 1.3).

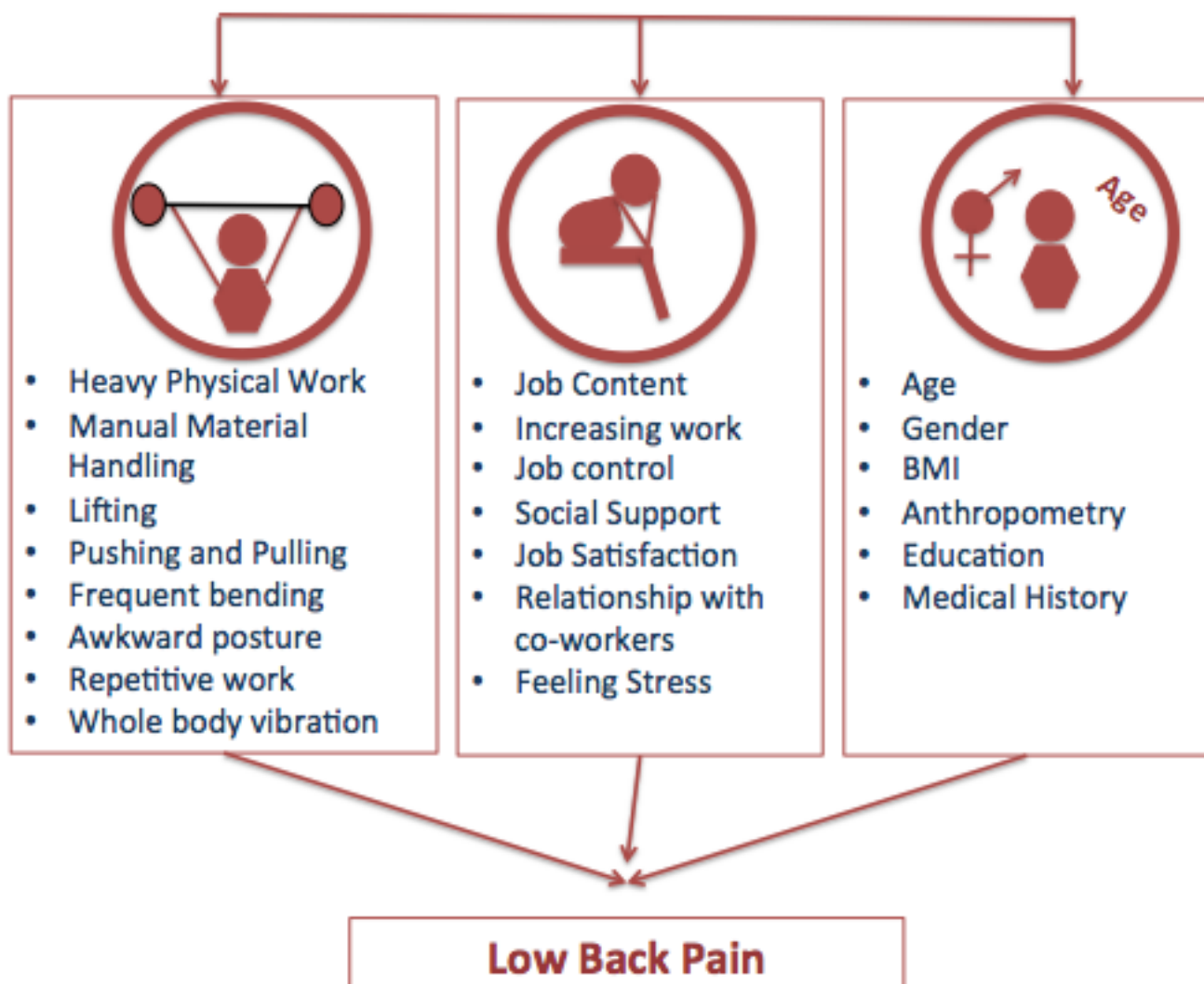


Figure 1.3: The relationship of incidence of LBP with physical, psychological and personal factors (sourced by Ali Asghar Norasteh, 2012)

Factors associated with LBP were personal characteristics/factors (such as age, gender, high BMI, habits (smoking), hobbies, LBP past medical history, second jobs, multiple pregnancies and migraine) and physical factors (such as awkward posture, heavy load lifting, frequency, heavy loads, vibration, repetition of task), (Bejita et al., 2004; Devereux et al., 2002; Lorusso et al., 2007; Eriksen et al., 2004; Merryweather et al., 2009; Gallagher and Heberger, 2013) and psychosocial factors (such as stress, anxiety, mood, cognitive functioning, and pain behavior) (van Tulder et al., 2002; Manek and MacGregor, 2005; Gungor, 2013).

1.4.1 Physical Risk Factors

Heavy workload is identified as a risk factor of LBP, both as a general factor compared to jobs with low physical demands, and as more specific work factors such as frequent bending or twisting of the back, heavy lifting and patient handling (Andersen, 2007). The risk factors of posture, force, repetition and velocity represent many of the commonly cited potential physical risk factors for the development of upper limb repetitive motion disorders (Spielholz et al., 2001). Manual material handling (MMH), lifting, pulling, pushing, twisting, awkward posture and whole-body vibration (WBV) are considered among the most important physical factors. Probably the most common cause of LBP is lifting. The load to the back muscles and subsequent load on the discs and vertebrae increase proportionately with increasing lifting loads. Figure 1.4 illustrates the change in disc pressure by posture and exercise (Nachemson, 1976). In this study, more than 100 individuals have demonstrated how the load on the lumbar disc varies with the position of the subjects body motions such as standing and sitting. According to the results, reclining reduces the pressure by 50-80%, unsupported sitting increases the load by 40%, forward leaning and weight lifting by more than 100% and the forward flexion and rotation by 400% as compared with the pressure resulting from an upright position (shown in Figure 1.4).

Bernard et al., (1997) selected 18 studies with odds ratios (OR) (ranging from 1.2 to 12.1) and relative risk (RR) (ranging from 2.2. to 4.3), which indicate that low back disorders are associated with heavy physical work. In addition to this, Roffey et al. (2010) undertook a systematic review of the association of occupational sitting, occupational pushing or pulling and

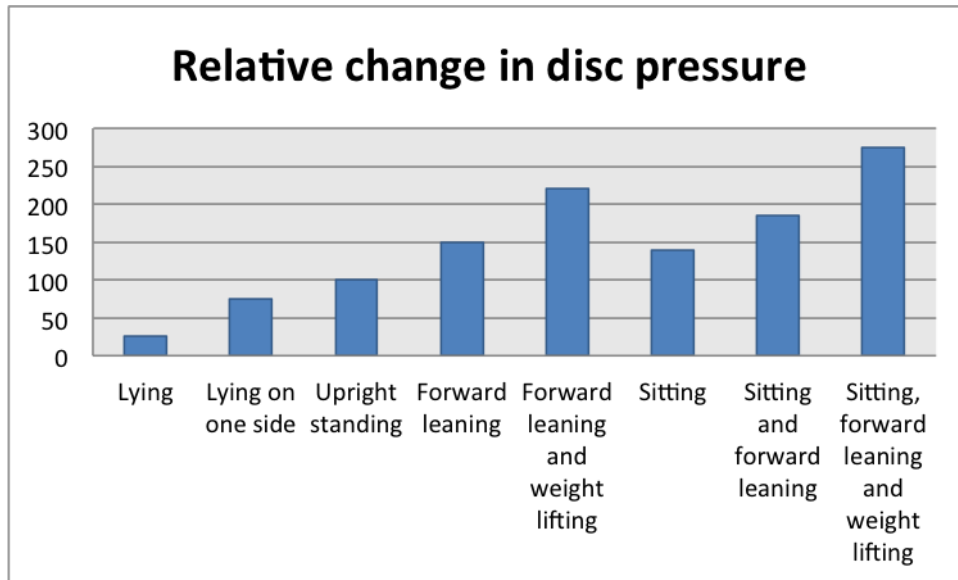


Figure 1.4: Relative change in pressure (or load) in the third lumbar disc in various positions in living subjects (Nachemson, 1976)

workplace manual handling or patient assisting and LBP (Roffey et al., 2010b, 2010c, 2010d). According to the review (2010), thirteen studies (12,793 participants, 7 countries) reported that a total of 83 estimates of the association between specific categories of occupational pushing or pulling and LBP (with a 38.1% prevalence). Furthermore, sixteen studies (19%) were found to be statistically significant; 10 (52%) of these were classified as weak, 4 (24%) were classified as moderate, and 2 (10%) were classified as protective (Roffrey et al., 2010d, 2010e).

In 2010, a total of 24 studies were studied (75,103 participants, 12 countries) and 108 separate estimates were conducted between specific categories of occupational sitting and specific types of LBP outcomes (Roffrey et al., 2010b). According to Roffreys results, occupational pushing or pulling, and occupational sitting do not appear to be independently causative of LBP in workers (Roffrey et al., 2010b, 2010c). However, they did not incorporate personal characteristics into their modeling. The association between workplace manual material handling and LBP was investigated using 32 studies (22,143 participants, 16 countries) and reported with a total of 329 estimates of the association.

Bernard et al. (1997) also examined the relationship between back disorders and lifting or forceful movements using 18 studies and concluded that there is strong evidence that low-back disorders are associated with work-related lifting or forceful movements (Bernard et al., 1997a;

Brown 1975; Bigos, 1991). Wai et al. also performed a systematic review in order to investigate the association of occupational lifting and carrying, and LBP (Wai et al., 2010b, 2010c). In Wai's review, thirty-five studies (88,864 participants, 16 countries) found an association with a total of 224 separate risk estimates (variables associated with negative health outcomes). They concluded that there was moderate evidence for the association between specific types of lifting and LBP, and some evidence for the association between lifting greater than 25-35kg and LBP (Wai et al., 2010b).

In addition to pushing, pulling, MMH and lifting, trunk flexion/rotation/torsion and awkward postures (bending and twisting) and also known as physical factors. Bernard et al., selected 12 studies and investigated the relationship between back disorders and bending, twisting and awkward postures. According to the studies, high correlations between back disorders and bending as well as with twisting and awkward postures were found (Bernard et al., 1997a).

In addition, Wai et al., performed a systematic review in order to investigate the association of bending, twisting and LBP. In this review they collected 35 studies (44,342 participants, 15 countries) with a total of 243 estimates of the association. They concluded that occupational bending or twisting is unlikely to be independently causative of LBP in workers and the strength of association was often rated as weak or moderate, additionally none demonstrated a statistically significant dose response (Wai et al., 2010a).

1.4.2 Psychosocial Factors

Psychosocial factors are defined as factors influencing health, health services and community well-being stemming from the psychology of the individual and the structure and function of social groups which lead to altered spinal loading due to increased muscle tension and also affects the nutrition of intervertebral discs, nerve roots and other spinal tissues (Hartvigsen et al., 2003, Bongers et al., 1993, Bergenudd et al., 1991). For example, pain that under optimal circumstances might be tolerated by workers, may, in a stressful psychosocial environment, lead to injury reporting due to decreased pain tolerance (Burton and Er, 1997, Hartvigsen et al., 2003).

Bongers et al. reviewed 46 articles published between 1973 and 1992 dealing with psychosocial factors at work as risk factors for low back pain (Hartvigsen et al., 2003, Bongers et al., 1993). They found that there is a relationship between psychosocial factors and low back pain. However, the association was weak and they suggested further studies with improved epidemiological methodology in order to obtain accurate relationships. They also observed that self-reported work demands (particularly monotonous work); poor social support at work; personality traits, emotional problems, and stress symptoms; and back trouble are also associated with low back pain.

Furthermore, Bernard et al. reviewed 7 studies and observed that intensified workload and found significant associations between back disorders and perceptions of intensified workload (Bernard et al., 1997a). Only one study examined the relationship between social support and back disorders and found weak evidence for an association. Moreover, Hoogendoorn et al also performed a review with 11 cohort and 2 case-control studies and they found strong evidence for low social support in the workplace and low job satisfaction as risk factors for back pain (Hoogendoorn et al., 2000). In this review, the strongest relationship with LBP was found for high quantitative job demands, low supervisory support and low co-worker support. Davis and Heaney (2000) stated that job satisfaction and job stress (workers reactions to psychosocial work characteristics) are more consistently and more strongly associated with LBP than any other psychosocial work characteristics (such as work overload, lack of influence over work, quality of relationship with coworkers).

1.4.3 Personal Factors

The presence and severity of low back pain is associated with several socio-demographic factors, among them sex, age, education level, smoking, and occupation (Manek and MacGregor, 2005).

A systematic review of the literature comparing the prevalence of low back pain in different age groups finds lower prevalence rates in younger adult patients (ages 20-35) with rates increasing with age until ages 60 to 65, after which there is a decline in the frequency of pain (Lawrence et al., 1998, Hestbaek, et al., 2003, Walker, 2000, Loney and Stratford, 1999, Rubin,

2007). Moreover, Burdorf and Sorock have done systematic research, 12 studies were examined suggesting a positive relationship between age and back disorders (Burdorf and Sorock, 1997). Generally, age and years of work are correlated; the longer the years of work the greater the occupational exposure, additionally the likelihood of disc degeneration and herniation increases with aging (Guo et al., 1995). In the older age population, women have a higher prevalence of low back pain than men, possibly related to a higher risk for osteoporosis involving the spine (Bressler, et al., 1999; Rubin, 2007; Kopec et al., 2004; Linton, et al., 1998).

1.5 Objectives of the research

The impact of physical factors such as manual material handling (MMH), lifting, lowering, pushing, pulling and awkward postures has been studied. However, studies investigating other risk factors such as personal factors for LBP are limited. When focusing on the physical limits of the lumbar spine during lifting/carrying, it is important to estimate the internal response of the spine to these external loads. The impact of personal characteristics on internal geometries and subsequent low back pain requires further study. using morphometric measurements of the lower back are very important indicators which each one alone can be a risk of potential back injuries (Sesek et al., 2014; Waters et al., 1993; Chaffin and Park., 1973). Identifying the causes of LBP can be difficult; it can be due to working conditions or personal habits/interactions that occur beyond the workplace. Some studies have found strong relationships relating personal characteristics to low back geometry and identified several promising areas to research further. Currently, a major obstacle in the literature is that determining the risk factors for low back pain is a complex task since back pain is a multifactorial disorder with many etiologies.

In order to analyze the impact of personal characteristics, Magnetic Resonance Imaging (MRI) scans were used to precisely measure low back geometry, to investigate the relationship between gross anthropometric characteristics and internal low back geometry, to consider novel approaches to quantifying lumbar degeneration and to improve the predictive ability of ergonomic models by incorporating subject specific information. The objectives of this research are:

- To explore the relationship between age, gender, height, weight and spinal morphology (disc degeneration), specifically its detrimental effects (disc compression, concavity etc.).
- To improve model precision by increasing sample size and the quantity of demographic information collected using previous studies as a basis.
- To verify whether personal characteristics make a significant difference for low back pain by directly altering and evaluating several ergonomic assessment methods.
- To investigate Scan/Rescan Reliability of the MRI-based measurement methods proposed in this research.

1.6 Research and Dissertation Organization

A manuscript format is used in the presentation of this dissertation and it is organized in accordance with Auburn University dissertation guide [Auburn University, 2015a]. This dissertation is comprised of six chapters. Chapter One discusses LBP, the prevalence of LBP, occupational LBP, and risk factors of LBP. Chapter Two is a comprehensive review of the literature, highlighting the different studies focused on LBP and the impact of personal characteristics on LBP. The next chapters (3, 4 and 5) discuss the study designs in detail. Each of these chapters separated as a different manuscript format, which contain their own introduction, methods, results, discussion, limitations and conclusions. Chapter 3 discusses the scan/rescan reliability of the MRI technique itself. Chapter 4 focuses on a novel approach to quantify vertebrae degeneration. Chapter 5 explains the importance of personal characteristics in modifying existing ergonomic tools. Finally, Chapter 6 delivers a summary of the overall findings and interpretations of these studies.

1.7 Closing Statement

The risk factors for the development of LBP are multidimensional, with physical attributes, socioeconomic status, general medical health and psychological state, and occupational environmental factors all playing a role in contributing to the risk of experiencing pain (Rubin,

2007). At the present time, the prevention and treatment of low back pain has not been very successful. The bottom-line is that low back pain cannot be fully prevented, primarily because aging, genetics, and personal behavior cannot be controlled. However, risk factors related to these personal characteristics can be factored into risk assessments to improve understanding of low back pain progression and to prioritize jobs for ergonomic improvement.

Over the last 20 years, vast improvements in MRI technology have led to the development of quantitative imaging techniques (Stelzeneder, et al., 2011). These techniques offer more accurate results and can be performed in any anatomical plane. Recent improvements in the resolution of MRI have provided visualization of the detailed spinal structures such as disc material, vertebral bodies and neural structures [Kimura et al., 2001; Danielson, et al., 1998; Fennell et al., 1996; Hamanishi, et al., 1993; Okada et al., 1994; Willen et al; 1997]. Recently, transverse relaxation time (T2) mapping has been applied to the spine that has the potential to quantitatively evaluate deterioration of the molecular composition and structural integrity of intervertebral discs (Perry et al., 2006).

Three different studies all relating LBP were developed; each addressing a gap in the literature. These gaps include lack of research studies on the impact of personal characteristics on LBP, questions regarding the accuracy of using MRI-derived inputs, and lack of quantitative measures of vertebral degeneration. These research studies could provide benefit to surgeons, ergonomists, and especially the working population impacted by low back pain.

Chapter 2

Literature Review

2.1 Problem Statement

LBP is a common symptom that can lead to disability and major socio-economic and professional repercussions. Despite advances in imaging technology, the etiology of the underlying pain is frequently illusive. Morphological changes related to normal disc aging often appear on MR imaging without any corresponding symptoms. Despite an incomplete understanding of the relationship between physical changes and pain, these MRI-detectible morphological changes show predictive promise and warrant further discussion (Ract et al., 2015).

Interest in biomechanical models of the spine, particularly detailed knowledge regarding spinal morphometry and the relationships between vertebral segments and corresponding intervertebral discs has been increasing. Several quantitative studies have investigated the external geometry of the vertebrae and adjacent intervertebral discs for different regions of the human spine.

Morphometric studies are typically investigated by two different methods: 1) using cadaveric vertebrae and 2) by obtaining medical images such as magnetic resonance imaging (MRI) or Computerized Tomography (CT) scan. Medical images can come from patients seeking medical attention or from asymptomatic subjects. MRI images can be relatively expensive to obtain, Hence, the appeal of historical medical MRI records. There is a tradeoff between cost and potential confounding resulting from subjects with medical conditions that may alter the characteristics of their low back.

Determining the risk factors for LBP is a complex task since back pain is a multifactorial disorder with many possible etiologies (Manchikanti, 2000). Many epidemiologic studies have focused on risk factors for LBP, analyzing occupational, non-occupational, and psychosocial factors to investigate the contributions of the various risk factors for LBP (Waddell, 1996, Heliövaara et al., 1991, Barnekow-Bergkvist, 1998, Viikari-Juntura et al., 1991, Manchikanti, 2000).

Most studies focus mainly on work-related LBP issues. In many studies, subjects were observed from different age groups, but primarily from adult populations. These studies tend to focus on adult populations who already have LBP symptoms and complaints. Evidence from a single study, no matter how well designed and executed, is rarely enough to determine whether or not a particular risk factor is causal (Bombardier et al., 1994, Manchikanti, 2000). Sample size and scope limitations can limit exploration of LBP risk factors. Ideally, epidemiological studies of LBP should include data from a wide range of ages and health status.

Increasingly, improved methods for measuring spinal structures have been employed, primarily MRI measurements. However, the reliability and repeatability of such methods has not been previously systematically studied. MRI-based morphometric analyses show great promise for exploring vertebral relationships by increasing the accuracy, and possibly the repeatability, of measurements. Some have questioned the repeatability of these MRI-based morphometric measurements. Early on, Pope et al., (1977) and Andersson et al. (1981) suggested that morphometric measurements must be performed using a standard vertebral position, control of the film-specimen-focus distances, and optimal visualization of bony landmarks. Most studies have used regression analysis to observe the correlation between the vertebral or intervertebral disc boundaries. Moreover, the relationship between anatomical measurements of vertebrae and intervertebral discs in the lumbar spine has been investigated, however, many of these studies lacked depth and information regarding subject personal characteristics.

The accuracy and the reliability of mathematical models of the human spine depend directly on the measurement of spinal geometry as well as the underlying biomechanical models themselves (Robin, 1994). Low back models based on imprecise measures, or the measurement

of non-representative structures (e.g., unhealthy or injured spines), will not be accurate (Miller and Dickson, 1996; Maurel et al., 1997; Parent et al., 2002; Aebi, 2005). In biomechanical models, assumptions are often made which consider the spine as a single straight line without considering volume or the curvature of the spine (Merryweather et al., 2009). Other models incorporate measurements for average persons into models without considering the impact of personal characteristics or differences between individuals (Chaffin, 1969). Surgical procedures to correct spinal deformity or repair injuries are typically guided using average values of vertebral dimensions of a healthy spine or the experience of the surgeon. However, these average values will vary by individual because each person has a different morphometry and different low back structure. One size does not fit all. Ideally, a surgeon would operate with some knowledge about what a healthy geometry would look like for a given individual. This knowledge about lumbar spine biomechanics is important to develop the optimal clinical treatment methods as well as new spinal implants (Putzer et al., 2016). Gallagher claimed that spine geometry is essential to model spinal movements accurately (Gallagher, 2003).

Consideration of low back spinal deformities such as scoliosis, height and weight changes in vertebrae (disc herniation/degeneration) related to age, as well as other changes, both natural (due to aging) and unnatural (due to injury) will further enhance modeling of low back injury risk. Natarajan and Andersson (1999) suggested that having accurate descriptions of geometry might influence the mechanical responses of lumbar motion segments to physiologic loads. Simply stated, incorporation of personal characteristics into risk estimation models is necessary to achieve the best possible predictions and to improve risk assessment of work-related LBP. Statistical analysis can determine specific geometric parameters for both clinical purposes and implementing subject-specific modeling of the low back for biomechanical research.

A number of studies have provided geometric data regarding the intervertebral discs *ex vivo* (cadaver) (Einstein, 1977; Postacchini, 1983; Videman et al., 1990) and *in vivo* (live individual) (Nissan and Gilad, 1984; Twomey and Taylor, 1987) using direct measurements: x-ray, Computed Tomography and Magnetic Resonance Imaging. These measurements have been most often been performed on unhealthy subjects/patients. There is a lack of data regarding

healthy spinal geometries and the relationships among the various vertebral levels. This research aims to address that gap regarding spinal parameters and their healthy values (e.g., disc spaces, vertebral concavity, etc.).

2.2 Low Back Pain

There are a significant number of historical studies regarding LBP from early medicine that regard medical diagnosis, prognosis and medical ethics. These sources lead other researchers to track the evolution of knowledge and look forward to developing new treatments in order to solve health problems (Pynt et al., 2002). Hippocrates who is considered the father of the spine surgery (Marketos and Skiadas, 1999) was the first person to use the term low back pain (LBP) and describe sciatic pain (Castro et al., 2005, Mafuyai et al., 2013). LBP has been identified with humans since the Bronze Age. Since then, numerous studies have been done concerning the diagnosis and treatment of LBP. An American Egyptologist, Edwin Smith discovered a Papyrus which was a manual on trauma to the head, upper limbs and spine from 1500 BCE that describes a diagnostic test and treatment for a vertebral sprain (Maharty, 2012, Kamal, 2015). This manual contains descriptions of 48 traumatic cases, 6 involving the cervical spine, and 2 of those 6 are clearly injuries to the spinal cord (Donocan, 2007). Through the Medieval period, traditional medicine practitioners provided treatments for back pain based on the belief that it was caused by spirits (Maharty, 2012).

During second century, Galen conducted a research-oriented study of spinal disorders and he inspired treatises about anatomy and diseases of the spine (Marketos and Skiadas, 1999). In addition to this, he also documented lordosis, kyphosis, scoliosis and succession (the presence of fluid in a body cavity). In the 4th century, Caelius Aurelianus made the first clinical description of sciatica (Castro et al., 2005). In the 15th century, Serefeddin Sabuncuoglu, a Turkish physician, wrote several medical books, including a color-illustrated surgery treatise, Imperial Surgery (Naderi et al., 2002). Ambroise Pare (around 1510) and Michel Mercatus (around 1590) started to use a method of suspension (traction) to align spinal fractures. During the 18th century, researchers Weber, Rauber and Messener began to perform studies related to the biomechanics of the lower back. In 1895, William Conrad Rontgen established x-ray

imaging and the evolution of spinal disorders entered a new path (Tubiana, M., 1996). The introduction of technologies such as X-rays provided physicians with new diagnostic tools. This helped in revealing the intervertebral disc as a source for back pain in some cases. In 1938, Lutz et al reported that orthopedic surgeon Joseph S. Barr (Lutz et al., 2003) found that cases of disc-related sciatica pain improved with back surgery. As a result of this work, in the 1940s, the vertebral disc model of low back pain became prevalent (Maharty, 2012). This model dominated the literature through the 1980s, aided further by the rise of new imaging technologies such as CT and MRI (Lutz et al., 2003). In 1977, M. Gazi Yasargil published the results of 105 surgeries for patients with herniated lumbar disc treatment aided by microscope, which he had used for micro discectomy surgery since 1967 (Yasargil, 1977).

2.3 Lumbar Region

In human anatomy, the basis of articulation as well as nerve passage and the axis of symmetry and muscle connection are through or along the spine. The spine is also known as the spinal or vertebral column. The spine is the main or central part of the skeleton. The spine has a strong and flexible structure and it plays a critical role in movements; it allows twisting, bending and reaching activities, it supports the trunk and it protects the spinal cord from external harm. Its structure allows for movement while protecting nerve roots.

The vertebrae are thirty-three in number, and have received the names cervical, dorsal, lumbar, sacral and coccygeal, according to the position which they occupy; seven being found in cervical region, twelve in the dorsal (also known as thoracic), five in the lumbar, five in the sacral and four in the coccygeal (Gray, 2012).

The lumbar spine (low back) is located in the 3rd region of the spine, which is located after the thoracic (2nd region). The average length of lumbar spine is approximately 7 inches. The entire length of the spine is composed of a series of vertebrae, each with attaching muscles, ligaments, and intervertebral discs. A Superior view of lumbar vertebrae is shown in Figure 2.1. There are twenty-three total vertebral discs in the spine. These flexible discs and the vertebral ligaments allow for a slight movement between each vertebral joint and when combined across

the vertebrae of the upper three regions result in a significant range of motion. Lumbar vertebrae are strong enough to support the upper body and yet flexible enough to facilitate needed mobility (Scheuer and Black, 2000).

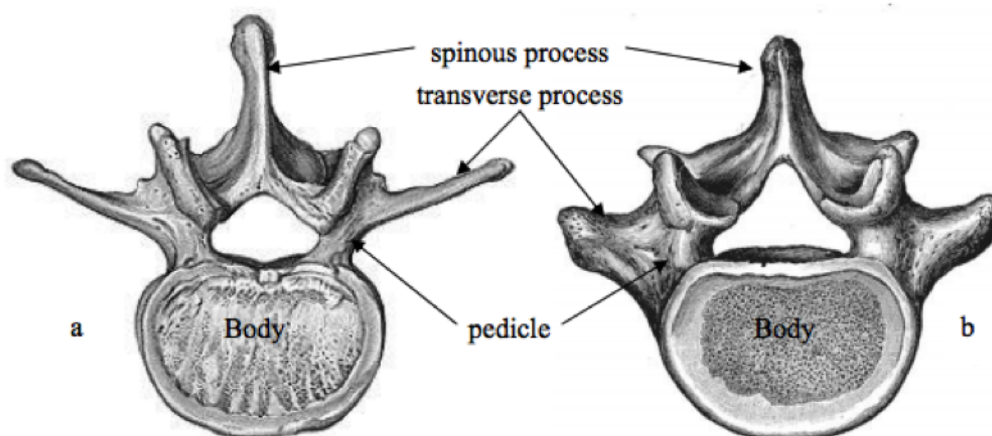


Figure 2.1: Superior view of the fourth (a) and fifth (b) lumbar vertebrae illustrating normal anatomical features and differences in L5 morphology (sourced by Fysioweb 2005 and Clemente, 1985)

As a structure that is involved with most bodily functions in some way, it is not surprising that the spine is involved in many workplace injuries. Lower back pain is specific to the lumbar region, which consists of five vertebrae. These vertebrae are identified by their positions L1 thru L5 descending down the spine, and are bones that are spaced by their intervertebral discs which are composed very much like a large single oblate spheroid structure, with the tough outer structure (annulus fibrosis) containing a softer nucleus (Nucleus Pulposus) (shown in Figure 2.2). These discs contact the vertebrae at vertebral endplates that are cartilaginous plates nested in the vertebral body. The vertebral body will have a couple of branch-like pedicles which are bony structures that space the posterior elements in such a way as to allow for a cavity through which the spinal cord runs. The posterior elements are the attachment points for the Erector Spinae muscles of the back. Various ligaments also connect along the vertebrae, with a ribbon-like continuous ligament connecting the fronts of the vertebrae called the Anterior Longitudinal Ligament and a Posterior Longitudinal Ligament facing the interior of the vertebrae along the back of the vertebral body.

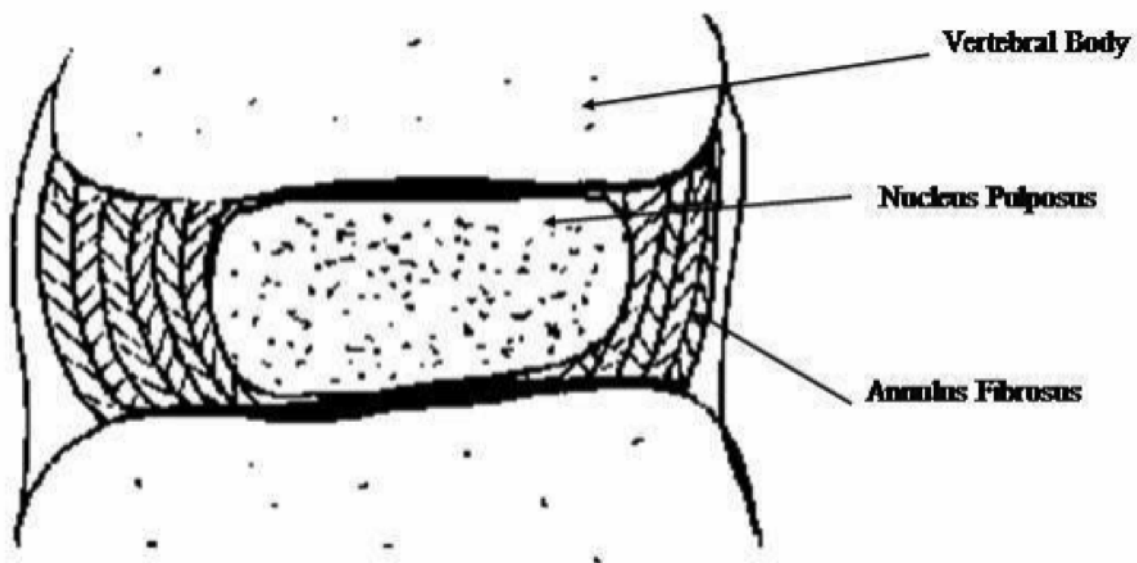


Figure 2.2: Intervertebral Disc Diagram (sourced by McKay Osteopaedic Research Laboratory, 2005)

2.3.1 General Characteristics of Vertebrae

Each vertebra consists of a vertebral body anteriorly, the neural arch posteriorly, and a series of processes that serve as connection points for ligaments and muscles (Oxland, 2016). Each vertebra is capable of sustaining significant loads resulting from the weight of the trunk (Gallais, 2008) and consists of two essential parts: 1) an anterior solid segment or body, and 2) a posterior segment or arch which is formed by two pedicles and two laminae, supporting seven processes four articular, two transverse, and one spinous (Gray, 2012). An intervertebral disc that acts as a gel-like cushion separates each vertebra. Intervertebral discs help to absorb loads placed on the vertebrae by internal (muscles) and external (loads) forces. The body or center is the largest part of the vertebra. The bodies of the vertebrae are piled one upon the other, forming a strong pillar, for support of the cranium and trunk; the arches form a hollow cylinder behind the bodies for the protection of the spinal cord (Gray, 2012). When the vertebra is observed in detail, it appears from above and below vertebrae to be flattened. The shape of the vertebrae shows some differences according to the viewpoint. For instance; when it is seen from front side, it is convex from side to side and concave from above or downward. On the

other hand, when it is seen from behind, it is flat from above or downwards and concave from side to side.

2.3.2 Characteristics of Lumbar Vertebrae

The lumbar spine vertebrae, when compared with thoracic and cervical vertebrae, are the largest segments of the movable portion of the vertebral column (Gray, 2012). This is because each lumbar vertebra (Axial view of vertebrae is shown in Figure 2.3 and Sagittal view of vertebrae is shown in Figure 2.4) carries most of the body weight. Lumbar vertebrae are also wider than the vertebrae of both the cervical and thoracic regions. Spinal motion is constrained by vertebral facet joints and varies along the spinal column. The lumbar spine allows flexion and extension, but limits twisting motions. The higher levels allow greater twisting and lateral flexion, particularly the cervical spine. According to Gray, 2012; the shape of lumbar vertebrae is defined as follows:

The body is large, and has a greater diameter from side to side than front to back, slightly thicker in front than behind, flattened or slightly concave above and below, concave behind and deeply constricted in front and at the sides, presenting prominent margins, which afford a broad basis for the support of the superincumbent weight.

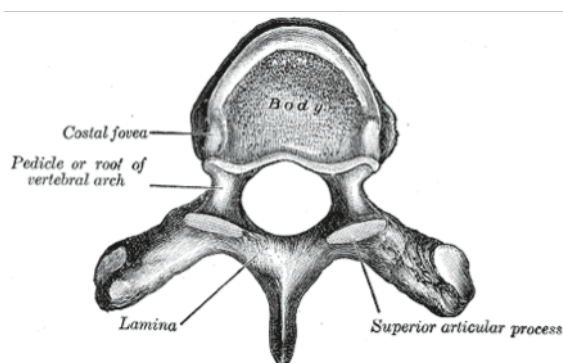


Figure 2.3: Axial View of lumbar Vertebrae (Gray, 2012)

2.3.3 Intervertebral Disc (IVD)

The human spine has twenty-three (23) intervertebral discs. They are approximately 7 to 10 mm thick and 4 cm in diameter in the lumbar region (Twomey and Taylor, 1987, Roberts

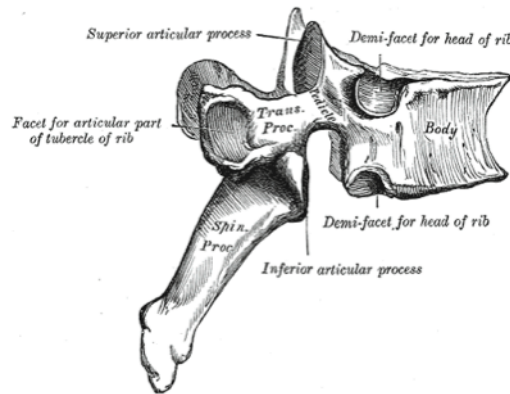


Figure 2.4: Sagittal View of lumbar Vertebrae (Gray, 2012)

et al., 1989, Raj, 2008). These discs provide flexibility (bending and twisting) of the spine, as well as providing cushioning for impacts. Intervertebral discs are located between two vertebral bodies and consist of three main parts: the annulus fibrosus, nucleus pulposus, and vertebral endplates. They are the main joints of the spinal column and occupy one-third of its height and they transmit loads arising from body weight and muscle activity through the spinal column (Raj, 2008). The annulus fibrosus is composed of a series of 15 to 25 concentric sheets of collagen fibers, which are packed together and surround the nucleus pulposus (Raj, 2008). The nucleus pulposus also contains collagen fibers but these are organized randomly (Inoue, 1981) and under pressure the nucleus can be deformed without a loss of the volume.

2.4 Vertebrae Morphology Research Studies

Vertebral morphology is a quantitative method to identify osteoporotic vertebral fractures that relies on the measurement of distinct vertebral dimensions, calculating relative changes (Guglielmi et al., 2008). Barnett and Nordin introduced this technique in 1960 and they used transparent ruler to measure vertebral heights on conventional lateral radiographs of the thoracolumbar spine (Barnett and Nordin, 1960).

In this research, 49 epidemiologic studies of LBP risk factors were reviewed. The Distribution of the articles with respect to journals is shown in Table 2.1 and the Classification with respect to study design and main focus area is shown in Appendix A. Most of these studies used survey questionnaires for LBP assessment and direct measurements of structures using

MRI, CT or X-Rays. These techniques have been developed to quantitate vertebral deformities, usually on the basis of the heights of vertebral bodies (Jensen et al., 1981; Gallagher et al., 1988; Hendlund et al., 1988). In addition to this, different population groups (Swedish, Dutch, U.S., Finnish, and English) and different occupational groups (nurses, clerical employees, school lunch preparers, baggage handlers, and individuals working in construction, agriculture, maritime, petroleum, paper products, transportation, automobile, aircraft, steel and machine manufacturing industries) were examined in these studies. Furthermore, these studies also specifically include the relationship between low back disorders and physical workplace factors (such as heavy physical work, lifting, bending and twisting, whole-body vibration and static work postures), psychosocial factors (motivation, relationship with coworkers), and personal factors (age, gender, BMI).

Fifty nine (59) percent of these studies investigated the impact of physical characteristics on back pain conducting questionnaires (Kelsey, 1975; Kelsey et al., 1984; Videman et al., 1984; Bergenudd and Nilsson, 1988; Abenheim et al., 1988; Svensson and Andersson, 1989; Burdorf and Zondervan, 1990; Boshuizen et al., 1990; Bongers et al., 1990; Videman et al., 1990; Burdorf et al., 1991; Punnett et al., 1991; Garg and Moore, 1991; Bovenzi and Zadini, 1992; Holmstrom et al., 1992; Marras et al., 1993 and 1995; Bovenzi and Betta, 1994; Johansson and Rubenowitz, 1994; Ozguler et al., 2000; Kerr et al., 2001; Elders and Burdorf, 2001; Jansen and Burdorf, 2003; Vieira et al., 2008; Genevay et al., 2011; Ramond-Roquin et al., 2015; Oliveira et al., 2015; Jadhav, 2016; Jia et al., 2016). These questionnaires included workers' working posture and conditions and medical history. Fifteen (15) of those related to personal characteristics with most studying the impact of age, ethnic groups, pregnancy and gender (Eisenstein, 1977; Postacchini, 1983; Swensson and Andersson, 1983; Mohseni-Bandpei et al., 2009; Hershkovich et al., 2013; Song et al., 2014; Frilander et al., 2016). Twenty two (22) of these were Morphometric studies (Berry et al., 1987; Amonoo-Kuifi, 1990; Panjabi et al., 1991; Lee et al., 1995; Hall et al., 1998; Dai, 2001; Semaan et al., 2002; Singh et al., 2011; Banerjee et al., 2012; Aly and Amin, 2013; Torrie et al., 2014). Two (2) percent of them were related with Leisure activities (Burton, 1996). And last but not least, two (2) percent were related with psychosocial factors (Govindu and Babski-Reeves, 2014).

Most of the morphometric studies have focused on vertebrae and IVD degeneration, which are the most common reasons for LBP and the leading causes of musculoskeletal disability worldwide (Wang et al., 2015). There is growing evidence that the majority of LBP is associated with intervertebral disc (IVD) degeneration (IDD) (Kadow et al., 2014). Lumbar intervertebral disc degeneration increases with age (West et al., 2010). When age differences were examined, it was observed that almost 40% of people who are under 30 years and 90% of people who are older than 50 years faced IVD problems (Cheung et al., 2009; Torrie et al., 2015). The literature suggests that IDD is one of the main risk factors for LBP (Torrie et al., 2015; Takatalo et al., 2011; Hancock et al., 2012). Torrie et al. (2015) In this study, authors screened 608 patients over 5.3 years in order to observe lumbar disc degeneration at all lumbar intervertebral levels. In order to classify the degrees of disc degeneration, they used Pfirrmann grading criterion. Their analysis found that the proportion of high-graded (Pfirrmann's IV and V, least healthy) degeneration scores was higher for the lumbar levels (inferior levels), particularly the L5/S1. The authors asserted that Lumbar disc degeneration has largely been ascribed to biomechanical and structural alterations to the disc, which are attributed to aging and pathological physical loading.

Disc degeneration is characterized by a reduction in the production of proteoglycan, consequent disc dehydration and an increase in the collagen content of the nucleus pulposus (NP), making it more fibrous (Hadjipaviou et al., 2008; Pearce et al., 1991; and Ract et al., 2015). As the nucleus becomes more solid, it loses its elasticity and its shock-absorbing capability. The annulus fibrosus (AF) subsequently has to withstand a greater level of stress because of the reduced shock absorption of the NP and itself becomes less flexible with its organization being modified with the formation of clefts. These clefts are more susceptible to failure. This can progress to partial or even total disc collapse, sometimes contributing to the disc bulging beyond the intervertebral space (Ract et al., 2015).

The need to be able to diagnose LBP has been known for over a century (Breen et al., 2012). The first attempt to identify LBP was with plain x-ray studies (Fick, 1904; Todd and Pyle, 1928; Gianturco, 1944; Hasner et al., 1952; Miles and Sullivan, 1961). Growing awareness of the drawbacks of ionizing radiation, the limitations of radiological measurements

Table 2.1: Distribution of the articles with respect to journals

American Journal of Public Health	1
Applied Ergonomics	1
Asian Spine Journal	1
BMC Genomics	1
BMC Musculoskeletal Disorders	1
BMJ Open	1
British Journal of Industrial Medicine	1
Clinical Biomechanics	1
Clinical Orthopaedics and Related Research	1
Ergonomics	4
Indian Journal of Occupational and Environmental Medicine	1
International Archives of Occupational and Environmental Health	1
International Journal of Industrial Ergonomics	2
International Journal of Sport Psychology	1
International Orthopaedics	1
Joint Bone Spine	2
Journal of Anatomy	1
Journal of Bone and Joint Surgery	1
Journal of Epidemiology and Community Health	1
Journal of Orthopaedic Research	1
Journal of the History of Medicine and Allied Sciences Orthopedics	1
Occupational and Environmental Medicine	2
Occupational Medicine	1
Occupational Medicine	1
Rev Chir Orthop Reparatrice Appar Mot	1
Scandinavian Journal of Rehabilitation Medicine	1
Scandinavian Journal of Work, Environment, and Health	1
Spine	15
Spine Deformity	1
Total	49

(Nash, 1979), and the need for simple instruments for use in widespread screening programs, all reignited interest in surface detection of spinal abnormalities (Chang, 2008).

Direct measurements of the spine in multiple planes provide valuable information for understanding the human vertebrae and to improve subject specific biomechanical models. The research efforts have been made to measure the geometry of low back and medical imaging techniques have been used in a number of studies.

2.4.1 Using X-ray Films for LBP assessments

Physicist Wilhelm Roentgen discovered x-rays on November 8 1895, which led to the first medical imaging technology and the first radiographic images of human anatomy (Bushberg et al., 2012). X-ray films were the primary source to access lateral geometric characteristics such as vertebral body height, and intervertebral disc height of lumbar segments.

Plain X-ray films are quick and require relatively low cost to assess the spine (Lateef and Patel, 2009). Good quality x-ray images provide essential information on spinal bone structure, which can be used to analyze individual vertebrae and the overall contour of the spine (McVey et al., 2003; Chang, 2008). The measurement of vertebral body height using lateral radiographs has become an established tool in the identification of vertebral deformities (Barnett and Nordin, 1960; Hurxthal, 1968; Rea et al., 2000). Nissan and Gilad (1984) measured the sagittal plane dimensions of several anatomic structures of vertebrae using lateral radiographs of 157 patients. Amanoo-Kuofi (1990) performed a cross-sectional study and collected plain lateral radiographs of 615 lumbar spines from 310 females and 305 males. Their results indicated that discs have significant variations of both anterior and posterior heights with age. These changes were more pronounced in females than males and posterior height changes were more common than anterior height changes in both males and females.

These films are helpful in fracture screening for bony deformities including degenerative changes, sacroiliitis, disc and vertebral body height, and assessment of bony density. They are mainly used to detect spinal deformities. However, plain x-rays are not sensitive for herniated discs and are not helpful in diagnosing nerve root impingement (Jarvik and Deyo, 2002). Overall, they are poor for detecting soft tissue deformities. Also, radiographs were generated by a radiographic source projecting beams towards the spine onto the film, geometric dimensions measured are subjected to varying magnification error depending on the spine-to-film and source-to-spine distance ranging from 7.5% up to 30% (White III and Panjabi, 1990; Tang, 2013). Because of these limitations, MRI and CT techniques were recommending for detailed examinations and findings (Jarvik and Deyo, 2002; Lateef and Patel, 2009).

2.4.2 Using Computed Tomography (CT) for LBP Assessments

Computed Tomography (CT) which is also known as CAT (Computed Axial Tomography) scan was invented by British engineer Godfrey Hounsfield and physicist Allan Cormack in 1972 (Abrams and McNeil, 1978). This technique produces superior tomographic sections of the spine and provides greater visualization of the anatomical characteristics, particularly the soft tissues (Teplick, 1992). CT is more expensive than radiography, carries a higher radiation dose, and may be warranted only in high-risk patients (Hanson et al., 2000) but it has improved accuracy and faster diagnosis (Nunez and Queneer, 1998). Also, it has become a primary diagnostic technique in clinical practice for demonstrating the majority of significant spinal abnormalities (Krause et al., 1991; Schroeder et al., 2011). The images can provide a very valuable transverse section of the spine for accurate measurements of vertebral endplates (Teplick, 1992; Schnebel et al., 1989). CT techniques have been used in the literature to explore the morphometry of the lumbar spine and provide geometric dimensions of both lumbar vertebral bodies and intervertebral disc structures. Colombini et al. (1989) collected axial CT scans to measure the major and minor diameters of lumbar discs and cross-sectional area (CSA).

In 1998, Hall et al. conducted a cross-sectional study to analyze shapes and dimensions of vertebral body endplates (L4, L5, and S1) and to identify gender differences. In Zhou et al. (2000) study, a total of 378 lumbar vertebrae from 126 subjects were examined using CT images to measure depth and width of the vertebral endplate, and anterior and posterior vertebral height. Banerjee et al. conducted a cross-sectional study in 2012; studying 95 CT scans from Indians to measure pedicle axis length and exploring the differences between Asian, European and American populations. Aly and Amin (2013) also conducted a cross sectional study; collecting 300 CT scans from Egyptian patients to measure the mid-sagittal diameter, inter-pedicular distance and lateral recess depth.

Most of these studies measured the vertebral endplate because CT is excellent at demonstrating bony degenerative changes (Tins, 2010). However, accommodating the intervertebral angles is difficult with CT scanner. CT is, in principle, well suited to image bony abnormalities

and in developmental abnormalities. However, the associated radiation dose encourages the use of MRI where possible (Tins, 2010).

2.4.3 Using Cadaveric Specimens for LBP Assessments

The availability of human cadaveric specimens is limited (Blohm, 2012). With time after thaw and exposure to air, both the soft tissues and hard tissues change in properties, thus altering the rigidity response of the spine segment (Mark et al., 2003). In earlier studies, bony landmarks (vertebral bodies) were removed from the spinal column to perform morphometric measurements. Several studies have measured vertebral body dimensions to understand human anatomy in greater detail (Einstein 199=77; Berry et al., 1987; Panjabi et al., 1992).

Einstein (1977) performed a cross-sectional study analyzing 2,166 lumbar vertebrae of 433 adult Black South African and White European skeletons. They observed that lumbar canal of Black South Africans is narrower and the overall lower limit of normal of the mid-sagittal diameter is 15 mm. Postacchini (1983) also performed a cross-sectional study and they collected lumbar vertebrae from both Italians and Indians. They compared the differences in spinal structures between Italians and Indians and they found that the average dimensions of the spinal canal, the lateral recesses, and the vertebral body were significantly greater in Italians. In 1987, Berry et al. performed a morphometric study performing 27 measurements for thoracic (T2, T7, T12) and Lumbar (L1-L5) vertebrae. They observed that vertebral body heights decrease in the lower lumbar region. In 1990, Videman et al., studied cadaver specimens from 86 males to examine disc degeneration and the degree of spinal pathology. They found that the type of work performed was related to the development of spinal changes/deformation.

2.4.4 Using Magnetic Resonance Imaging (MRI) for LBP assessments

By the late of 1980s, the use of MRI technique began to increase for the measurement of vertebrae morphology and the development of ergonomic models related to back. MRI is increasingly used more than CT because researchers did not wish to expose subjects to the ionizing radiation as of CT. MRI provides excellent resolution and contrast among all bony structures and soft tissues in sagittal, transverse, and frontal tomographic sections, since most

anatomical structures have different signal intensities depending on acquisition sequence techniques (such as T1-weighted and T2-weighted) (Teplick, 1992; Tang, 2013).

Initially, MRI image quality was not good as it is today. However, MRI technology even if it was 1.5T, 3T or 7T has always provided a better and deeper understanding of the lumbar region. MRI images provide more detailed information on human body as a whole. MRI can be defined as a method by which the spatial distribution and magnetic properties of nuclei can be imaged through the use of magnetic fields (Johansson, 2014). The strength of the magnetic field can be altered electronically from head to toe using a series of gradient electric coils, and, by altering the local magnetic field by small increments, different image slices of the body will resonate at different frequencies (Berger, 2002).

In the spine, MRI is the primary imaging modality for detecting disease because no other modality can provide adequate contrast resolution to differentiate the intraspinal soft tissue structures while simultaneously revealing spinal cord or canal pathology (Vertinsky et al., 2007). When compared with CT, MRI is a better approach for quantifying disc degeneration (Modic and Herfkens, 1990; Sether et al., 1990; Parkkola and Kormano, 1992; Takatalo et al., 2009; Yu et al., 2012; Hu et al., 2011) and for the development of a disc degeneration grading system (Pfirrmann et al., 2001). According to Li et al. (2014), MRI is the gold standard for evaluating the relationship of disc material to soft tissue and neural structures. In a T2-weighted MRI, a healthy Nucleus Pulposus (NP) appears as a bright elliptical structure, while AF is imaged as a hypointense region bordering the NP (Grenier et al., 2005).

MRI has important advantages for imaging the musculoskeletal system (Schibany et al., 2005; Shapiro, 2006; Barr et al., 2007), providing better visualization of anatomic and pathologic structures, including cartilage, bones and ligaments (Schibany et al., 2005; Link et al., 2006; Phan et al., 2006). These advantages increase the use of MRI in research studies seeking a better understanding of the human body. Also, MRI becomes popular among researchers because MRI uses harmless radio waves not ionizing radiation as in CT. MRI scans may allow better understanding of the risk factors for LBP and allow improved biomechanical modeling of the lumbar spine using subject specific information.

2.5 The Impact of Personal Risk Factors on LBP

Not all musculoskeletal disorders are solely related to work injuries. They are also related to other biomechanical hazards, physical workload, morphological disadvantages, genetic predisposition, personal traits and habits (Vieira, Kumar, Narayan, 2008). According to Kumar (2001), musculoskeletal health can be maintained by controlling for risk factors but it is only feasible to control for the biomechanical and psychosocial ones. According to Bejia et al. 2004; factors associated with LBP were separated into individual factors such as advanced age, gender, height, weight and high BMI.

Determining the risk factors for LBP is often challenging due to the heterogeneity across research methods: However, it is clear that personal factors has an impact on LBP (Hoy et al., 2010). The association of factors such as age, gender, weight, height, BMI with LBP has been reported in several studies (Miranda et al., 2001; Krause et al., 1998; Porter and Gyi, 2002; Ying et al., 1997; Leboeuf-Yde, 2000). An epidemiological review by Manchikanti (2000) considered more than 200 papers and they found that age was a probable risk factor of low back pain whereas gender and obesity were possible risk factors.

2.5.1 Age

The body changes with increasing age and the intervertebral disc is one of the first parts of the body to change (Snook, 2004). While some studies of specific populations have not shown any correlation between age and LBP (De Vitta et al., 1997; Guo, 2002; Anderson, 1992; Barreira, 1994; Hildebrandt et al., 2000; Matsui et al., 1997), Age was strongly associated with musculoskeletal pain (Mianda et al., 2001; Loney and Stratford, 1999; Lawrence et al., 1998; Dionne et al., 2006).

The occurrence of LBP among the general population increases with age and starts declining after 65 years of age and then gradually decreases (Loney and Stratford, 1999; Lawrence et al., 1998). Dionne et al. found that the prevalence continues to increase with age for more severe forms of LBP (Dionne et al., 2006). Several studies also have shown that LBP is a very common problem among teenagers (Dionne et al., 2006; Jeffries et al., 2007; Grimmer et al.,

2006; Hakala et al., 2002; Hakala et al., 2006; Olsen et al., 1992). According to Garg (1992), MacGregor (2005) and Rubin (2007), the first episode of LBP typically begins early in life in between 30s and 50s, and the duration and severity of LBP increased with age. Frymoyer (1992) noted that herniation at lower lumbar levels occurred in earlier ages, while herniation at upper levels was more common among older populations. According to Miller et al. and associates, in their review of cadaver studies found that only 7% of people in their 20s exhibit annular tears; 20% in their 30s; 41% in their 40s; 53% in their 50s; 85% in their 60s; and 92% of people over 70 show signs of annular tears (Miller, Schmatz, and Schultz, 1988). According to the National Center for Health Statistics (NCHS) shown in Figure 2.5, older populations (45 to 75 years) experienced higher prevalence rates for LBP than younger populations (18 to 44 years) (NCHS, 2014).

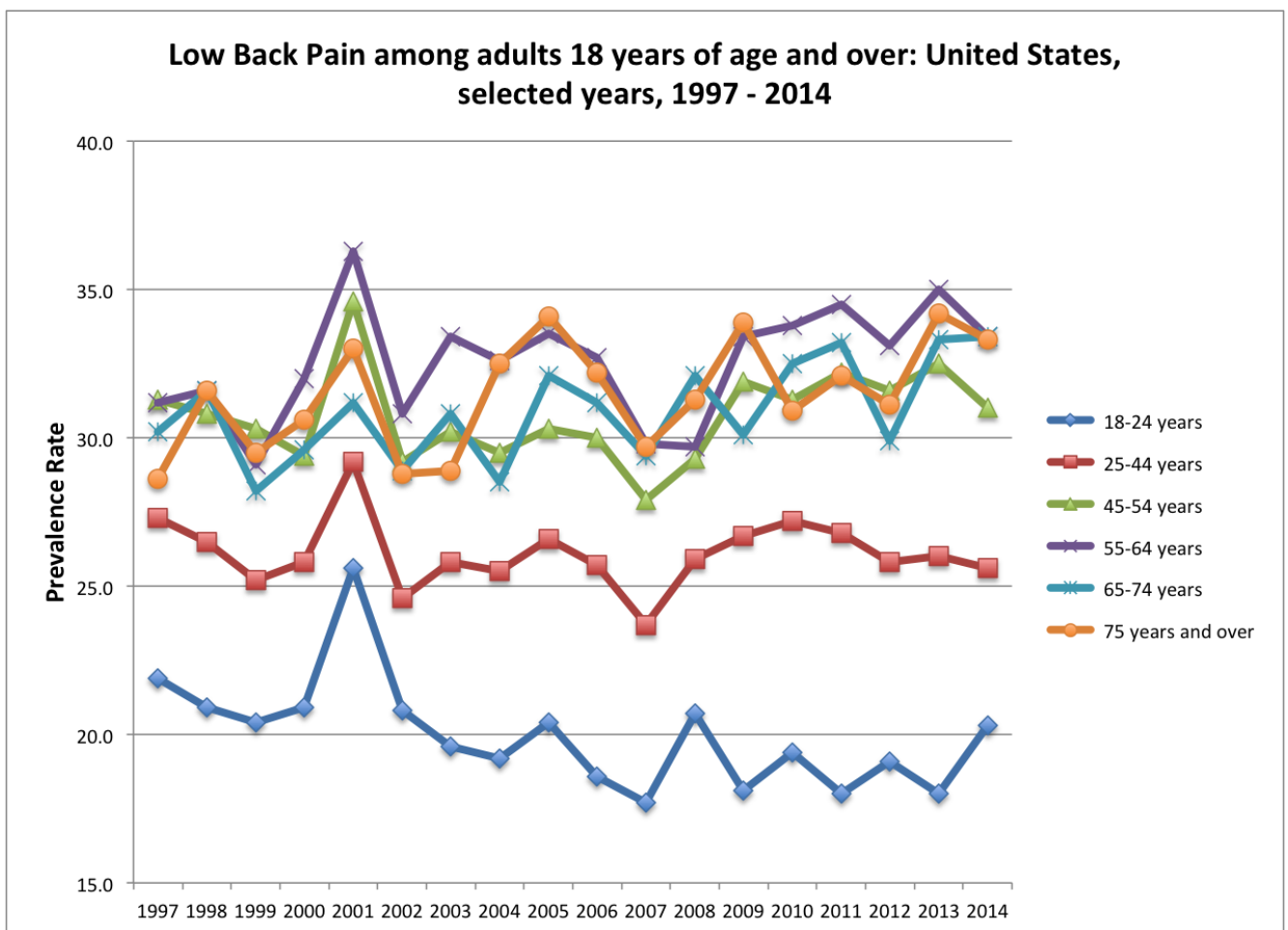


Figure 2.5: Low back pain among adults 18 years of age and over: United States, selected years 1997-2014 (NCHS, 2011, Table 41)

2.5.2 Height, Weight and BMI

Studies on the impact of height, weight and BMI on LBP are relatively rare. However, height and BMI were found to be associated with lumbar intervertebral disc herniation. For instance, individuals who, due to their heights, work under unfavorable ergonomic conditions have a higher probability to trigger LBP (Matsui et al., 1997; Han et al., 1997).

The existence of a possible relationship between being overweight and LBP is reasonable, since weight increases load on the spine, which can increase the pressure on the intervertebral disc and other structures of the spine, triggering pain (Andrusaitis et al., 2006). A few studies demonstrate a correlation between obesity and functional impairment of the spine secondary to weakness and stiffness of the lumbar muscles, possibly leading to LBP and disability (Vismara et al., 2010). Obesity can cause changes to spinal geometry and place higher forces on intervertebral discs, increasing the load on the spine. Rubin (2007) also found that obesity was an independent predictor for the development and severity of LBP.

Heliovaara (1987) conducted a study and observed that females with 170 cm height and males with 180 cm height or more were three (3) times more likely to experience sciatica which is caused by herniation of lumbar intervertebral discs. Bostman (1993) explored that patients who experienced disc herniation or low back related surgery were more likely to be tall and overweight. Han et al (2010) conducted a 2-year cohort study collecting 1200 subjects and found that obese people have a higher risk of experiencing LBP.

2.5.3 Gender

Several studies have found no significant gender differences in the prevalence of LBP (Kopeck et al., 2004; Toroptsova et al., 1995; Linton et al., 1998). However, some studies found that gender differences are a significant risk factor for low back pain (Hoy et al., 2010; Matsui et al., 1997; Bressler et al., 1999; Smith et al., 2004; Thomas et al., 1999; Linton et al., 1998; Sesek et al., 2013). In systematic review by Hoy et al. (2010), it is shown that both the mean and median prevalence of LBP was higher in women. Also, women were more likely to take

time off work and use health-care because of their LBP, as well as being more likely to develop chronic LBP (Linton et al., 1998; Smith et al., 2004; Thomas et al., 1999).

Garg and Moore (1992) found that females have more susceptible structure than men while performing heavy and physically demanding jobs. A literature Review by Frymoyer (1992) reported that there is little or no evidence regarding the impact of gender differences in terms of vulnerability to work-related LBP. According to the National Center for Health Statistics (NCHS) (shown in Figure 2.6), females have been experiencing a higher prevalence of low back pain than males (NCHS, 2011; Gore et al., 2012).

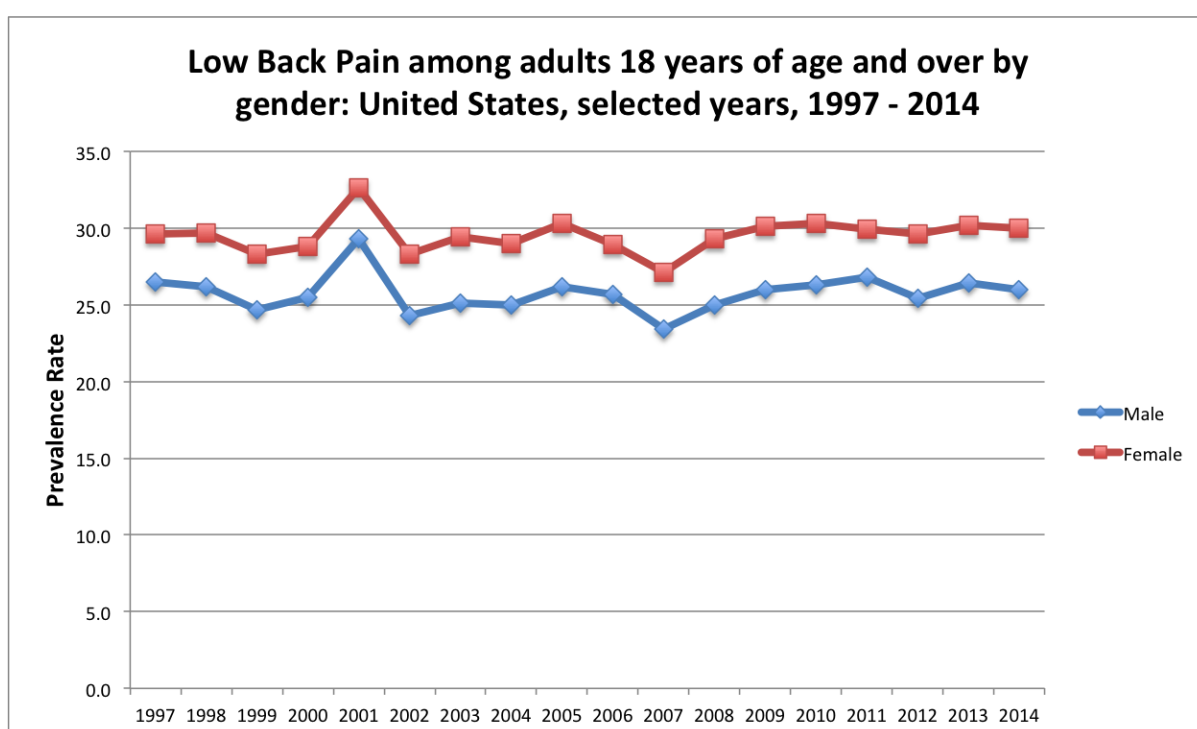


Figure 2.6: Low back pain among adults 18 years of age and over by gender: United States, selected years 1997-2014 (NCHS, 2011, Table 41)

2.5.4 Intervertebral Disc (IVD) Size

Intervertebral disc degeneration (IDD) is the most common diagnosis in patients with LBP and a leading cause of musculoskeletal disability worldwide (Wang et al., 2015). There is growing evidence that the majority of low back pain is associated with IDD (Kadow et al., 2014). Lumbar IDD increases with age (West et al., 2010). When age differences were examined, it was observed that almost 40% of people who are under 30 years and 90% of people who

are older than 50 years faced with IDD problems (Cheung et al., 2009; Torrie et al., 2015). The literature suggests that IDD is one of the main risk factors for low back pain (Torrie et al., 2015; Takatalo et al., 2011; Hancock et al., 2012). Torrie et al. (2015) In this study, the authors screened 608 patients over 5.3 years in order to observe lumbar IDD at all lumbar intervertebral levels. In order to classify the degrees of disc degeneration, they used the Pfirrmann grading criterion. Their analysis found that the proportion of high-graded (Pfirrmann IV and V, least healthy) degeneration scores was higher for the lower lumbar levels (inferior levels), particularly the L5/S1. The authors asserted that Lumbar IDD can largely be ascribed to biomechanical and structural alterations to the disc, which are attributed to aging and pathological physical loading.

IDD is characterized by a reduction in the production of proteoglycan, consequent disc dehydration and an increase in the collagen content of the nucleus pulposus (NP), making it more fibrous (Hadjipaviou et al., 2008; Pearce et al., 1991; and Ract et al., 2015). As the nucleus becomes more solid, it loses its elasticity and its shock-absorbing capability. The annulus fibrosus (AF) subsequently has to withstand a greater level of stress because of the reduced shock absorption of the NP and itself becomes less flexible with its organization being modified by the formation of clefts. These clefts are more susceptible to failure. This can progress to partial or even total disc collapse, sometimes contributing to the disc bulging beyond the intervertebral space (Ract et al., 2015).

2.6 Development of Biomechanical Models and Ergonomic Tools for Low Back

The primary functions of the lumbar spine are to support the upper body (Meakin et al., 1996, Reeves et al., 2007, Zeinali-Davarani, 2008), transfer weight from the upper body to the legs and to provide mobility in the lower back (Adams et al., 2002). The mechanical behavior of the spine, which supports loads while simultaneously enabling movement (e.g., for muscles to balance all external loads to the spine) has been described by Chaffin (1969) and Schultz and Andersson (1991). The spine behaves as a complex structure capable of motion in three planes, functioning primarily to protect the spinal cord, to transfer loads between the head and trunk to pelvis, and to stabilize the trunk (Keller et al., 1987).

Over the years, three core methods to study the back and, ultimately, recommend a maximum weight that can be manually handled have been employed by researchers. Biomechanical models and laboratory studies are used to help determine how forces act on the body and how these exposures can result in physiological responses that may ultimately lead to LBP-related injury. Biomechanical models are used to quantify job risk by estimating back muscle forces, with larger forces corresponding to higher likelihoods of injury. In general, the most accurate models are also the most complex, creating demand for models that are both straightforward and accurate (Loertscher et al., 2009).

The value of incorporating ergonomic principles into the industrial work environment to control musculoskeletal injuries, such as LBP, has been debated extensively in recent years (Marras et al., 2000). Typical biomechanical studies will look at the magnitude and direction of forces exerted during manual handling tasks, exertion required to operate tools and equipment, the location where external forces act on the body and the posture required while performing these tasks. Psychophysical laboratory studies have been used to determine maximum voluntary perceived 'acceptable levels' of work intensity by asking subjects to adjust their workload so that the resulting discomfort and fatigue is 'acceptable' to them. Physiological studies as they relate to lifting consider repetitive handling to determine the effects the activity has on the subject's oxygen use and endurance. These studies are not focused on a one time maximum lift but rather on how often a lift that is within the normal capacity of the subject can be performed before fatigue sets in. Even with all the attention paid to back injury and lifting techniques, there is no consensus on how to prevent back injuries. Many have turned to worker training as a method to minimize the incidence of back injuries. Results of this approach do not seem encouraging. A study by Sharp and Legg (1998) demonstrated that training could be used as a means to increase the capacity of novice lifters. It is thought that this lifting improvement resulted from increased coordination and potential increase in muscular endurance.

One of the main concerns with current ergonomic models is that variation in the capabilities and limitations of individual workers can render risk assessments inaccurate, particularly if a given worker varies significantly from average in terms age, health status, size, weight, or injury history. However, identifying the causes of LBP is difficult since LBP results from both

working conditions and activities that occur beyond the workplace as well as individual worker characteristics.

Merryweather et al. (2008) recently discussed the importance of cumulative spinal loading and the need to develop models capable of accounting for cumulative stress in the spine from manual material handling (MMH). Also, it has been argued that relatively high forces have more impact on the likelihood of injury than a higher number of cycles delivering the same cumulative load (Coenen, et al., 2012; Brinckmann et al., 1988; Gallagher and Heberger, 2013; Gallagher et al., 2017).

2.6.1 NIOSH Lifting Equation

This equation was developed in 1981 in order to provide guidance on the physical stresses associated with lifting. Then this equation was revised in 1993 (the Revised NIOSH Lifting Equation, RNLE) to include some additional parameters: trunk twisting and coupling (grip). The RNLE is a job analysis method commonly used to quantify biomechanical stressors to the low back from the lifting and lowering of loads in workplaces (Garg, et al., 2013; Waters et al., 2011) defined this equation as a practical analysis tool for evaluating the physical demands of two-handed manual lifting tasks. The main objective of the RNLE was to prevent and reduce the occurrence of lifting and lowering overexertion injuries and LBP among workers (Garg, 1995). An asymmetry (twisting) multiplier (AM) and coupling (grip) multiplier (CM) as well as the concept of a Lifting Index (LI) were added in 1991. The LI allows the user to compare the lifting demands associated with different lifting tasks in which the load weights vary (Waters et al., 1993). In addition to the coupling and asymmetry changes in the revised method, modifications included a 17kg reduction of the load constant, modifications to the horizontal multiplier, modifications to the effect of frequency and replacing multiple limits (the action limit and the maximum permissible limit) by a single limit (recommended weight limit) (Dempsey, 2002).

This method provided guidance to workers on acceptable weight limits for lifting tasks intended so that nearly all healthy workers could perform lifting tasks over a substantial period of time (e.g., up to 8 hours) without an increased risk of developing lifting-related LBP (Waters, Putz-Anderson and Garg, 1994, p. 4). This method can be used to assess two-handed lifting

and lowering tasks, but there are some limitations such as failure to account for age, gender, and other personal characteristics. Marras and Karwowski (2006) highlighted that this model does not apply to cases like lifting/lowering with one hand, lifting/lowering while seated or kneeling, lifting/lowering in a restricted workplace, etc. Furthermore, while the RNLE considers four major characteristics of the lift itself (force, posture, repetition and duration), it was not intended to be applied to lifting/lowering on slippery surfaces; lifting/lowering in unfavorable environments (extremely cold or hot, vibration etc.); or application to one-handed lifts (Zhang and Mondelo (2014).

2.6.2 University of Michigan, 3D Static Strength Prediction Program (3DSSPP)

3DSSPP was developed by the Center for Ergonomics at the University of Michigan College of Engineering and it is a 3D biomechanical model, which was developed to incorporate posture and loads into an inverse dynamics calculation to determine joint loads (Merryweather et al., 2008). It is software which anticipates static strength requirements for tasks such as lifts, pushes or pulls. This program uses postural data, force parameters and male/female anthropometry to analyze manual material handling tasks and to provide an estimated job simulation. This software allows for users to input anthropometric data, and obtain the forces and moments computed by the program, (rather than by manual calculation) and the output from this software involves spinal compression forces, the percentiles of humans who could perform the task, and data comparisons to NIOSH guidelines, which generate color-coded warnings (Bush et al., 2012). This model predicts spinal compressive force acting at L4/L5 intervertebral disc for a static working posture in the three dimensional directions using anthropometry, hand load and posture data (Chaffin, 1969; Chaffin and Baker, 1970; Garg and Chaffin, 1975; Chaffin and Erig, 1991). The Lumbar Disc Compressive Force at L5/S1 disc level is calculated as the sum of Erector Spinae/Rectus Abdominus, abdominal force, upper body weight above L5/S1 level, and hand load (3DSSPP Manual, 2017). This model has been widely used in many studies as design criteria for manual materials handling jobs or a risk assessment tool for LBP (Chaffin, 1997; Waters et al., 1998; Lavender et al., 1999; Marras et al., 1999; Garg and Kapellusch, 2009; Lu et al., 2015).

2.6.3 The Utah Back Compressive Force Model

The Utah Back Compressive force model is a force assessment tool was developed in 2000 (AIHA Ergonomic Tool Kit). This method was created in an attempt to simplify the collection of biomechanical data and quickly estimate back compressive force (BCF) in the spine. Merryweather, Blosswick and Sesek (2008) performed a study to calculate the dynamic back compressive force, and they found load displacement velocity constants (LDVC) for squat and stoop lifting techniques and an equation for determining dynamic BCF. Merryweather et al. (2008) stated, 'Persons exposed to increased levels of BCF are usually at a higher risk for developing injuries to the low back and spine than workers without these risk factors' (p. 12).

2.7 Specific Aims

The main hypothesis of this research is that individual differences in the musculoskeletal structures of the lumbar spine can be predicted by considering a subject's external gross anthropometry.

Aim 1 - To evaluate MRI Scan/Rescan reliability using a total of thirty-six subjects. Subjects were placed into the MRI machine by two different examiners (blinded to subject identity and scanning order) and these examiners performed the scanning and subsequent structural measurements. Inter- and intra reliability of the MRI process itself will be evaluated.

Aim 2 To develop a novel approach for quantifying disc/vertebra degeneration using fifty subjects' (50) MRI scans and comparing these with Pfirrmann IVD grading scores which are indicative of spinal degradation and subsequent LBP.

Aim 3 - To focus on subject personal information to adjust existing ergonomic assessment tools to improve their predictive power to facilitate efficient field analysis by practicing ergonomists.

The proposed studies established an accurate, repeatable model minimizing current limitations and providing greater insight into the mechanism of low back geometry and the impact of personal characteristics.

Chapter 3

MRI SCAN/RESCAN RELIABILITY

Abstract

Including more precise geometric dimensions of the lower lumbar vertebrae into biomechanical models of the back can improve their accuracy and value. Geometric dimensions have been estimated and approximated in several ways, most recently using Magnetic Resonance Imaging (MRI) techniques. The reliability of MRI-based measurement of structures has been shown to be high (e.g., 0.90 ICC) (Tang et al., 2016; Gungor et al., 2015). However, a limitation of reliability evaluations is that they often only compare assessments of identical MRI images (e.g., same exact image slice); differences are only a function of analyst dexterity (in tracing or measuring the structures). This does not provide an adequate assessment of the reliability of the entire process (from collection of MRI to analysis of MRI) itself. Ideally, a reliability test should compare estimates of biomechanical structures using different scans analyzed by different analysts. This presents a worst case scenario and provides a robust test of the process repeatability. In addition to use in biomechanical models, accurate knowledge of normal and degenerative lumbar intervertebral discs and specific measurements of lumbar vertebrae and discs are crucial for surgeons and radiologists in order to perform proper spinal implants (Salar et al., 2016; Zhou et al., 2000). Existing databases of vertebral and intervertebral dimensions tend to be limited with respect to measures of repeatability/reliability with relatively narrow study populations and/or parameters recorded (Zhou et al., 2000). The objectives of this study were (1) to provide a more accurate data set of lumbar spinal characteristics from 144 Magnetic Resonance Imaging (MRI) scans which were reviewed and measured using the Osirix software program and (2) to assess inter- and intra-rater reliability of the MRI process itself. A total of

144 MRI scans were obtained from university students who ranged from 19 to 32 years of age and did not report chronic or current LBP complaints. Two analysts were blinded to subject identity and MRI scan orders were randomized. Reliability for the entire process was evaluated using the aforementioned worst-case scenario of comparing two distinct scans of the same subject with different researchers performing each MRI scan and different researchers performing measurements of the various aspects of vertebral and intervertebral disc dimensions. Geometric dimensions were consistent with measurements obtained in previous MRI-based studies. As expected, larger discrepancies were observed in the worst case scenarios (scanners and analysts both different). However, worst case variation was relatively low with 3.6% average absolute difference for anterior endplate measurements, for example, as compared to 2.6% average absolute difference for analysts re-rating their own scans after 1 month. The process for obtaining MRI-derived biomechanical measures appears to be robust.

Keywords Lumbar vertebrae, Intervertebral discs, vertebral and intervertebral dimensions

3.1 Introduction

Low back pain is one of the most prevalent and costly health problems exposed by industry (Lurie et al., 2008). Direct measurements of the spine in multiple planes can provide valuable information about the human vertebrae, particularly for improving subject specific biomechanical models. Research efforts have been made to measure the geometry of the low back using medical imaging techniques and been reported in a number of studies. However, a comprehensive review of the reliability and veracity of the methods themselves has not been studied at the level presented herein. Specifically, a comparison of different scans by operators and reviewed/measured by different analysts has not been conducted on substantive sample size.

In addition to biomechanical model inputs, accurate knowledge of the bony anatomy of the spine, especially of the vertebral endplate, is necessary for the design of the vertebral body replacement (Gstoettner et al., 2008). The dimensions of lumbar disc implants have typically been based on early-published geometrical measurements of the vertebrae and the majority of these measurements were collected from cadaver-based studies (Gstoettner et al., 2008). Using incorrectly sized implants may lead to subsidence (gradual caving in), loosening, and

eventually biomechanical failure (Gstoettner et al., 2008, Lakshmanan et al., 2012, Chen et al., 2011). Accurate and comprehensive anthropometric data for the lumbar spinal vertebrae, a frequent site for implantation surgery, is incomplete (Zhou et al., 2000).

Magnetic resonance imaging (MRI) is increasingly used to assess patient lumbar spine health. MRI has important benefits for imaging the musculoskeletal system (Schibany et al., 2005; Shapiro, 2006; Barr et al., 2007), which provide better visualization of anatomic and pathologic structures, including cartilage, bones and ligaments (Schibany et al., 2005; Link et al., 2006; Phan et al., 2006). Morphometric analysis helps to determine the relationships of vertebrae with the anatomical dimensions of low back structures. These morphometric measurements have been questioned by reviewers, specifically, the repeatability of the MRI data collection process used here and used previously by Tang (2013) and Gungor (2014). According to Pope et al., (1980) and Andersson et al. (1981) among others, morphometric measurements need to be performed using a standard vertebral position, control of the film-specimen-focus distances and optimal visualization of the bony landmarks. Many studies have established regression relationships to predict low back parameters, but the veracity of their measurement methods has not been adequately studied. Specifically, the means themselves by which these parameters have been measured have not been studied.

High-resolution MRI of the low back has gained significant interest as a technique, which is capable of precise measurements of morphological features (Li et al., 2010). In order to evaluate how precisely these data are collected, a comprehensive scan-rescan study was conducted. Scan-rescan variability is very important because poor reliability of the measurement method itself could call into question the usefulness and accuracy of the regression results. Rovaris et al., (1998) suggested that scan-rescan variability should be compared with the intra-observer variability with three repeated volume measurements of the same scan. However, evidence that such studies were conducted is nonexistent. It has been shown, however, that scan results may sometimes show differences with different technicians. This is sometimes caused by artifacts or placing the patients differently as in feet first or head first. This position sometimes shows differences because of patients preference (for instance, when they have severe problems that limit the postures in which they can be positioned). Moreover, using or not using knee support

also may affect the scan results because when knee support was not using during the scan, there is more stress on the back, which may affect the back muscles. Also, subject discomfort may contribute to movement, resulting in image artifacts.

Some of studies (such as Morey et al., 2010) have argued that repeated MR scanning of the same subject, even if using the same scanner and acquisition parameters, does not result in identical images due to small changes in image orientation, changes in pre-scan parameters, and magnetic field instability. Morey also stated that these differences might lead to appreciable changes in estimates of volume for different structures. Again, this has not yet been demonstrated for a parameter estimation process such as the one studied herein. During the scan-rescan procedure, they suggest that the patients/subjects should be tested in the same MRI machine on the same day and with the same posture. Our experiment presents a much more robust reliability test, by using different researchers to position and scan the subjects. Our experiment explores, the true scan-rescan ability of proposed data collection methods. Morey et al. (2010) suggested that statistical reliability should be evaluated using the volume of structure, the ratio of volume to surface area for the structure, the magnitude of the inter-scan interval and the method of segmentation. In order to conduct the reliability analysis, scan-rescan procedures were introduced. A scan-rescan analysis using repeated scans with short inter-scan time intervals is important to accurately measure the reliability of the imaging data being acquired, and increase confidence in the consistency of results (Black et al., 2008).

3.2 Materials and Methods

3.2.1 Study Sample Size

MRI scans of the lumbar intervertebral segments (L2/S1) and trunk/core muscles of thirty-six (36) subjects (20 males and 16 females) who were 19 years of age or greater were scanned on a 3T scanner using standardized T2 weighted protocol. Subject demographics (age, gender, height and weight) were obtained. The average age was 23.7 years for males (SD 3.1) and the average mean was 25.4 years for females (SD 4.7). Subjects provided informed consent form (can be found in Appendix B.4) in accordance with Institutional Review Board (IRB) at

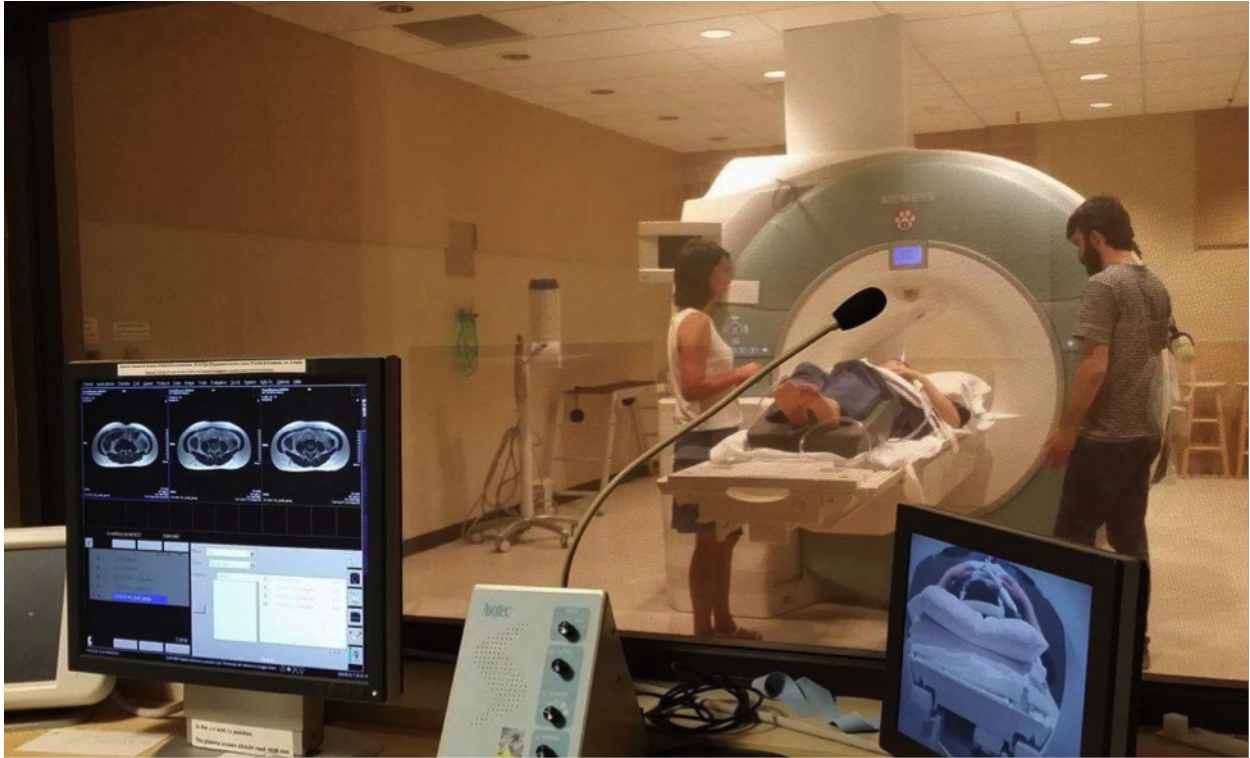


Figure 3.1: MRI Procedure

Auburn University. Subject survey and MRI data were linked using a unique subject ID not related to their personal information. Potential participants who had (1) degenerative changes in the lumbar spine (e.g., crushed vertebral body, trauma, etc.) and/or Erector Spinal Muscles (ESMs) (e.g., atrophy); (2) obvious spinal deformities; or (3) any known pathology relevant to and likely to alter low back geometry (e.g., scoliosis and tumor) were not included in this study (Gungor et al., 2015).

Auburn University MRI Research Center (AUMRIC) Level-3 Certified personnel performed the MRI procedure. MRI data were obtained using a dedicated abdominal coil (Figure 3.1). Subjects were placed in a lying position (supine posture) on the scanner, foot support was provided and they were instructed to keep their body stable (no motion during MRI scans to minimize artifacts).

3.2.2 Measuring Methods

MRIs were performed on a 3T unit (Siemens Verio open-bore, Auburn University Research Park, Alabama) using a dedicated abdomen coil. The protocol included the following

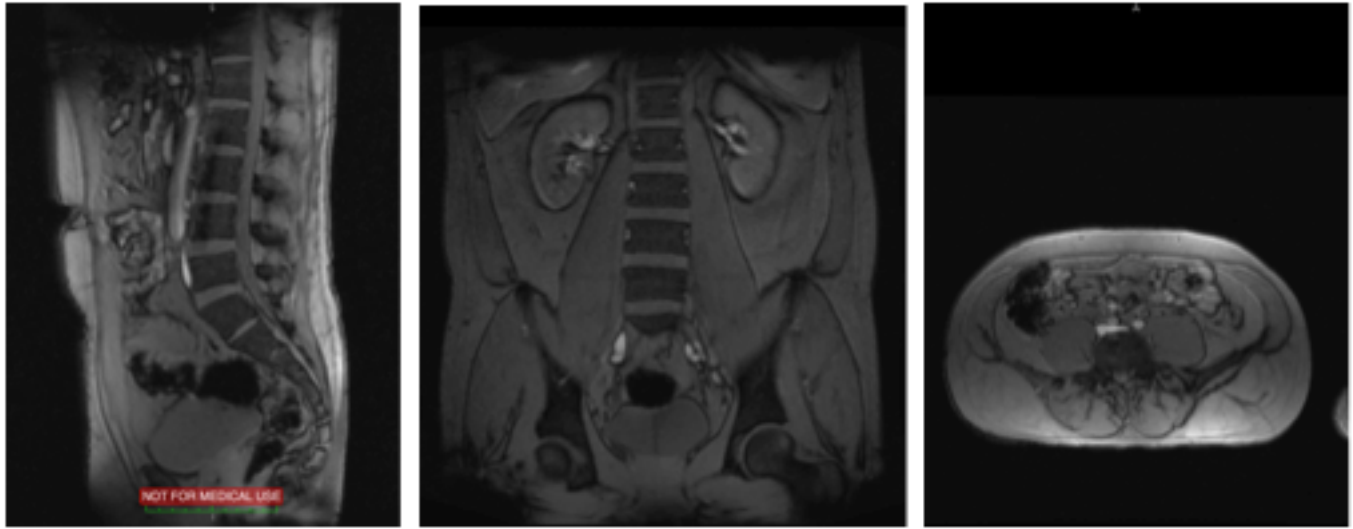


Figure 3.2: Localizer MRI Scan

sequences: Axial Continuous T2-weighted, Sagittal Continuous T2-weighted, and Axial Multi group T2-weighted images with the following parameters; T2-weighted spin-echo (TR 3440 ms; TE 41 ms). All MR images were obtained at a 3-mm slice thickness with 385 FoV read and 100% FoV phase.

After subjects were positioned, a localizer scan (preview scan) was performed by one of the Level-3 MRI certified observers to verify the subject was placed straight. If yes, T2-weighted sagittal, T2-weighted axial continuous scan and T2-weighted axial multi group scans were performed from L2/L3 to L5/S1. An example of localizer scan can be seen in Figure 3.2. Two level-3 MRI certified analysts were provided scans and performed measurements in random order.

To determine the intra and inter-rater reliability of MRI parameters, two operators who were blinded to subject identity and scan order performed the scanning procedures. In addition, reliability for the entire process was evaluated using a worst-case scenario of comparing two distinct scans of the same subject with different researchers performing each MRI scan and different researchers performing the measurement of those scans using Osirix software (v8.0.1, 2016, Antoine Rosset, Bernex, Switzerland).

A sample flyer used to request participants interest for the study is included in Appendix C.1. Thirty six (36) subjects, Auburn University students, who met the experiment criteria,

were selected to participate in this study. The screening form used to decide whether participants met the eligibility requirements is found in Appendix F.2.

Two MRI Level 3 Certified Professionals reviewed the MRI images. In total, 20 parameters were measured, 15 parameters from the Sagittal MRI scans (11 measurements were related to the vertebral body endplate and 4 were related to the IVD), and 5 parameters from the Axial MRI scans (all were muscle cross sectional areas). These parameters were measured for the L2/L3, L3/L4, L4/L5, and L5/S1 lumbar regions. Parameters are as follows: Anterior Vertebrae Height (AVH), Posterior Vertebrae Height (PVH), Vertebral Height Index (VHI), Average Height Index (AHI), Anterior IVD Height (AIVDH), Posterior IVD Height (PIVDH), IVD Height Index (IVDHI), Concavity Height (CH), Sagittal Vertebrae Body Width (SVBW), Sagittal Vertebrae Body Height (SVBH), Height/Weight Index (HWI), Superior Vertebrae Body Length (SVBL) and Inferior Vertebrae Body Length, Length Index (LI), IVD Grading (Pfirrmann scores), Cross Sectional areas of Psoas Right (PR), Psoas Left (PL), Erector Spinae Right (ESR) and Erector Spinae Left (ESL), and Disc Size (Figures 3.3, 3.4, 3.5).

3.2.3 Repeatability of Measurements

In order to assess the reliability and the repeatability of measurements, two different observers measured all parameters three times with at least one month between repeated measurements of the same scan. Data from two observers and six sets of measurements were compared. In the lumbar MRI scans, there are 50 different slices, which can be chosen to perform measurements. In order to test the reliability, specific image slices were not selected prior to measurements. Each observer chose the slice they thought was most appropriate for the measurement in question. The agreement of observers in choosing the same slice or within one slice is shown in Table 3.1. The results show that, on average, the same slice was selected 61% of the time and observations were within one slice 90% of the time. This is across all conditions including analysts looking at the same scans and worst-case comparisons of different scans and different analysts.

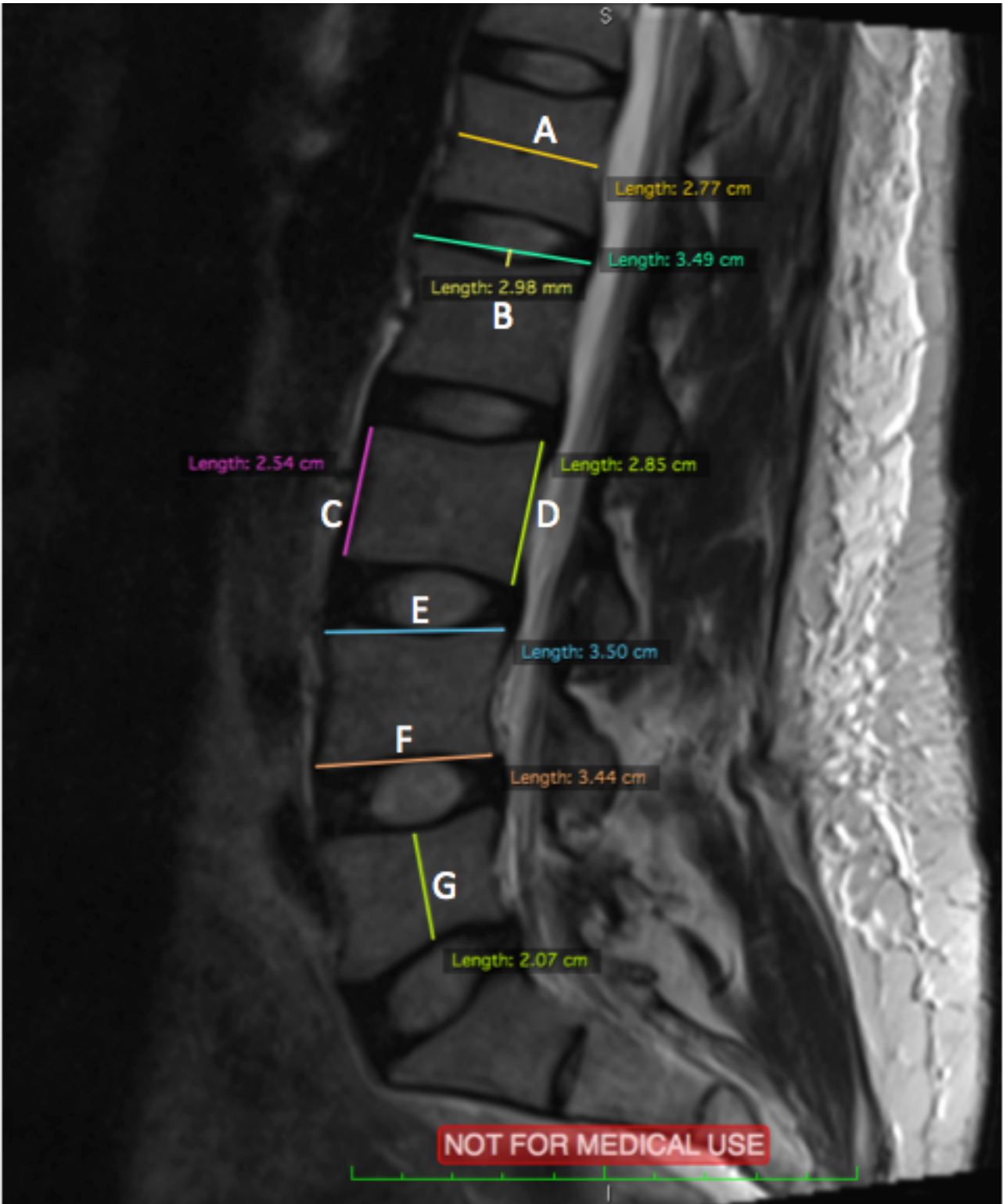


Figure 3.3: Sagittal MRI scan with measurements of A (Sagittal Vertebrae Body Width), B (Concavity Height), C (Anterior Vertebral Height), D (Posterior Vertebral Height), E (Superior Vertebral Body Length), F (Inferior Vertebral Body Height), and G (Sagittal Vertebral Body Height)

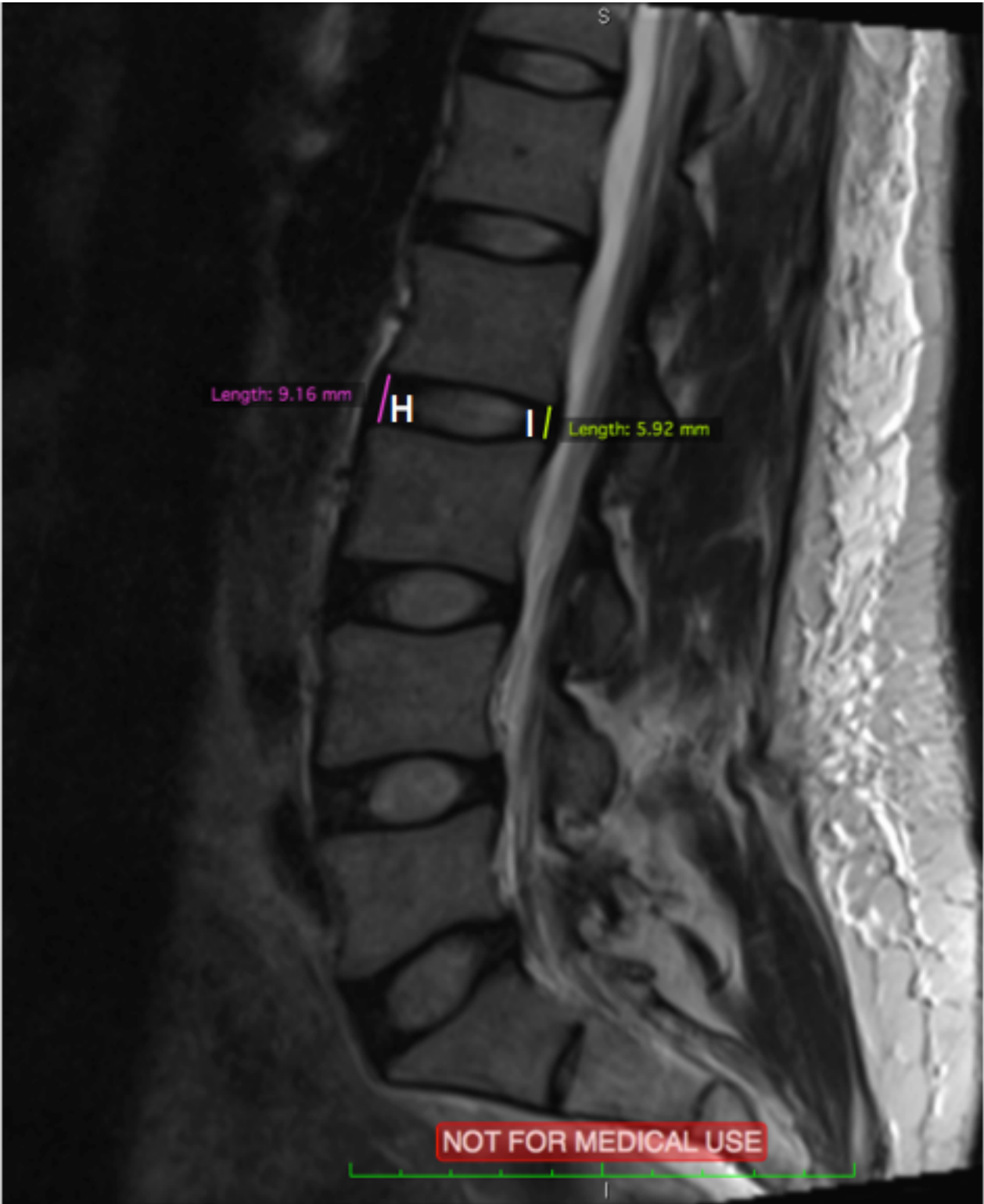


Figure 3.4: Sagittal MRI scan with measurements of H (Anterior IVD Height), and I (Posterior IVD Height)

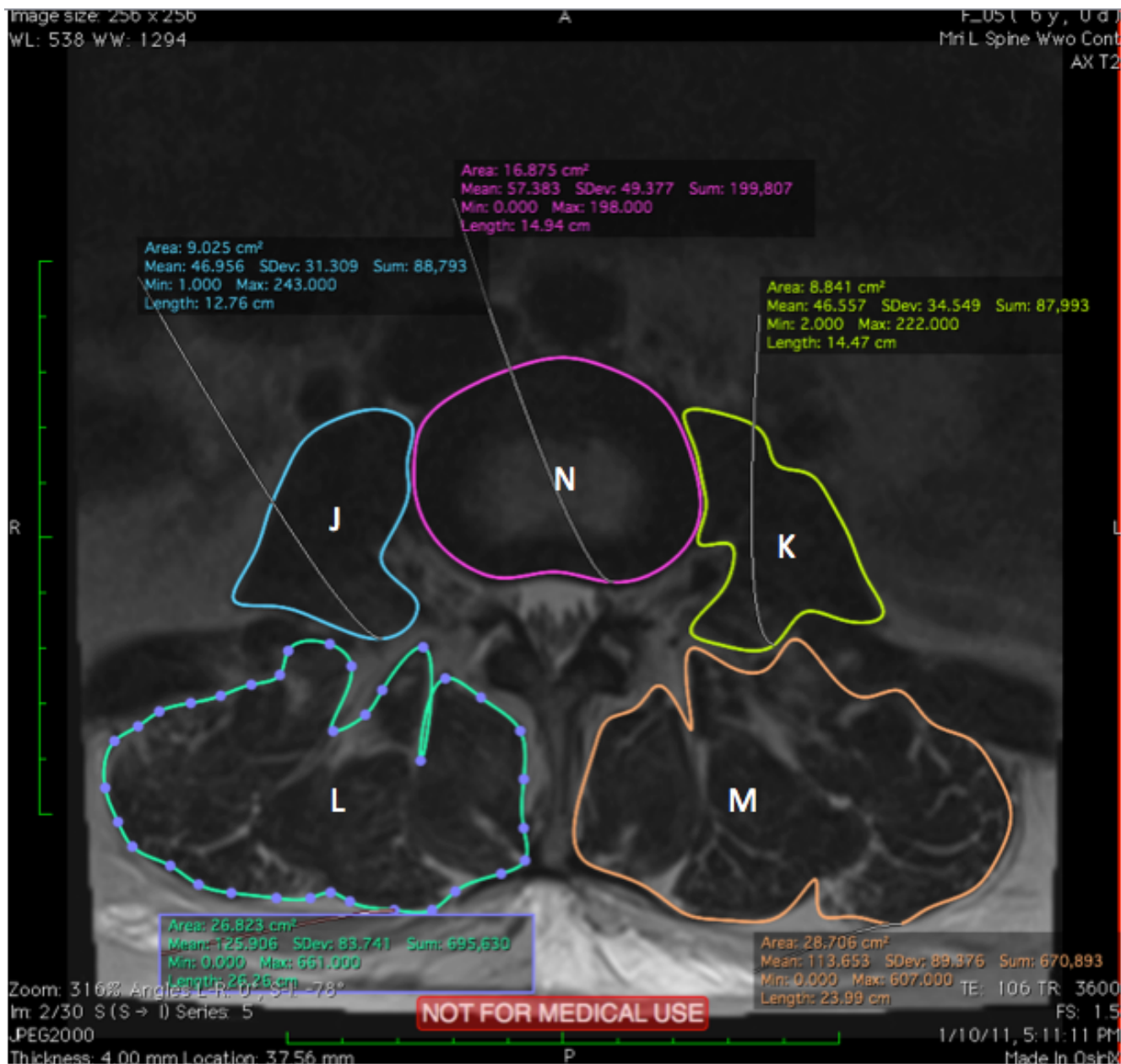


Figure 3.5: Axial MRI scan with measurements of J (Cross-sectional area of Psoas Right), K (Cross-sectional area of Psoas Left), L (Cross-sectional area of Erector Spinae Left), M (Cross-sectional area of Erector Spinae Right) and N (Disc Size)

Table 3.1: Probability of selecting absolute and near image number agreement

Agreement	-1 Category	Absolute Agreement	+1 Category
AY1 vs AX1	0.25	0.48	0.12
AY1 vs AX2	0.22	0.51	0.10
AX1 vs AX2	0.09	0.79	0.10
BY1 vs BY2	0.09	0.78	0.11

3.2.4 Statistical Analysis

The highest levels of absolute agreement occurred when subjects reanalyzed the same scans: AX1 vs. AX2 and BY1 vs. BY2 with 79% and 78% absolute agreement, respectively (First Letter (A and B) represents the scanner, Second Letter (X and Y) represents the reader and 1 and 2 is the number of observation). The lowest absolute agreement occurred with different analysts, regardless of scan. However, it should be noted that analysts were within 1 slice of each other 78%-85% of the time for these three comparisons and in no case did analysts differ by more than two slices (6mm).

3.3 Results

Table 3.2, 3.3, 3.4 summarize the mean values, standard deviations and range of data for the lower lumbar spine, which were obtained from the MRI measurements. Table 3.5, 3.6, 3.7 summarize the Scheffe Test results for different dimensions. These tests were done choosing four different scenarios which are Inter-rater reliability (Same scan different observers/analysts), Intra Best X (Observer X measures her own scan two different times), Intra Best Y (Observer Y measures his own scan two different times) and Worst Case (Different scans observed by different analysts). According to the results, the most different measurements were observed in Worst Case which was predicted before the study.

3.3.1 Vertebral Body Measurements

In order to understand the general shape of the vertebral body, and gender, height, weight and age differences, various measurements were applied; Anterior Vertebrae Body Height (AVBH), Posterior Vertebrae Body Height (PVBH), Sagittal Vertebrae Body Width (SVBW), Sagittal Vertebrae Body Height (SVBH), Superior Vertebrae Body Length (SVBL) and Inferior Vertebrae Body Length (IVBL).

Table 3.2: IVD Lumbar Disc Measurements (L2/L3, L3/L4, L4/L5, L5/S1) (Mean, STD, Range)

Dimensions	Sex	L2/L3	L3/L4	L4/L5	L5/S1
Anterior IVD Height (AIVDH)	Male	5.88 ± 0.97 (4.26-8.92)	7.14 ± 1.3 (4.11-10.08)	8.51 ± 1.25 (5.75-12)	7.61 ± 2.35 (1.05-10.33)
	Female	5.24 ± 0.84 (3.1-7.06)	6.46 ± 1.17 (3.59-9.67)	8.38 ± 1.43 (5.64-11.6)	8.72 ± 1.85 (5.42-15.5)
	Total	5.598 ± 0.97 (3.1-8.92)	6.83 ± 1.28 (3.59-10.08)	8.45 ± 1.34 (5.64-12)	8.10 ± 2.21 (1.05-15.5)
Posterior IVD Height (PIVDH)	Male	4.12 ± 0.77 (2.85-6.27)	1.94 ± 0.38 (1.14-2.99)	4.76 ± 0.98 (3.06-7.93)	4.15 ± 1.03 (2.15-6.84)
	Female	3.99 ± 0.66 (2.53-5.55)	1.52 ± 0.24 (1.03-2.08)	5.35 ± 1.19 (3.14-9.27)	4.53 ± 0.83 (2.89-6.36)
	Total	4.068 ± 0.724 (2.53-6.27)	1.76 ± 0.38 (1.03-2.99)	5.02 ± 1.11 (3.06-9.27)	4.32 ± 0.97 (2.15-6.84)

Table 3.3: Vertebral Body Dimensions of lumbar region (L2, L3, L4, L5, S1) (Mean, STD, Range)

Dimensions	Sex	L2	L3	L4	L5	S1
Anterior Vertebrae Height (AVH)	Male	2.66 ± 0.17 (2.09-3.14)	2.77 ± 0.19 (2.32-3.25)	2.83 ± 0.19 (2.4-3.42)	2.89 ± 0.19 (2.29-3.2)	3.09 ± 0.19 (2.59-3.57)
	Female	2.46 ± 0.188 (1.96-2.82)	2.6 ± 0.17 (2.20-2.91)	2.62 ± 0.19 (2.05-3.05)	2.67 ± 0.19 (2.3-3.15)	2.98 ± 0.23 (2.39-3.37)
	Total	2.57 ± 0.21 (1.96-3.14)	2.69 ± 0.20 (2.20-3.25)	2.74 ± 0.22 (2.05-3.42)	2.8 ± 0.22 (2.29-3.2)	3.04 ± 0.22 (2.39-3.57)
Posterior Vertebrae Height (PVH)	Male	2.78 ± 0.19 (2.33-3.18)	2.84 ± 0.18 (2.3-3.2)	2.73 ± 0.16 (2.27-3.03)	2.52 ± 0.19 (2.02-2.83)	2.47 ± 0.26 (1.55-3.14)
	Female	2.57 ± 1.94 (2.02-2.99)	2.6 ± 0.17 (2.05-2.93)	2.48 ± 0.17 (2.13-3)	2.26 ± 0.18 (1.85-2.65)	2.29 ± 0.21 (1.81-3.26)
	Total	2.69 ± 0.22 (2.02-3.18)	2.73 ± 0.21 (2.05-3.2)	2.62 ± 0.21 (2.13-3.03)	2.40 ± 0.22 (1.85-2.83)	2.39 ± 0.26 (1.55-3.26)
Sagittal Vertebrae Body Width (SVBW)	Male	2.90 ± 0.23 (2.29-3.41)	3.08 ± 0.22 (2.67-3.98)	3.12 ± 0.25 (2.57-3.74)	2.98 ± 0.24 (2.32-3.75)	2.26 ± 0.26 (1.75-2.96)
	Female	2.57 ± 0.25 (1.78-3.14)	2.74 ± 0.25 (2-3.18)	2.79 ± 0.25 (2.14-3.18)	2.69 ± 0.26 (2.1-3.32)	1.89 ± 0.21 (1.43-2.4)
	Total	2.75 ± 0.28 (1.78-3.41)	2.93 ± 0.29 (2-3.98)	2.98 ± 0.3 (2.14-3.74)	2.86 ± 0.29 (2.1-3.75)	2.09 ± 0.3 (1.43-2.96)
Sagittal Vertebrae Body Height (SVBH)	Male	2.32 ± 0.23 (1.71-2.71)	2.37 ± 0.27 (1.72-3.35)	2.41 ± 0.24 (1.77-2.88)	2.34 ± 0.25 (1.65-2.76)	2.55 ± 0.25 (1.87-3.13)
	Female	2.24 ± 0.17 (1.85-2.71)	2.27 ± 0.16 (1.96-2.73)	2.77 ± 0.16 (1.83-2.66)	2.15 ± 0.19 (1.63-2.49)	2.44 ± 0.21 (1.94-2.8)
	Total	2.28 ± 0.21 (1.71-2.71)	2.33 ± 0.23 (1.72-3.35)	2.34 ± 0.22 (1.77-2.88)	2.26 ± 0.25 (1.63-2.76)	2.50 ± 0.24 (1.87-3.13)
Superior Vertebrae Body Length (SVBL)	Male	3.08 ± 0.20 (2.38-3.58)	3.22 ± 0.19 (2.63-3.88)	3.27 ± 0.22 (2.76-3.84)	3.28 ± 0.22 (2.83-4)	3.05 ± 0.24 (2.31-4.25)
	Female	2.77 ± 0.25 (1.93-3.3)	2.91 ± 0.23 (2.18-3.36)	2.97 ± 0.23 (2.42-3.33)	2.99 ± 0.22 (2.51-3.37)	2.76 ± 0.24 (2.31-3.17)
	Total	2.94 ± 0.27 (1.93-3.58)	3.08 ± 0.26 (2.18-3.88)	3.13 ± 0.27 (2.42-3.84)	3.15 ± 0.26 (2.51-4)	2.92 ± 0.28 (2.31-4.25)
Inferior Vertebrae Body Length (IVBL)	Male	3.14 ± 0.19 (2.57-3.71)	3.22 ± 0.22 (2.26-3.76)	3.31 ± 0.22 (2.92-3.88)	3.14 ± 0.24 (2.36-4.05)	1.94 ± 0.38 (1.14-2.99)
	Female	2.81 ± 0.25 (1.91-3.3)	2.91 ± 0.24 (2.21-3.29)	2.99 ± 0.24 (2.27-3.35)	2.89 ± 0.28 (2.33-3.44)	1.52 ± 0.23 (1.03-2.08)
	Total	2.99 ± 0.27 (1.91-3.71)	3.08 ± 0.28 (2.21-3.76)	3.16 ± 0.28 (2.27-3.88)	3.03 ± 0.29 (2.33-4.05)	1.76 ± 0.38 (1.03-2.99)

Table 3.4: Muscle size dimensions for (L2/L3, L3/L4, L4/L5, L5/S1) (Mean, STD, Range)

Dimensions	Sex	L2/L3	L3/L4	L4/L5	L5/S1
Psoas (Right) (PR)	Male	12.78 ± 1.30 (9.22-16.01)	14.93 ± 1.26 (11.53-17.89)	15.55 ± 1.39 (11.25-20.35)	13.85 ± 1.56 (10.38-17.98)
	Female	9.83 ± 1.11 (7.94-13.1)	11.53 ± 1.09 (9.43-13.64)	12.11 ± 1.03 (9.87-15.97)	10.95 ± 0.79 (8.86-12.73)
	Total	11.47 ± 1.91 (7.94-16.01)	13.42 ± 2.06 (9.43-17.89)	14.02 ± 2.11 (9.87-20.35)	12.56 ± 1.93 (8.86-17.98)
Psoas (Left) (PL)	Male	12.43 ± 1.47 (9.43-16.32)	14.69 ± 1.37 (10.52-17.9)	15.28 ± 1.41 (12.45-20.21)	13.73 ± 1.48 (10.76-16.83)
	Female	9.63 ± 1.06 (7.35-12.43)	11.15 ± 1.07 (8.42-17.9)	12.04 ± 1.02 (9.1-20.21)	10.98 ± 0.97 (8.88-13.31)
	Total	11.19 ± 1.90 (7.35-16.32)	13.12 ± 2.16 (8.42-17.9)	13.84 ± 2.04 (9.1-20.21)	12.51 ± 1.87 (8.88-16.83)
Erector Spinae (Right) (ESR)	Male	21.11 ± 1.81 (17.33-26.01)	21.39 ± 1.89 (17.43-28.52)	18.83 ± 3.02 (11.38-28.05)	13.05 ± 2.86 (7.58-20.79)
	Female	18.12 ± 1.70 (14.57-21.84)	18.37 ± 1.71 (13.94-23.92)	18.2 ± 2.17 (10.8-26.42)	12.66 ± 2.67 (8.55-20.07)
	Total	19.78 ± 2.30 (14.57-26.01)	20.05 ± 2.35 (13.94-28.52)	18.55 ± 2.69 (10.8-28.05)	12.88 ± 2.78 (7.58-20.79)
Erector Spinae (Left) (ESL)	Male	20.19 ± 1.7 (17.47-25.28)	20.73 ± 1.66 (17.31-27.06)	18.71 ± 2.96 (10.59-26.44)	12.71 ± 2.82 (8.25-21.05)
	Female	17.49 ± 1.42 (14.28-21.74)	18.14 ± 1.73 (14.68-23.47)	17.96 ± 1.85 (14.41-23.71)	11.97 ± 2.11 (8.42-18.77)
	Total	19.32 ± 2.28 (14.28-25.28)	19.58 ± 2.12 (14.68-27.06)	18.38 ± 2.55 (10.59-26.44)	12.39 ± 2.55 (8.25-21.05)
Disc (Axial View) Length (DAL)	Male	13.93 ± 0.96 (10.39-16.94)	14.27 ± 0.96 (11.82-17.11)	14.12 ± 0.85 (11.93-16.96)	12.95 ± 1.03 (10.45-15.76)
	Female	12.72 ± 0.84 (10.31-14.6)	13.16 ± 0.85 (10.43-15.48)	13.24 ± 0.74 (11.4-15.06)	12.39 ± 0.83 (10.81-14.69)
	Total	13.39 ± 1.09 (10.31-16.94)	13.77 ± 1.06 (10.43-17.11)	13.73 ± 0.91 (11.4-16.96)	12.71 ± 0.98 (10.45-15.76)

Table 3.5: Scheffe Test Results for IVD Dimensions (L2/L3, L3/L4, L4/L5, L5/S1)

Dimensions	Contrast Coefficient (X X Y Y Y X)	L2/L3	L3/L4	L4/L5	L5/S1
Anterior Intervertebral Disc Height (AIVDH)	Inter rater	0.0000	0.0000	0.1713	0.9801
	Intra Best X	0.9998	0.9996	0.9930	0.9901
	Intra Best Y	1.0000	0.9999	1.0000	0.9998
	Worst Case	0.0000	0.0072	0.9882	0.7139
Posterior Intervertebral Disc Height (PIVDH)	Inter rater	0.0118	0.0105	0.1054	0.0447
	Intra Best X	0.9999	0.9987	1.0000	0.9370
	Intra Best Y	0.9803	1.0000	0.9997	0.9999
	Worst Case	0.9137	0.6239	0.9652	1.0000

Table 3.6: Scheffe Test Results for IVD Dimensions (L2/L3, L3/L4, L4/L5, L5/S1)

Dimensions	Contrast Coefficient (X X Y Y Y X)	L2	L3	L4	L5	S1
Anterior Vertebral Height (AVH)	Inter rater	0.7305	0.9963	0.9904	0.9903	0.9944
	Intra Best X	0.9618	0.9974	1.0000	0.9995	0.9943
	Intra Best Y	0.9998	0.7578	0.9607	0.9129	0.9949
	Worst Case	0.8759	0.5398	0.2904	0.1672	0.0830
Posterior Vertebral Height (PVH)	Inter rater	0.0000	0.0000	0.1028	0.0766	0.0496
	Intra Best X	0.9865	0.9943	0.8590	0.9999	1.0000
	Intra Best Y	0.8429	0.5571	0.9992	0.8121	0.9745
	Worst Case	0.0000	0.0000	0.0426	0.0001	0.0127
Sagittal Vertebrae Body Width (SVBW)	Inter rater	0.7059	0.0000	0.0002	0.0973	0.3597
	Intra Best X	0.9997	0.9736	1.000	0.9912	1.0000
	Intra Best Y	0.9910	0.9601	1.0000	1.0000	1.0000
	Worst Case	0.0463	0.0074	0.0003	0.7799	0.1002
Sagittal Vertebrae Body Height (SVBH)	Inter rater	0.0006	n/a	0.1873	0.9884	0.7720
	Intra Best X	0.9822	n/a	1.0000	1.0000	0.9992
	Intra Best Y	1.0000	n/a	1.0000	1.0000	1.0000
	Worst Case	0.0266	n/a	0.7488	0.9996	0.9863
Superior Vertebrae Body Length (SVBL)	Inter rater	0.0216	0.0000	0.0002	0.0002	0.9887
	Intra Best X	1.0000	0.9836	1.000	1.0000	1.0000
	Intra Best Y	0.9881	1.0000	0.9994	1.0000	0.9993
	Worst Case	0.0034	0.0000	0.0000	0.0000	0.0321
Superior Vertebrae Body Length (SVBL)	Inter rater	0.0220	0.0071	0.1949	0.3384	n/a
	Intra Best X	0.9992	0.9998	0.9995	0.9927	n/a
	Intra Best Y	1.0000	1.0000	1.0000	0.9997	n/a
	Worst Case	0.0000	0.0001	0.0143	0.0396	n/a

Table 3.7: Scheffe Test Results for IVD Dimensions (L2/L3, L3/L4, L4/L5, L5/S1)

Dimensions	Contrast Coefficient (X X Y Y Y X)	L2/L3	L3/L4	L4/L5	L5/S1
Psoas (Right) (PR)	Inter rater	0.0062	0.0000	0.3871	1.0000
	Intra Best X	0.9995	0.9995	0.9768	1.0000
	Intra Best Y	0.7508	0.9971	0.9850	0.9999
	Worst Case	0.3513	0.4985	0.9999	0.6617
Psoas (Left) (PL)	Inter rater	0.0000	0.0000	0.1611	0.9961
	Intra Best X	0.9999	0.9960	0.5602	0.9960
	Intra Best Y	0.9568	1.0000	1.0000	1.0000
	Worst Case	0.0052	0.0172	0.7525	0.8238
Erector Spinae (Right) (ESR)	Inter rater	0.0000	0.0000	0.0000	0.0000
	Intra Best X	1.0000	0.9999	0.6923	0.9997
	Intra Best Y	0.9999	0.9995	1.0000	1.0000
	Worst Case	0.0035	0.0000	0.0001	0.0000
Erector Spinae (Left) (ESL)	Inter rater	0.0020	0.0000	0.0000	0.0000
	Intra Best X	0.9993	0.9759	0.9970	0.9953
	Intra Best Y	0.9999	0.9768	0.9965	1.0000
	Worst Case	0.6163	0.0001	0.0000	0.0000
Disc (Axial View) Length (DAL)	Inter rater	0.0000	0.0000	0.0000	0.9961
	Intra Best X	0.9999	0.7589	0.9877	0.9778
	Intra Best Y	0.9856	0.9789	0.9995	0.9002
	Worst Case	0.7368	0.5038	0.0321	1.0000

3.4 Discussion

Lumbar vertebrae and IVD measurements have been performed by a number of studies (Berry et al., 1987; Einsenstein, 1983; Fang et al., 1994; Gilad and Nissan, 1985; Larsen and Smith, 1980; Nissan and Gilad, 1984; Postacchini et al., 1980; Van Schaik et al., 1985; Zhou et al., 2000). In all of these studies, the accuracy of the measurement techniques were not reported. Only sample sizes were reported; no measures of repeatability were included. In the present study, the age range was not broad enough to draw conclusions regarding age differences in lumbar spine measurements. However, the number of subjects was sufficient to explore the repeatability of the measurement process itself and to provide accurate information regarding geometric dimensions of both vertebrae and IVD for the age range studied. Most previous studies have used cadaveric specimens to perform morphometric measurements (Einstein, 1977; Postacchini, 1983; Videman et al., 1990; Mark et al., 2003; Blohm, 2012). However, using cadaveric specimens has both advantages and disadvantages. Whereas bony landmarks were clear to perform measurements, IVDs were hard to observe in cadaveric specimens. Some other studies used CT or X-rays to perform measurements. X-rays are helpful in fracture screening bony deformities including degenerative changes, sacroiliitis, disc and vertebral body height (Parizel et al., 2010; Latees Patel, 2009). However, plain x-rays are not sensitive for herniated discs (Jarvik and Deyo, 2002). On the other hand, CT is excellent at demonstrating bony degenerative changes (Tins, 2010). However, measurements of the intervertebral angles is difficult with CT. MRI is the primary imaging modality for detecting disease. When it is compared with CT, MRI is a better approach to quantify disc degeneration (Modic and Herfkens, 2012).

According to several studies, the most common levels to be affected in the lumbar spine by significant abnormalities are at L3/L4, L4/L5 and L5/S1. In this study, the L5/S1 was observed as the most affected disc particularly for females. Intervertebral disc degeneration (IDD) is one of the most well-known causes of LBP. MRI has been the gold standard for assessing IDD (Pfirrmann et al., 2001; Schneiderman et al., 1987; Thompson et al., 1990). There have been several IDD classification schemes which were proposed by Pfirrmann or

Schneiderman to determine the degree of degeneration levels. Both of these classifications rely on signal intensity to indicate grades of degeneration severity (Samartzis et al., 2013). Accurate knowledge of the dimensions of both vertebral endplate and intervertebral disc size are essential for understanding the LBP. The results of this study indicate that the depth and width of the lumbar vertebral endplate tended to increase from the second to the fourth and then decreased at the fifth and S1 vertebrae. Anterior vertebral height tended to increase from the second lumbar to the S1 vertebrae but Posterior vertebral height decreased from third to the S1. AIVDH increased from the L2-L3 to the L4-L5 but it decreased at L5/S1. Also, PIVDH tended to increase from L2-L3 to the L4-L5, then decreased at S1. Mean IVD height in the lumbar regions (L2-S1) was 4.83 ± 0.8 mm for the L2/L3 disc, 5.65 ± 1.03 mm for the L3/L4 disc, 6.73 ± 1.23 mm for the L4/L5 disc, 6.27 ± 1.5 mm for the L5/S1 disc. Both Superior vertebral length and Inferior vertebral length increased from L2 to L5 but decreased at S1. The results are helpful to form an anthropometric model of the lumbar spine and provide practical data for spinal research. In addition to this, testing the reliability of MRI itself is also important indicator for researchers.

3.5 Conclusion

The scan matters! There are differences based on the scan taken. Average absolute differences were greatest when different scans were compared. For example, the average absolute difference expected between measures of the same scan for the L2 Anterior Vertebrae Height was 3% (max observed 11%) while the average absolute difference expected for worst case comparisons of the L2 Anterior Vertebrae Height was 4.5% (max observed 20%)

Chapter 4

Morphometric Analysis of Lumbar Vertebrae: A Novel Approach for Quantifying Vertebral Endplate Degeneration

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Abstract

A novel morphometric measurement of endplate degradation was compared with qualitative ratings of intervertebral disc degeneration (Pfirrmann Grading) in a double-blinded study to investigate a novel, quantitative method for relating disc morphology and bony changes using MR imaging techniques known as the Concavity Index (CI). By adding a quantitative measure of vertebral endplate degeneration, the CI could provide further insight into structural changes related to disc breakdown and subsequent LBP. The continuous nature of the CI may also allow medical professionals to more closely monitor a patients low back health. T2-weighted MRI scans of the sagittal profile of the lumbar endplates (L2-S1) were collected from 50 subjects (25 females and 25 males) whose ages ranged from 20-40 years. Three trained examiners independently measured the height and the concavity levels of each lumbar vertebrae (L2-S1) as well as assessed the health of the intervertebral discs using Pfirrmanns lumbar disc degeneration grading method. CIs were computed by dividing measured concavity level by disc height (CL/DH). A larger CI was hypothesized to be indicative of spinal degradation and subsequent LBP. Intra- and inter-rater reliabilities were assessed for both the CI measurements and Pfirrmanns lumbar disc degeneration grades. The categorical intra-observer agreement for Pfirrmann ratings ranged from 26 to 63%. However, the CI, which is a continuous measure, varied by only 2%

among raters. The CI appears to be related to disc degeneration as observed by a modest correlation with Pfirrmann ratings ($r = .25$). Endplate concavity is indicative of fracturing and damage and is hypothesized to lead to subsequent disc degeneration due to impediment of nutrient flow to the discs themselves. The CI shows promise as a means for potentially quantifying low back health and identifying risk for future LBP prior to significant disc degeneration.

Key words. Vertebrae degeneration, magnetic resonance imaging, Concavity Index, Pfirrmann Grading

4.1 Introduction

LBP (LBP) is one of the most common musculoskeletal disorders (MSDs) facing the working world. LBP can be defined as pain limited to the region between the lower margins of the 12th rib and the gluteal folds (Andersson, 1977). Between 75% and 85% of the U.S. population will experience at least one episode of back pain during their lifetime (AAOS, 1999, Smith et al., 2014). The economic burden of the condition to society is enormous due to the large number of workdays lost by patients with chronic LBP, expensive medical costs, and productivity losses (Maetzel and Li, 2002). The overall mean prevalence was $31.0\% \pm 0.6\%$, the one-year prevalence was $38.0\% \pm 19.4\%$, and the lifetime prevalence was $39.9\% \pm 24.3\%$ (Manchikanti et al., 2014).

LBP is associated with degeneration of intervertebral discs (Maniadakis and Gray, 2000) and changes to the vertebral endplates (Adams, 2012). A small study on teenagers found that significant disc degeneration occurs several years after an injury to a vertebral endplate (Kerttulla, et al., 2000; Adams, 2004). Furthermore, the endplate has been considered as a part of the intervertebral disc. Recent studies have looked at Modic changes, which involve endplate changes visible using MRI methods to examine endplate changes.

Thus, detailed knowledge of spinal morphometry and the relationships between geometrical dimensions of the vertebrae and the intervertebral discs has been increasing (Kunkel et al., 2011; van der Houwen et al., 2010). Interest in vertebrae shapes has been of particular interest. In 2012, Lakshmanan et al. conducted a study to identify the presence of common endplate patterns across lower lumbar spine levels from L3 to S1. They discovered that the majority of

lumbar endplates were concave, while the majority of sacral endplates were flat (Lakshmanan et al., 2012).

Several investigators have conducted studies on vertebral morphology (Tang et al., 2016; Gungor et al., 2015; Neubert et al., 2013; Singh et al., 2013). Many of these studies have depended on direct measurement from X-ray films, MRI scans and cadaveric specimens. Larsen et al. (1985) evaluated the superior and inferior vertebral margins in order to obtain information on the degrees of curvature the lumbar bodies. They explained that a horizontal concavity was always found in L1-L3, in L5 a posterior convexity was prevailing, and L4 occupied an intermediate position. They proposed that concavity was the result of physical loading. In vertebral motion segment testing, the endplate is the first structure to become damaged, and is clearly the weakest link when the spine is loaded in compression (Adams, 2004). Additionally, Adams (2004) has shown that compressive loading fractures the vertebral body endplate before damaging the disc. Increases in concavity related to subsidence can result in vertebral endplate scarring that may impede the flow of nutrients to the IVD. It is proposed that increased concavity is related to increased endplate damage and therefore subsequent disc degeneration (Adams, 2004). In other words, increases in concavity proceed and are related to disc degeneration (Wang et al., 2012).

In a morphometric study, Berry et al. (1987) measured selected human vertebrae to provide data for surgical implant designs. For this purpose, 27 dimensions were measured from the thoracic (T2, T7, T12) and Lumbar (L1- L5) regions. Berry et al (1987) claimed that; Vertebral body height increases caudally except posteriorly where, after an initial increase, it decreases in the lower lumbar region. Major and minor vertebral body diameters and the major spinal canal diameter slightly increase caudally, whereas minor spinal canal diameter exhibits little or no change. While valuable contributions, these studies were limited in that they focused solely on the morphological measurements of the lumbar spine vertebrae. None of the studies investigated the relationship between the vertebrae structure and LBP. The relationship between vertebral disc degeneration and LBP is well established (Kumar et al., 2001; Kepler et al., 2013). This study proposes a novel approach for quantifying vertebral concavity and relating this to disc degeneration. Unlike measures of disc health which are subjective and discrete,

our approach uses a mathematical model which quantifies endplate health with a continuous measure.

Magnetic Resonance Imaging (MRI) is commonly used to assess the patients lumbar spine problems because degradation and structural changes in height of both vertebral bodies and discs can be visualized clearly in MRI scans (Benneker et al., 2005; Boos, et al., 1994; Pfirrmann et al., 2001, Schiebler et al., 1991; Rim, 2016). The most commonly used grading method was introduced by Pfirrmann et al. (Emanuel et al., 2015; Farshad-Amacker et al., 2015; Pfirrmann et al., 2001; Rim, 2016). The Pfirrmann grading system is related to the height and health of the intervertebral discs and is widely used as an accredited standard in both research and clinical applications (Niu et al., 2011; Niinimaki et al., 2009; Rajasekaran et al., 2004; Perry et al., 2006; Trattinig et al., 2010; Blumenkrantz et al., 2010; Marinelli et al., 2010; Nguyen et al., 2008). According to the scoring system, Grades I and II have normal disc height and have a healthy structure when compared with other levels. Grade III and IV demonstrate some height changes (becoming narrower) relative to other discs and the disc structure also begins to change. The last step is Grade V where the distinction between disc nucleus and annulus is completely lost and the disc space has collapsed completely. The grading scale and progression from a healthy disc to a severely compromised disc is illustrated in Figure 1 (Pfirrmann et al., 2011).

Despite the strengths of the Pfirrmann classification system, the method lacks a means to precisely quantify damage or degradation. According to Rim (2016), Pfirrmann grading is suitable for qualitative measurement, but cannot easily be used for quantitative assessment (Rim, 2016; Modic et al., 1988). The Pfirrmann grading system is a subjective method and ratings may categorically differ between examiners (Salar et al., 2016, Rim, 2016). Despite its semi-quantitative nature, it can and has been used as a measure of IVD health (Niu et al., 2011; Niinimaki et al., 2009; Trattinig et al., 2010; Blumenkrantz et al., 2010; Marinelli et al., 2010). The 5-point system proposed by Pfirrmann et al. is not effective for measuring relatively small differences: it lacks the resolution to finely distinguish severity. While other scales such as an 8-category system by Griffith et al. (2007) have been proposed, they have not reached the widespread acceptance of the Pfirrmann Scale. The objective of this study was to

investigate a novel, quantitative method for relating disc morphology and bony changes using a MR imaging technique known as the 'Concavity Index' (CI). While an imperfect measure, the Pfirrmann grading systems has been used a proxy for low back health since it enjoys widespread use and is accepted by members of the medical community. Thus, this research does not seek to eliminate the Pfirrmann grading system. Rather, by adding a quantitative measure of vertebral endplate degeneration, the concavity index (CI) could provide further insight into structural changes related to disc breakdown and subsequent LBP. The continuous nature of the CI may also allow medical professionals to more closely monitor a patients low back health.

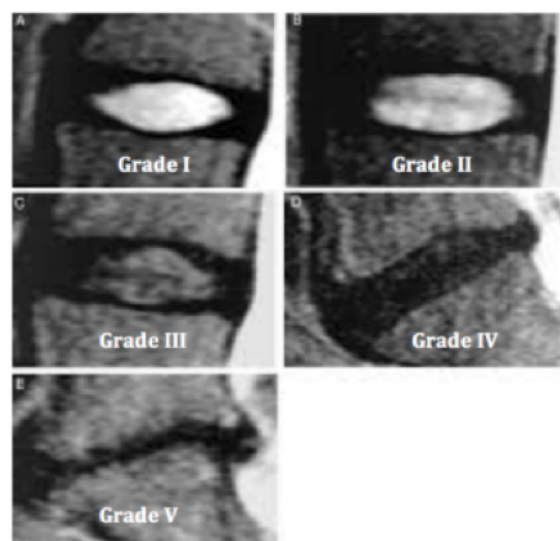


Figure 4.1: Pfirrmann Grading Scores

4.2 Methods

4.2.1 Subject Data

Fifty subjects (25 male and 25 female) aged 20-40 (mean 31.1 years, SD 5.4) without current or chronic episodes of LBP were examined on a whole body 3T Magnetic Resonance Imaging machine (Siemens Verio openbore). All imaging was performed in the supine position. A T2-weighted image, which provides a comprehensive perception of disc structure and good tissue differentiation, was used for the morphological evaluation of the intervertebral discs. A sagittal T2 sequence was applied for the evaluation of the lumbar spine. MRI was performed on the intervertebral discs L2/L3, L3/L4, L4/L5 and L5/S1. The study was approved by the

Auburn University institutional review board (IRB) and signed informed consent was obtained from all participants. The protocol included the following sequences: Axial Continuous T2-weighted, Sagittal Continuous T2-weighted, and Axial Multi group T2-weighted images with the following parameters; T2-weighted spin-echo (TR 3440 ms; TE 41 ms). All MR images were obtained at a 3-mm slice thickness with 385 FoV read and 100% FoV phase.

4.2.2 Image Assessment

Three, Level-3 MRI certified observers, blinded to each others measurements, graded each of the 200 lumbar intervertebral discs and adjacent vertebral bodies using both the Pfirrmann Grading system and the CI in a randomized sequence. Observers did not receive any formal, medical training regarding Pfirrmann grading; they used the instructions provided by Pfirrmann et al. (2001) in their seminal work on IVD grading. T2-weighted sagittal MRI scans were used for both Pfirrmann grading and the CI evaluation of lumbar endplates. T2-weighting was selected to match conditions used by Pfirrmann in their paper. To calculate the CI, each examiner measured the height and the concavity levels of the lumbar discs (L2/L3, L3/L4, L4/L5 and L5/S1). CIs were measured as follows: The superior aspect of vertebral body lengths, which are the distances in the sagittal plane between anterior and posterior borders of vertebral body, were traced first. Then, the perpendicular distance between this line and the vertebral body was measured. This was defined as the concavity level. The concavity level was then divided by the corresponding disc height (CL/DH) (shown in figure 4.2). All measurements were performed using softcopies of sagittal lumbar spine T2-weighted images and the Osirix software system. The lead author demonstrated how the CI was measured using images from a previous lumbar spine MRI study. Each analyst performed 2 or 3 measures of CI under her direction. No other training was provided regarding the CI. Analysts were not directed to specific images, but rather chose the image to be used for CI calculations on their own by reviewing each subjects set of scans. Each analyst selected the images for CI and Pfirrmann analysis independently. This was done to establish a more robust assessment of the CI measurement process.



Figure 4.2: Measurement of Concavity Index

4.2.3 Statistical Analysis

Tests of inter-rater reliability (IRR) were performed to demonstrate the consistency among observational ratings by the three independent observers. The data were divided into two categories: continuous data (Concavity Index) and categorical data (Pfirrmann Grading Scores). Thus, IRR analyses for each data set were performed separately. For the Concavity Index data set (continuous), Intraclass Correlations (ICCs) were calculated. For the Pfirrmann grading data set (categorical), Cohens kappa coefficient was computed. Pearson correlation coefficients were used to quantify the strength of the linear relationship between the Pfirrmann Grading and Concavity Index. Intra-class correlation coefficient (ICC), which is a more desirable method of reliability, which can reflect both of the degree of correlation and agreement between measurements were applied (Koo and Li, 2016). For this study, one-way random-effects and two-way random effects models were applied.

4.3 Results

4.3.1 Grading by Pfirrmann Grading System

The absolute agreement between observers was relatively low for the Pfirrmann Grading system. For example, Rim et al. (2016) found Pfirrmann Grading average interobserver agreements of medical professionals was moderate (0.575 ± 0.251) ranging from poor to excellent.

Table 4.1: Probability of absolute and near (1) category inter-observer agreement

Agreement	-1 Category	Absolute Agreement	+1 Category	Kappa
Obs I vs Obs II	0.28	0.38	0.32	0.18
Obs II vs Obs III	0.16	0.63	0.17	0.61
Obs I vs Obs III	0.34	0.26	0.36	0.18

Table 4.2: Pearson Correlation Coefficient between observers for Concavity Index

	Observer I	Observer II	Observer III
Observer I	1.00	0.99	0.99
Observer II	0.99	1.00	0.98
Observer III	0.99	0.98	1.00

In the present study, the highest absolute agreement between any two observers was 63% and the lowest was 26%. Table 4.1 displays Cohens Kappa analysis between observers where -1 and +1 represent differences of 1 category. The difference between - and + can be described as an observer scoring lower (-) or higher (+) than their fellow observers.

4.3.2 Grading by Concavity Index

The strengths of the linear agreements between measurements between observers for the CIs were very high (0.98) suggesting that CI measurements are very consistent and offer a potentially reliable, quantitative alternative to subjective evaluation methods like Pfirrmann Grading. Table 4.2 shows the correlation coefficients among CI observers. Each observers ratings against one another and illustrates the high level of agreement among observers (r^2 ranging from 0.963 to 0.983).

4.3.3 Agreement between Pfirrmann Grading System and Concavity Indices

Readings from all observers were averaged to produce average CI and Pfirrmann scores for each participant. These averages were plotted to determine if a relationship between Pfirrmann score and CI was present (Figure 4.4). The relationship between CI and Pfirrmann is modest with variation in CI at each Pfirrmann level. Possible explanations for this modest relationship include a relatively healthy population (few grade 5 discs) and the fact that the Pfirrmann score

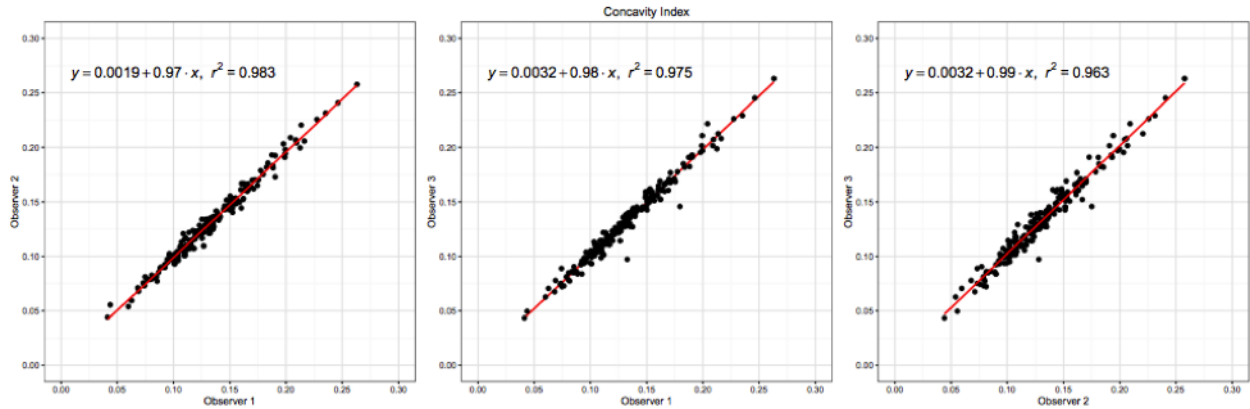


Figure 4.3: Agreement between Observers for Concavity Index

is based on three different measures. The Pfirmann grade is a function of the homogeneity of the disc, the intensity of signal from the annulus, and disc height. Two parts of this score (homogeneity and signal) would seem to have little relationship to physical dimensions. Some Pfirmann grades may have been driven by these other measures and some of these may not be predictable by a measure based solely on physical dimensions. This could partially account for the relatively low fit between CI and Pfirmann.

Another possible explanation for lack of fit may be a function of observer experience with Pfirmann grading. Figure 4.5 shows that the distributions of CIs for Pfirmann Grading within observers were not similar. Figure 4.5 shows a consistent relationship between CIs and Pfirmann Grading for Observer I whereas this clear relationship is lacking for both observer II and III. While none of the observers were medical professionals, observer I had previous experience in an MRI setting and was more familiar with making observations of this type.

There appears to be a clear observer effect with respect to Pfirmann gradings. However, no such observer effect was detected when ICCs were computed for CIs. In fact, ICC model results were similar for one-way and two-way random effects analyses with both yielding ICC values of 0.985 and standard errors of 0.0026 and 0.0027, respectively. The results show that ICC is very high. Agreement for Pfirmann ratings was relatively poor.

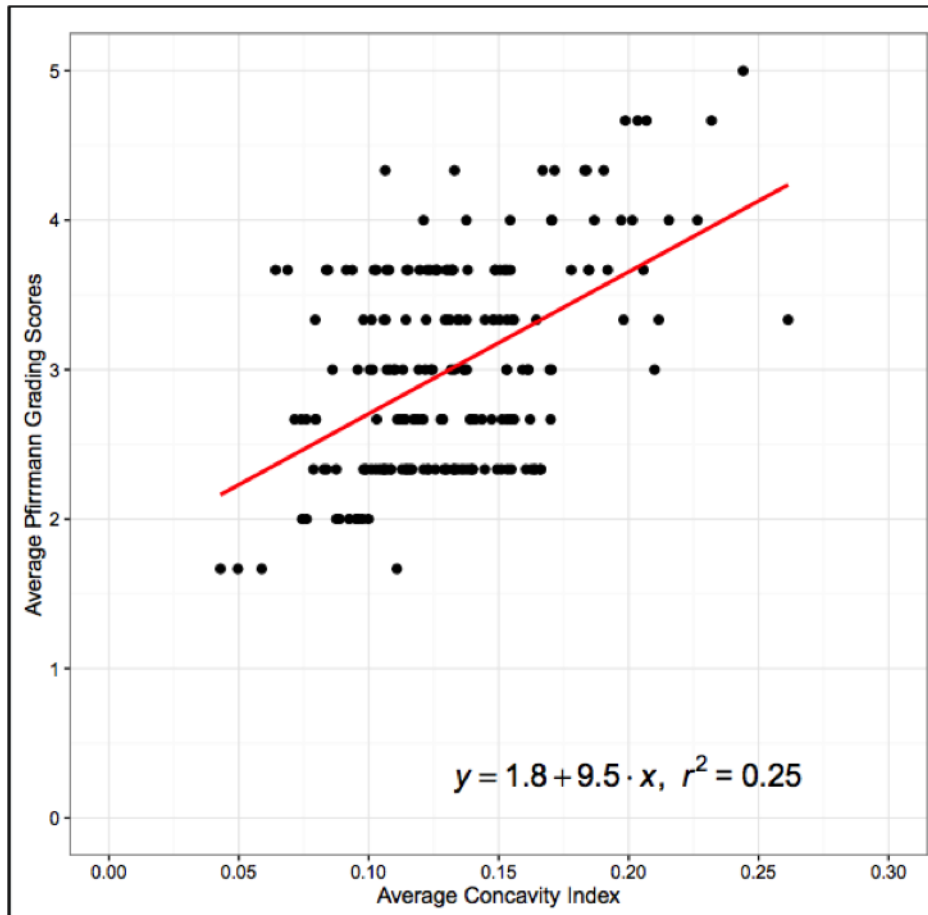


Figure 4.4: Relationship between Pfirmann Grading and Concavity Index

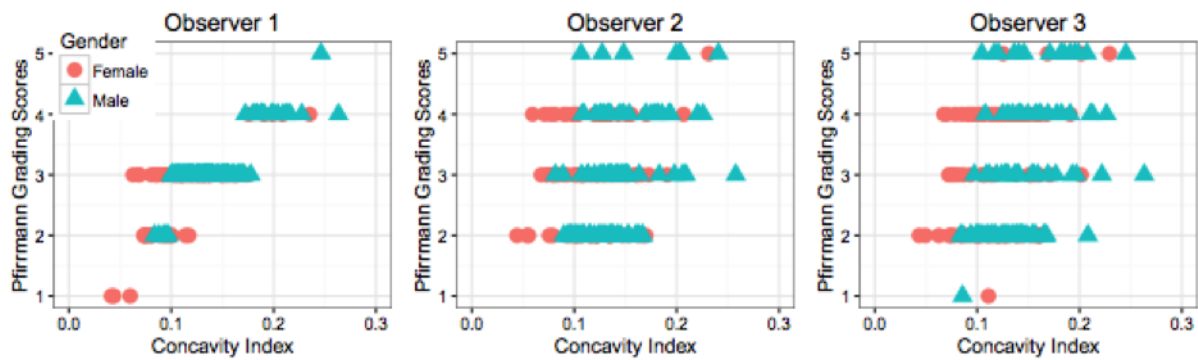


Figure 4.5: Agreement between Concavity Index and Pfirmann Grading between observers

4.4 Discussion

Most inter-rater disagreement for the Pfirrmann scores were within one category and occurred when classifying grade II and III discs. The difference between grades II and III is heavily dependent on disc height which can be difficult to reliably assess visually. This is further complicated since normal disc height is not uniform across all levels in all subjects and disc height often decreased at L5-S1 compared with other levels, even when disc health appeared to be otherwise healthy (e.g., good color and uniformity). Since the study population was asymptomatic, very few Grade 5 discs were observed. Surprisingly, there were also very few Grade 1 discs. A broader range of subject ages and symptom status would likely provide a greater distribution of Pfirrmann grades and CIs. With a greater distribution of data, relationships may become more clear. Pfirrmann grading relies solely on visual appearance of T2-weighted images. It is possible, however, to more quantitatively determine water and proteoglycan content of discs using MRI signals other than T2-weighted images. This may be used to enhance the Pfirrmann grading system and make the process more objective. The novice Pfirrmann graders in this study might benefit from such an enhancement.

Also, this study did not consider subject symptoms or LBP. A prospective study including subjects with and without LBP would address this limitation. All of the subjects in this study were young (20 to 40 years of age) and were relatively healthy college students without LBP. A diverse sampling of subjects from a greater age range and with varying occupational risk factors could help address this limitation. In this way, both Pfirrmann grades and CIs could be related to LBP outcomes, increasing knowledge about the relationship between gradual degenerative processes and LBP ratings. Accurate knowledge of normal and degenerative lumbar intervertebral discs is important for both surgeons and radiologists. Using the CI, medical professionals can potentially make more accurate and early diagnostic interpretations and, subsequently, more precise surgical interventions regarding lumbar vertebrae and intervertebral discs. Future work should include medical professionals, which have been shown to have greater agreements for Pfirrmann grading (Pfirrmann et al., 2004; van Rijn et al., 2005; Jacobs et al., 2016). The CI demonstrated very high agreement despite the lack of medical experience of the research team.

Furthermore, adding objective elements to the Pfirrmann grading system (such as water content evaluation using other MRI signals) could be beneficial for both inexperienced and experienced observers alike.

An ideal classification system for disc degeneration should be simple, easy to apply, discriminatory, and reproducible with good intra- and inter-rater reliability (Griffith et al., 2007). Results of this anatomic study of morphometric measurement for the lumbar vertebrae suggest that the CI method described within has promise for objectively quantifying low back health and possibly predicting future LBP. The CI allows for relative comparisons because it is a continuous measure rather than an ordinal scale. On the contrary, and consistent with other studies (Rim, 2016), agreement between observers for Pfirrmann grading was relatively low. The Pfirrmann scoring system is simple and easy to use, but its subjective nature lacks the ability to subtly discriminate degradation. The CI, on the other hand, has demonstrated strong intra-rater reliability while being a more objective approach to assessing vertebral health. Together, CI and Pfirrmann paint a more complete picture of intervertebral motion segment health.

4.5 Conclusion

A novel approach for quantifying vertebral degeneration has been proposed and there appears to be a positive linear relationship between the CI and Pfirrmann grading. The Pfirrmann grading system is widely used and accepted. The CI may provide a complimentary measure capable of predicting disc degeneration and that could be used in conjunction with the Pfirrmann grading to provide a more complete assessment of the health of a given spinal motion segment. The CI is easy to apply, requiring limited previous knowledge of MRI scans or low back geometry. The CI should be studied further. A prospective study with a more diverse subject population with a variety of occupational exposures would provide more insight regarding the progression of disc degeneration. The CI in conjunction with the established Pfirrmann ratings can provide a more complete picture of low back health and could potentially provide a more comprehensive assessment of spinal segment health.

Chapter 5

Improving the Predictive Capability of the Revised NIOSH Lifting Equation by Incorporating Personal Characteristics

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Abstract

The impact of manual material handling such as lifting, lowering, pushing, pulling and awkward postures have been extensively studied. Many models using these external demands to predict injury have been proposed and employed by safety and health professionals. However, ergonomic models incorporating personal characteristics into a comprehensive model are lacking. This presentation explores the utility of adding personal characteristics such as the estimated L5/S1 Intervertebral Disc (IVD) cross sectional area, height, age, gender and Body Mass Index to the Revised NIOSH Lifting Equation (RNLE) with the goal to improve injury prediction. A dataset with known RNLE Cumulative Lifting Indices (CLIs) and related health outcomes was used to evaluate the impact of personal characteristics on RNLE performance. The dataset included 29 cases and 101 controls selected from a cohort of 1,022 subjects performing 667 jobs. RNLE performance was significantly improved by incorporation of personal characteristics. Adding gender and intervertebral disc size multipliers to the RNLE raised the odds ratio for a CLI of 3.0 from 6.71 (CI: 2.2 20.9) to 24.75 (CI: 2.8 215.4). Similarly, performance was either unchanged or improved when some multipliers were removed. The most promising RNLE change involved incorporation of the multiplier based on the estimated IVD cross-sectional area (CSA). This multiplier was developed by normalizing against the IVD CSA

for a 50th percentile woman. This multiplier could assume values greater than one (for subjects with larger IVD CSA than a 50th percentile woman). Thus, CLI could both decrease and increase as a result of this multiplier. Increases in RNLE performance were achieved primarily by decreasing the number of RNLE false positives (e.g., some CLIs for uninjured subjects were reduced below 3.0). Results are promising, but confidence intervals are broad and additional, prospective research is warranted to validate findings.

Key Words: NIOSH lifting equation, personal characteristics, BMI, Age, Gender

5.1 Introduction

Musculoskeletal disorders (MSDs) are recognized as having occupational etiologic factors as early as the beginning of the 18th century. However, it was not until the 1970s that occupational factors were examined using epidemiologic methods, and the work-relatedness of these conditions began to appear regularly in the scientific literature (Bruce et al. 1997; Ferguson et al. 2005; Woolf A.D., 2011; Zhang and Mondelo, 2014).

It has been well recognized that LBP (LBP) risk is associated with a combination of personal factors, psychological or psychosocial factors, as well as physical exposures (NRC, 2001). However, most ergonomic assessment tools do not consider personal characteristics directly, rather they focus on the physical factors associated with job demands. Da Costa (2010) designed and conducted a systematic review to evaluate the risk factors for work-related musculoskeletal disorders for the neck, shoulder, wrist/hand, low back, hip, knee, ankle and feet. Da Costas review supports that heavy physical work, awkward postures, lifting, psychosocial factors, BMI and age all have a strong relationship with LBP. The relationship between occupational LBP and physical risk factors has been previously investigated primarily in field surveillance studies (Lotters et al., 2003; Marras et al., 1995; Marras et al., 1993; Norman et al., 1998; Punnett et al., 1991; Waters et al., 1999; Bernard et al., 1997; Hoogendoorn et al., 2000). However, most of these studies have focused almost exclusively on the impact of work demands such as lifting, awkward postures, trunk flexion, heavy weight, force and repetition, static and forceful movements (Marras et al., 1995; Marras et al., 2010; Garg et al., 2013). Several risk assessment tools have been developed to evaluate LBP risk resulting from manual

material lifting tasks. The most well-known and widely used tool among the ergonomics community is the Revised NIOSH Lifting Equation (RNLE) (Dempsey et al. 2005; Waters et al., 1993; Waters et al., 1994; Gallagher et al., 2017).

Changes to the RNLE have been suggested. However, most of these changes have focused on the physical demands of the job. For example, there have been recent efforts to improve risk determination for jobs with varying lifting demands and to estimate risk for an entire, variable work shift (Garg and Kapellusch, 2016; Waters et al., 2007). Despite these techniques demonstrating good estimations for LBP risk at the population level, there remains room for improvement regarding individual risk assessment. Indeed, an inherent limitation of these assessment tools is that they only address the work demands, and ignore the capability of the worker performing these tasks. That is, these tools may be able to assess the risk of work activities to the general public, but not the risk to an individual worker. Because identifying the causes of LBP is difficult since it is multifactorial, involving personal, physical job factors, and workplace psychosocial characteristics (Davis and Heaney, 2000; Lu, 2014) it seems reasonable to investigate the predictive capabilities of assessment tools which incorporate not only work demands, but also individual characteristics of the worker performing the job.

The RNLE attempts to assess the risks of LBP resulting from various manual material handling tasks by calculating a recommended weight for specified two-handed, symmetrical lifting tasks. The RNLE is a job analysis method commonly used to quantify biomechanical stressors to the low back from lifting and lowering of loads in workplaces (Garg, et al., 2013). The main objective of the revised equation was to prevent and reduce the occurrence of lifting and lowering overexertion injuries and LBP among workers (Garg, 1995). An asymmetry (twisting) multiplier (AM) and coupling (grip) multiplier (CM) as well as the concept of a Lifting Index (LI) were added to the original (1981) NIOSH Lifting Equation (Waters et al., 1981, Waters et al., 1993). In addition to the coupling and asymmetry changes in the revised method, modifications included a 17 kg (37.5 lb) reduction of the load constant, modifications to the horizontal multiplier, modifications to the effect of frequency and replacing multiple limits (the action limit and the maximum permissible limit) by a single limit (recommended weight limit) (Dempsey, 2002).

This equation is accepted as a useful and valuable tool for the design and evaluation of manual lifting impacts to occupational health (Jager, Luttmann, 1999) and it has gained widespread popularity in the United States and internationally as a tool for assessing the physical demands of two-handed manual lifting tasks (Waters, Baron, Kemmlert, 1998). However, variation in the capabilities and limitations of individual workers can render risk assessments inaccurate for many workers. This is particularly true as the workforce changes; more females are entering into traditionally male occupations requiring manual handling and as the US workforce is increasingly obese and aging (Dall et al., 2013; Ricci and Chee, 2005). Suggestions have been made on how to modify the equation or multipliers used in the equation to improve its reliability, better estimate stressors faced by varying populations, expand the functionality, or simplify the RNLE (Sesek et al, 2003, Sesek et al., 2013). This research explores the potential impact of these factors and proposes several ways to incorporate these characteristics into the RNLE. Specifically, multipliers were created to explore age, gender, BMI, and a scaling factor based upon intervertebral disc diameter.

Sesek et al., (2003) explored the idea of simplifying the RNLE to see if its predictive ability for determining workers who are at risk of suffering a low back injury could be maintained but with less computation. Those findings suggest that predictive ability can be maintained while simultaneously simplifying the assessment effort. The goal of the present study is to explore both adding and subtracting multipliers to enhance model performance with the aim of minimizing RNLE user computational burden. In that spirit, the new personal characteristic multipliers can be easily integrated before or after RNLE computation. Therefore, existing RNLE data can be modified for specific workers without the need to re-analyze the physical job itself. By considering both adding and subtracting multipliers, models can be explored that potentially have fewer or no net difference in multipliers while exhibiting improved performance.

5.2 Methodology

This study modified the RNLE by considering additional multipliers and the elimination or modification of existing multipliers. New multipliers included: age, gender, Body Mass Index (BMI), IVD Cross sectional area (CSA) and a new coupling multiplier with lower coefficients

for non-optimal couplings. The vertical, distance, coupling, and asymmetry multipliers were also considered for elimination. A retrospective, case-control methodology was employed to determine the predictive ability of the RNLE and modified RNLE measures.

The database was modified to allow multipliers to be switched on or off so that various combinations could be explored. First, multipliers were added individually to determine their impact on the model. Next, multipliers were added in various combinations to determine their impact on model performance. Then, existing multipliers were removed individually and in combinations to measure the impact on model performance. Finally, combinations of both adding and subtracting various multipliers were considered. All combinations were evaluated based on odds ratio, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) as compared to baseline (normal) RNLE performance with all six original multipliers in place. All outputs are recorded in tables comparing new models to baseline RNLE data.

A database from an epidemiological study involving a large automotive manufacturer was used to explore modifications to the RNLE. The database included historical injury data and symptom interviews, which had been performed one-to-one with participants (Sesek, 1999). Personal identifiers such name and date of birth were not included in data set. Researchers in the current study were blinded to all images and potential identifying information and had data on age, height, weight, and gender only. All data were analyzed in aggregate. Information regarding low-back related injuries was known for each subjects job, but not whether that specific individual had reported an injury.

5.2.1 An automotive manufacturing ergonomic field study

The data were collected from six different automotive plants, and consisted of 667 manufacturing jobs with 1,022 participants as well as job-specific, historical injury data. Well-defined lifting activities meeting the RNLE criteria for analysis (e.g., two-handed, symmetric lifts) were selected for this study. Administrative jobs or jobs that did not require any lifting tasks or did not have well-defined tasks were not used in this analysis.

Personal characteristic variables investigated for this study study included height, weight, age and gender (used to estimate the lower lumbar spinal geometry and compute BMI) and self-reported ratings of perceived discomfort.

Subjects were asked to report their LBP discomfort on the day they were interviewed as well as to report any LBP symptoms for the previous year. In addition, data were available regarding which jobs had one or more LBP-related medical visits during the previous year. Injuries on those jobs may or may not have been to subjects working on those jobs during the data collection. Cases were defined as subjects who had both LBP symptoms in the previous year and whose job had one or more LBP-related medical visits in the previous year.

There were 130 subjects: 29 cases and 101 controls. The subject population was composed of 101 males and 29 females aged 23-65 (mean 42 years, SD 11.2), heights from 59-76 inches (mean 69.5, SD 3.6), weights from 115-350 pounds (mean 191.0, SD 45.1), and Body Mass Index from 17.0 to 54.8 (mean 27.6, SD 5.6). The prevalence of LBP for this population was 22% (29/130).

The automotive database contained numerous instances of jobs involving several different tasks (up to six), for which the RNLE was calculated using the cumulative lifting index (CLI). Cases and controls were those subjects meeting case-control definitions for whom all data were available. For example, some subjects did not report height, weight or gender and were therefore excluded.

Cases were defined as subjects who reported LBP related symptoms in the previous year and whose job had one or more reports to medical regarding LBP in the previous year. The reports were defined as first time office visits (FTOV) related to LBP and may or may not have been related specifically to the subject studied. Controls were subjects who had no LBP symptoms in the previous year and whose job did not have any reports to medical regarding LBP in the previous year. Ergonomic analyses were blinded to subject symptoms and job health outcomes. Data were collected by ergonomists and engineering graduate students studying ergonomics. Health and symptoms data were collected by occupational health nurses who were likewise blinded to the ergonomic analyses.

5.2.2 A morphometric study of low back geometry using MRI technology

Previous research has yielded a regression equation to predict the size of an individuals intervertebral disc (IVD) cross-sectional area (Tang, 2013; Tang et al., 2014). That study used subjects without current or chronic episodes of LBP and examined them using a whole body 3T Magnetic Resonance Imaging machine (Siemens Verio open-bore). The IVD cross-sectional area used for this study was the L5/S1 IVD measured at its center (see Line B in Figure 5.1 below).

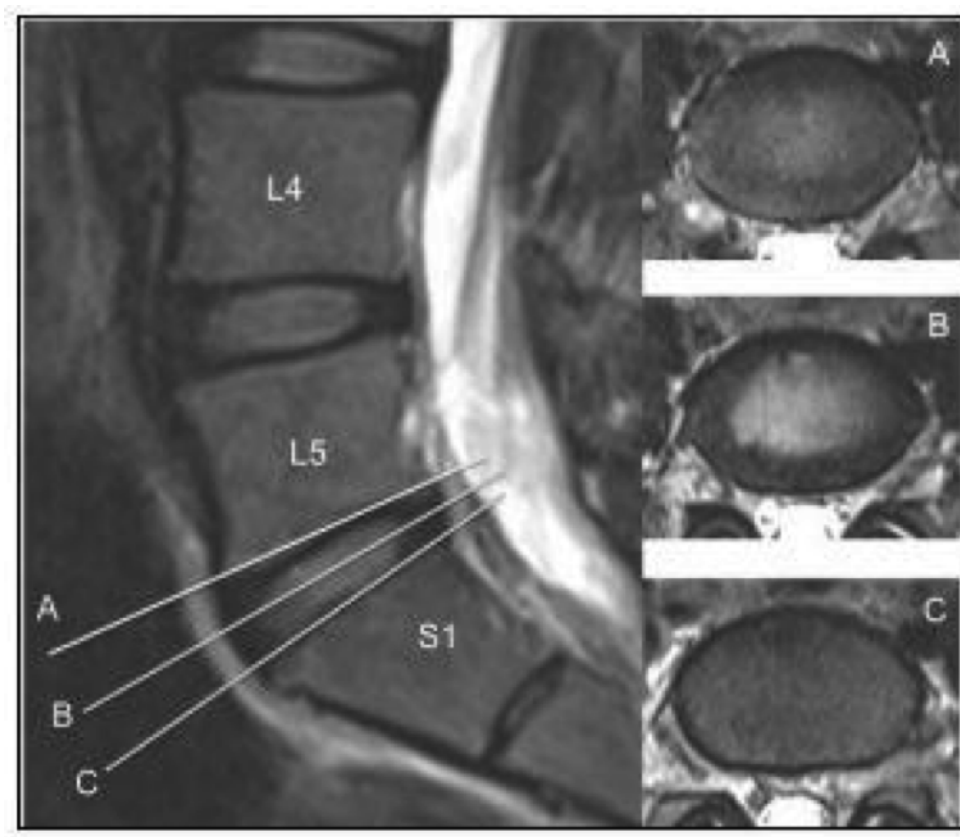


Figure 5.1: Sample of MRI scan in sagittal and transverse planes

Institutional review board (IRB) approval was obtained and all data were analyzed in aggregate. Regression models were developed using geometric measurements of the MRI scans as compared with subject anthropometric characteristics (Tang et al., 2014). Osirix software (version v4.1.1, 32-bit, Pixmeo, Geneva, Switzerland) was used to measure disc sizes. The regression is based on subject height and gender.

$$\text{L5/S1 IVD CSAs} = [-16.959 + 0.179 * \text{Height} * 2.54 + 1.7 * \text{Gender}] \text{ cm}^2$$

(Gender (G) = 0 for females and 1 for males)

IVD area was used to scale risk up or down for smaller and larger subjects, respectively. A 50th percentile female IVD area was used to normalize risk. Subjects with smaller estimated IVD areas were considered at higher risk and those with larger IVD areas were considered to be at lower risk. Normalizing to a 50th percentile female was selected because the RNLE is a relatively conservative test and produces a significant number of false positives (e.g., indicates a job is hazardous when the job does not result in symptoms and/or injury). In this way, the IVD multiplier can both decrease risk from baseline for those with larger IVD area and increase risk for those with smaller than 50th percentile female IVD area. This is the only multiplier tested that can have values greater than 1.0. The IVD multiplier could have been normalized to any size disc, but was targeted to a smaller than average size to account for false positives common with the RNLE.

5.3 Experimental Design

The RNLE provides an empirical method for computing a recommended weight limit (RWL) for manual lifting. The actual weight lifted is divided by the RWL to create a lifting index (LI). The LI has been used to estimate risk for developing lifting-related LBP (Liles and Mahajan, 1985; Chaffin et al., 1973; Marras et al., 1999; Waters et al., 2011). Higher LIs are associated with higher risk for LBP. LIs can be used to prioritize jobs for hazard abatement indicating which jobs are generally most difficult. However, not all workers will be at the same risk when performing a given set of lifting tasks. The RNLE does not consider personal differences and how these might impact a specific individuals risk for LBP. The RNLE consists of six multipliers (horizontal multiplier (HM), vertical multiplier (VM), Distance Multiplier (DM), asymmetry multiplier (AM), frequency multiplier (FM), and a coupling multiplier (CM)) and a load constant (LC) of 51 pounds. RWL is simply calculated as the product of all multipliers and the load constant:

$$\mathbf{RWL = LC \times HM \times VM \times DM \times AM \times FM \times CM}$$

The actual weight lifted is divided by the computed recommended weight limit to create the lifting index (LI). When the LI is ≥ 3.0 , the lift is considered to pose risk for nearly all workers according to NIOSH (Waters, et al., 1993).

$$\mathbf{LI = Actual Weight / RWL}$$

Modifications to the RNLE were proposed and several novel multipliers that describe fundamental characteristics of the subject were selected for evaluation. These multipliers are gender (GM), body mass index (BMIM), age (AGEM), an approximation of the low back intervertebral disc (IVD) size (IVDM) as a scaling factor to adjust risk based on a subjects specific anthropometry. The IVDM was intended to normalize the risk as a function of subject size. Individual subjects were normalized by dividing their estimated IVD area by that of a 50th percentile female. Note: while traditional RNLE multipliers can be no greater than 1.0, the IVDM can be greater than 1.0 suggesting that an individual with a larger IVD area would be at less risk than their smaller counterparts.

$$\mathbf{IVDM = Subject L5/S1 IVD Area / 50th percentile female L5/S1 IVD Area}$$

A new, more conservative CM was also proposed and tested. The RNLE uses the following multipliers good coupling = 1.0, fair coupling = 0.95, and poor coupling = 0.90. The proposed new coupling multiplier (NCM) uses 1.0, 0.80, and 0.70 for good, fair, and poor couplings, respectively. A gender multiplier (GM) of 2/3 was applied to female subjects. Males were assigned 1.0 for GM. This multiplier was suggested in the Applications Manual for the Revised NIOSH Lifting Equation (Waters et al, 1994). It has previously been demonstrated to improve the RNLE predictive ability (Sesek et al., 2013, Waters et al., 2011). A BMI multiplier (BMIM) was applied to penalize subjects whose BMI was greater than 30. The BMIM consisted of 30/BMI for BMIs > 30 and 1.0 for BMIs ≤ 30 . An age multiplier (AGEM) to account for strength losses expected from aging was also tested. The age multiplier was 1.0 for subjects under the age of 40 and decreased by 1% (0.01) for each year of age beyond 40. To evaluate RNLE multipliers, an LI of 3.0 was used to classify jobs as more or less risky. Odds ratios were computed for models with various combinations of old and new multipliers. All new multipliers were tested individually and in groups to see if predictions could be improved for the RNLE. Similarly, existing multipliers were removed to determine their overall contribution

to risk estimation. The new multipliers work just as the original multipliers and can be simply included in the RWL calculations as shown in below:

$$\mathbf{RWL = LC \times HM \times VM \times DM \times AM \times FM \times CM \times GM \times BMIM \times AGEM \times IVDM}$$

However, since these factors are intrinsic to the subject, they do not have to be computed task-by-task at the RWL level and can be used to modify an existing CLI directly. One simply computes the CLI as per NIOSH guidelines and then modifies the output as shown in below;

$$\mathbf{CLI_{mod} = CLI / (GM \times BMIM \times AGEM \times IVDM)}$$

It is recommended that personal modifiers be accounted for at the CLI level to simplify the personalization of RNLE results for multiple workers on the same job. Modifications to the RNLE were proposed to account for an increasingly diverse, aging, and obese population of workers. For example, a given job may present more risk to an elderly and obese worker than a young and fit worker. Direct comparisons are made between the predictions of the unmodified CLI and the proposed CLI modifications. For all analyses, a CLI cutpoint of 3.0 was used to differentiate high and low risk jobs.

5.4 Results

Table 5.1 shows the impact of adding personal multipliers to the RNLE as compared to the baseline (original) RNLE CLI. Each column represents the addition of a single multiplier to the baseline RNLE.

Table 5.1: Addition of Personal Multipliers

	CLI (Baseline)	+BMIM (No Change)	+AGEM (No Change)	+GM (Increase)	+IVDM (Increase)
Odds Ratio	6.71	6.71	6.71	7.83	19.8
(95% CI)	(2.2 - 20.9)	(2.2 - 20.9)	(2.2 - 20.9)	(2.6 - 24.0)	(2.2 - 177.2)
Pvalue	0.0057	0.0057	0.0057	0.0015	0.0073
Sensitivity	0.30	0.30	0.30	0.33	0.17
Specificity	0.94	0.94	0.94	0.94	0.98
PPV	0.60	0.60	0.60	0.63	0.83
NPV	0.82	0.82	0.82	0.82	0.80

The IVD multiplier (IVDM) had the greatest impact on the RNLE, significantly improving overall odds ratio. However, the sensitivity dropped substantially (from .30 to .17). The GM modestly improved the odds ratio and overall model performance. The addition of an AGEM or BMIM did not alter the RNLE. Next, multipliers were added in combinations to see if RNLE performance could be further increased. Table 5.2 illustrates impact of various combinations of proposed multipliers, ranging from lower to higher performance.

Table 5.2: Combination of Adding

	CLI (Baseline)	+BMIM +AGEM (Decrease)	+BMIM, +AGEM, +GM OR +BMIM, +GM (Decrease)	+GM, +AGEM (Decrease)	+IVDM, +AGEM (Increase)
Odds Ratio	6.71	4.33	4.5	6.64	9.8
(95% CI)	(2.2 - 20.9)	(1.5 - 12.2)	(1.7 - 12.3)	(2.3 - 19.6)	(1.8 - 53.5)
Pvalue	0.0010	0.0057	0.0032	0.0006	0.0084
Sensitivity	0.30	0.30	0.33	0.33	0.17
Specificity	0.94	0.91	0.90	0.93	0.98
PPV	0.60	0.50	0.50	0.59	0.71
NPV	0.82	0.81	0.82	0.82	0.80

Table 5.3: Combination of Adding cont.

	CLI (Baseline)	+BMIM, +AGEM,+GM, +IVDM (Increase)	(+BMIM, +IVDM, +GM) or (+BMIM, +IVDM, +AGEM) or (+IVDM, +AGEM, +GM) (Increase)	+BMIM, +IVDM (Increase)	+IVDM, +GM (Increase)
Odds Ratio	6.71	9.84	12.25	19.80	24.75
(95% CI)	(2.2 - 20.9)	(2.4 - 41.0)	(2.3 - 64.5)	(2.2 - 177.2)	(2.8 - 215.4)
Pvalue	0.0010	0.0017	0.0031	0.0076	0.0036
Sensitivity	0.30	0.23	0.20	0.17	0.20
Specificity	0.94	0.97	0.98	0.99	0.99
PPV	0.60	0.70	0.75	0.83	0.86
NPV	0.82	0.81	0.80	0.80	0.80

RNLE performance was maximized by adding both the IVDM and GM. The IVDM had the greatest impact and combinations that included it performed the best. An odds ratio near 25 was achieved by combining the IVDM and the GM. It should be noted, however, that sensitivity remained significantly lower than baseline with performance (odds ratio; improvements coming from the reclassification of false positives as true negatives. Also, the confidence interval, while significant, is very large (2.8 - 215.4). Unlike all of the other multipliers, the IVDM can actually reduce estimated risk; reducing some over-estimation of risk. Multipliers were also removed to measure their impact on model performance. As with the new multipliers, existing multipliers were investigated individually. Table 5.4 shows the impact of removing individual multipliers from the RNLE.

Table 5.4: Removing Multipliers

	CLI (Baseline)	-DM (Decrease)	-CM (No change)	-AM (No change)	-VM (Increase)
Odds Ratio	6.71	5.7	6.71	6.71	12.25
(95% CI)	(2.2 - 20.9)	(1.8 - 18.1)	(2.2 - 20.9)	(2.2 - 20.9)	(2.3 - 64.5)
Pvalue	0.0010	0.0032	0.0010	0.0010	0.0031
Sensitivity	0.30	0.27	0.30	0.30	0.20
Specificity	0.94	0.94	0.94	0.94	0.98
PPV	0.60	0.57	0.60	0.60	0.75
NPV	0.82	0.81	0.82	0.82	0.80

The removal of the distance multiplier (DM) decreased RNLE performance. Removing the coupling (CM) and asymmetry (AM) multipliers did not change RNLE performance. Interestingly, removing the vertical multiplier (VM) actually increased the RNLE performance. This was achieved by reducing false positives and it should be noted that sensitivity decreased because some true positives were also erroneously reclassified as true negatives. Next, combinations of RNLE multipliers were removed and performance evaluated. Table 5.5 shows these combinations.

Removing some combinations of multipliers decreased performance or modestly increased performance. However, removing the VM along with other multipliers including removing all

Table 5.5: Combination of subtracting multipliers

	CLI	-AM,-DM	-CM,-DM	-CM,-AM	-DM,-VM	-CM,-VM; -AM,-VM; -CM,-VM,- AM;-CM,- VM,-AM,- DM
	(Baseline)	(Decrease)	(Increase)	(Increase)	(Increase)	(Increase)
Odds Ratio	6.71	5.7	6.91	8.14	12.25	24.75
(95% CI)	(2.2 - 20.9)	(1.8 - 18.1)	(2.1 - 23.2)	(2.5 - 26.8)	(2.3 - 64.5)	(2.8 - 215.4)
Pvalue	0.0010	0.0032	0.0017	0.0006	0.0031	0.0036
Sensitivity	0.30	0.27	0.27	0.30	0.20	0.20
Specificity	0.94	0.94	0.95	0.95	0.98	0.99
PPV	0.60	0.57	0.62	0.64	0.75	0.86
NPV	0.82	0.81	0.81	0.82	0.80	0.80

multipliers other than the horizontal multiplier (HM) and the frequency multiplier (FM) actually significantly improved overall model performance increasing the odds ratio to nearly 25. However, sensitivity was decreased from 0.30 to 0.20 and the confidence interval is broad (2.8 - 215.4). This is a function of a relatively small sample size. Similar to the results obtained from adding new multipliers, these results suggest that the RNLE may be overly conservative; therefore reducing some of the factors that increase the models predicted risk will eliminate false positives. Unfortunately, some true positives were also reclassified as false negatives.

Finally, combinations of both adding and subtracting multipliers were explored to determine if RNLE performance could be further improved. Table 5.6 shows these combinations.

While it was not possible to improve performance further, it is possible to achieve the best improved overall performance with no net change in number of multipliers. The replacement of the coupling multiplier (CM) with the new coupling multiplier (NCM) showed slight increase in model performance suggesting that stiffer penalties for poor coupling may be warranted. The NCM, however, was not present in any of the highest performing combinations. Overall, RNLE performance was greatly enhanced by adding the IVDM and GM while eliminating the CM and AM. However, sensitivity decreased (from 0.30 to 0.20). Positive and negative predictive values were robust at 0.86 and 0.80, respectively.

Table 5.6: Adding and subtracting multipliers

	CLI (Baseline)	-CM,+NCM (Increase)	+GM,+IVDM; +GM, +IVDM, -CM, -AM (Increase)	+GM,+IVDM,- CM (Increase)	+IVDM,+GM,- AM (Increase)
Odds Ratio	6.71	7.83	24.75	24.75	24.75
(95% CI)	(2.2 - 20.9)	(2.6 - 24.0)	(2.8 - 215.4)	(2.8 - 215.4)	(2.8 - 215.4)
Pvalue	0.0010	0.0003	0.0036	0.0036	0.0036
Sensitivity	0.30	0.33	0.20	0.20	0.20
Specificity	0.94	0.94	0.99	0.99	0.99
PPV	0.60	0.63	0.86	0.86	0.86
NPV	0.82	0.82	0.80	0.80	0.80

5.5 Limitations

Specific injury outcomes were unknown for subjects in the original study. Therefore, the true impact of personal characteristics cannot be fully assessed from this study. A prospective study including personal characteristics with corresponding individual subject injury outcomes is warranted. Asymmetry in the original study was not precisely captured (it was recorded in discrete categories rather than continuously), perhaps impacting the performance of this multiplier. However, in practice the asymmetry measure is difficult to estimate, hence the discrete categories selected in the original study. Perhaps a simplified means of assessing the impact of asymmetry should be studied further. Some subjects may not have been on their current job for 1 year or more (employees were on their current jobs for an average of 3.3 years). Therefore, subjects with symptoms in the previous year, but related to previous jobs may be misclassified in this study as cases. This misclassification, however, should present no systematic bias towards improving results and should only result in misclassification noise. This is particularly likely since the union environment in which the data were collected typically resulted in persons transferring to less difficult jobs as they earned seniority. This may also explain why the age multiplier was not effective since older workers tend to have more seniority and can preferentially select less demanding jobs.

Future work should better control subject inclusion criteria and, ideally, follow subjects prospectively, thereby minimizing potential recall bias associated with retrospective symptoms questions. Most importantly, sample size was relatively lowly. While all odds ratios were statistically significant, the confidence intervals were very wide. A larger sample size with more power could provide better approximations of true odds ratios. Results, however, are promising and suggest that the RNLE is a robust tool, capable of assessing relative risk even when heavily modified. This implies that the primary mechanism of risk is a function of the horizontal distance (present in all models tested) and the frequency of lifting. However, it appears that further improvements can be made.

5.6 Discussion

This research indicates that personal characteristics can be successfully and simply factored into ergonomic assessment tools such as the RNLE to improve their performance. Further, some factors may be removed from tools without a decrement in performance. In the case of the RNLE, personal characteristics may even be integrated after job level data collection to improve risk estimation for some individuals. In fact, for the RNLE it may be easier to do so after computing the CLI; simply dividing the CLI by these multipliers to account for individual differences. Further study is underway to explore additional personal characteristic driven multipliers and to revisit the unsuccessful ones studied here (BMI and Age). This study demonstrates that model performance cannot solely be assessed by univariate analyses. Various combinations of multipliers should be explored to determine the best performing models. This is particularly true for the traditional multipliers, all of which can hold maximum values of 1.0. In other words, risk estimates increase (or stay the same) when these multipliers are employed. The IVDM, on the other hand, can increase or decrease risk since it can have values both less than and greater than 1.0 (suggesting that an individual may be more or less susceptible to injury than other workers). Future work should consider other multipliers that can hold values greater than 1.0 and/or consider modifying existing multipliers to allow values above 1.0. Multipliers exceeding 1.0 can especially help to minimize false positive classifications. While model

Table 5.7: Adding and Subtracting Multipliers

	CLI (Baseline)	+IVDM, +GM (Increase)
Odds Ratio	6.71	10.29
(95% CI)	(2.2 - 20.9)	(2.9 - 36.6)
Pvalue	0.0010	0.0003
Sensitivity	0.30	0.30
Specificity	0.94	0.96
PPV	0.60	0.69
NPV	0.82	0.82

performance was significantly enhanced by incorporating personal characteristics, model sensitivity (detecting cases) was relatively low and was, in fact, lower than the baseline sensitivity in the best performing models (sensitivity reduced from 0.3 to 0.2). While positive predictive value (PPV) was relatively high, with 86% of subjects with CLIs over 3.0 properly identified as cases, only 1 in 5 cases, however (0.2), were identified using the new RNLE model (+IVDM, +GM). More work is needed to produce models. Ergonomists can also alter decision points to impact sensitivity. For example, Table 5.7 shows the impact of reducing the CLI decision cutpoint from 3.0 to 2.5.

Sensitivity returned to 0.30 (baseline) along with modest improvements to specificity and PPV. The practice of ergonomics often requires tradeoffs since models are imperfect. If a company has the resources to investigate and improve more jobs, then they may opt for models or decision cutpoints with superior sensitivity.

One of the best performing models included one that simply eliminated 4 of the RNLEs current multipliers. While one may be tempted to simply remove these multipliers and use this more efficient tool, caution is advised due to the study limitations described above. However, it may be possible to pre-screen all jobs using such a tool (with HM and FM only) and a conservative decision cutpoint to increase sensitivity. A second, more complex tool with additional multipliers could be applied to those pre-screened jobs identified as potentially risky to better assess their risk. The current RNLE requires a relatively significant time commitment to analyze jobs, particularly jobs with multiple lifting tasks. Such a hybrid 2-stage approach may be attractive for rapid screening with a subsequent deep dive analysis (e.g., including personal

characteristics and additional multipliers) for tasks quickly identified as potentially hazardous. A high negative predictive value for the first stage is prerequisite for such an approach. A multi-stage analysis methodology is currently being investigated for the fatigue failure based LiFFT tool (Gallagher et al., 2017).

5.7 Conclusion

Personal characteristics appear to drive a significant proportion of manual material handling (MMH) risk and should be considered when assessing MMH risk. Models incorporating a subjects estimated intervertebral disc size were the most promising and should be explored further. This study demonstrated the potential value of including these personal characteristics on diverse set of subjects and lifting tasks from 6 different automotive manufacturing sites. The subjects included a wide range of ages, BMIs, and was comprised of 22% female workers. Likewise, future work should also include subject populations that are as diverse as possible, particularly since the workforce is both older and increasingly obese. Identifying the contributions of obesity to MMH risk may further demonstrate the value of wellness programs aimed at assisting workers in maintaining healthy lifestyles and physical conditions.

Chapter 6

CONCLUSION

LBP (LBP) represents one of the most costly and prevalent musculoskeletal disorders (MSDs). MSDs are the leading cause of disability in the United States and represent 48 percent of all self-reported chronic medical conditions (BMUS, 2011). Studies that incorporate personal factors for LBP into biomechanical models are very limited. Biomechanical models of the human spine are highly dependent on the ability to accurately describe musculoskeletal structures and predict spinal loading. Biomechanical models using simplified geometric representations of the human spine (e.g. one model for males and one model for females) become less capable to accommodate the large variations in overall population and, therefore, can poorly characterize the risk of work-related LBP for specific individuals. The cross-sectional area is a critical morphometric characteristic that dictates to the mechanical properties of a lumbar motion segment. In this dissertation, the impact of personal characteristics such as age, gender, height, weight and the CSAs of the lower lumbar IVDs were incorporated into RNLE to make it subject-specific.

The prevalence and costs of LBP related injuries remain high. Personal characteristics have been shown to impact injuries and injury potential. Despite this, few models attempt to incorporate these personal factors. This research demonstrated that personal factors could be successfully interpreted into biomechanical models. The objective of this study was to explore the relationships among age, gender, height, weight and spinal morphology (disc degeneration), specifically its detrimental effects, to improve model precision by increasing sample size and the quantity of demographic information, and to verify whether personal characteristics make a significant change for LBP by directly altering and evaluating the RNLE.

Morphometric data for the lower lumbar region has been collected using different techniques such as cadaver, and imaging technologies like CT, X-ray and MRI. In general, the main aim of morphometric measurements is to improve the understanding of human spinal structure. Imaging techniques can differ widely. For instance, Radiographs (X-ray images) are good to identify bony landmarks and to measure sizes such as height and length. However, they are not sensitive for herniated disc and are not helpful in diagnosing nerve root impingement. Computed tomography (CT) scans can be used to measure morphometric characteristics of the spine in the transverse plane and are excellent for demonstrating bony degenerative changes. However, they are less capable of evaluating the herniated or degenerated disc when it is compared with Magnetic Resonance Imaging (MRI) technique. MRI provides better visualization of anatomic and pathologic structures, including cartilage, bones and ligaments. MRI uses harmless radio waves not ionizing radiation as in CT. MRI also allows better measurements and therefore better understanding of the risk factors of LBP. MRI shows great promise for improving biomechanical modeling of the lumbar spine using subject specific information. This research demonstrates the high degree of repeatability associated with MRI as a means of measuring biomechanically relevant structures. When capabilities and limitations of different imaging techniques were compared, MRI scans were used to collect high-resolution images and perform morphometric measurement for both lumbar vertebral endplates and intervertebral discs. This dissertation consisted of three different studies; MRI Scan-Rescan Reliability (study 1) study collected thirty-six (36) subjects (20 male, mean age = 24 years \pm 3.1; 16 female, mean age = 25 \pm 4.7) to assess reliability of MRI (analysis were shown in chapter 3). For the second study, MRI scans were obtained from fifty (50) subjects (25 females, mean age = 29 years \pm 5.8; 16 male, mean age = 32 \pm 4.7) who has no current LBP and self-reported low back injury. Each examiner measure Concavity Index and Pfirmann Grading. A linear relationship between average CI and corresponding Pfirmann classification was observed. While overall agreement among Pfirmann raters was high, 10% of ratings disagreed by two categories. CIs had an average coefficient of variation of just 0.95% across all participants and lumbar regions

(analyses were discussed in Chapter 4). Chapter 5 investigated the feasibility of incorporating personal risk factors into existing Revised NIOSH Lifting Equation to determine the risk estimation.

Morphometric data of the lower lumbar spine (L2-S1) obtained using an advanced image processing software (Osirix), which provided the measurement of the actual shape of the vertebral endplates and IVDs. These analyses clearly demonstrated the ability of MRI-derived techniques to obtain accurate morphometric data with excellent intra- and inter-rater reliabilities.

This dissertation has several limitations. First, subjects in Study 1 and Study 2 had small range of age (from 20 to 40 years). Age was not significantly correlated with the lower lumbar spinal morphometry. In addition, due to the small range of age and number of subjects, disc degeneration was not fully investigated in this dissertation. Future studies should include more subjects with a wider range of ages to investigate the impact of age on disc herniation/degeneration. Secondly, subjects were scanned in supine posture, which may adjust the spinal curvatures and the spinal loading when compared with scanning in a standing posture.

Future work is underway to address the limitations found here and to expand on the most promising findings. For example, modifications of other ergonomic assessment methods, such as the LiFFT tool (Gallagher et al., 2017) is forthcoming. In addition, work on scan/rescan of muscle lever arm estimation has begun. Personal characteristics have profound impacts on biomechanical stress and subsequent LBP risk and should be considered in ergonomic assessment methods.

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Appendices

Appendix A

Classification with respect to study design and main focus area

Table A.1: Distribution of the articles with respect to journals

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
1	Kelsey	1975	Case-Control	Herniated discs were studied and there were 223 cases and 494 controls.	The association between workplace factors (such as time spent sitting, chair type, lifting, pulling, pushing, and driving) and LBP.	N/A	Two different age groups were examined.	The results indicate that sitting over a long period of time and driving were highly associated with LBP.
2	Einstein	1977	Cross-sectional	2,166 Lumbar vertebrae of 433 adult South Black African and white European skeletons were analyzed.	N/A	N/A	Specific population - South Black African' spinal structure was observed.	Statistical analysis indicated that spinal Black Africans' lumbar canal is narrower and the overall lower limit of normal of the mid-sagittal diameter is 15mm.

Table A.2: Distribution of the articles with respect to journals

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
3	Postacchini	1983	Cross-sectional	Lumbar vertebrae from both Sixty (63) Italians and Fifty eight (58) Indians were collected.	N/A	N/A	Spinal structure differences between Indians and Italians were observed.	The average dimensions of the spinal canal, the lateral recesses, and the vertebral body were significantly greater in Italians.
4	Svensson and Andersson	1983	Cross-sectional	940 Men within age ranged of 40-47 years were analyzed	Blue collars and white collars were compared	N/A	Age information was collected but the association between age and LBP were not found.	Men with manual work had a significantly longer average sickness absence than white-collar workers. Also, the intensity of work-recovery was lower in blue-collar workers.

Table A.3: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
5	Kelsey et al	1984	Case-Control	232 cases which all diagnosed prolapsed lumbar disc was examined.	Interviews and Questionnaires were used to get information on work related activities.	N/A	N/A	Work related lifting (without twisting the body) and twisting without lifting were highly associated with prolapsed lumbar disc. The combination of these two factors (lifting and twisting) also has a huge impact. Also, the highest association was discovered in simultaneous lifting and twisting with straight knees.
6	Videman et al	1984	Cross-sectional	Finish nurses were studied to observe the prevalence of LBP and sciatica in relation to age, workload, free time activities and pregnancy.	The impact of work-related activities of nurses such as patient handling and lifting on LBP were studied.	N/A	N/A	Working conditions of both nurse aides and qualified nurses were compared and it is observed that nurse aides had higher rates of LBP because of their work load.

Table A.4: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
7	Berry et al	1987	Morphometric study	27 dimensions were measured from thoracic (T2, T7, T12) and lumbar (L1-L5).	N/A	N/A	Selected human vertebrae were observed to provide accurate results for implant design surgeries.	Vertebral body height decreases in the lower lumbar region.
8	Bergenudd and Nilsson	1988	Cohort Study	323 males and 252 females - Malmö, Sweden	Exposure levels were conducted by questionnaire since 1942 and jobs were classified into three groups; (1) light physical work - white collars (2) Moderate physical work - nurses, shop assistants, bakers and light industry (3) Heavy-Carpenters, bricklayers, and heavy industry	N/A	Gender differences were compared - females had higher risk of having low back pain than males.	Workers who exposed moderate or heavy physical working conditions had more back pain.

Table A.5: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
9	Abenheim et al	1988	Case-control	2342 Cases of all-occupational back injuries in Quebec.	Industrial sector and the number of episodes of absence from work were recorded.	N/A	Age and sex information were collected to rate of back problems.	Men had a higher chance of recurrence, also age showed protective effects on the probability of recurrence due to the lower recurrence rate for older people.
10	Svensson and Andersson	1989	Cross-sectional	A random sample of Swedish women who were in between 38 and 64 years old.	Variables including working hours, amount of overtime, lifting, frequency of forward bending and twisting, work posture, satisfaction with work, fatigued, education levels and number of rest breaks were collected.	Stress is related with low back pain.	No association has been discovered between age and incidence and prevalence of LBP.	Physical exposures (such as lifting, bending, twisting, other work postures, sitting, standing, monotony, and physical activity at work) were related with LBP. However, lifting, standing and bending forward have higher association than others.

Table A.6: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
10	Svensson and Andersson	1989	Cross-sectional	A random sample of Swedish women who were in between 38 and 64 years old.	Variables including working hours, amount of overtime, lifting, frequency of forward bending and twisting, work posture, satisfaction with work, fatigued, education levels and number of rest breaks were collected.	Stress is related with low back pain.	No association has been discovered between age and incidence and prevalence of LBP.	Physical exposures (such as lifting, bending, twisting, other work postures, sitting, standing, monotony, and physical activity at work) were related with LBP. However, lifting, standing and bending forward have higher association than others.
11	Burdorf and Zondervan	1990	Cross-sectional	33 crane operators in a Dutch steel company	Questionnaire was conducted to get information on heavy physical work, lifting, WBV and sedentary postures	N/A	N/A	Results specify that crane operators were significantly more likely to experience LBP with frequent/repetitive twisting, bending, stooping, static sedentary postures and WBV.

Table A.7: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
12	Boshuizen et al	1990	Cross-sectional	Dutch male truck drivers	Questionnaire which includes vehicle types driven, awkward postures, and hour of work were asked to truck drivers to measure the impact of vehicle vibration on LBP.	N/A	N/A	it is observed that sick leaves for the back disorders increased by the level of vibration exposure and duration of exposure.
13	Bongers et al	1990	Cross-sectional	163 Dutch male helicopter pilots	Exposure levels were obtained with questionnaire by asking time spent in bent or twisted posture.	N/A	N/A	The total flight time and total vibration dose have an huge impact on chronic back pain problems.

Table A.8: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
14	Videman et al	1990	Cross-sectional	86 males who were died at Helsinki hospital were examined to determine the degree of lumbar spinal pathology.	Cadaver specimens were used to examine the disc degeneration and the degree of spinal pathology. Also, work related information was conducted from the families. These information were used to establish a link between physical factors and low back disorders.	N/A	N/A	Sedentary or heavy work were highly correlated with the low back pain. The type of works were found to be responsible for the development of spinal changes/deformation.
15	Amonoo-Kuofi	1990	Cross-sectional	Plain lateral radiographs of the 615 lumbar spines (310 females and 305 males) were studied	N/A	N/A	The anterior and posterior heights of the discs of subjects (310 females age ranged 10-61 years and 305 males age ranged of 10-64) were measured.	Results indicate that all discs have a significant variations of both anterior and posterior heights with age. Changes were more striking in females. In both males and females, the posterior height changes more common than the anterior height.

Table A.9: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
16	Burdorf et al	1991	Cross-sectional	Male concrete fabrication workers and a group of maintenance workers	OVAKO working posture system and a questionnaire was used.	N/A	N/A	Workload, postural load and whole body vibration are significantly associated with low back pain.
17	Punnett et al	1991	Case-control	219 automotive assembly worker	Questionnaire was performed to collect information on non - and occupational activities. Workers jobs were videotaped and work cycles were reviewed investigate the impact of posture on LBP.	N/A	No association between age and gender to LBP has been discussed.	Back disorders are associated with non-neutral postures and the duration of the non-neutral posture.

Table A.10: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
18	Panjabi et al	1991	Cross-sectional	3D surface anatomy of thoracic vertebrae using 144 vertebrae	N/A	N/A	Thoracic spine was analyzed into three segments/regions; upper, middle and lower.	Both thoracic and lumbar spine information was used for creating a detailed schematic representation of spine and an accurate mathematical models of the human spine.
19	Garg and Moore	1991	Cross-sectional	Sixty (60) healthy individuals participated	Participants were asked to complete some two sagittally symmetric MMH tasks while standing on the center of a force platform.	N/A	Age-related differences in lower back biomechanics during sagittal symmetric simulated manual handling tasks were investigated.	Older individuals may be at a higher risk for developing lower back pain when completing similar manual handling tasks.

Table A.11: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
20	Bovenzi and Zadini	1992	Cross-sectional	Male bus drivers	WBV and cumulative vibration exposures were calculated using the work duration, hours, and previous exposures	N/A	N/A	Three measures of vibration (total vibration dose, equivalent vibration magnitude, and duration of exposure) were conducted and all exposure levels were statistically significant with WBV.
21	Holmstrom et al	1992	Cross-sectional	Randomly selected male construction workers	Questionnaire was obtained from the workers who are experiencing lifting, handling and work postures. Also a clinical exam such as active spinal mobility test was performed in order to test lumbar flexion.	N/A	No relationship with leisure activity, height or weight has been investigated	Manual material handling, stooping and kneeling postures are highly correlated with LBP. On the other hand, no association between sitting and LBP has been observed.

Table A.12: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
22	Marras et al	1993 (1995)	Cross-sectional	403 jobs from varied manufacturing companies	Existing medical reports/records in each industry were collected to determine the number of work-related low-back disorders.	N/A	N/A	Jobs were ranked into three categories (working position, velocity and acceleration of the lumbar spine) were analyzed and results indicated that repetitive lifting jobs are highly associated with low back pain.
23	Bovenzi and Betta	1994	Cross-sectional	Male tractor drivers	Questionnaire was performed for collecting information on awkward postures, number of hours for operating and vibration levels.	N/A	N/A	Relationship between vibration exposure and low back pain vibration dose responses were highly correlated with LBP.

Table A.13: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
24	Johansson and Rubenowitz	1994	Cross-sectional	209 white-collar workers and 241 blue-collar workers in eight Swedish metal companies	A questionnaire which includes questions on musculoskeletal systems, psychosocial and physical load factors were conducted for this study.	N/A	N/A	For blue-collars; workload factors and work-related symptoms were not significant with LBP whereas psychosocial job factors and musculoskeletal symptoms were correlated. For white-collars; neither psychosocial factors nor back symptoms were correlated with LBP.
25	Lee et al	1995	Cross-sectional	1800 measurements were performed on the transverse and sagittal diameters of vertebral bodies and spinal canals using 90 Korean lumbar vertebrae.	N/A	N/A	Lumbar spinal canal in Koreans were analyzed to observe the ethnic differences.	The mean mid-sagittal diameter of the lumbar spinal canal in Korean population was less than white and African populations.

Table A.14: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
26	Burton	1996	Cross-sectional	A questionnaire survey was conducted from 216 participants who were 11 year old children.	N/A	N/A	A 5 year study for determining the history of back pain during adolescence in boys and girls and exploring the influence of sports participation and lumbar flexibility.	Findings indicate that back pain is more common in boys especially by age 15 years, and there is a significant relationship between sports and back pain for boys.
27	Hall et al	1998	Cross-sectional	Shapes and dimensions of vertebral body endplates (L4, L5 and S1) from 25 males and 21 females were analyzed	N/A	N/A	Gender differences in shapes and dimensions of vertebral body	Even if overall shapes were similar, female endplates were smaller than male.

Table A.15: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
28	Ozguler et al	2000	Cross-sectional	A self administered questionnaire was performed to 725 workers from four occupational sectors to test the associations between non-specific low back pain and several risk factors.	Associations between work related conditions such as awkward postures, frequent lifting, and frequent bending and low back pain were found.	N/A	The impact of gender and BMI were observed.	Warehouse and hospital workers occupations were considered at high risk of experiencing low back pain. The role of gender for LBP was not clear in this study. However, it is observed that women visit a doctor more than a men. The impact of BMI also tested; BMI of 22.60 or more were more likely to visit a health professional and take treatment on low back pain.
29	Dai	2001	Cross-sectional	53 patients (32 women and 21 men with age ranged of 42-73 years) who has degenerative spondylolisthesis at the L4-L5 level were studied.	N/A	N/A	morphological abnormalities of the lumbar facet joints were observed in the patients who has degenerative spondylolisthesis.	Patients with degenerative spondylolisthesis had more facet joint tropism than normal control subjects

Table A.16: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
30	Kerr et al	2001	Case-control	137 case subjects reported a new episode of low back pain to their employer, a large automobile manufacturing complex and 179 control subjects were selected randomly from the study base as cases.	Physical demands were assessed with direct measurements of subjects at their usual jobs.	Individual, clinical and psychosocial variables were assessed by interview.	N/A	Physical and psychosocial demands of work are risk factors for low back pain.
31	Elders and Burdorf	2001	Cross-sectional	229 scaffolders and 59 supervisors performed a questionnaire which includes MMH, awkward postures, strenuous arm position, perceived exertion, psychosocial load, need	The impact of work related conditions on low back pain were observed.	The impact of psychosocial conditions on low back pain was observed.	The impact of age on low back pain was observed.	Overall, the findings indicate that work related risk factors may vary with different definitions of low back pain. It is observed that Scaffolders were at high risk of developing low back pain due to their working conditions.

Table A.17: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
32	Semaan et al	2002	Cross-sectional	160 lumbar vertebrae were analyzed	Subjects over 40 has more degenerative spine.	N/A	N/A	The mean height of the pedicle was almost 16 mm for L1 to L4 and 21 mm for L5. Pedicle width was 7mm for L1 and L2 then rapidly widened to reach 10 mm for L5.
33	Jansen and Burdorf	2003	Cross-sectional	769 workers in nursing homes and older people were observed to determine the relation between physical load and low back pain.	Self-administered questionnaires which includes information on back problems for a period of 12 months were obtained from the workers.	N/A	N/A	The results indicates that there is a high correlation between physical loads and low back pain.

Table A.18: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
34	Cunningham et al	2006	Cross-sectional	A standard questionnaire and random sampling of hospital employees was conducted	A disproportional sample of hospital employees were taken; Administration (76), Medical (21), General support (41), Nursing (49), and Allied professionals (59)	Job satisfaction, social support and mental stress information were collected	N/A	The highest level of sick leave was among nurses and general support staff.
35	Vieira et al	2008	Retrospective Cohort study	Low back disorder claims were conducted from a steel company and a hospital. A questionnaire which include questions on workers' personal traits, life style, history of low back disorder, occupational factors, and the body part discomfort level.	Survey results conducted from 64 welders and 47 nurses from steel company and hospital.	N/A	There were no differences in ages and body mass indexes between welders and nurses.	Low back disorders is common among welders and nurses who have high risk of experiencing low back discomfort by the end of the shift.

Table A.19: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
36	Mohseni-Bandpei et al	2009	Cross-sectional	1100 randomly selected pregnant women were participated in this study to determine the prevalence of LBP.	N/A	N/A	A structured questionnaire (demographic, lifestyle) were used to obtain the pain intensity and functional disability.	This study indicate that more than half of the pregnant women experiencing LBP during pregnancy.
37	Singh et al	2011	Cross-sectional	Morphometric measurements of 100 cadaveric thoracic spines from Indian population were performed.	N/A	N/A	The gender differences in thoracic spines were observed.	The results shows pedicles in females were smaller than males about 5mm in mid-pedicle width dimensions.

Table A.20: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
38	Genevay et al	2011	Cross-sectional	A mailed survey was performed and 1298 employees from different occupational categories (administration staff, nurses, nurse assistants, physicians, support staff and allied health professionals) were attended.	4 point scale (never, sometimes, often, very often) the frequency of eight conditions: working on a computer, handling of patients, maintaining positions for long period of time, pushing or pulling loads, night work, working more than 8 hours per day, carrying loads, working at a poorly adapted work station were conducted with questionnaire.	N/A	The demographic information such as age, gender and BMI were conducted but no associations were investigated.	Nurses had a higher risk of experiencing low back pain and also higher amount of days away from work.

Table A.21: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
39	Banerjee et al	2012	Cross-sectional	95 CT scans were collected from Indians - 73 males and 22 females	N/A	N/A	The morphometric measurements were performed and compared with Asian, European, and American populations.	The statistical analysis showed that pedicle axis length for Indians were smaller at C3, C4 and C5 than Asians, whereas C6 and C7 levels were bigger than Asian.

Table A.22: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
40	Aly and Amin	2013	Cross-sectional	CT scans from 300 Egyptian patients (162 males and 138 females) were analyzed.	N/A	N/A	Mid-sagittal diameter, interpedicular distance and lateral recess depth values were measured for Egyptian population.	It is observed the narrowest level is L3 and the range of mid-sagittal diameter was 11.07 to 26.07mm, the range of the interpedicular distance was 17.00 to 43.41.
41	Hershkovic et al	2013	Cross-sectional	The study population included 829,791 adolescents (470,125 males and 359,666 females).	N/A	N/A	The association between the BMI and body height to spinal deformities were investigated	The prevalence of spinal deformities was significantly greater among the under-weight male and female patients. Increased BMI had a protective effect for developing spinal deformities. No gender differences observed.

Table A.23: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
42	Song et al	2014	Cross-sectional	36 elderly patients with lumbar disc degeneration were selected and they were graded using Pfirrmann grading system.	N/A	N/A	All patients were selected from age range from 65 to 77 years. The health of the disc were analyzed with respect to gender differences.	Results indicate that the sex could influence the severity of disc degeneration.
43	Torrie et al.	2014	Retrospective Cohort study	608 consecutive patients were screened. Lumbar spinal subtype and pelvic parameters were collected from standing lumbar radiographs and they were categorized using Roussouly and Pinheiro-Franco's classification methods. In addition to this, disc degeneration was classified using Pfirrmann grading system.	N/A	N/A	A total of 139 patients (91 females (mean age of 32.6 years) and 48 males) were observed. using classification methods for both lumbar spinal subtype (LSS) and lumbar disc degeneration (LDD) were used to understand the impact of age.	A total of 608 patients were screened but 469 patients were excluded because of some reasons such as back disorders, missing information/data or surgery history. It is observed that median ages of patients were most likely to have back pain.

Table A.24: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
44	Govindu and Babski-Reeves	2014	Cross-sectional	A questionnaire was performed to 60 participants (26 males and 34 females) who were already experienced low back pain. Their job involves manual material handling, and prolonged sitting/standing conditions.	A questionnaire on force, posture, repetition and vibration exposures at work were also collected.	The perceived Stress Scale (PSS) questionnaire and Job Content questionnaire (JCQ) were used.	Information on age, gender, BMI, family history of low back pain, physical activity level, alcohol consumption and smoking habits were collected via questionnaire.	Personal, occupational and psychosocial factors were found to be influence LBP. It is found that psychosocial risk models has the most adequate model, it is followed by personal factors and last one is occupational risk factors. In detail, disc degenerative levels increased with age, obesity also a possible risk factor leading to LBP.

Table A.25: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
45	Ramond-Roquin et al.	2015	Prospective Cohort Study	A random sample of French people from various occupations were participated in this study with a survey	The results indicate that frequent bending, forward or sideways or both has a huge impact on LBP	Low job decision authority, low skill discretion, high psychological demands, low support from coworkers and low support from supervisors have an impact on LBP	The impact of age also considered in this study and for that reason, participants were divided into four groups (20-29, 30-39, 40-49 and 50-59)	21 biomechanical, organizational, psychosocial and individual factors were assessed in order to discover the association between potential risk factors and LBP. All of them has different impact on LBP but the highest association is belongs to the biomechanical factors

Table A.26: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
46	Oliveira et al.	2015	Case-Control	24 twin pairs that were generally and broadly discordant for LBP history	Survey questionnaire was conducted in order to assess the association between physical work to LBP	N/A	To observe how lifestyle and environmental factors affect twin's health status even if they have the same genetic structure	Twins' LBP is related to physical workload
47	Frilander et al.	2016	Longitudinal Cross-sectional study	Health records from 135 males aged 30-50 years were collected	A nationwide health survey were conducted from records of prior compulsory military service	N/A	Several personal information such as height, weight and age were collected to determine the impact of BMI over LBP	Obesity increase the mechanical load on the spine by causing more stress on lumbar spine which means being overweight or obese in every stage of age increase the risk of having LBP

Table A.27: Distribution of the articles with respect to journals Continued

Number of Studies	Author	Year	Study Design	Population	Physical Factors	Psychosocial Factors	Personal Factors	Outcome
48	Jadhav	2016	Cross-sectional	For this study, 178 drivers and 184 non-drivers were recruited to compare the prevalence of LBP.	178 drivers with minimum 2 years of service, no LBP complaints before they started to their current job were joined to this study.	N/A	N/A	It is observed that drivers are at a higher risk for LBP with experiencing prolonged sitting in one posture, night shifts, job dissatisfaction, tobacco use, and lack of exercise.
49	Jin et al.	2016	Cross-sectional	A survey was performed to 151 operation and maintenance personnel in wind farms to investigate the prevalence of low back pain.	Subjects were selected following some criteria; male, having worked no less than 1 year in the current position, no history of significant trauma, no diagnosed rheumatic or tumour and having never had an accident involving the low back region previously.	The results indicate that obsessive compulsive, somatization and depression have an impact on low back pain.	The impact of body dimensions were tested but the sample size of the study was too small to discover accurate results.	This study used a survey method to discover the association between LBP to ergonomic, psychosocial and lifestyle factors. The findings highlighted the prolonged static postures, particularly the squatting position as a risk factor of LBP. The strongest association was discovered with heavy lifting objects and LBP.

Appendix B

IRB Consent Letter



The Auburn University Institutional Review Board has approved this Document for use from 10/21/15 to 10/20/16 Protocol # 15-404.MR.1510

(NOTE: DO NOT SIGN THIS DOCUMENT UNLESS AN IRB APPROVAL STAMP WITH CURRENT DATES HAS BEEN APPLIED TO THIS DOCUMENT.)

**INFORMED CONSENT
for a Research Study entitled**

“Comprehensive Assessment of MRI Scan/Re-scan Variations and Reliability”

You are invited to participate in a research study that uses magnetic resonance imaging (MRI) to obtain disc height and sizes for lumbar levels (L2/L3, L3/L4, L4/L5, and L5/S1) as well as evaluating disc health by disc degeneration grading system. In addition to this, the compressive assessment of scan-rescan variations will be conducted. Menekse Salar, Auburn University Ph.D. Candidate, is conducting the study under the direction of Dr. Richard Seseek, Associate Professor in the Auburn University Department of Industrial and Systems Engineering. You were selected as a possible participant because you are 19 years of age or older.

What will be involved if you participate? If you decide to participate in this research study, you will be asked to undergo magnetic resonance imaging (MRI) scans.

You will first be asked screening questions to make sure it is safe for you to undergo an MRI scan. You will then be asked to lie on a bed that slides into the long tube of the scanner. The scanner is a magnet with a small-enclosed space. Radio waves and strong, changing magnetic fields are used to make images of your body. You will be given earplugs and earphones to protect your ears since these changing magnetic fields cause loud knocking, thumping, or ping-pong noises. You will be asked to remain very still at these times. To help you keep your head perfectly still, we will put cushions around your head.

Two scans will be performed in a single session with approximately fifteen minutes of rest between scans. Each scan lasts about 10 minutes and will never exceed 30 minutes in the bed. Each scan will obtain MRI pictures of the low back and trunk muscles from the lumbar 2 to the lumbar 5 region of the back. Your total time in the scanner will be no more than 50 minutes. Your total time commitment will be approximately 1½ hours.

Please note that none of the scans done during this study are appropriate for clinical interpretation. This means that they are not designed to assess any medical condition you may have. They are not designed to reveal any clinically relevant problems. Rather, they are intended solely for research purposes.

Figure B.1: Consent Letter (Page 1 of 4)

Are there any risks or discomforts?

The risks associated with participating in this study are:

1. The most obvious personal risk from having an MRI is blunt trauma due to metallic objects being brought into the magnetic field. As such, all necessary steps will be taken to make sure neither you nor anyone else who enters the MRI scanner room is in possession of an unrestrained metal object and no unauthorized person will be allowed to enter the MRI scanner room.
2. Participants who have iron or steel implants or clips from surgery within their body or metallic objects such as shrapnel or metal slivers in their body may be pulled by the magnet and cause injury.
3. The MRI machine produces an intermittent loud noise, which some people find annoying.
4. Some participants may feel uncomfortable being in an enclosed place (claustrophobia) and others find it difficult to remain still.
5. Some people experience dizziness or a metallic taste in their mouth if they move their head rapidly in the magnet.
6. Some people experience brief nausea when being put into or taken out of the scanner.
7. Heating and/or burns to persons with tattoos.
8. Some people may experience tingling or twitching sensations.
9. Suffocation resulting from total system failure (emergency magnet shutdown and simultaneous ventilation failure).
10. Unlikely breach of confidentiality (your personal identifiers linked to your MRI images).

Although long-term risk of exposure to the magnet is not known, the possibility of any long-term risk is extremely low based on information accumulated over the past 30 years.

To minimize these risks, we will:

1. Have you fill out a screening form to determine if you have iron or steel implants, clips from surgery, or other metallic objects in your body. If you have implants, clips, or objects in your body, you will not be able to undergo an MRI scan.
2. Ask you to change into surgical scrubs supplied by the center and remove any watches, rings, earrings, or other jewelry or metallic objects. You will be provided a private place to change and you may retain your undergarments. If you are female, you will be asked to remove your bra if it has an underwire or metal fasteners.
3. Scan you with a handheld metal detector to detect any unknown metallic objects.
4. Provide you with either earplugs or a set of headphones specifically designed to work in an MRI scanner.
5. Maintain visual and verbal contact with you during the scan and check with you frequently to determine if you are having any negative feelings or sensations.
6. If some unknown risk becomes a safety issue, the research team will immediately stop the scan and remove you from the scanner.

Figure B.2: Consent Letter (Page 2 of 4)

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Protocol # 15-404 MR 1510

7. You can stop the scan at any time and be immediately removed from the scanner.

Are there any benefits to yourself or others? If you participate in this study, you can expect to receive no direct benefits. Your participation, however, provides the investigator with a greater understanding of the geometry of the low back and trunk muscles in the lumbar region of the back. This may be useful in developing regression equations that can estimate the relative contribution of each back muscle during lifting activities.

Will you receive compensation for participating? To thank you for your time, you will receive \$40.00 in compensation. You will be compensated for whatever portion of the experiment you complete (e.g., \$20.00 for completing ½ of the experiment).

Are there any costs? If you decide to participate, you will not incur any costs. If you require medical attention, you will be responsible for all costs for medical treatment.

If you change your mind about participating, you can withdraw at any time during the study. Your participation is completely voluntary. If you choose to withdraw, your data can be withdrawn as long as it is identifiable. Your decision about whether or not to participate or to stop participating will not jeopardize your future relations with Auburn University, the Samuel Ginn College of Engineering, the Department of Industrial and Systems Engineering or the Auburn University MRI Research Center.

Your privacy will be protected. Any information obtained in connection with this study will remain confidential. Information obtained through your participation may be used to fulfill an educational requirement, published in a professional journal and/or presented at a professional meeting. Your personal information will be linked to the MRI image data using a randomly-generated code. Your personal identifying information such as your name will never be included with the MRI image data. Only your height, weight, age, and gender will be linked to the images. Since MRI data is difficult and expensive to obtain, we will maintain a copy of the code list for a period of 3 years after this experiment. It is possible, that we may contact you about participation in future studies. However, if you do not wish to be contacted in the future, please indicate when signing this consent form and we will delete all links between your personal identifying information and your MRI image data. The confidential link between your personal information and the image data will be stored in a locked filing cabinet in the principal investigators office.

Incidental findings. These procedures are carried out purely for experimental purposes. The MRI scans that are acquired in this study are not the same as those acquired during a clinical examination as requested by a Medical doctor. Therefore, they are not useful to investigate any abnormalities or medical condition you may have. Furthermore, the investigators who will analyze these images are not medical doctors and are not trained to evaluate these scans.

Figure B.3: Consent Letter (Page 3 of 4)

It is possible however that an abnormality may be noticed. If this happens, a brief diagnostic scan will be performed and referred to a radiologist for reading. If you choose to provide the name and contact information of your primary physician, the results of the scan will be provided to them. If you do not have primary physician or do not provide contact information for your primary care physician, the results will be provided to Dr. Fred Kam, M.D. at the Auburn University Medical Clinic, who will discuss the results of the scan with you at your expense.

If you have questions about this study, please ask them now or contact Professor Richard F. Seseek at (334) 844-1552 (seseek@auburn.edu). A copy of this document will be given to you to keep.

If you have questions about your rights as a research participant, you may contact the Auburn University Office of Human Subjects Research or the Institutional Review Board by phone (334)-844-5966 or e-mail at hsubjec@auburn.edu or IRBChair@auburn.edu.

HAVING READ THE INFORMATION PROVIDED, YOU MUST DECIDE WHETHER OR NOT YOU WISH TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES YOUR WILLINGNESS TO PARTICIPATE.

Participant's signature Date Investigator obtaining consent Date

Printed Name

Printed Name

_____ Please initial here if you are interested in participation in future ergonomics studies. By initialing here you provide your consent to future solicitations for study participation. We will not contact you further if you do not initial here.

Please provide your preferred email or phone contact: _____

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Participant's initials _____

Figure B.4: Consent Letter (Page 4 of 4)

Appendix C

Sample Recruitment Flyer

Low Back Modeling Research Study



- *Are you a student at Auburn University?*
- *Are you 19 years of age or older?*
- *Do you want to know what your back looks like?*
- *Are you willing to participate in an MRI study?*

If you answered **YES** to these questions, you may be eligible to participate in the following study: **Comprehensive Assessment of MRI Scan/Rescan Variations and Reliability**

The purpose of this research is to evaluate the inter-rater reliabilities associated with MRI measurement, as well as reliability of the entire MRI data collection process by assessing scan/rescan variations.

There is no direct benefit to you for participating in the study. Participants will receive monetary compensation for participating.

This study is being conducted by the Industrial and Systems Engineering Department at Auburn University. MRI images will be captured at the Auburn University MRI Research Center.

Please contact **Menekse Salar** (mzs0053@auburn.edu -- (678) 907-2896), **Fehmi Capanoglu** (mfc0006@auburn.edu -- (205) 585-8382), or Dr. **Richard Seseek** (seseek@auburn.edu - (334) 844-1552) for more information.

Figure C.1: Flyer

Appendix D

Data Collection Form

Data Collection Form

Subject Code: _____
(Do NOT enter any names or other identifiers!)

Gender: _____

Age: _____

Height: _____

Weight: _____

Scan 1

Researcher positioning subject: _____

Researcher operating MRI Scanner: _____

Scan 2

Researcher positioning subject: _____

Researcher operating MRI Scanner: _____

Figure D.1: Data Collection Form

Appendix E

Data Collection Instruments

1. Siemens Verio Open-Bore 3T MRI Scanner



1.1. Lumbar coils



2. Anthropometric Kit (for height)



Figure E.1: Instruments (Physical)

3. Osirix Software Program (for measuring relevant low back structures)

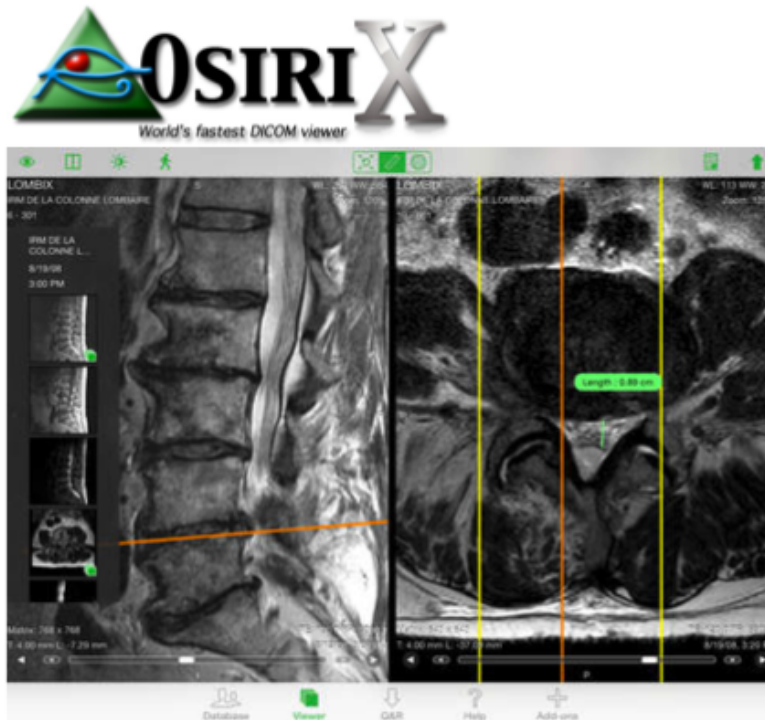


Figure E.2: Instruments (Software)

Appendix F

MRI Pre-Entry Screening Forms

MRI Pre-Entry Screening Form	<small>Auburn University MRI Research Center 560 Devall Drive Suite 202 Auburn, AL 36849 Tel: (334) 844-6747 Fax: (334) 844-0214</small>
This form to be used for: Screening of research subjects immediately prior to an MRI study (File completed form with Principal Investigator) <i>Instructions for completing this form available at http://www.eng.auburn.edu/research/centers/mri/forms</i>	

Name _____
Last First MI

Address _____ City _____

State _____ Zip Code _____

Phone () _____ () _____ () _____
Home Work Cell

Birthdate _____ Email Address _____

AUMRIRC Use Only

Principal Investigator: _____

IRB Protocol # _____

Subject # _____

Date/Time of MRI study __/__/____ __:____

Subject Weight (lbs) _____

Primary Physician (Optional):
 Name _____ Phone () _____

1.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? If yes, give date and type of surgery, and indicate where on your body using the diagram. Date: __/__/____ Type of surgery: _____ Date: __/__/____ Type of surgery: _____ Date: __/__/____ Type of surgery: _____
2.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Have you had any medical condition that prevented you completing an MRI exam in the past or had any related to a previous MRI examination or procedure? If yes, please describe: _____
3.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? If yes, please describe: _____



WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the AU MRI Research Center staff BEFORE entering the MR system room. **The MR system magnet is ALWAYS on.**

4.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have a cardiac pacemaker or implanted cardioverter defibrillator (ICD)?
5.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is there a possibility of metal in your head (for example aneurysm clips, do not include dental work)? If yes, please describe: _____
6.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Have you had an injury to the eye involving a metallic object or fragment (for example, metallic slivers, shavings, foreign body), or have you ever needed an eyewash having worked with metals? If yes, please describe: _____
7.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have an implanted medical device that is electrically, magnetically, or mechanically controlled or activated? If yes, please describe: _____
8.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Females Only: Are you pregnant or is there any possibility that you may be pregnant?
9.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have a breathing problem or motion disorder?
10.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Are you claustrophobic?
11.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have inner ear disorders or experience vertigo or dizziness?
12.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have tattoos or permanent makeup that contains metal?
13.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have body piercing jewelry that cannot be removed?

Figure F.1: Pre-Entry Screening Form (Page 1 of 2)



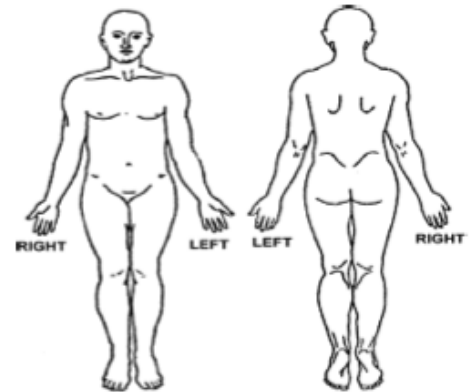
WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the AU MRI Research Center staff BEFORE entering the MR system room. **The MR system magnet is ALWAYS on.**

Please indicate if you have any of the following:

- 14. Yes No Neurostimulation system
- 15. Yes No Spinal cord stimulator
- 16. Yes No Internal electrodes or wires
- 17. Yes No Bone growth/bone fusion stimulator
- 18. Yes No Cochlear, otologic, or other ear implant
- 19. Yes No Insulin or other infusion pump
- 20. Yes No Implanted drug infusion device
- 21. Yes No Any type of prosthesis (eye, penile, etc.)
- 22. Yes No Heart valve prosthesis
- 23. Yes No Eyelid spring or wire
- 24. Yes No Artificial or prosthetic limb
- 25. Yes No Metallic stent, filter, or coil
- 26. Yes No Shunt (spinal or intraventricular)
- 27. Yes No Vascular access port and/or catheter
- 28. Yes No Radiation seeds or implants
- 29. Yes No Swan-Ganz or thermodilution catheter
- 30. Yes No Medication patch (Nicotine, Nitroglycerine)
- 31. Yes No Any metallic fragment or foreign body
- 32. Yes No Wire mesh implant
- 33. Yes No Tissue expander (e.g., breast)
- 34. Yes No Surgical staples, clips, or metallic sutures
- 35. Yes No Joint replacement (hip, knee, etc.)
- 36. Yes No Bone/joint pin, screw, nail, wire, plate, etc.
- 37. Yes No IUD, diaphragm, or pessary

- 38. Yes No Dentures or partial plates
- 39. Yes No Tattoo or permanent makeup
- 40. Yes No Body piercing jewelry
- 41. Yes No Hearing aid
(Remove before entering MRI scanner room)
- 42. Yes No Other implant _____

Please mark on the figure(s) below the location of any implant or metal inside of or on your body.



IMPORTANT INSTRUCTIONS

Before entering the MR scanner room, you must remove all metallic objects including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clippers, tools, clothing with metal fasteners, & clothing with metallic threads.

Please consult the research staff if you have any question or concern BEFORE you enter the MR scanner room.

NOTE: You may be advised or required to wear earplugs or other hearing protection during the MR procedure to prevent possible problems or hazards related to acoustic noise.

I attest that the above information is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo.

This form is valid only on the day it is completed.

Signature of Person Completing Form: _____
Signature Date

Form Completed By: Subject Relative _____
Print Name Relationship to Subject

Form Information Reviewed By: _____
Print Name Signature

Form Information Reviewed By: _____
Print Name Signature

Figure F.2: Pre-Entry Screening Form (Page 2 of 2)