Spring 5-31-2009

In vitro comparison of a new stand-alone anterior lumbar interbody cage device with established fixation techniques

Nitin Chawla
New Jersey Institute of Technology

ABSTRACT

IN VITRO COMPARISON OF A NEW STAND-ALONE ANTERIOR LUMBAR INTERBODY CAGE DEVICE WITH ESTABLISHED FIXATION TECHNIQUES

by
Nitin Chawla

Around 70% of the population in the United States experience low back pain at some point of their lives, of these 4% underwent surgical intervention on the lumbar spine to relieve the pain. Spinal arthrodesis, i.e. joint fusion, is beneficial in many cases as the final option for patients suffering from certain types of low back pain (LBP). In order to promote solid fusion across a decompressed spinal segment, interbody spacers/cages are used with and without posterior instrumentation to provide an initial "rigid" fixation of the segment.

In this study three fresh/frozen human cadaveric lumbar spines were used. Each lumbar spine was dissected into two Functional Spinal Units (FSUs, L3-L4 and L5-S1) making a total of 6 motion segments.

The objective of this study was to evaluate the biomechanical behavior of a new stand-alone anterior lumbar interbody device, by assessing its performance in terms of FSU motion in comparison with the intact FSU and FSUs additional posterior fixation (i.e., facet bolts and pedicle screws).

Descriptive statistics and analysis of variance (ANOVA) was used to determine if the differences between the different treatment groups are significant or not. Statistical analysis was also used to determine the contribution of the supplemental fixation for the anterior interbody fusion device (AFD) system.

IN VITRO COMPARISON OF A NEW STAND-ALONE ANTERIOR LUMBAR INTERBODY CAGE DEVICE WITH ESTABLISHED FIXATION TECHNIQUES

by
Nitin Chawla

A Thesis
Submitted to the Faculty of
New Jersey Institute of Technology
in Partial Fulfillment of the Requirements for the Degree of
Master of Science in Biomedical Engineering

Department of Biomedical Engineering

May 2009

Blank Page

APPROVAL PAGE

IN VITRO COMPARISON OF A NEW STAND-ALONE ANTERIOR LUMBAR INTERBODY CAGE DEVICE WITH ESTABLISHED FIXATION TECHNIQUES

Nitin Chawla

5/21/09

Dr. William C. Van Buskirk, Thesis Co-Advisor — Date
Distinguished Professor of Biomedical Engineering, NJIT

5/26/09

Dr. Robert F. Heary, Thesis Co-Advisor — Date
Professor of Neurological Surgery
Director, Spine Research Laboratory, UMDNJ-NJMS

5/21/09

Dr. Richard A. Foulds, Thesis Committee — Date
Associate Professor of Biomedical Engineering, NJIT

5/28/09

Dr. Max Roman, Thesis Committee — Date
Assistant Research Professor
Director, MS Program of Biomedical Engineering, NJIT

BIOGRAPHICAL SKETCH

Author: Nitin Chawla

Degree: Master of Science

Date: May 2009

Undergraduate and Graduate Education:

- Master of Science in Biomedical Engineering
  New Jersey Institute of Technology, Newark, NJ, 2009

- Bachelor of Science in Biomedical Engineering
  New Jersey Institute of Technology, Newark, NJ, 2006

Major: Biomedical Engineering

Presentations and Publications:

Bharat Biswal, Nitin Chawla, "Determination of the Variability of fMRI Responses Using Deconvolution Analysis", poster presentation at the HBM (Human Brain Mapping) Conference in Florence, Italy, June 2006, Abstract 25W-AM.

Bharat Biswal, Nitin Chawla, "Determination of the Variability of fMRI Responses Using Deconvolution Analysis", poster presentation at the International Society for Magnetic Resonance in Medicine (ISMRM), Seattle, Washington on May 6-12, 2006, Abstract 2441.

Panteleimon Athanasiou, Nitin Chawla, Elizabeth Leichtnam, "Assistive Robotic Manipulator Interface", Senior project won 3rd place for the poster competition at the 32nd Annual Northeast Bioengineering Conference (NEBC), Lafayette, PA on April 1-2, 2006.

Bharat Biswal, Nitin Chawla, "Determination of the Variability of fMRI Responses Using Deconvolution Analysis", oral presentation at the Northeast Bioengineering Conference (NEBC), Hoboken, NJ, April 2-3, 2005 Abstract 3.1.3.

In Hindi:

मैं अपने माता, पीता, बहिनों और जीजाजी का शुक्रिया अदा करना चाहता हूँ | उनके सालो की मेहनत और धैर्य की वजह से आज मैं इस मुकाम तक पहुच सका हूँ | मेरे माता पीता ने मेरी सफलता के लिए कई बलिदान दिए | मैं उनका यह एहसान कभी नहीं भुला पाऊंगा | उन्होंने मेरी सारी मानोकामनाये बेझिझक पूरी की |

आज मैं जो कुछ भी हूँ अपने परिवार की वजह से हूँ | भगवान् इन सबको लंबी उम्र और खुशहाल ज़िन्दगी दे |

Translated in English

I would like to express gratitude towards my parents, sisters and brothers-in-law. Due to their years of efforts and patience, I was able to reach this new milestone in my life. To this day they have always fulfilled my wishes. My parents have made many sacrifices to ensure my success and well being. I will never forget their favors.

Whatever I am today is because of the support and encouragement from my family. I wish to God to bless them with long, healthy and happy life.

ACKNOWLEDGMENT

The work contained herein was made possible by many generous people who have supported my efforts. I am deeply indebted to my primary advisor, Dr. Robert F. Heary, for his tremendous support throughout the study. Without his help, this study would not be possible. I would like to thank members of my committee who provided significant insight into problems related to the content of my work, revealing situations I would not have considered: Dr. William C. Van Buskirk, Dr. Richard A. Foulds and Dr. Max Roman. I would like to thank Dr. Aria Sabit for his contribution during testing.

A special thanks to Dr. Lisa Ferrara for being an inspiration. Her knowledge and previous experiences guided me well throughout the process of this study. I would like to thank Bharath Kumar Parepalli for his contribution and support to this work. His expertise in performing in-vitro studies and support throughout the process really brought me this far. I would also like to thank Greg Conner for his support in the study. Both Bharath and Greg spent hours with me performing biomechanical testing. I would like to thank Biomet Spine for funding the project. I would like to acknowledge the following from Biomet Spine for their support and encouragement throughout this project Anthony Defalco, Rui Ferreira and Kirk Bailey.

Finally, I take this opportunity to express my profound gratitude to my parents, sisters and brothers-in-law for their moral support and patience during my study at NJIT; Especially my brother in law Dharmesh Thakkar for helping me with the corrections and formatting of this document.

TABLE OF CONTENTS

TABLE OF CONTENTS
(Continued)

Chapter | Page

TABLES OF CONTENTS
(Continued)

LIST OF TABLES

LIST OF TABLES
(Continued)

Table **Page**

LIST OF FIGURES

Figure **Page**

LIST OF FIGURES
(Continued)

Figure **Page**

LIST OF FIGURES
(Continued)

Figure **Page**

CHAPTER 1

INTRODUCTION

1.1 Overview

This chapter gives an overview of the anatomy of the spine, focusing on the lumbar spine. It discusses intervertebral disc aging and degeneration. Finally, the study design and objectives are addressed.

1.2 Background

1.2.1 Anatomy of the Human Spine

The spine, also known as the vertebral column or the spinal column consists of series of bones called vertebrae. The spine consists of four main regions (Figure 1): cervical (neck), thoracic (chest), lumbar (lower back) and sacrum (pelvic).

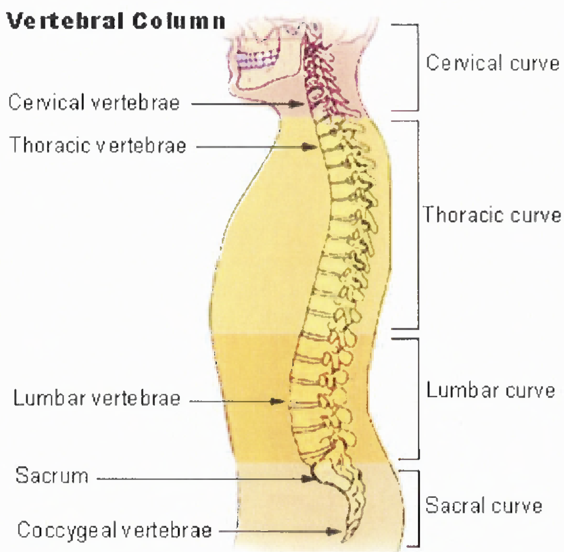


Figure 1.1 Vertebral Column Illustration.
[3]Source: http://training.seer.cancer.gov/module_anatomy/unit3_5_skeleton_divisions.html#

The cervical spine consists of 7 vertebrae and its main role is to support weight of the head (approximately 10-12 pounds). It has the greatest range of motion. The normal curve of neck is called lordosis (Figure 1.2).[1]

The thoracic spine helps protect the organs inside the chest such as heart and lungs by creating a cage. It consists of 12 vertebrae each connected to two ribs. The normal thoracic curve is called kyphosis (Figure 2).

The human lumbar spine consists of five vertebrae (L1 through L5) that are subjected to the highest forces and moments of the spine (Figure 1.3). Thus, they are the largest and strongest of the vertebral bodies. These bones are optimized for structural support as opposed to flexibility (Figure 1.4). The normal curve of lumbar region is also called lordosis (Figure 1.2).

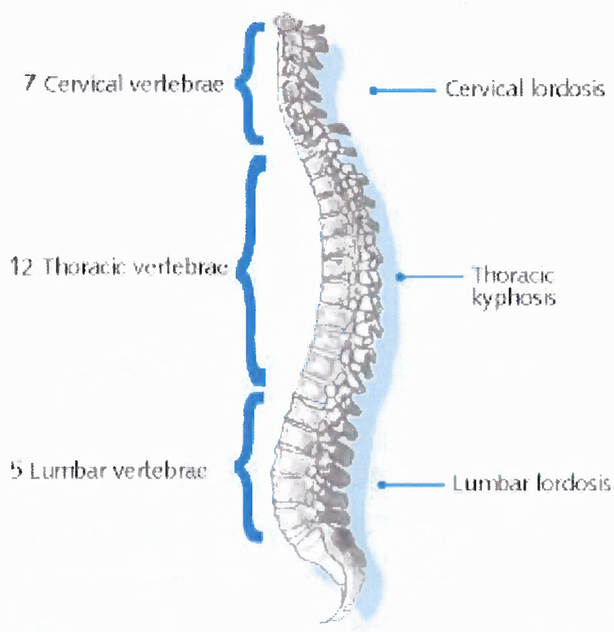


Figure 1.2 Spine Curves.
[2]Source: http://www.nationalpainfoundation.org/MyTreatment/articles/BackAndNeck_Part_2.asp

The sacrum is a formation of five fused vertebrae that form the sacrum and coccyx.

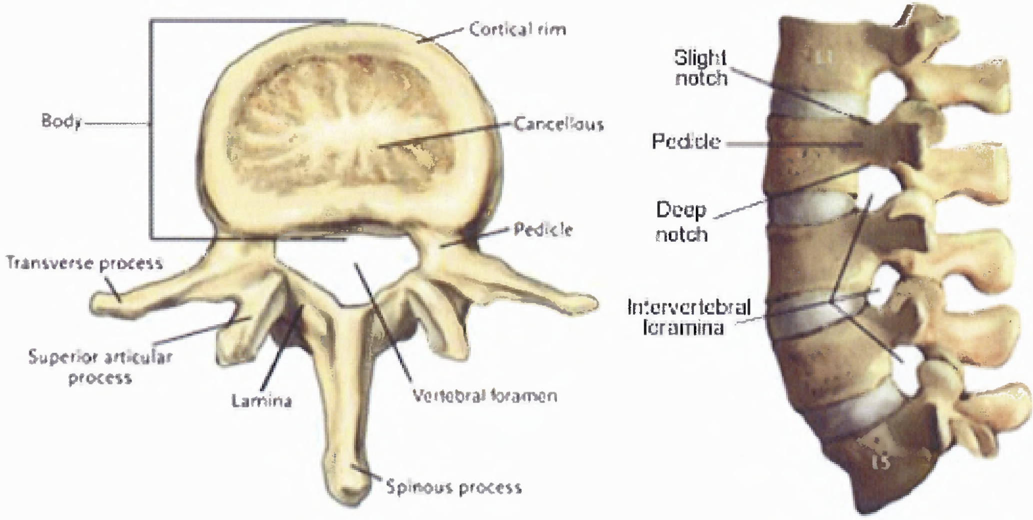


Figure 1.3 Left: An axial view of typical vertebra; Right: Lateral view of lumbar spine.

[12]Source: Bellenir K. Back & Neck Disorder Sourcebook [Omnigraphics, Inc.], 1997. Available from: http://www.back.com/anatomy-lumbar.html. Accessed January 26th, 2009.

Each vertebra has its distinctive features based on its location but they all share some basic attributes. All vertebral bodies are drum shaped allowing it to bear load; the posterior arch is formed by lamina, pedicles and facet joints; and the transverse processes attach to muscles.[1]

Pedicles are short and rounded thick processes that protrude backward (Figure 1.3 and 1.4) on either side, made of thick cortical bone. They act as side walls protecting the spinal cord and nerve roots. The space created between the facet joints and pedicles of a vertebral body is called the vertebral foramen (Figure 1.3) through which spinal nerves pass, connecting to the rest of the body.[1]

Laminae are two plates of bone that extend medially from pedicles, forming a wall of vertebral foramen (Figure 1.3). Lamina and pedicles form the vertebral arch. [12] The lamina from both sides extends and joins to form the spinous process.

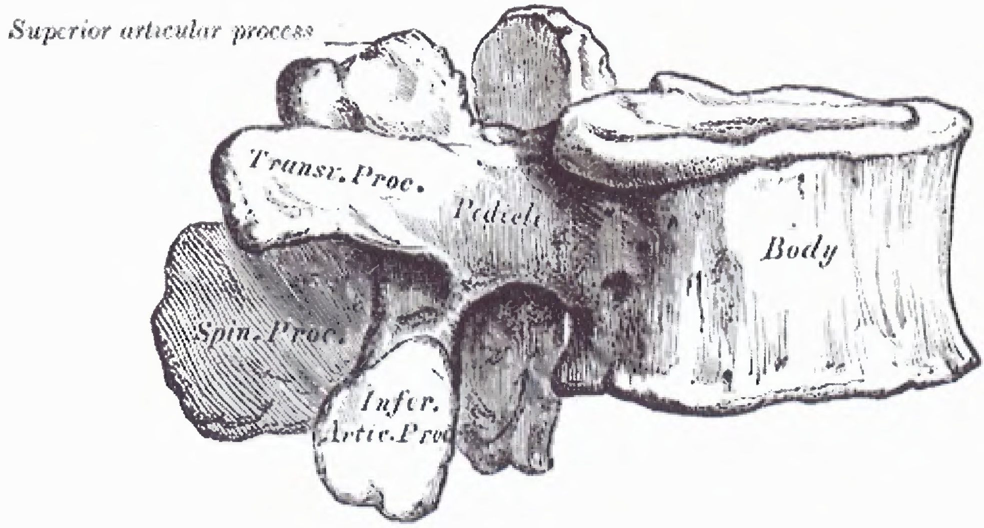


Figure 1.4 Lumbar Vertebra.

[26] Source: Gray H, Clemente CD. *Anatomy of the human body*. 30th American ed. Philadelphia: Lea & Febiger, 1985.

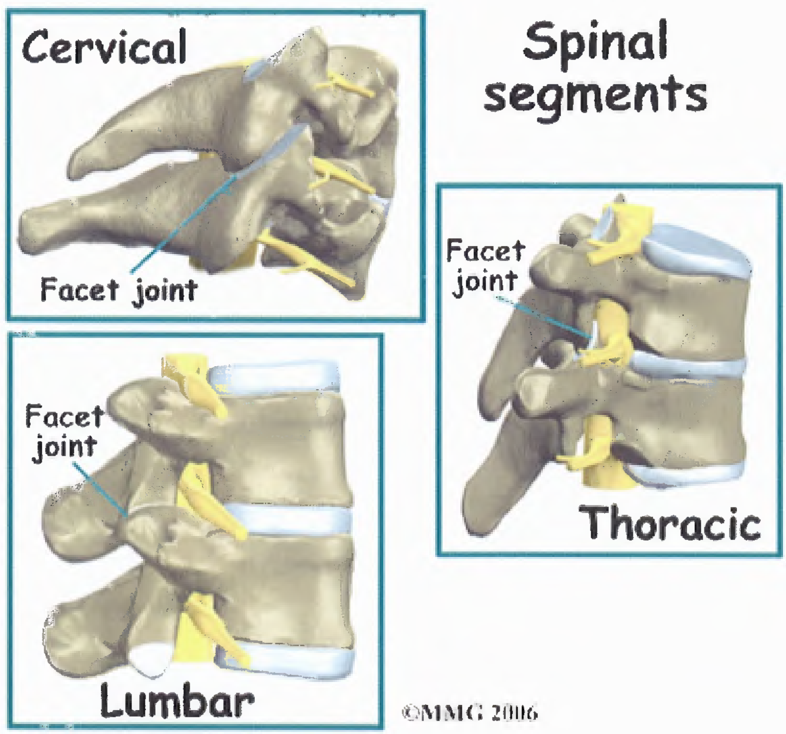


Figure 1.5 Facet joints.

[7]Source: http://www.eorthopod.com/public/patient_education/6633/facet_joint_injections.html

Facet joints are articular processes (Figure 1.3a) between vertebral bodies (Figure

1.5). The facet joints along with the intervertebral discs at each level allow the body to flex, extend, bend and rotate, providing the six degrees of motion. They are covered with smooth cartilage (like the knee joint) that helps sections of vertebral bodies articulate smoothly.[12]

Transverse processes project on each side of vertebral body. They act as points of attachment with ligaments and muscles.

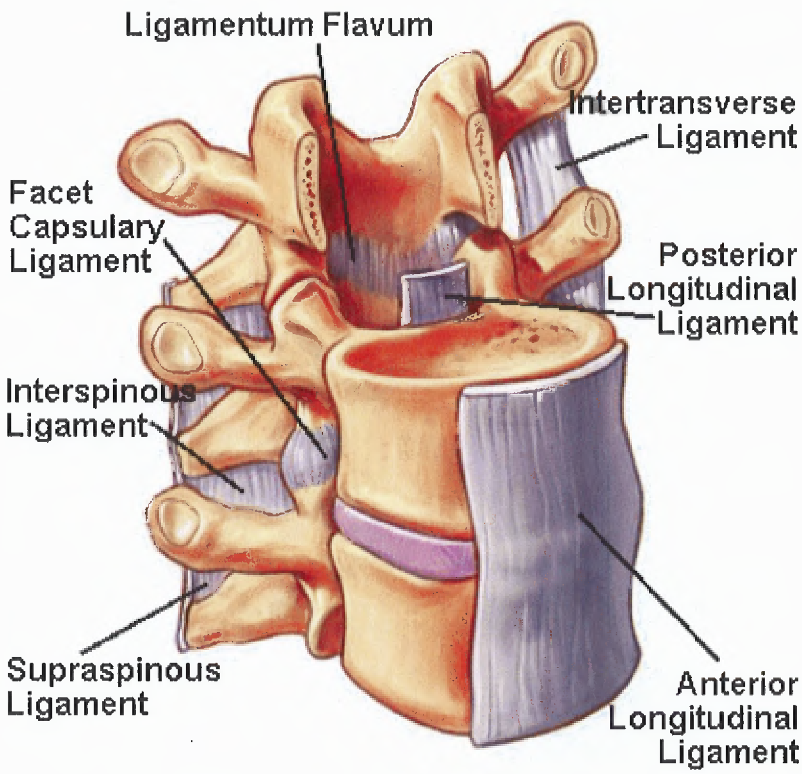


Figure 1.6 Spinal Ligaments.

[50]Source: http://www.spineuniverse.com/displayarticle.php/article1394.html

The ligaments and tendons hold a critical role in supporting the structure of spine. Ligaments connect bone to bone and hold the vertebrae and discs together; on the other hand tendons connect bone to muscles. Both work together in stabilizing the spine and guarding it against extreme movements that can cause damage.[50]

It is important to understand the differences in role certain ligaments play in the lumbar spine. A study carried out by Rissanen et al.[49] found that interspinous ligaments can be expected to make very minor or no contribution to the clinical stability of the lower lumbar spine in an adult. On the other hand supraspinous ligaments play a major role in the lumbar spine. A study carried out by Myklebust et al.[38] observed ligaments individually by removing all but the ligament to be tested. When compressive force was applied, the interspinous ligaments failed in range between 95-185 N, and the supraspinous ligaments yielded in range of 293-750 N.

Currently the exact role of ligamentum flavum (aka yellow ligament) is unknown. The yellow ligament is significantly thicker in the lumbar region (4-6 mm) except at L5-S1 (1.5 mm). This can be related anatomically to much greater flexion/extension and axial rotation of L5-S1 in comparison with lumbar FSU's located above it.[61]

Intervertebral discs, as the name suggests, are located between vertebrae. They act as shock absorbers of the spine and constitute of 1/3 of the total length of the spine. They are the largest organs in human body that do not have their own blood supply.[12] The disc contains an outer region called annulus fibrosus that acts as a retaining ring around a white jelly-like region called the nucleus pulposus (Figure 1.7). The annulus which contains collagen fibers that are oriented at $\pm 30^{\circ}$ with the horizontal provides weight bearing strength.[4]

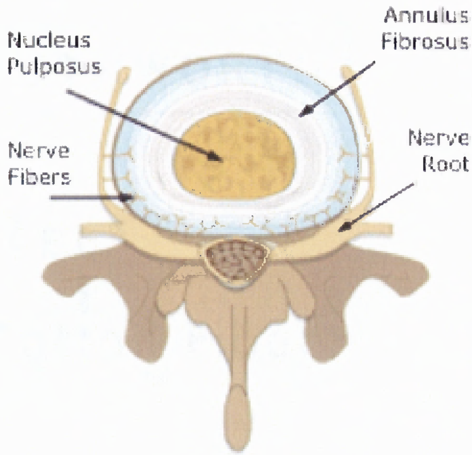


Figure 1.7 Intervertebral Disc.
[4]Source: http://www.spinalrestoration.com/patients/index.html

The material properties of anatomy found in the lumbar spine has been listed in Table 1.1. Some of the data from the literature vary because of variation among specimens.

Table 1.1 Material properties of intact human lumbar spine

Anatomy	Young's Modulus (MPa)	Poisson's Ratio
Bony Regions		
Cortical Bone	12000	0.30
Cancellous Bone	100	0.20
Posterior Bone	3500	0.25
Intervertebral Disc		
Annulus	2.5	0.45
Annulus Fibers	357.5-550	0.30
Nucleus Pulposus	1.0	0.4999
Endplate	24	0.4
Ligaments		
Anterior Longitudinal	15.6, 17.8, 20.0	0.30
Posterior Longitudinal	10.0, 20.0	0.30
Transverse	12.0, 59.0	0.30
Ligamentum Flavum	8.5, 13.0, 19.5	0.30
Interspinous	9.8, 12.0	0.30
Supraspinous	4.2, 8.8, 15.0	0.30
Capsular	8.48, 32.9	0.30

Source: [24,62,63]

1.2.2 Disc Aging and Degeneration

Back pain has a strong correlation with disc degeneration.[33] Disc degeneration directly affects the spinal muscles and ligaments, altering the disc height and its mechanics. In long run it can lead to spinal stenosis, which is a major cause of debilitating pain in elderly.

Disc degeneration can begin as early as age 11-16 years.[15] According to Miller, J et al.[35] approximately 20% of population in teens show mild signs of degeneration which increases steeply with age, more prominently in males. It is estimated that 10% of men at the age of 50 and 60% at the age of 70 have severely degenerated discs.

Figure 1.8 Lumbar DDD.
[5]Source:

http://www.eorthopod.com/public/patient_education/6495/lumbar_degenerative_disc_disease.html

During disc degeneration, the biggest change that occurs is loss of proteoglycan, which has a direct effect on its ability to bear load.[34] The osmotic pressure of the disc falls due to the loss of proteoglycan, which leads to reduction of its ability in maintaining hydration during loading conditions.[54]

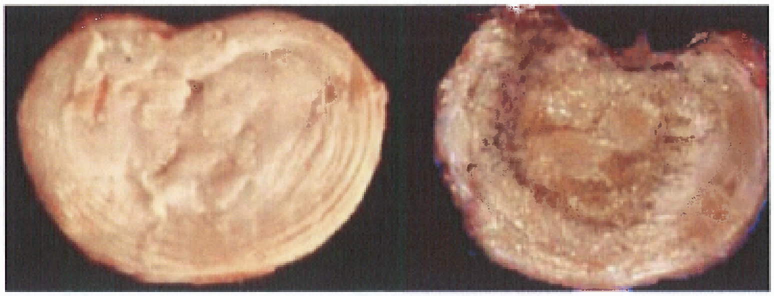


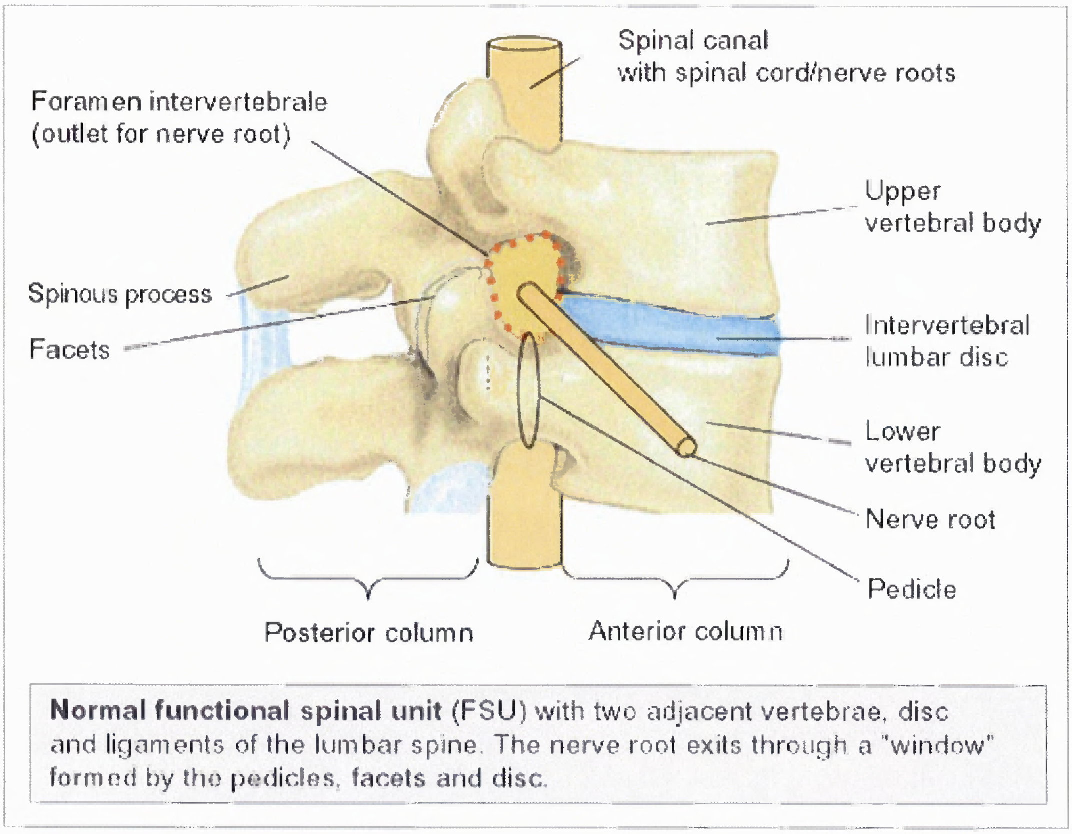
Figure 1.9 The normal and degenerated lumbar intervertebral disc.

[55]Source: Urban JP, Roberts S. Degeneration of the intervertebral disc. *Arthritis Res Ther* 2003; 5:120-30

The figure above shows a normal disc on the left in which the annulus lamellae surrounding the nucleus can be clearly differentiated. On the other hand the degenerated disc on the right has dehydrated nucleus and disorganized annulus.[55]

1.3 Objective

The objective of this study is to look at the effect different types of fixation hardware applies on the FSU stiffness and its range of motion. In this study a new stand-alone anterior interbody fusion device (AFD) will be assessed. The study will biomechanically evaluate the fixation of the AFD with supplemental posterior stabilization, to determine if supplemental fixation provides significantly greater stability to the interbody fusion site.



Normal functional spinal unit (FSU) with two adjacent vertebrae, disc and ligaments of the lumbar spine. The nerve root exits through a "window" formed by the pedicles, facets and disc.

Figure 1.10 Functional Spinal Unit.

[6]Source: http://www.eurospine.org/cm_data/motion_Fig05_en.jpg

To evaluate the stability of the segment, the biomechanical behavior of the FSU will be mapped for a variety of testing paradigms listed in Chapter 3. The goal is to biomechanically quantify the relative stiffness and changes in the motion occurring in the lumbar spine motion segment after implantation under simulated physiological loading paradigms.

CHAPTER 2

LITERATURE REVIEW

2.1 Overview

Back pain is a leading cause of work disability throughout the world. On the list of reasons for visits to physicians, low back pain ranks second after upper respiratory problems [28,9]. Around 70% of the population in the United States has experienced low back pain in their lives, in which 4% had to undergo surgical intervention on the lumbar spine. The annual cost of treatment for low back pain is estimated to be a staggering $50 billion yearly.

Spinal arthrodesis (joint fusion) in many cases is the final option for patients suffering from certain types of low back pain (LBP). The purpose of spinal fusion is to correct or prevent any further deformity and stabilize the spine after trauma. Pathologic degeneration of the bony elements, intervertebral disc, and soft tissues are the primary indications for spinal fusion.

Non-conservative treatments with surgical interventions that are currently being used include intervertebral fusion with a bone graft, fusion involving instrumentation with cages and posterior instrumentation and artificial discs. Fusion with cages using both posterior and anterior instrumentation has gained popularity amongst the surgeons to treat LBP caused by disc degeneration. Different materials like titanium, steel, PEEK (Polyether Ether Ketone) are being used for these cage devices.

2.2 Lower Back Pain

2.2.1 Causes

There are many causes of LBP mainly divided into three categories: Mechanical (80-90%), Neurogenic (5-15%) and Non-Mechanical Spinal Conditions (1-2%). Each category can then be subdivided into common known causes of LBP. Some of those causes are as follows [17]:

- Mechanical (Source of pain is in the spine or its supporting structures) – Degenerative Disc Disease, Spondylolysis, Spondylolisthesis, Instability, Vertebral Fracture
- Neurogenic (Symptoms that originate from irritation of a nerve root(s)) – Herniated Disc, Spinal Stenosis, Osteophytic Nerve Composition, Infection (for example: herpes zoster)
- Non-Mechanical Spinal Conditions – Infection, Inflammatory Arthritis (such as rheumatoid arthritis, spondyloarthropathies etc.)

Figure 1 depicts the anatomical condition when affected by some of the causes listed above

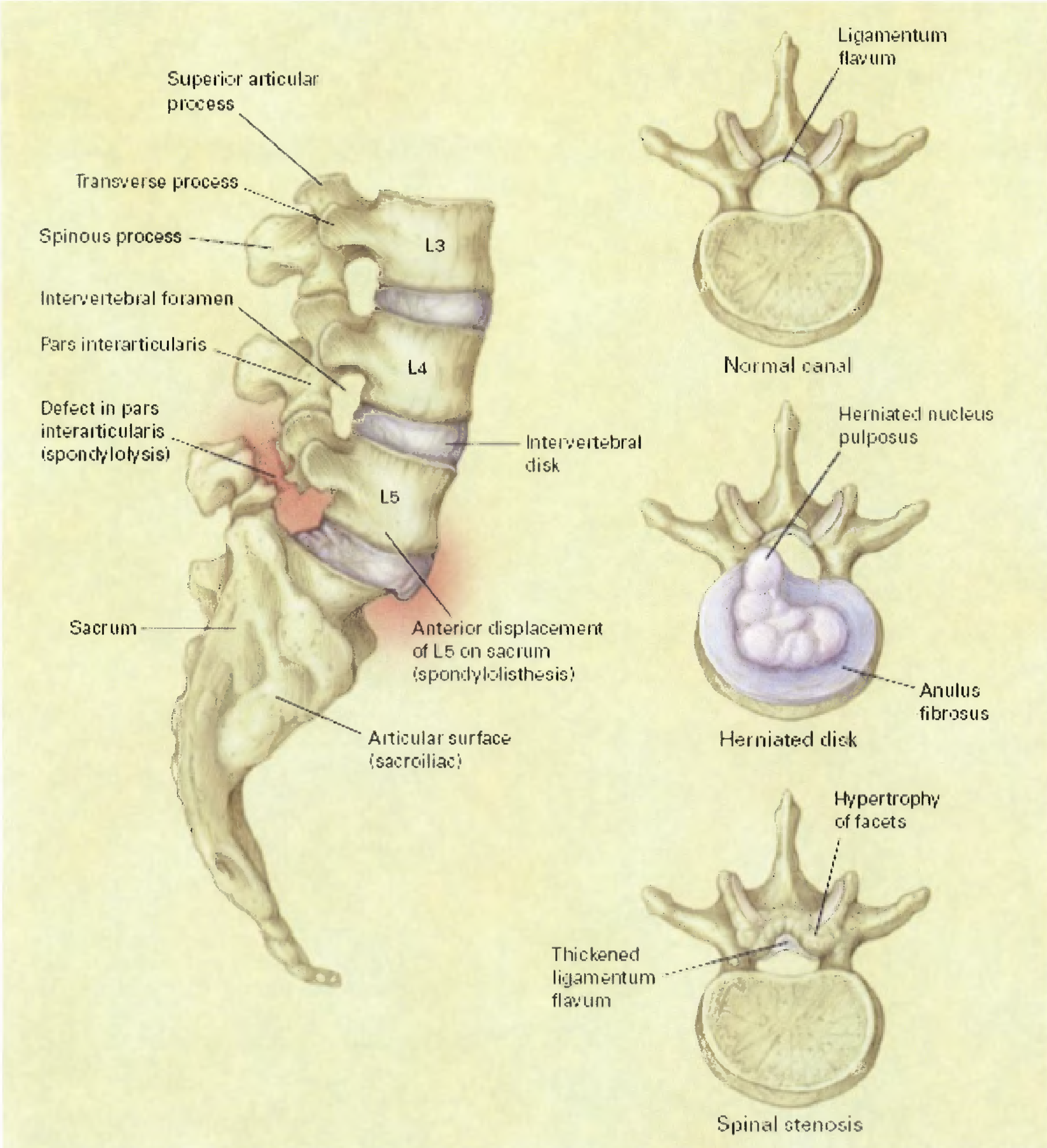


Figure 2.1 Common Pathoanatomical Conditions of the Lumbar Spine.

[19] Source: Deyo RA, Weinstein JN (2001) Low back pain. N Engl J Med 344:363-370

2.2.2 Treatment Options

Patients with LBP have different choices of treatment available depending on its cause and severity. Conservative treatments of LBP do not involve invasive methods. Aerobic exercise, muscular toning, stretching, patient education are part of physical therapy. This can be done along with administered medications prescribed by the doctor to control pain. A slow introduction of the patient's back into the workplace can help them ease into a normal routine and recovery into full function.

A frequent cause of LBP especially in young adults is degenerative disc disease (DDD). Patients with DDD can usually manage their pain by conservative methods (non-surgical). Patients can be treated by active or passive treatments. Active treatments require the patient's action for example exercising, quitting smoking, weight loss and ergonomics. Passive treatments can be done by administering pain medication, chiropractic manipulation, physical therapy, epidural injections, ultrasound treatments and massage.[53]

A surgical procedure is necessary in cases where non-surgical treatments are not successful after at least 6-12 months. Surgical treatments for LBP include fusion, motion-preservation (artificial disc replacement, posterior dynamic stabilization), laminectomy and nucleoplasty.

Spinal fusion surgery can be considered for patients whose LBP is caused by spondylolisthesis, DDD, spinal stenosis, herniated discs, spinal injury, infection, tumor and deformities. Spinal fusion may also be performed on patients as a follow up to decompression and debridement procedures.[21]

According to a review article on spinal fusion by Lee et al.[30], about 60-65% of all lumbar fusion cases are performed due to DDD, which encompasses internal disc disruption, disc resorption, stable disc degeneration, and unstable disc degeneration (degenerative spondylolisthesis and degenerative scoliosis).

2.3 Fusion

In 2001, the yearly rate of spinal fusion surgeries in United States reached close to 300,000.[18] There are many advantages of fusing a spinal segment. The reason for its popularity is because it can maintain corrected deformity, prevent progression of spinal deformity and stabilize the spinal structure at the treated level.[23]

The sole purpose of fusion is to reduce motion across a spinal segment by obtaining a solid union between two or more vertebrae. Fusion may involve use of supplemental fixation such as plates, screws and cages.

Fusion can be achieved from different surgical approaches. In past few decades mainly three techniques have been used to achieve circumferential interbody fusion surgery: PLIF, ALIF and TLIF (Posterior, Anterior and Transforaminal Interbody Fusion respectively).[37]

According to Wolff's law a healthy bone adapts and remodels itself when placed under load. This implies that the probability for fusion is much higher when grafts are placed under compression. It is important to note that 80% of the spinal loads and 90% of the articular surface are available for fusion in the interbody space (Figure 2.2). A study by Mummaneni et al.[37] compared the advantages of lumbar interbody fusion (LIF) over posterolateral fusion (PLF). The rate of fusion with interbody fixation is reported higher than PLF.

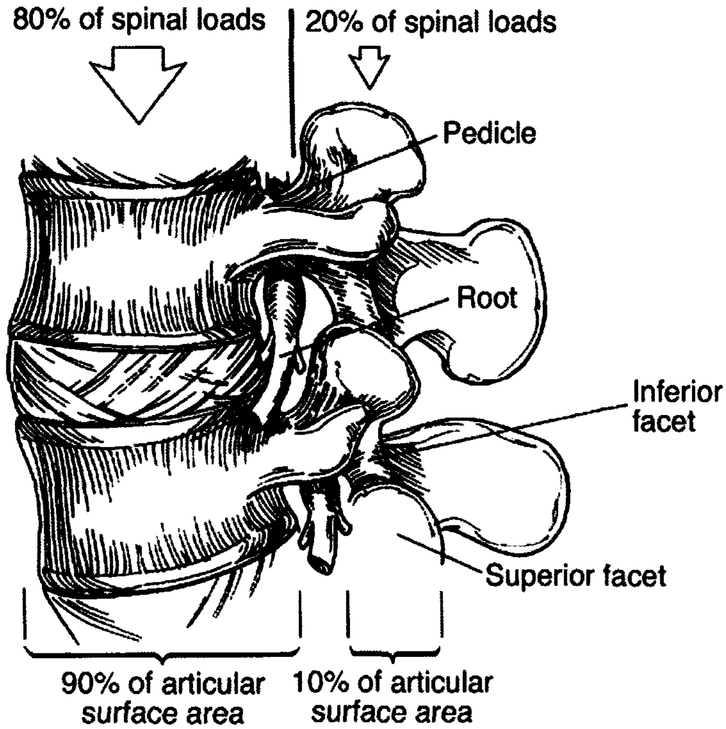


Figure 2.2 Illustration of spinal loads and articular surface area across the lumbar column.
[37]Source: Mummaneni PV, Haid RW, Rodts GE. Lumbar interbody fusion: state-of-the-art technical advances. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2004. J Neurosurg Spine 2004;1:24-30

A study published in the European Spine Journal, advocates 360° fusion using an ALIF (Anterior Lumbar Interbody Fusion) device in combination with posterior spinal instrumentation (pedicle screws or translaminar screws, or facet screws) also called the SCAPF (Simultaneous Combined Anterior and Posterior Fusion), reporting fusion rates between 85-95%.[39] Such combination surgeries require turning the patient, adding substantial muscle stripping, operative time, and blood loss.[13,22,31] This adds morbidity to the procedure causing extended recovery period.[11] Figure 2.3 shows X-ray of a patient who received threaded cylindrical ALIF devices augmented by translaminar screws from the posterior.

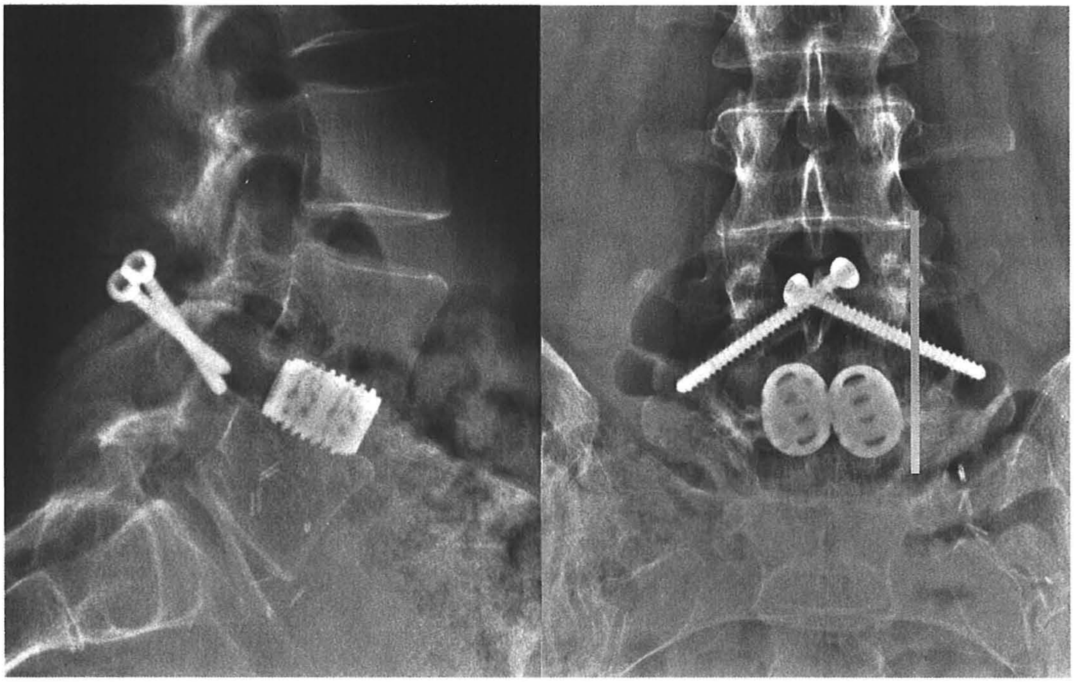


Figure 2.3 Anterior interbody fusion with threaded titanium cylinders with posterior translaminar screws.

[27] Source: Grob D, Humke T. Translaminar screw fixation in the lumbar spine: technique, indications, results. *European Spine Journal* 1998; 7:178-86.

2.4 In vitro Studies

It is important to understand the advantages of interbody fusion devices. They are designed to provide mechanical support to the vertebral bodies while fusion occurs. A study conducted by Polly et al.[47] assessed the effect of two different rod diameters of the pedicle screw system when implanted along with an intervertebral cage on construct stiffness and rod strain. For this study they used a long-segment anterior thoracic scoliosis model with varying levels of intervertebral reconstruction. Sixteen fresh-frozen calf spine specimens (T1 to L1) were tested for axial compression, flexion, extension and lateral bending. The specimens were implanted with variations in rod diameters (4 mm or 5 mm), and different number of cages (single/dual/three) were used. All the seven levels were used for intervertebral cage reconstructions with posterior fixation. The highest rod strain was observed in axial compression when no structural interbody supports were used. It was also noticed that using interbody cages significantly decreased rod strain of the pedicle screw system.[47]

A study by Lund et al.[32] compared the effects of three different designs of PLIF (Posterior Lumbar Interbody Fusion) cages with or without posterior instrumentation using human cadaveric spines. They used total of 18 FSU's (9 L2-L3 and 9 L4-L5) dividing into 6 FSU's for each interbody cage. During the tests multidirectional flexibility was tested by applying pure moments in flexion, extension, axial bilateral bending and axial bilateral torsion.[32] The study found no difference in stabilization between the three designs. All three designs performed well during flexion and lateral bending but performed poorly in extension and axial torsion. Addition of posterior transpedicular instrumentation provided much greater stabilization in flexion, extension and lateral bending. Adding cross-bracing to the pedicle instrumentation stabilized the spine axial rotation.

Goh et al.[25] conducted a study on the influence of a PLIF cage on lumbar spine stability. In this study eight lumbar FSU's were tested for intact, after total bilateral facetectomy and three sets of cage that were progressively larger in size for bending and torsional stiffness. They noted that after facetectomy, the FSU stiffness decreased by 48% in extension and 25% in lateral bending (LB) and 39% in torsion when compared to the intact FSU. With the posterior instrumentation of small cages in the facetectomized FSU's, only extension stiffness was restored. Medium cages restored LB stiffness whereas large cages restored torsional stiffness. The authors concluded that for facetectomized FSU's, cage size has an effect on LB and torsional stiffness.

A study by Wang et al.[58] was designed to compare the stability imparted by the Bagby-and-Kuslich (BAK) cages placed using an oblique and posterior approaches and the effect of supplementary posterior instrumentation. This study tested nine human cadaveric spines for intact, posterior destabilization, stabilization using two parallel BAK cages or one oblique BAK cage. In their conclusion, they stated that both cage insertion techniques provide similar stability and that posterior instrumentation gives additional stability to the spinal segment. They also derived that the oblique insertion is more favorable since it requires less exposure, enables precise implantation, and is less expensive.

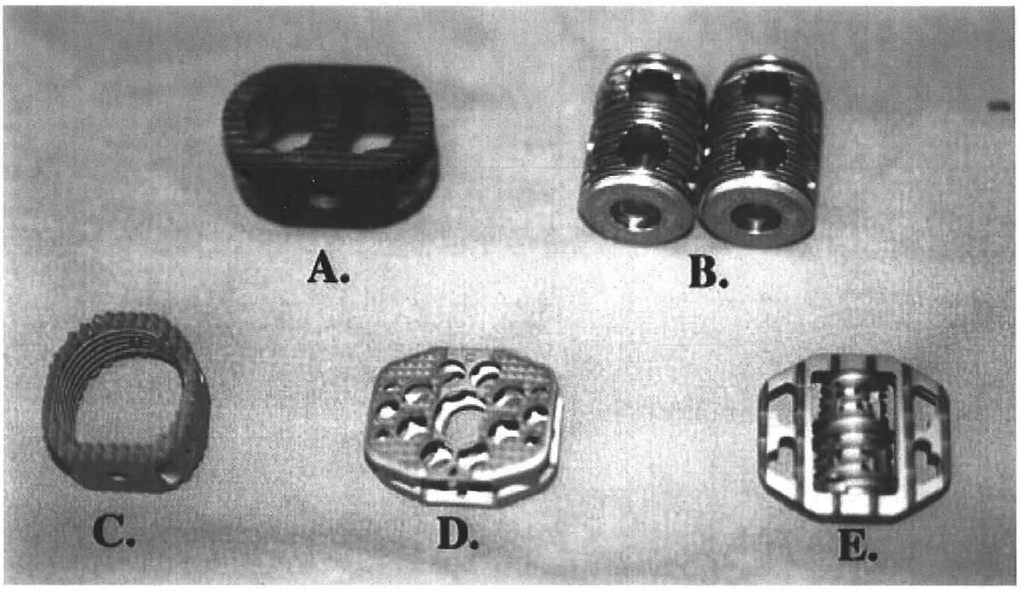


Figure 2.4 Comparison of five stand-alone anterior interbody cages. **A.** Anterior Lumbar I/F cage; **B.** Paired BAK; **C.** Titanium Interbody Spacer; **D.** SynCage; **E.** ScrewCage
[51]Source: Tsantrizos A, Andreou A, Aebi M, et al. Biomechanical stability of five stand-alone anterior lumbar interbody fusion constructs. Eur Spine J 2000;9:14-22.

Tsantrizos et al.[51] compared initial three-dimensional stability of five different stand-alone ALIF cages and their pullout resistance. In this study forty-two lumbar spines (L1-S1) were used. The study concluded that the cage design characteristics have an effect of initial stability. The pull-out force was higher for cages with sharp teeth. The stand-alone cage constructs reduced the ROM (Range of Motion) efficiently but residual ROM signified micro-motion at the cage-endplate interface.

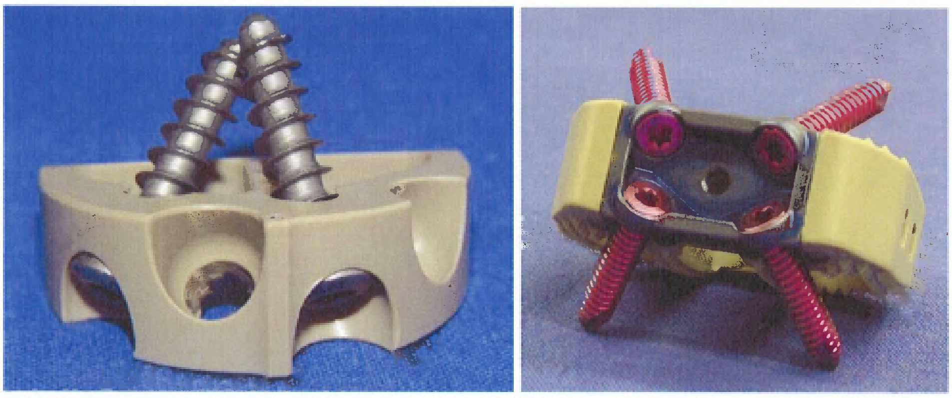


Figure 2.5 Stand-alone implants

A study by Schleicher et al. compared two stand-alone cages designed with integral locking screws. In figure 2.5 the cage on left is known as STALIF™ (Surgicraft Ltd., Redditch, UK) and on the right is known as SynFix-LR™ (Synthes GmbH, Oberdorf, Switzerland). In this study, biomechanical testing was performed on 16 human lumbar spines. These specimens were randomly assigned to one of the two implants. Both implant designs performed well in flexion and resisted compressive forces. However the comparison showed that SynFix-LR™ has better stabilization in rotation and extension than STALIF™. The divergent screws in SynFix counteract tensile forces, avoiding movements in extension that can impede bone healing during fusion.

2.5 Interbody device materials

There are many different materials currently used in the spinal implant market. This discussion will focus on the three most popular and readily used interbody implant materials: Titanium, PEEK and Stainless Steel.

Titanium and stainless steel are the most commonly used metals and are biomechanically well suited for use in interbody devices. Even with metal's high strength and durability during extreme environments, statistics have shown that given enough time and stress, any material will fail. Delayed or failed arthrodesis is equivalent to an interposition arthroplasty which is known to be notoriously disastrous in the appendicular skeleton. Besides a much higher Young's modulus, one of the major disadvantages while using the metals given above for interbody devices is their interference during radiographic demonstration of fusion. Both metals are radiopaque to X-rays and create significant scatter during MRI's and CT scans.[59]

PEEK (Polyether Ether Ketone) is a high performance/high strength biomaterial that has strong chemical and hydrolysis resistance, it also resists the effects of ionizing radiation. PEEK has good tribiological (a study that deals with the design, friction, wear, and lubrication of interacting surfaces in relative motion) properties with extensive biocompatibility.[29,36,60]

A study by Vadapalli et al. compared biomechanical performance between PEEK (Polyether ether Ketone) and titanium PLIF spacers using a Finite Element Analysis (FEA) approach. The study used a validated finite element model of an intact L3-L5 ligamentous lumbar segment (Figure 2.6). The study concluded that the stability of a spacer placed with posterior instrumentation was independent of the material properties, but the load transfer and additional parameters differed. The finite element results indicated that the stress magnitude in the endplate region for PEEK spacer was less than titanium spacer. Another advantage of PEEK when used as an interbody fusion device is its radiolucent properties, which allows for a clear evaluation of fusion and bone healing.[56]

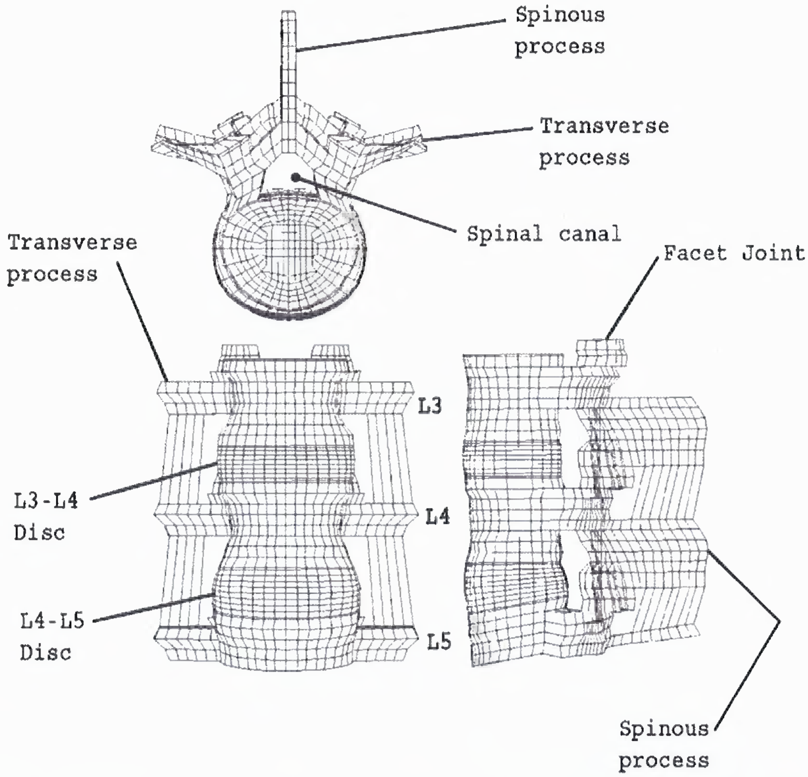


Figure 2.6 Experimentally validated finite element model of intact L3-L5 ligamentous segment[56]

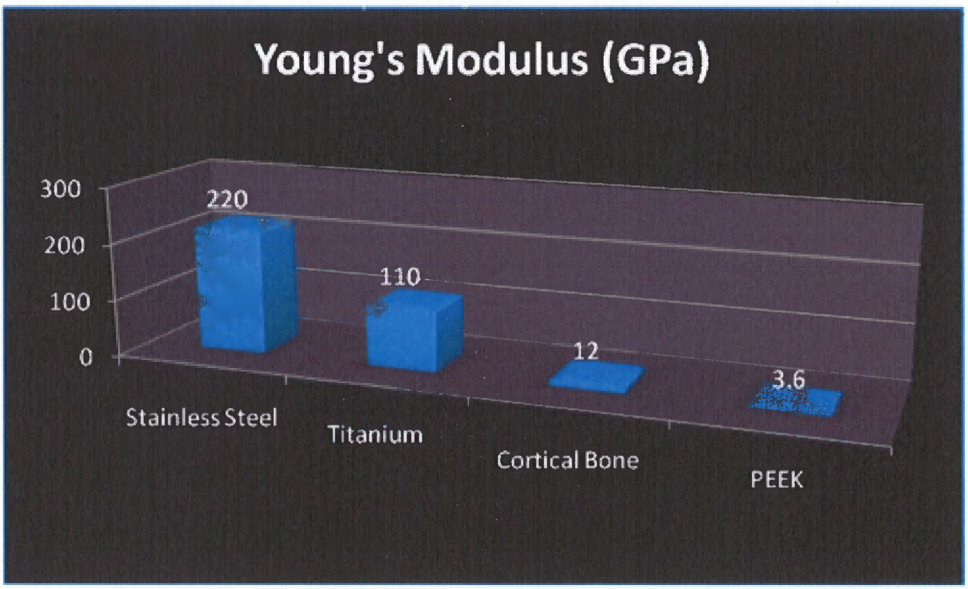


Figure 2.7 Comparison of Young's Modulus.

The reason for current industry trend shifting towards the use of PEEK as a preferred material is because its Young's modulus is closer to the cortical bone than that of metals (Figure 2.7). This allows for true load sharing between the bone and the device and less stress shielding. According to Wolff's Law, it is critical for bone to be loaded in order to maintain its density and strength by continued remodeling. PEEK is also a radiolucent material, which allows radiographical assessment of the bone healing.

2.6 Significance of Preload

ALIF cages have been proven to decrease the motion of the spine in all loading directions except extension. It is important to know stand-alone devices are dependent on compressive preload produced by annular pre-tensioning and muscle forces for initial stabilization.

A study by Patwardhan et al.[44,45] hypothesized that compressive preloading significantly affects the stability of the ALIF construct. During this study fourteen lumbar spines were used. The testing was performed in flexion/extension with an increasing preload from 0N to 1200N for the intact FSU and after insertion of two threaded cylindrical devices at level L5-Sl. The publication described a general reduction of motion in both flexion and extension after the device placement. It was noted that the reduction in motion was significantly greater at preloads of 800 to 1200 N when compared to reduction for preloads of 400 N or less. Without any preload applied on the motion segment, instability was observed in extension loading direction, immediately after the device was placed in between the vertebral bodies. In vivo, this instability is balanced by a preload, applied by muscular forces and annular pre-tensioning. In conclusion, the study determined that the external compressive preload significantly affected the stabilization provided by the implant device. The annular pretension has a minimal effect on the magnitude of preload required to achieve stability with stand-alone cages.

2.7 Summary

In past decades science has made leaps in technology to treat or reduce the pain involved during LBP. Patients can rely on many choices ranging from conservative approach of non-invasive procedures to cases where the only choice left is surgery. In many cases of patients whose LBP is caused by spondylolisthesis, DDD, spinal stenosis, herniated discs, spinal injury, infection, tumor and deformities, spinal fusion might be the optimal choice.[21]

With 80% of the spinal loads and 90% of the articular surface available for fusion in the interbody space (Figure 2.2), interbody spacers have become the gold standard for fusing spine. With orthopedic technologies constantly evolving in past few decades the preferred choice of material used to implant interbody spacers have also evolved. Studies suggest that even though the initial stability of a spacer placed with posterior instrumentation is independent of the material properties (when comparing metals with plastic), the load transfer and additional parameters differ.[56] Materials such PEEK have become the gold standard for interbody fusion devices. With many advantages such as its radiolucent properties, that allows for a clear evaluation of fusion and bone healing and Young's modulus being closer to that of cortical bone (compared to titanium alloy), PEEK has become the preferred choice of surgeons as an interbody spacer.

Many studies support the advantages of additional posterior fixation (such as pedicle and facet fixation). Adding the extra support does provide a reduction in motion which leads to faster fusion. On the other hand, it is important to understand the disadvantages of performing a 360° fusion, such as muscle stripping, increased operative time, and blood loss.[13,22,31] This adds morbidity to the procedure causing an extended recovery period.[11]

Several cages are designed to be implanted into the disc space using the anterior, posterolateral, anterolateral or posterior approach. The decision on the type of approach should be made based on several factors, such as the pathology present, the patient's spinal anatomy, the patient's history of prior surgery (either approach may be more difficult if there is significant scarring from prior surgeries), vascular anatomy (and conditions that may make an anterior procedure more difficult, such as calcification of vessels) and the surgeon's individual training and experience.[14]

An alternative to 360° fusion would be supplementary anterior fixation integrated into the interbody spacer. A stand-alone interbody spacer design that avoids flipping the patient, preserves endplates, supports 80% of the spinal loads that are observed by the interbody space will be an ideal fit.[37] Such a new interbody lumbar cage design called the Solitaire® (Biomet, Parsippany, NJ) that carries integrated screws for fixation with adjacent vertebral bodies was used in this study.

Solitaire® (henceforth referred to as AFD) interbody spacer has a large, oblong shape, with flat grooved superior and inferior surfaces and a large medial opening. It is designed with shallow angle screws described further in Chapter 5.

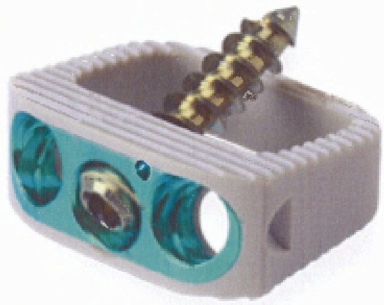


Figure 2.8 Solitaire® Anterior Spinal System

[8]Source: Solitaire™ Anterior Spinal System [Biomet]. Available from: http://www.biomet.com/spine/products.cfm?pdid=3&majcid=14&prodid=220. Accessed February 15, 2009.

CHAPTER 3

MATERIALS AND METHODS

3.1 Overview

We used human cadaveric specimens to evaluate the performance of implant devices. It was important to use human specimens instead of animal because of the differences in vertebral fixation. The morphological differences of human and animal articular facets can further explain these differences. The facets are important for support in different loading directions used in this study (flexion, extension, bilateral axial bending and bilateral lateral bending).[40] Following are the materials that we used for our study.

- 3 fresh cadaveric human lumbar spines (L1-S1): 3, L4-S1 motion segments; 3, L1-L3 motion segments = 6 total motion segments
- Embedding Material
- Anterior Interbody Fusion Device (AFD) – multiple sizes
- Pedicle Screws and Posterior Rods – multiple sizes
- Facet Bolts
- Optotrak Certus motion analysis system

3.2 Specimens Preparation

In vitro study was done using 6 fresh cadaveric spine specimens. The average age of the donors, 6 men, was 57.4 ± 10.9 years (range 37–67.8). The medical history of each donor was reviewed to exclude trauma, malignancy, or metabolic disease that might otherwise compromise the mechanical properties of the lumbar spine. Superficial musculature was then removed, with care taken to preserve all intervertebral ligamentous structures, the capsule of the facet joints, and annulus.

The spines were wrapped in zip lock bag and were kept frozen at -20°C until the day of testing to ensure that the material properties do not change.[20,42,46] DEXA scans (Figure 3.1) of the specimens were taken to eliminate specimens with bony abnormalities. Specimens with T-score better than -2.0 were considered in this study.

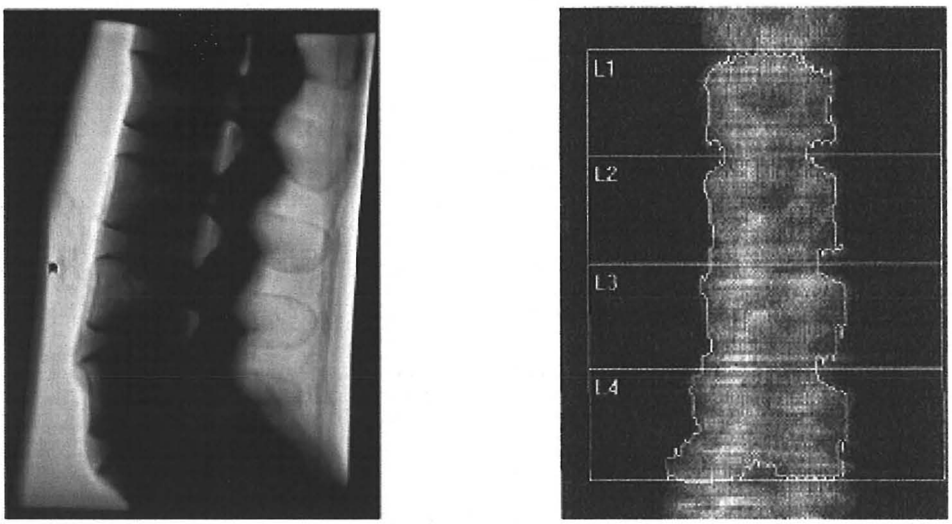


Figure 3.1 DEXA of a lumbar spine segment.

The spine specimens were thawed to room temperature and the 1st lumbar vertebrae to the sacrum were obtained. Thereafter the muscle and adipose tissue were cleaned from the specimen. Care was taken not to disturb the ligaments, bony structures or the disc. To separate the segment from the reminder of the spine a transverse cut was made through the T12-Ll disc and through the adjoining ligaments. All of the bony part below S1 was cut using a hack-saw. Each lumbar spine was split into two motion segments, 3 L1-L3 and 3 L4-S1, total of 6 segments.

After cleaning, each specimen was then potted using Bondo (a 2-part epoxy resin). For L1-L3 level, partial of L3 vertebra was potted by inserting screws into the bottom surface of the vertebral body as anchors and then pouring the resin into a mold designed to create a base that would bolt to the kinematic profiler loading frame. Ll was potted by inserting 1/4-20 thread through the vertebral body and pouring resin into a mold designed to mate to rods that can impart a moment on the spine. The spine was refrozen until the day before testing.

3.3 Test Setup

Using a system of arms, pulleys and weights, quasi-static loads were applied to the spines in opposite directions, thereby sequentially generating pure moments of 2.5, 5.0, 7.5 and 10 Nm. Preload is applied using two 45lbs (producing 400N total) dumbbells and metal wire (shown in Figure 3.5). The Optotrak Certus optical measurement device was used to track positions and motions of infrared light emitting diodes (LED) markers within a specific area.

To overcome the spine's viscoelastic effect, the spines were ranged maximally in all directions before data collection, also known as the pre-conditioning. After each load application, the system was allowed to stabilize for 30 seconds to minimize creep. Moments were applied in 6 degrees of freedom (DOF) to generate angular rotations for flexion, extension, right and left lateral bending (RB,LB) and right and left axial rotation

(RR,LR) as shown in Figure 3.2.

Three infrared LED's were rigidly attached on each specimen as shown in Figure 3.2. For example for L1-L3 motion segment, 1st LED was attached on L1 potting. 2nd LED was attached on L2 vertebral body and 3rd LED on the fixed base of L3 potting area (used for referencing). In order to enable the test setup to apply pure bending forces a moment arm was created using metal rods that were threaded onto all four sides of the motion segment, connected to the top potting fixture (Figure 3.2).

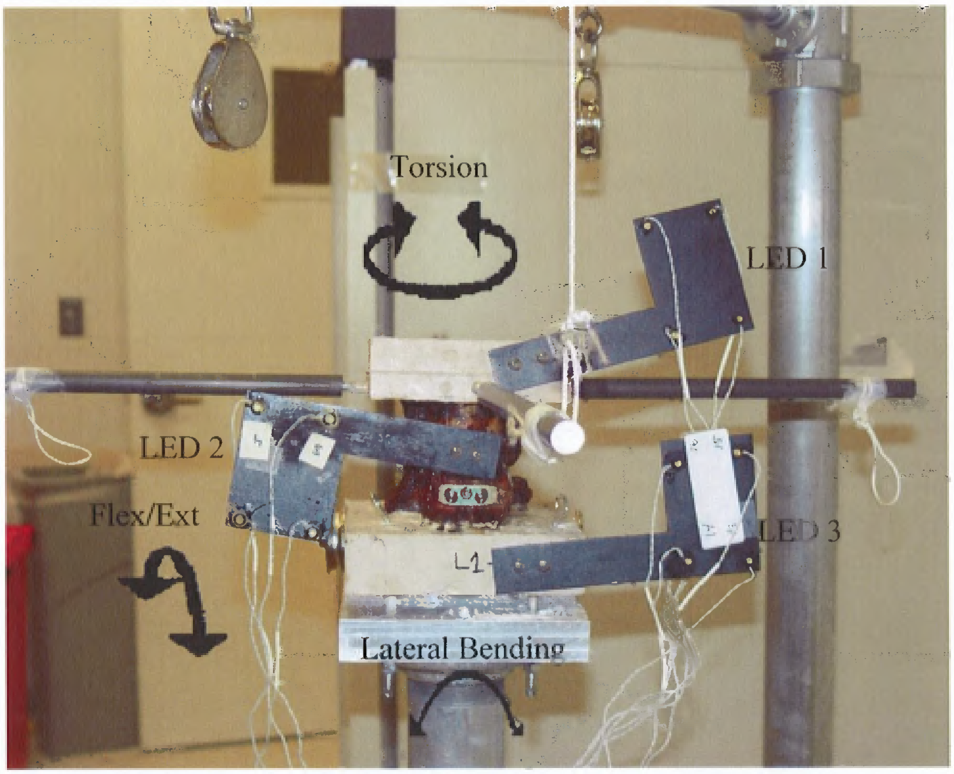


Figure 3.2 Specimen with LED's tested under 6 different loading conditions.

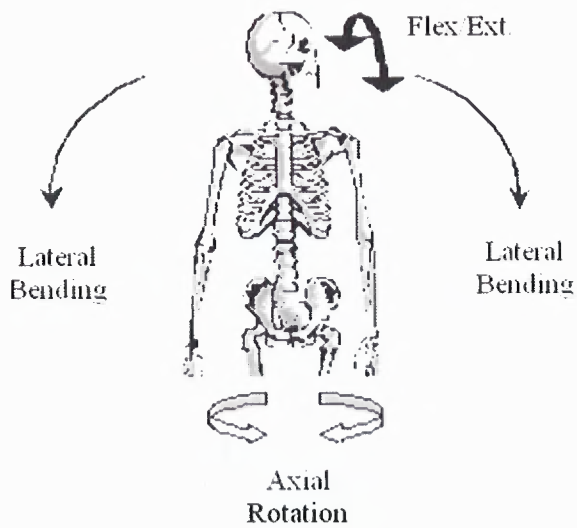


Figure 3.3 Schematic Diagram of loading in three degrees of freedom.

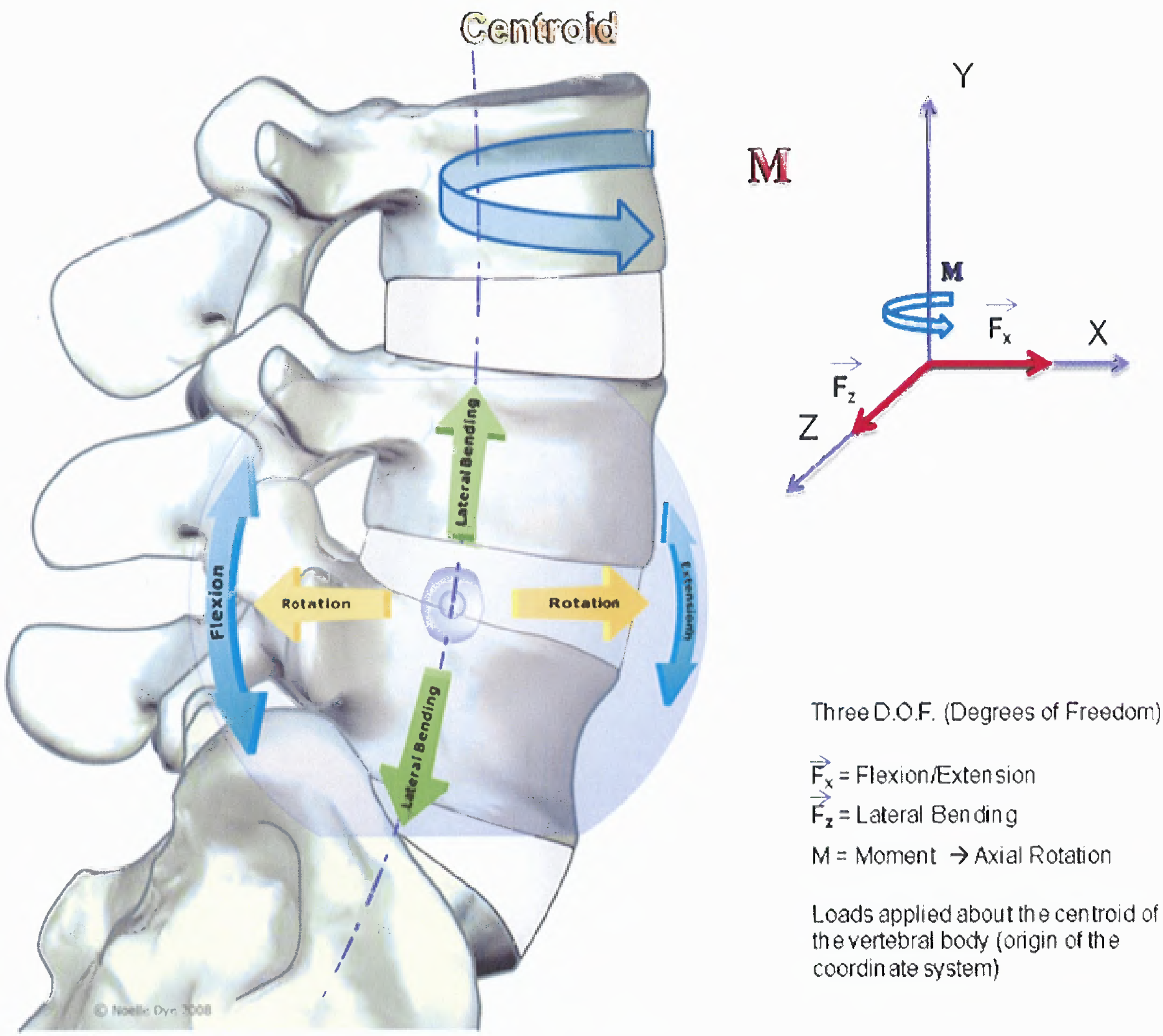


Figure 3.4 Free body diagram of FSU loading (Lateral View).

Figure 3.5 Two 45lbs (400N) dumbbells, used as preload.

These rods were connected to weights using strings attached to system of pulleys. Depending on the test mode, the configuration of the pulleys and location of weights were changed.

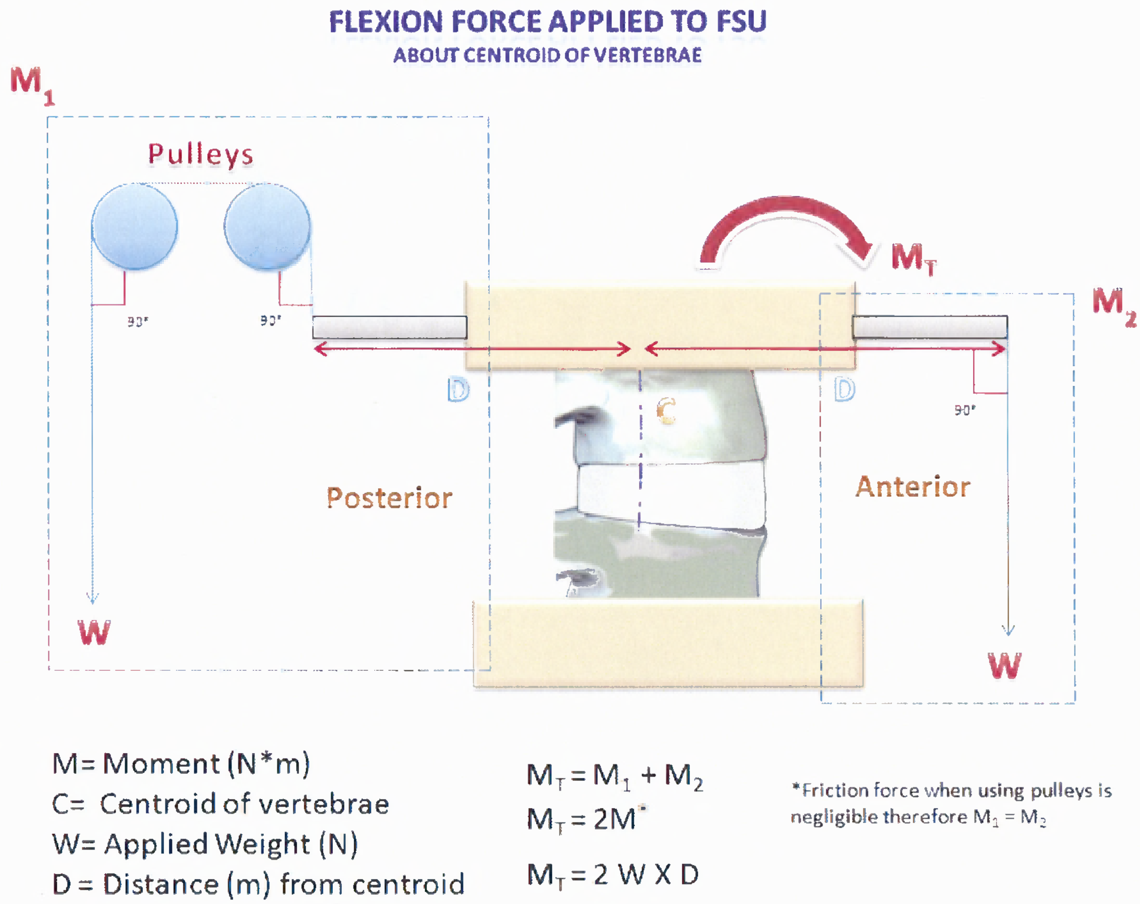


Figure 3.6 Free Body Diagram of representative flexion force applied to FSU.

The figure above shows a simple yet detailed free body diagram. It is a representation of how load was applied to the cadaveric spine in this study. Shown in the middle is a simplified FSU (lateral view of L2-L3 motion segment). Representative FSU fixtures showed through which rods have been placed. The weights have been applied (perpendicular) equally both from the posterior and anterior of the spine onto these rods at a distance D away from the centroid of the vertebrae. Each component moments M_1 and M_2 add up to create a flexion moment M_T. Since we used pulleys to apply load from posterior of the spine, the friction was considered negligible. Each moment equals the distance (meters) at which the load is applied times the load applied (Newtons). Therefore the total moment applied (Newton*meter) is the sum of the two moments.

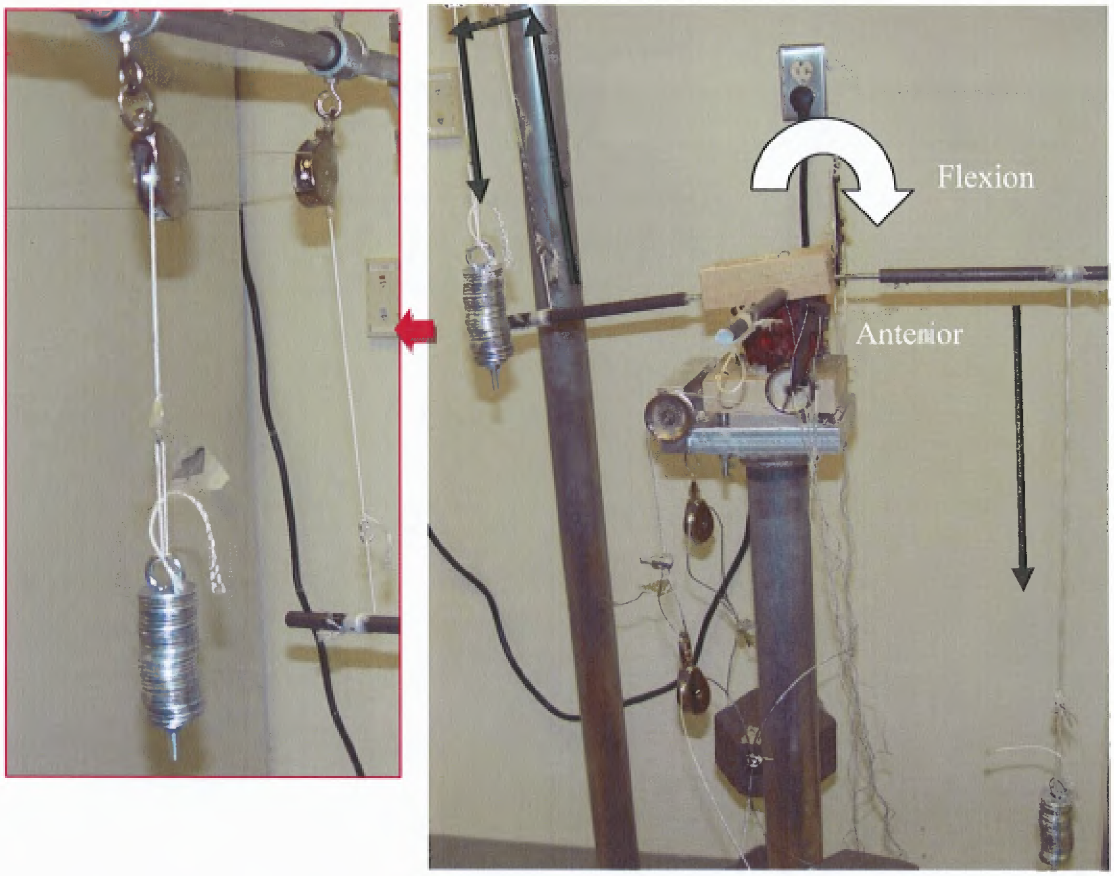


Figure 3.7 Example of flexion force applied using system of pulleys and strings.

Figure 3.7 shows an example of flexion force being applied using system of pulleys and strings. In this figure lateral view of the spine is shown. A direct weight of 1.25 N is pulling the metal rod downward on the anterior side of the spine and an indirect weight of 1.25 N (using pulleys) is pulling metal rod upward on the posterior side. This adding up to 2.5 N of flexion force being applied onto the motion segment. Similarly to apply extension force the configuration of the direct and indirect weight is switched, in which direct weight pulled posterior the metal rod downward and indirect weight pulled anterior metal rod upward. Rotational loads were applied by simply changing the configuration of the pulleys. Figure 3.8 and 3.9 show how left axial rotation was configured.

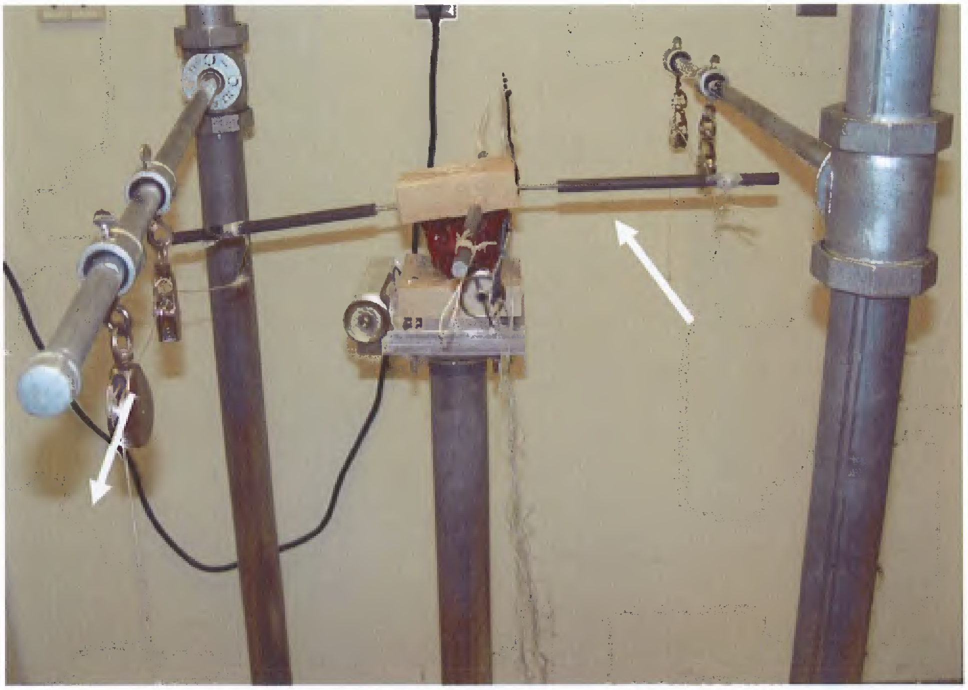


Figure 3.8 Lateral view of left axial rotation configuration (shown without weights).

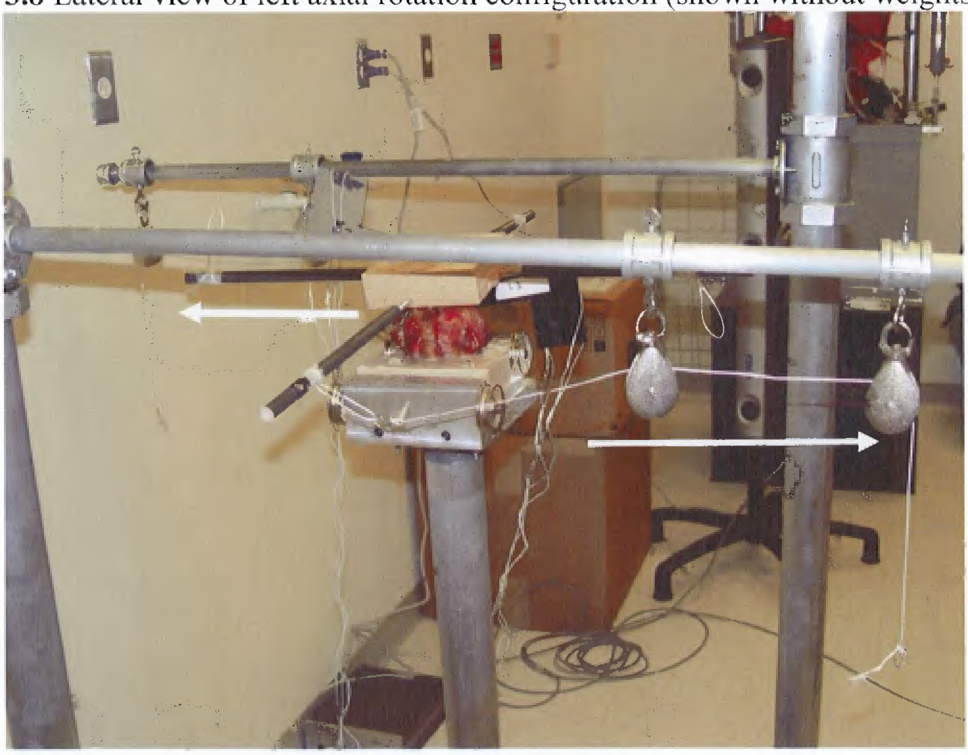


Figure 3.9 Posterior view of left axial rotation configuration (shown without weights).

Similarly the location of the pulleys points in the reverse direction to apply right axial rotational force.

Figure 3.10 Anterior view of left bending.

An example of left bending load applied on the specimen is shown in Figure 3.10. Total of eight weights were applied directly and indirectly, producing a moment of 10 Nm.

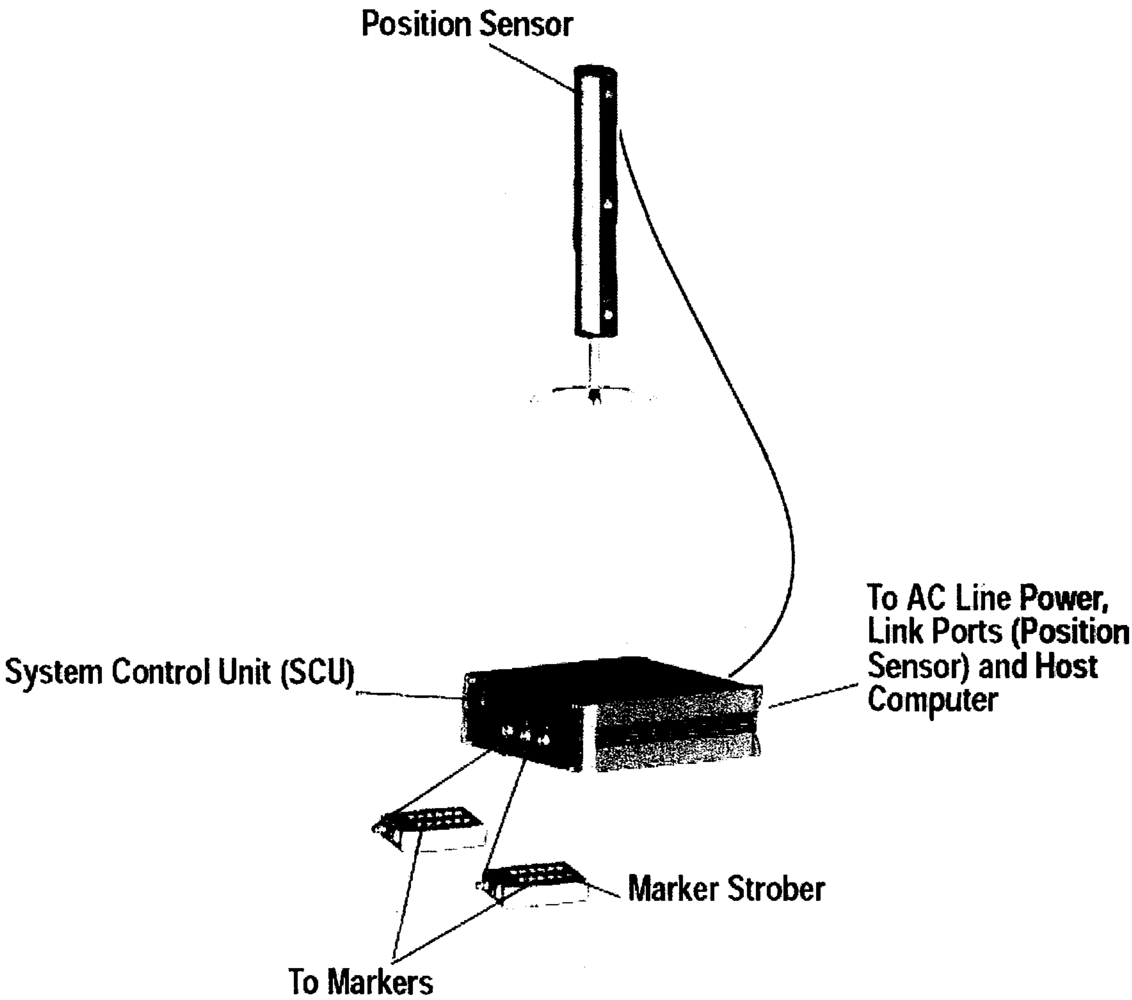


Figure 3.11 Schematic diagram of the Optotrak system.

Figure 3.11 shows the typical setup of the Optotrak system. Shown is position sensor that receives data directly from the Infrared LED's. The marker strobers connect to the IR LED and send the data to the SCI, which then sent to the computer.

Brief functional description of each component used in this setup is described in Table 3.1 below.

Table 3.1 Basic Optotrak Certus System Components.

Name	Description
Position Sensor	An optical instrument that detects infrared light emissions within a specific range.
System Control Unit (SCU)	A processing device that controls the operation of the Position Sensor and attached strobers. It is also processes the information collected by the Position Sensor and sends it to the host computer.
markers	Infrared light emitting diodes that are tracked by the Position Sensor when they are activated by the strober. A structure with three or more markers whose relative positions are fixed is called a *rigid body*.
smart markers	Smart markers are similar to normal markers, but in addition they allow for wireless connection to the system.
strober	A device controlled by and connected to the SCU, responsible for activating and deactivating markers. There are four strober types: • tool strober • marker strober • 3020 strober adapter • wireless strober
base stand	A device to support the Position Sensor.
cables	Thesystem is supplied with the following cables: • The *host cable* connects a host computer to the SCU. • *Link cables* connect a Position Sensor to the SCU, a USB interface to the SCU, or a Position Sensor to another Position Sensor. • *Power cables* connect the SCU and the Position Sensor to power mains. • *Strober extension cables* extend the distance between the SCU and a strober.
software applications	**First Principles** - integrates with the Optotrak Certus System to collect and interpret data. **DataView** - Allows you to view, edit and print the collected data. **6D Architect** - Allows you to characterize tools that you have designed and manufactured.
host computer	A user-supplied computer used to communicate with the Optotrak Certus System. The host computer sends system operation instructions to the SCU through software applications. The host computer then receives and interprets the data collected by the SCU.

It is important to understand the field of view of the optotrak sensor and ensuring that no object blocks the view between sensors and the infrared LED's (Figure 3.12). Precaution was taken throughout the study. Before running every test mode status of all LED's was confirmed to be green (i.e. sensor can detect the LED's).

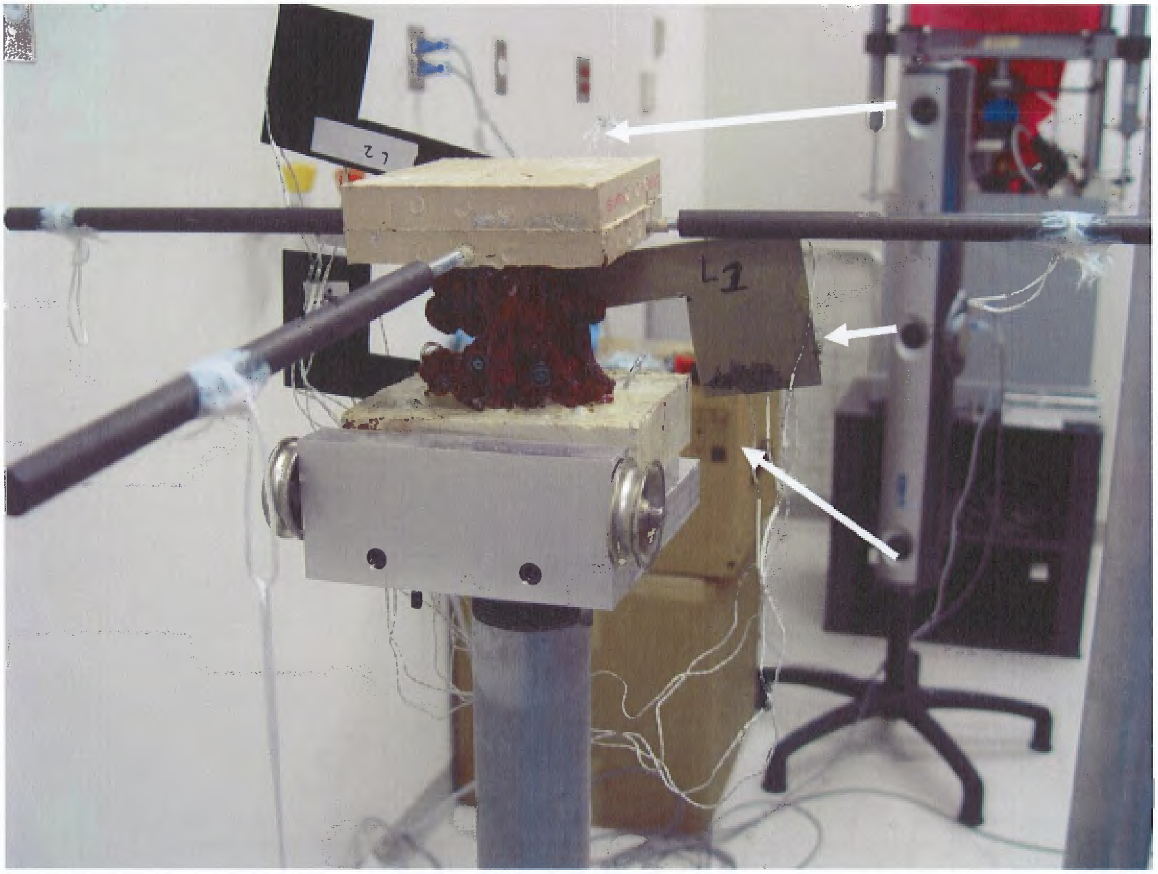


Figure 3.12 Optotrak optical sensors in direct field of view with LED's.

Figure 3.13 describes the operational measurement volume. Steps were taken to ensure that our test setup did not go outside of these defined parameters.

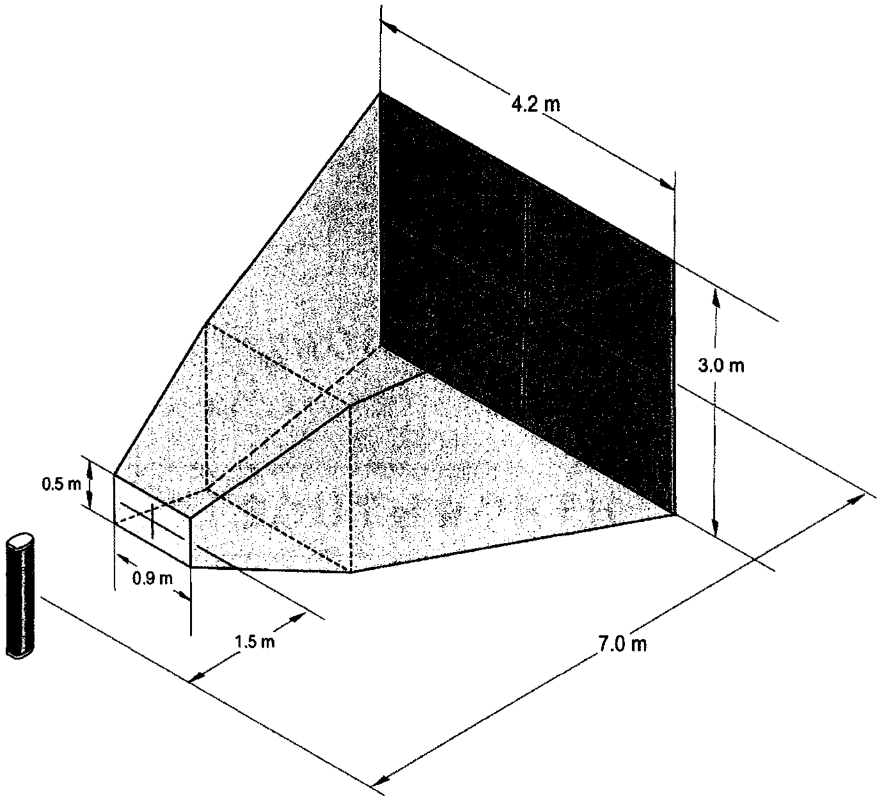


Figure 3.13 Operational Measurement Volume.

3.4 Methods

Each specimen was tested in intact condition (I) under all 6 load cases to a maximum moment of 10 Nm in steps of 2.5 Nm.

Table 3.2 Testing Sequence outline.

Sequence	Test Mode
1	Intact
2	AFD Interbody
3	Facet fixation added
4	Remove facet fixation
5	Pedicle screw fixation added
6	Remove pedicle screw fixation (i.e., remove rods only)

Each sequence mode was tested with and without preload of 400N with increasing pure moments of 2.5, 5.0, 7.5 and 10 Nm.

Before implanting the AFD device, discectomy (removal of annulus and nucleus pulposus) was performed from the anterior of the specimen using rongeurs and scrapers (Figure 3.14). After discectomy implant trial was used to determine the appropriate cage size needed for the level (L2-L3 trialed in Figure 3.15).

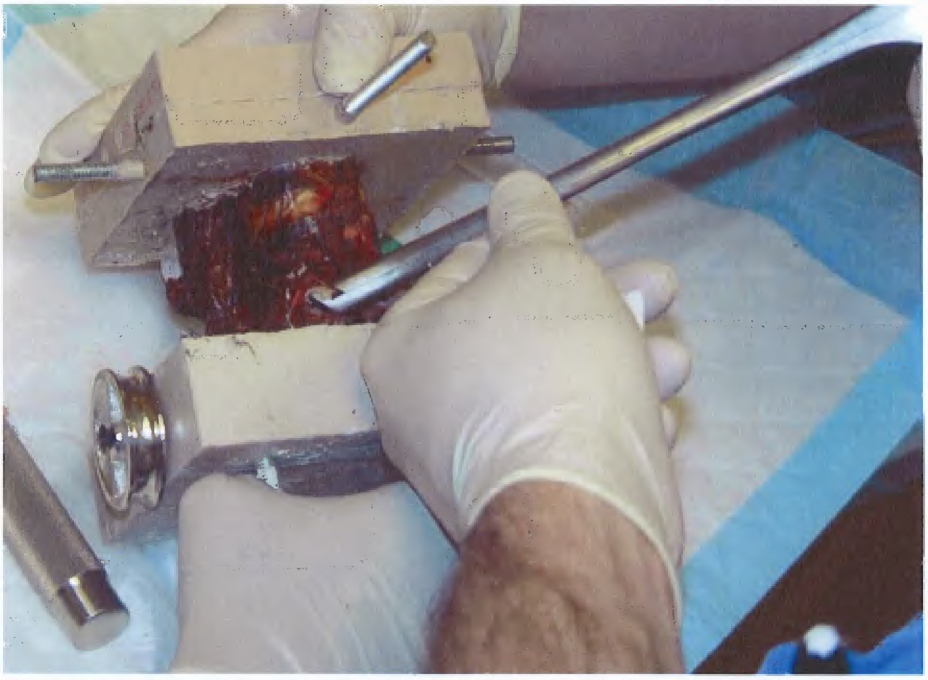


Figure 3.14 Discectomy performed in preparation for AFD implantation.

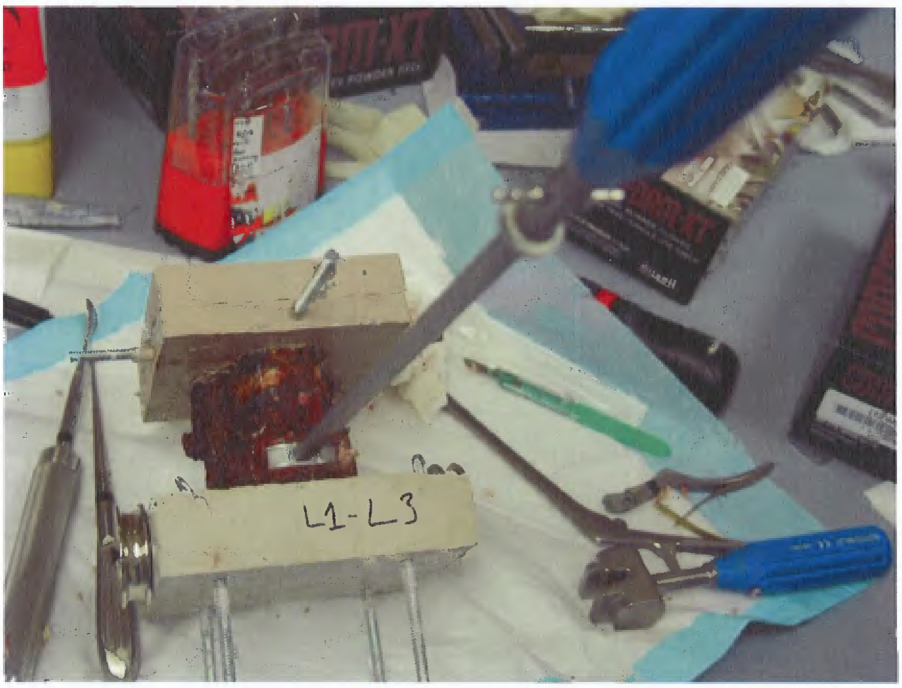


Figure 3.15 Implant Trial used to determine appropriate cage size.

Using appropriate insertion instrumentation the AFD is then placed inside the disc space. Three screws were then threaded into the vertebral body as shown in Figure 3.16. Two screws threaded into lower endplate and one into the upper endplate.

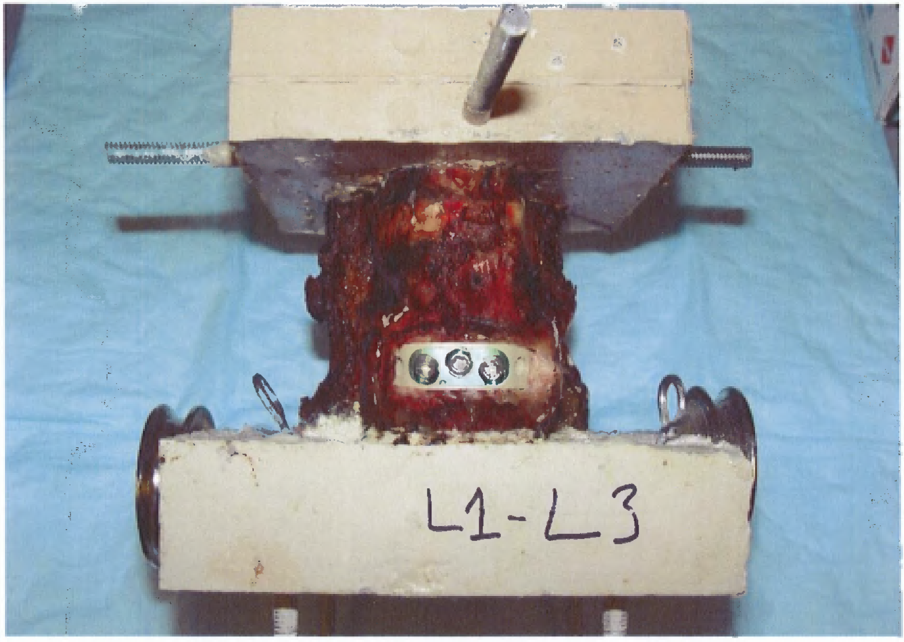


Figure 3.16 L2-L3 level implanted with AFD.

After successful implantation testing sequence #2 from Table 3.2 was performed (both with and without preload).

The next step was implantation of facet bolts. Posterior anatomy was prepared before implanting the facet bolts, the intertransverse ligaments were removed at the implanted level. Figure 3.17 shows the implantation of the facet bolts.

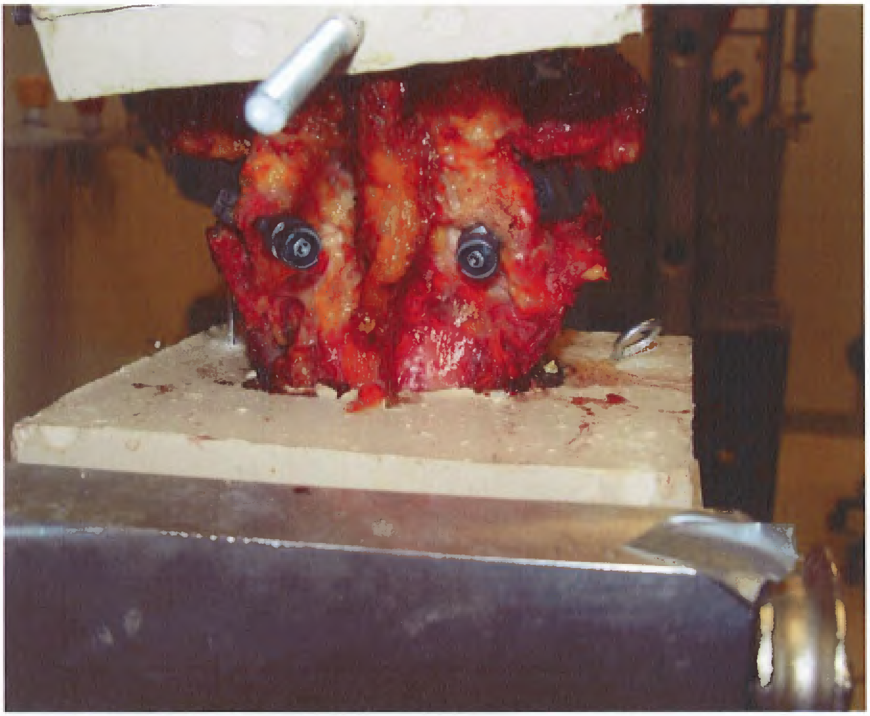


Figure 3.17 Both facet bolts implanted.

After implantation sequence #3 was run. After this test facet bolts were removed and construct was tested with just the AFD was tested under sequence #4. Sequence #4 was run for data comparison with sequence #2, to observe anatomical differences after implantation and removal of the facet bolts.

Figure 3.18 Implantation of pedicle screws.

For testing sequence #5 pedicle screws were implanted. Figure 3.19 shows four pedicle screws being implanted, both above (L5) and below (S1) the implanted AFD disc level. Rods were placed between both L5-S1 pedicle screws. Set screw was then placed to lock the rods in place.

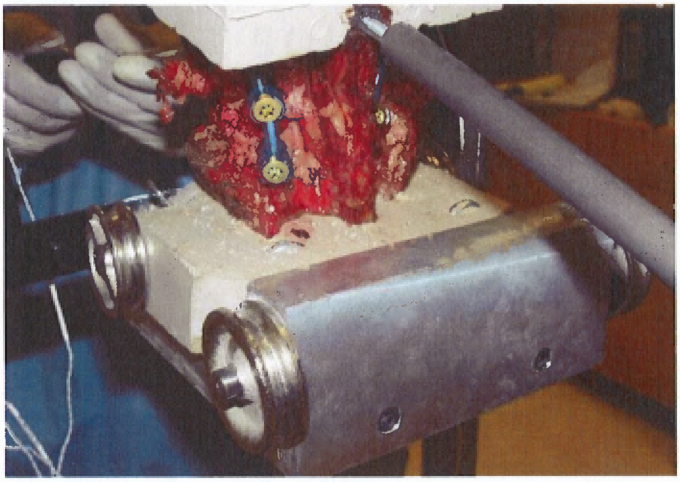


Figure 3.19 Specimen being prepared for Sequence #5 testing.

In the final sequence #6, only the set screws and rods were removed from the specimen leaving the pedicle screws behind (because they alone do not contribute to additional stiffness).

CHAPTER 4

RESULTS

4.1 Overview

This chapter presents the data collected during the study in various forms of graphs and tables. Comparison was made between the intact specimen with addition of implants (with and without the presence of preload). Data was collected at incremental loads of 2.5 Nm ranging between 2.5 Nm-10 Nm. Average motion data was calculated by pooling all six specimens change in motion values (units of motion in degrees of rotation). All data was normalized with intact as the reference, to observe the percentage difference in motion as implants were added. Only the highest load applied to the spine (10 Nm) was used during the comparison of motion reduction. Incremental load differences were also observed using Motion vs. Displacement graphs.

ANOVA (Analysis of Variance) was used to analyze the different sequences run at each test mode. ANOVA in its simplest definition is a statistical method for simultaneous for making simultaneous comparisons between two or more means. It is a method that yields values (P-values) that can be tested to determine whether a significant relationship exists between variables.

Each group being analyzed is categorized into "treatments". There are several types of ANOVA depending on the number of treatments and the way they are being applied to the subjects in the experiments (in our case spine specimens).

a. One-Way ANOVA - test for differences among two or more independent groups
b. Factorial ANOVA – Study effects of two or more treatment variables

c. MANOVA (Multivariate ANOVA) – Used when there is more than one dependent variable.

Six specimens were tested in this study. Three specimens received implants at L2-L3 and other three specimens received at L5-S1. The implant level is not categorical and data from all six specimens is pooled. The 6 degrees of motions (flexion, extension, left-bending, right-bending, left-rotation, and right-rotation) were analyzed separately. Each motion contains different implant and fixation status (Intact, AFD, AFD+Facet Bolts, AFD-Facet Bolts, AFD+Pedicle Screws, AFD-Pedicle Screws), which serve as treatments.

Treatments were compared to determine if a statistically significant amount of motion occurred. The degrees rotation was measured at our highest moment of 10 Nm. Analysis was repeated using the same design but with an experimental "Pre-Load" of 400 N. Since this study has multiple dependent variables such as six different fixation status and six different degrees of motion (test modes) the Multivariate ANOVA needs to be applied. Statistical Analysis Software (SAS Institute Inc.) was used to perform these statistical analyses.

- **Null hypothesis (H_0)** – No significant difference in amount of motion occurred between treatments.
- **Alternative hypothesis (H_1)** – A significant difference in amount of motion occurred between treatments.

It is important to understand that results derived from ANOVA only indicate whether the means differ significantly or not. They do not indicate which means differ from which other. Therefore it is necessary to perform pair-wise mean comparisons controlling individual test's error rates or error rate of the entire family of tests.

Based on assumption of equal variances we used the Student-Newman-Keuls method (SNK) Post-hoc analysis to derive whether treatments were significantly different from each other. The statistical results lying within the 95% level of significance (P-value <0.05) were considered for SNK evaluation. The treatments were divided by grouping letter. Means with the same SNK grouping letter are not significantly different. The graphs and tables in this chapter were divided by each individual test mode to observe the average means of all six specimens motion in degrees of rotation.

4.2 Extension

4.2.1 Extension without Preload

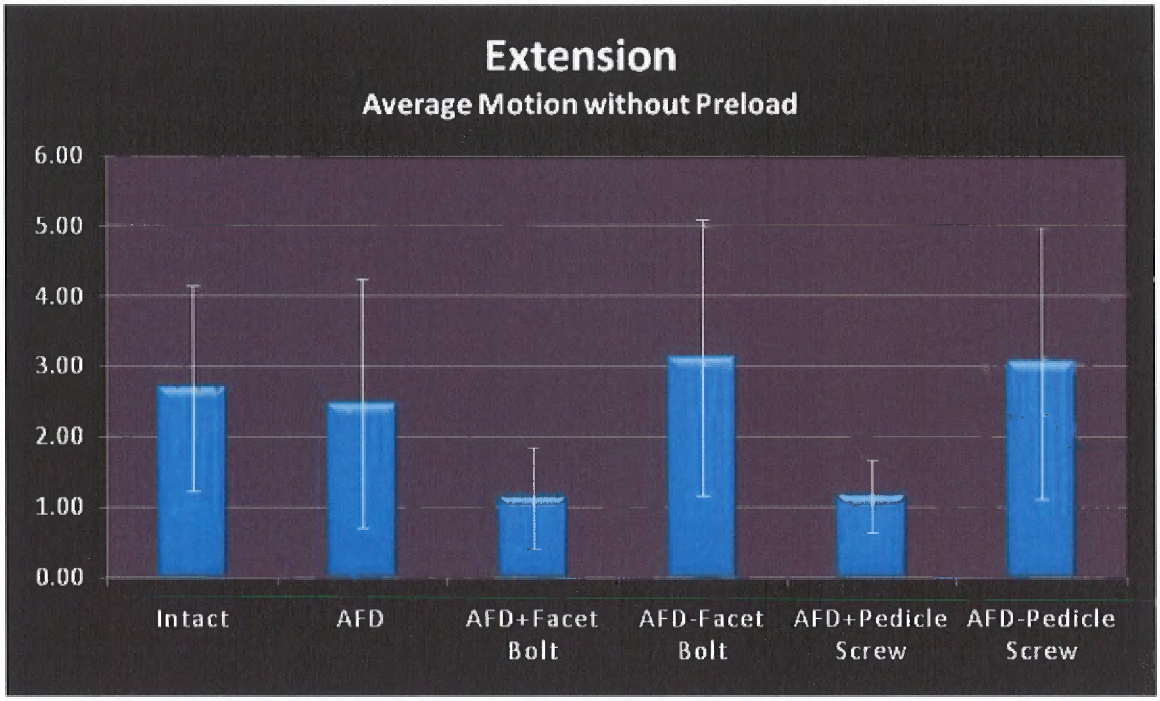


Figure 4.1 Average motion in extension test mode without preload.

Table 4.1: Extension Test Mode – Average Motion Values without Preload*

	Intact	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
average	2.70	2.48	1.13	3.13	1.15	3.06
Std	1.46	1.78	0.72	1.96	0.51	1.93

*Values rounded to nearest two decimal places

In extension without preload test mode the calculated p-value was 0.0825. This implies that in this test mode no significant difference was found between the treatments. Since the level of significance was lower than 95% (i.e. p-value > 0.05) SNK Post-hoc analysis was not applied.

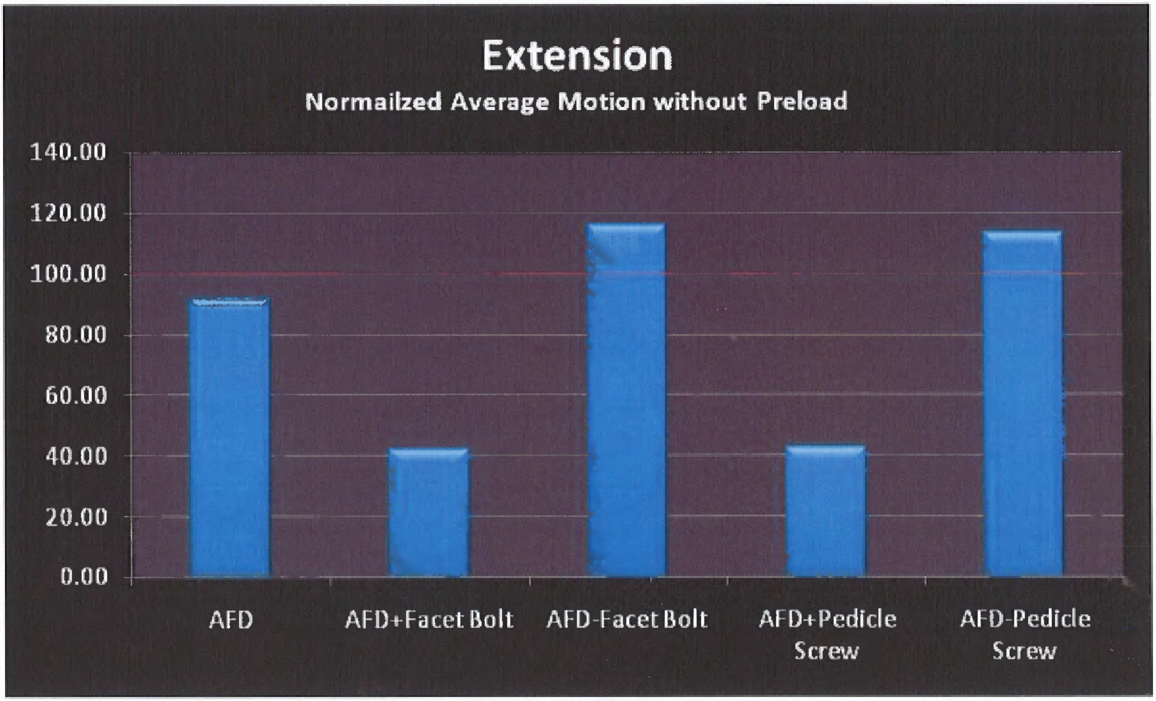


Figure 4.2 Normalized in extension mode, average motion without preload.

Table 4.2: Extension Test Mode – Normalized values without preload

	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
% to Intact	91.71	41.87	115.97	42.75	113.24

4.2.2 Extension with Preload

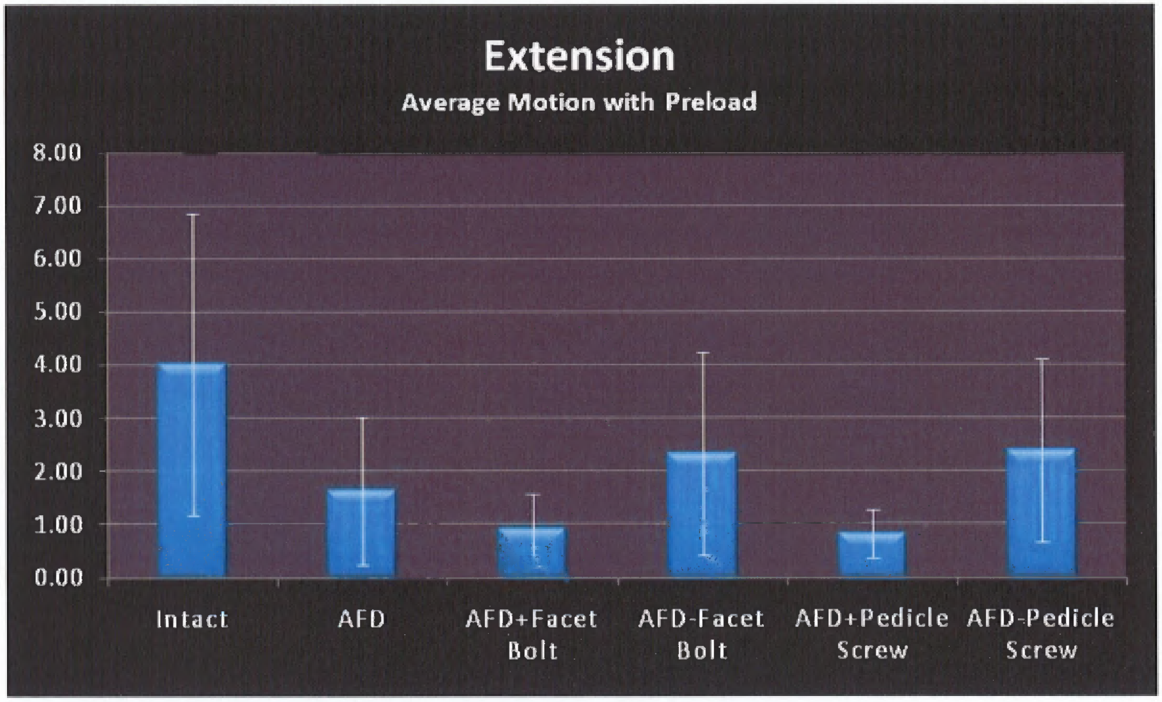


Figure 4.3 Average motion in extension test mode with 400N preload.

Table 4.3: Extension Test Mode – Average Motion Values with 400N Preload*

	Intact	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
average	4.01	1.63	0.89	2.32	0.81	2.39
Std	2.84	1.38	0.69	1.89	0.45	1.71

*Values rounded to nearest two decimal places

In extension with 400N preload test mode the calculated p-value was 0.0361, which is approximately 96.4% level of significance.

Table 4.4: SNK Post-hoc analysis results of treatments during extension with 400N preload

SNK Grouping	Mean	Treatment
A	4.0066	Intact
B A	2.3860	AFD-Pedicle Screws
B A	2.3202	AFD-Facet Bolts
B A	2.1930	AFD
B	0.8915	AFD+ Facet Bolts
B	0.8150	AFD+ Pedicle Screws

Table 4.4 shows a summary table of SNK groupings along with the mean values of the motion occurring at each treatment. Means with the same SNK grouping letter are not significantly different. On the other hand letters with different grouping letters are significantly different. Comparison between Intact (Group A), mean value 4.0066 and AFD (Group A) mean value 2.3860 show that there was not significant reduction in motion with addition of AFD in extension test mode.

However a direct comparison between Intact (Group A) with AFD+ Facet Bolts and AFD+ Pedicle screws (both in Group B) show that with additional posterior fixation added to the AFD construct (facet bolts and pedicle screws) a significant reduction in motion was observed.

For the treatments that have both letter A and B imply that there was no significant difference between those treatments compared to any other treatment in statistical analysis.

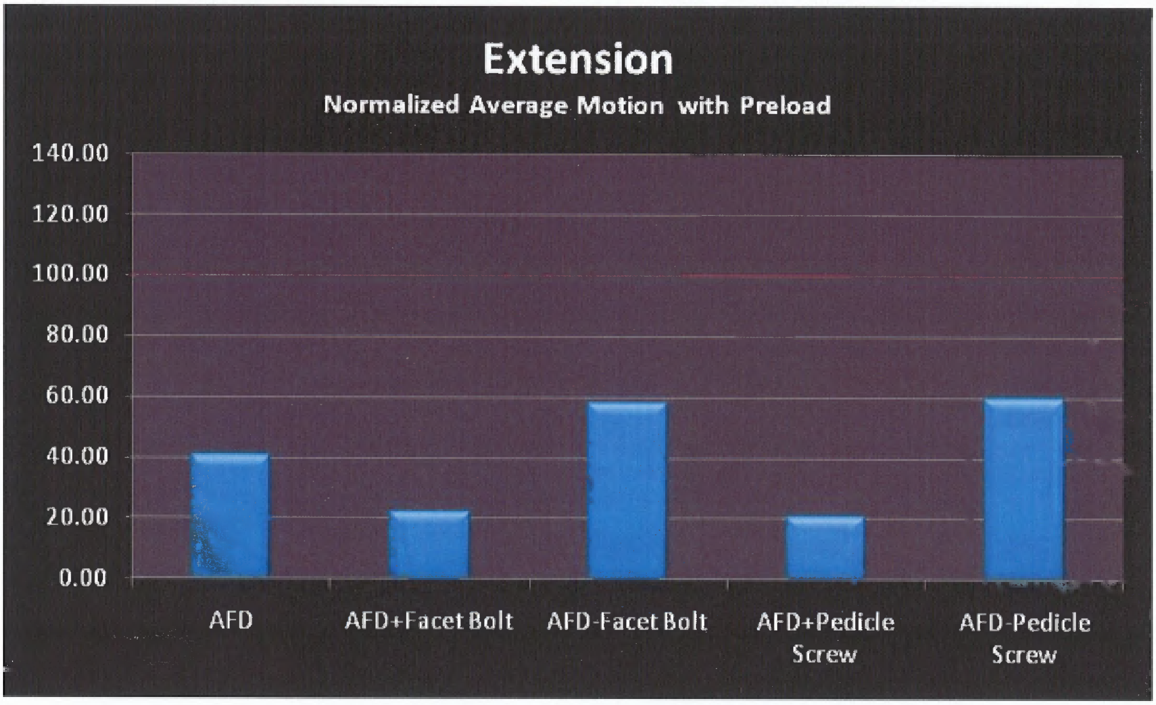


Figure 4.4 Normalized in extension mode, average motion with 400N preload.

Table 4.5: Extension Test Mode – Normalized values with 400N Preload

	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
% to Intact	40.57	22.25	57.91	20.34	59.55

4.3 Flexion

4.3.1 Flexion without Preload

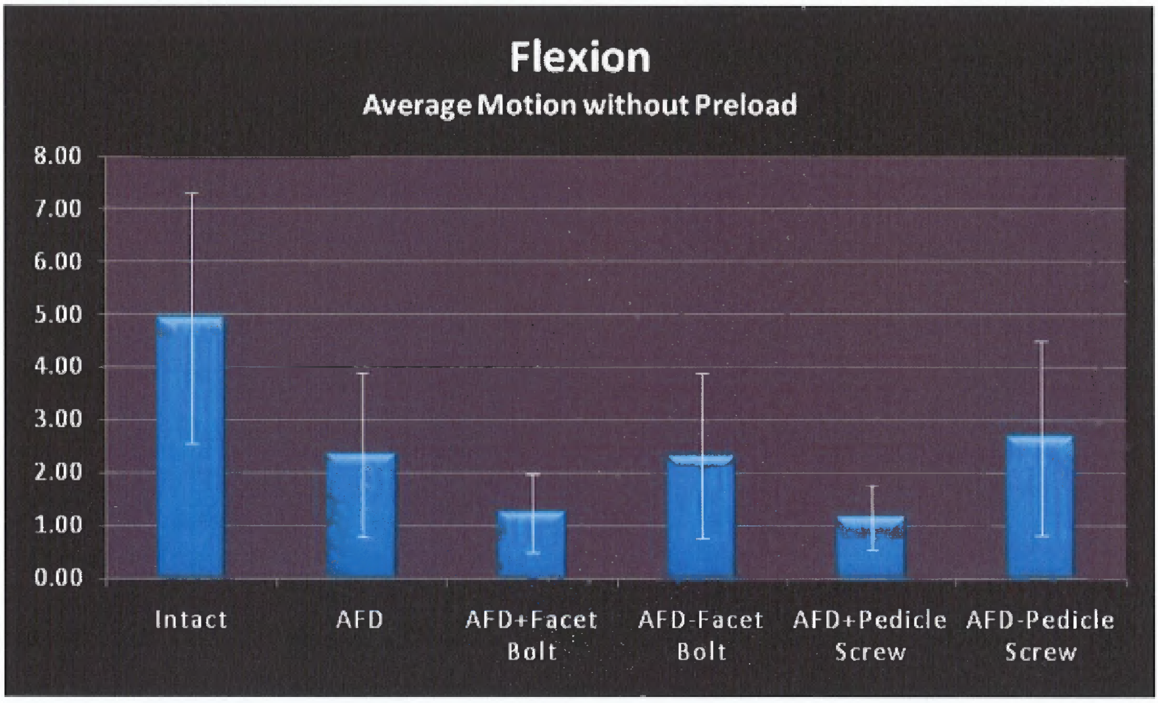


Figure 4.5 Average motion in flexion test mode without preload.

Table 4.6: Flexion Test Mode – Average Motion Values without Preload.*

	Intact	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
average	4.93	2.35	1.24	2.31	1.15	2.67
Std	2.37	1.56	0.75	1.57	0.61	1.84

*Values rounded to nearest two decimal places

In flexion without preload test mode the calculated p-value was 0.0033, which is approximately 99.67% confidence interval.

Table 4.7: SNK Post-hoc analysis results of treatments during flexion without preload.

SNK Grouping	Mean	Treatment
A	4.9262	Intact
B	2.6672	AFD-Pedicle Screws
B	2.3492	AFD
B	2.3145	AFD-Facet Bolts
B	1.2358	AFD+Facet Bolts
B	1.1535	AFD+Pedicle Screws

The SNK grouping shows that there was a significant difference in reduction in motion between Intact (Group A) and all other treatments (Group B). Since all other treatments are in Group B, this implies that in flexion test mode when comparing AFD to AFD with additional posterior fixation (i.e. Facet Bolts and Pedicle Screws) there is no significant difference in motion. This implies that with addition of posterior fixation to the AFD construct no significant reduction in motion was observed.

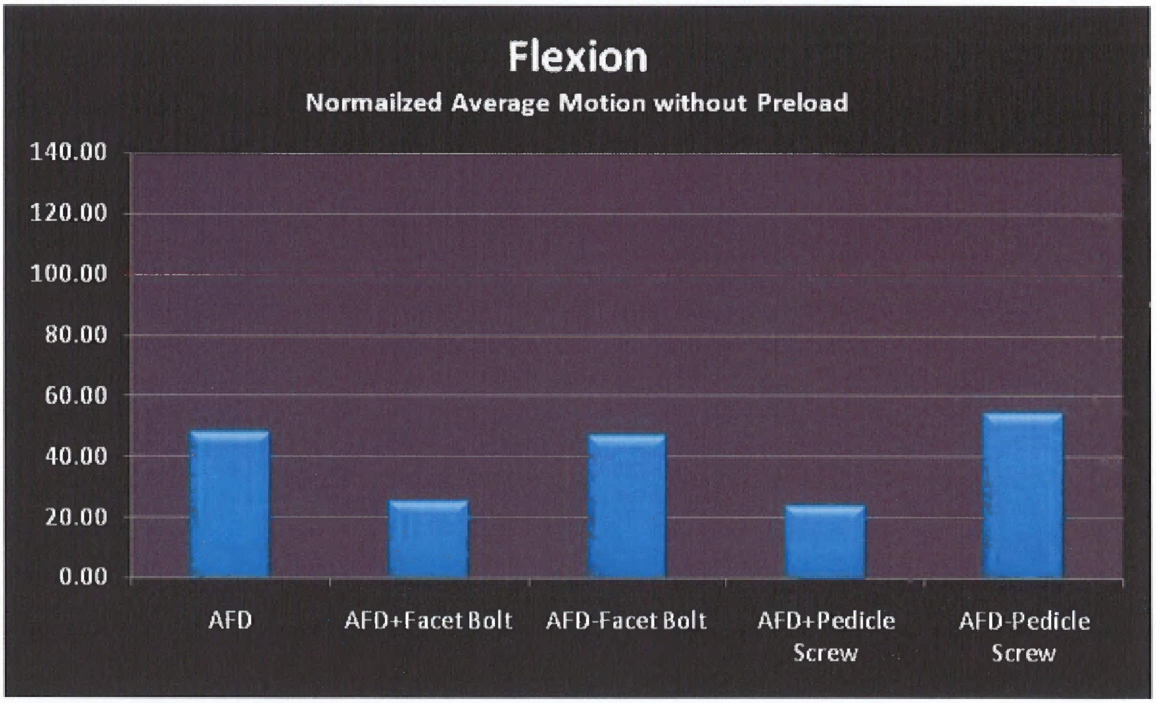


Figure 4.6 Normalized in flexion mode, average motion without preload.

Table 4.8: Flexion Test Mode – Normalized Values without Preload.

	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
% to Intact	47.69	25.09	46.98	23.42	54.14

4.3.2 Flexion with Preload

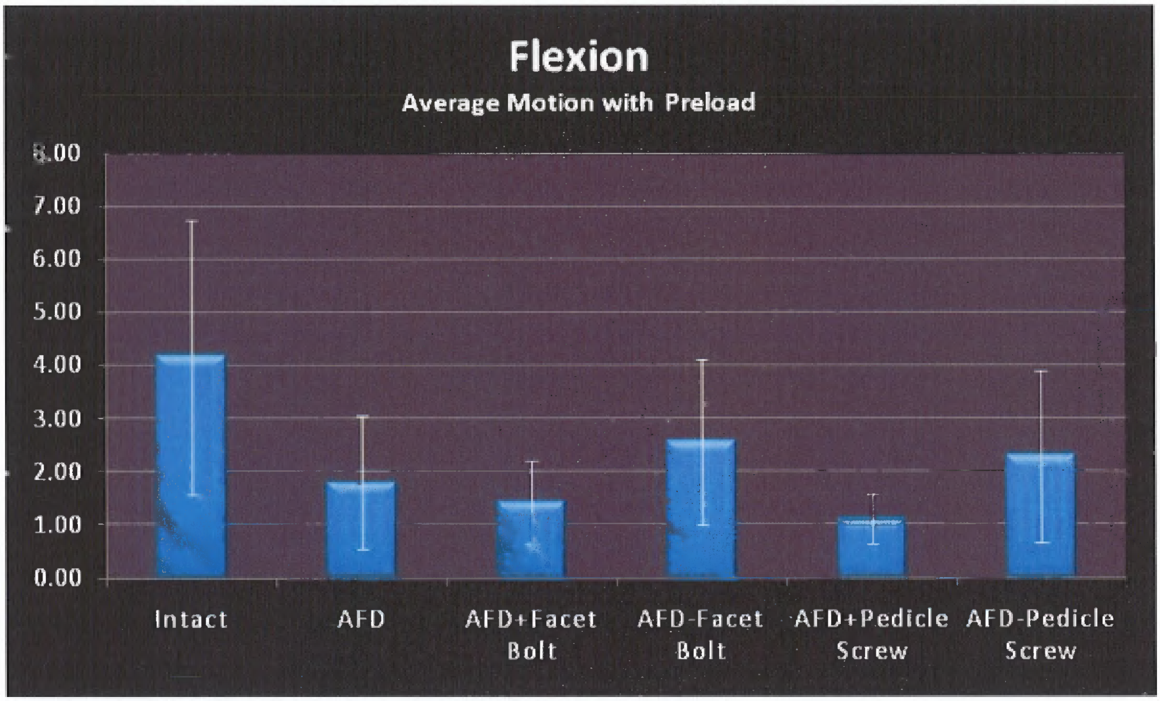


Figure 4.7 Average motion in flexion test mode with 400N preload.

Table 4.9: Flexion Test Mode – Average Motion Values with 400N Preload.*

	Intact	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
average	4.15	1.79	1.42	2.56	1.09	2.29
Std	2.59	1.25	0.78	1.56	0.47	1.61

*Values rounded to nearest two decimal places

In flexion without preload test mode the calculated p-value was 0.0323, which is approximately 96.77% level of significance.

Table 4.10: SNK Post-hoc analysis results of treatments during flexion with 400N preload

SNK Grouping	Mean	Treatment
A	4.1547	Intact
B A	2.5632	AFD-Facet Screws
B A	2.4689	AFD
B A	2.2894	AFD-Pedicle Screws
B	1.4224	AFD+Facet Bolts
B	1.0948	AFD+Pedicle Screws

Comparison between Intact (Group A), mean value 4.1547 and AFD (Group A) mean value 2.5632 show that there was not significant reduction in motion with addition of AFD in flexion with 400N preload test mode.

However a direct comparison between Intact (Group A) with AFD+ Facet Bolts and AFD+ Pedicle screws (both in Group B) show that with additional posterior fixation added to the AFD construct (facet bolts and pedicle screws) a significant reduction in motion was observed.

For the treatments that have both letter A and B imply that there was no significant difference between those treatments compared to any other treatment in statistical analysis.

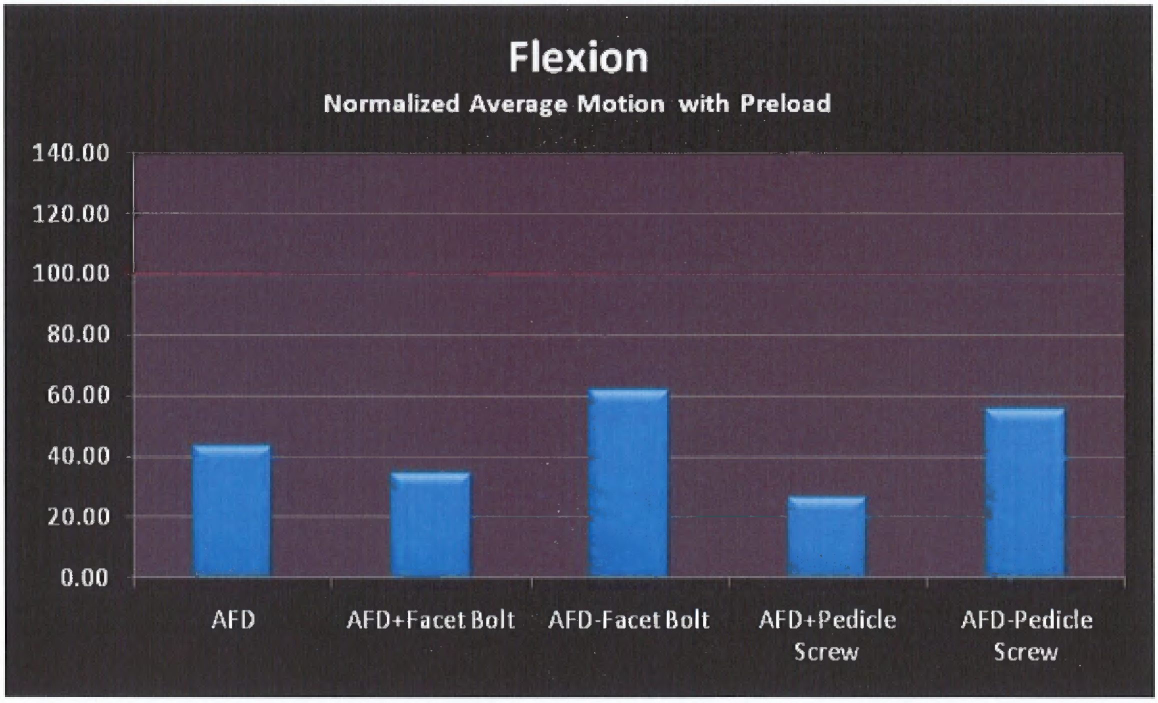


Figure 4.8 Normalized in flexion mode, average motion with 400N preload.

Table 4.11: Flexion Test Mode – Normalized Values without Preload.

	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
% to Intact	43.07	34.24	61.69	26.35	55.10

4.4 Left Bending

4.4.1 Left without Preload

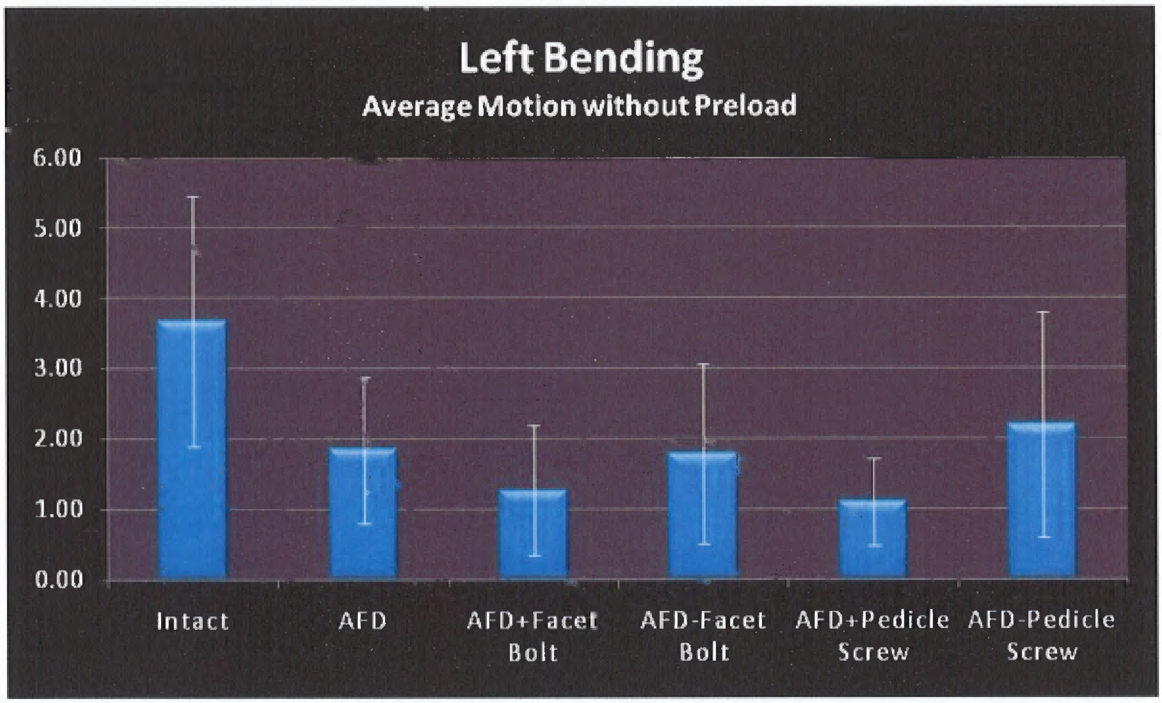


Figure 4.9 Average motion in Left Bending test mode without preload.

Table 4.12: Left Bending Test Mode – Average Motion Values without Preload.*

	Intact	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
average	3.67	1.84	1.26	1.78	1.10	2.19
Std	1.78	1.03	0.93	1.28	0.61	1.60

*Values rounded to nearest two decimal places

In left bending without preload test mode the calculated p-value was 0.0207, which is approximately 97.93% level of significance.

Table 4.13: SNK Post-hoc analysis results of treatments during left bending without preload.

SNK Grouping	Mean	Treatment
A	3.6723	Intact
B A	2.1856	AFD-Pedicle Screws
B A	1.8398	AFD
B A	1.7839	AFD-Facet Bolts
B	1.2619	AFD+Facet Bolts
B	1.0999	AFD+Pedicle Screws

Comparison between Intact (Group A), mean value 3.6723 and AFD (Group A) mean value 2.1856 show that there was not significant reduction in motion with addition of AFD in left bending without preload test mode.

However a direct comparison between Intact (Group A) with AFD+ Facet Bolts and AFD+ Pedicle screws (both in Group B) show that with additional posterior fixation added to the AFD construct (facet bolts and pedicle screws) a significant reduction in motion was observed.

For the treatments that have both letter A and B imply that there was no significant difference between those treatments compared to any other treatment in statistical analysis.

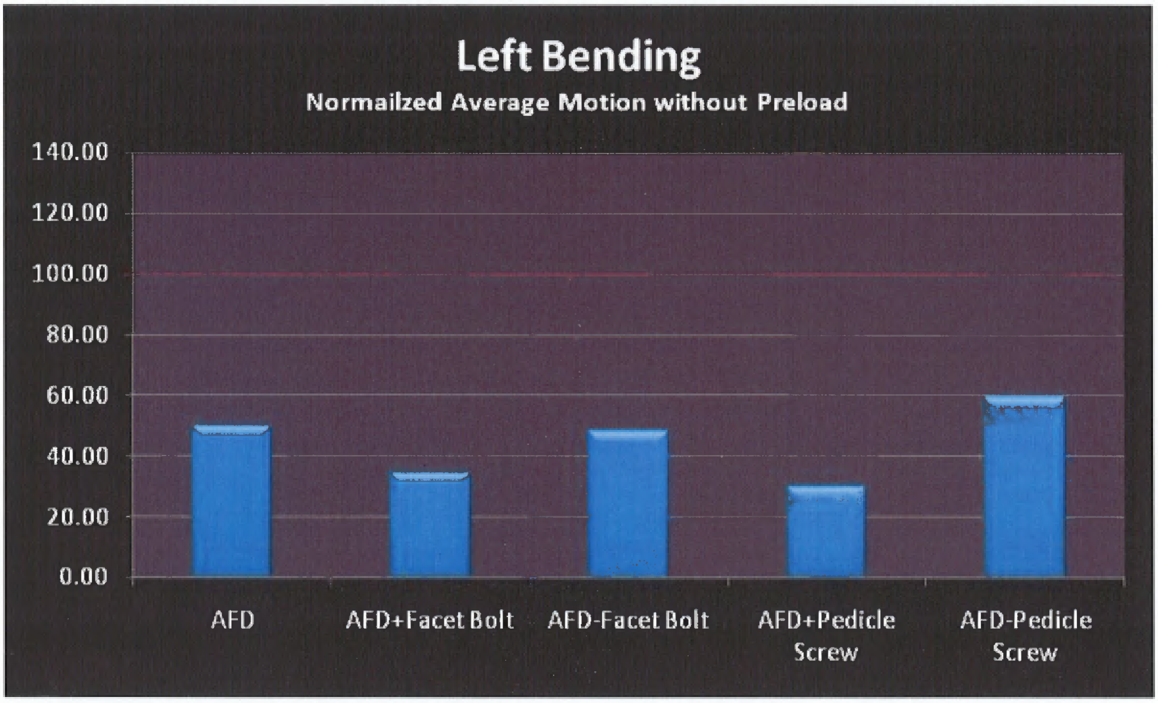


Figure 4.10 Normalized in left bending mode, average motion without preload.

Table 4.14: Left Bending Test Mode – Normalized Values without Preload.

	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
% to Intact	50.10	34.36	48.58	29.95	59.52

4.5 Right Bending without Preload

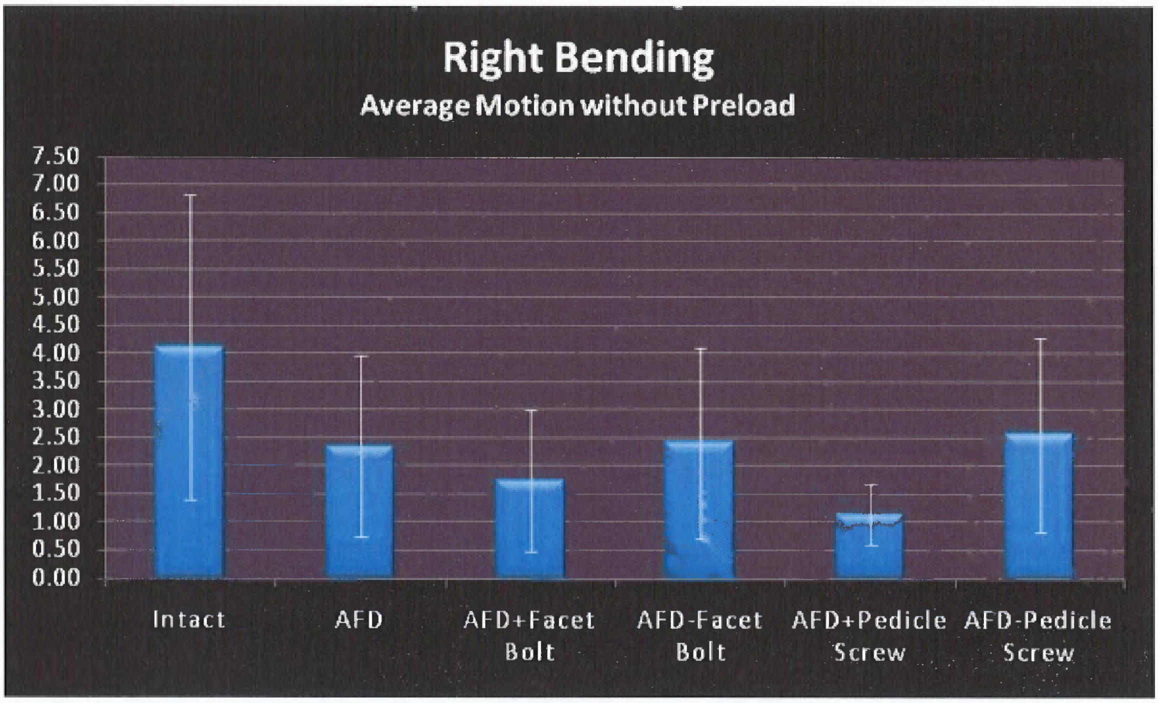


Figure 4.11 Average motion in Right Bending test mode without preload.

Table 4.15: Right Bending Test Mode – Average Motion Values without Preload*

	Intact	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
average	4.12	2.35	1.74	2.41	1.14	2.55
Std	2.71	1.62	1.25	1.69	0.54	1.72

*Values rounded to nearest two decimal places

In right bending without preload test mode the calculated p-value was 0.1009, which is approximately 89.91% level of significance. This implies that in this test mode no significant difference was found between the treatments. Since the level of significance was lower than 95% (i.e. p-value > 0.05) SNK Post-hoc analysis was not applied.

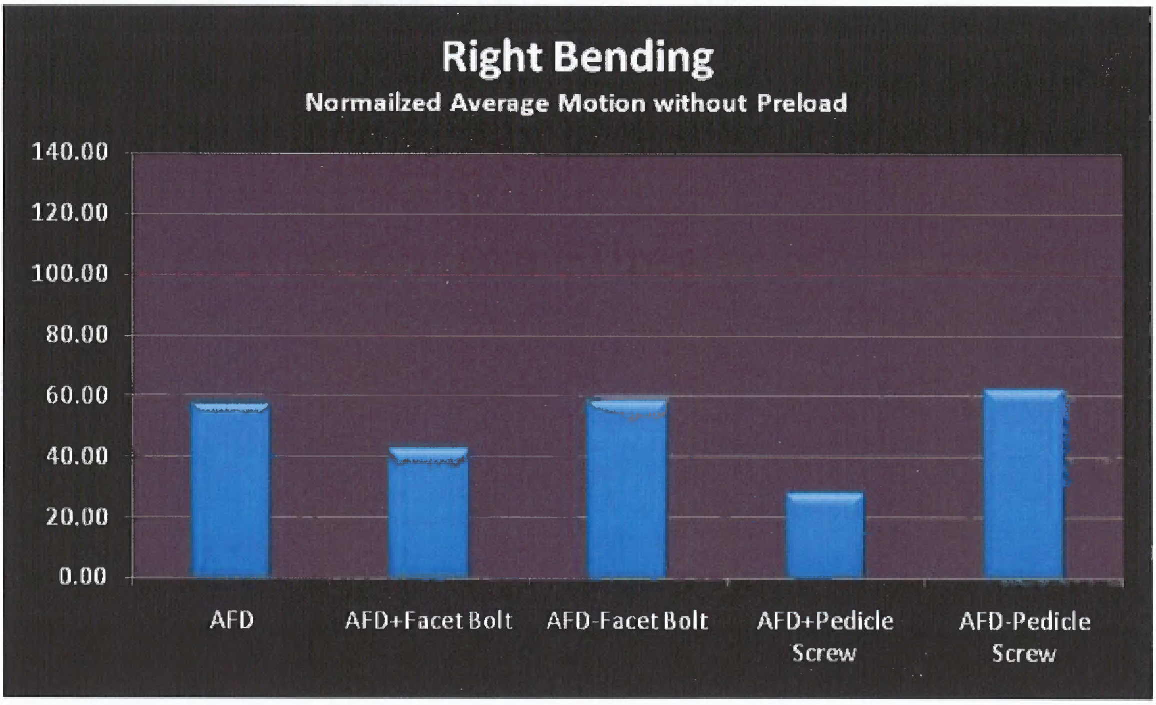


Figure 4.12 Normalized in right bending mode, average motion without preload.

Table 4.16: Right Bending Test Mode – Normalized Values without Preload.

	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
% to Intact	57.14	42.32	58.60	27.68	62.07

4.6 Left Rotation without Preload

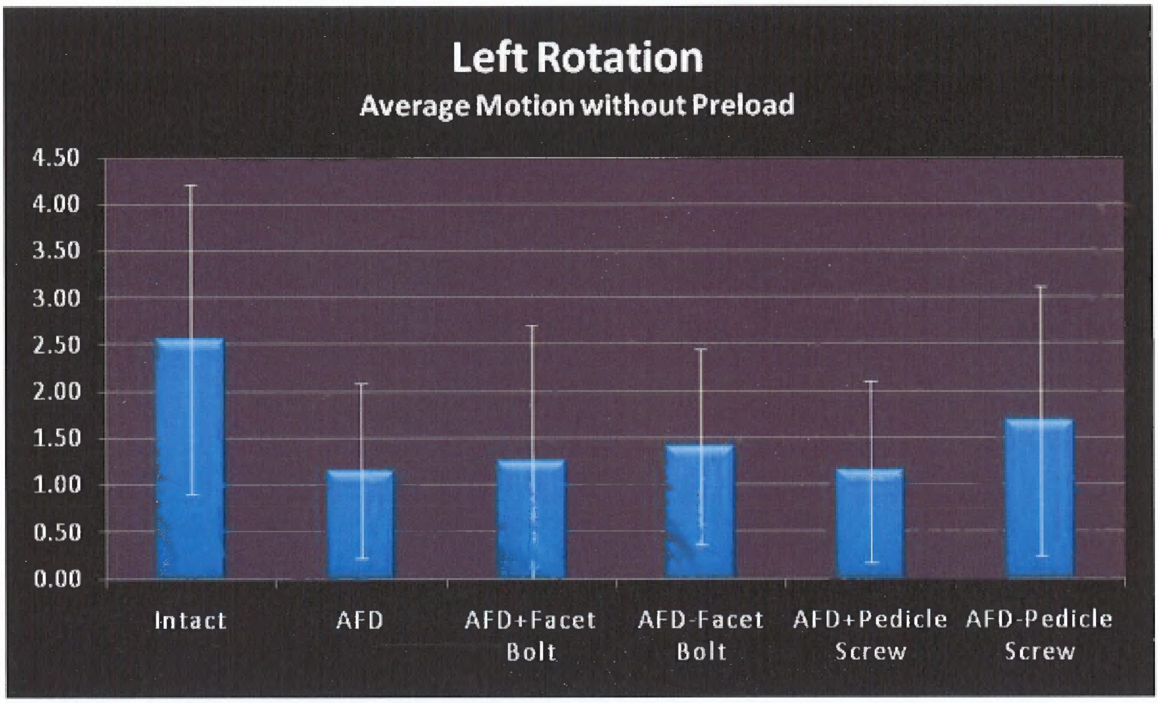


Figure 4.13 Average motion in Left Rotation test mode without preload.

Table 4.17: Left Rotation Test Mode – Average Motion Values without Preload.*

	Intact	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
average	2.56	1.15	1.25	1.40	1.14	1.68
Std	1.65	0.94	1.47	1.05	0.97	1.44

*Values rounded to nearest two decimal places

In left rotation without preload test mode the calculated p-value was 0.3958, which is approximately 60.42% level of significance. This implies that in this test mode no significant difference was found between the treatments. Since the level of significance was lower than 95% (i.e. p-value > 0.05) SNK Post-hoc analysis was not applied.

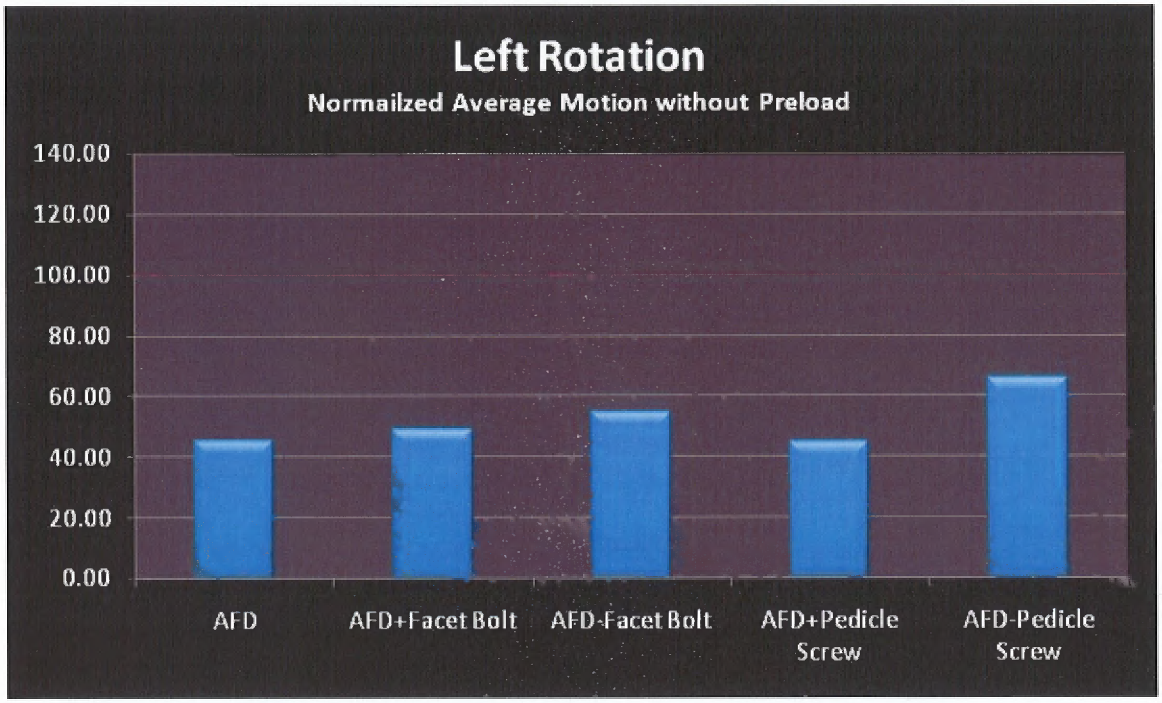


Figure 4.14 Normalized in left rotation mode, average motion without preload.

Table 4.18: Left Rotation Test Mode – Normalized Values without Preload.

	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
% to Intact	45.13	48.70	54.90	44.67	65.58

4.7 Right Rotation without Preload

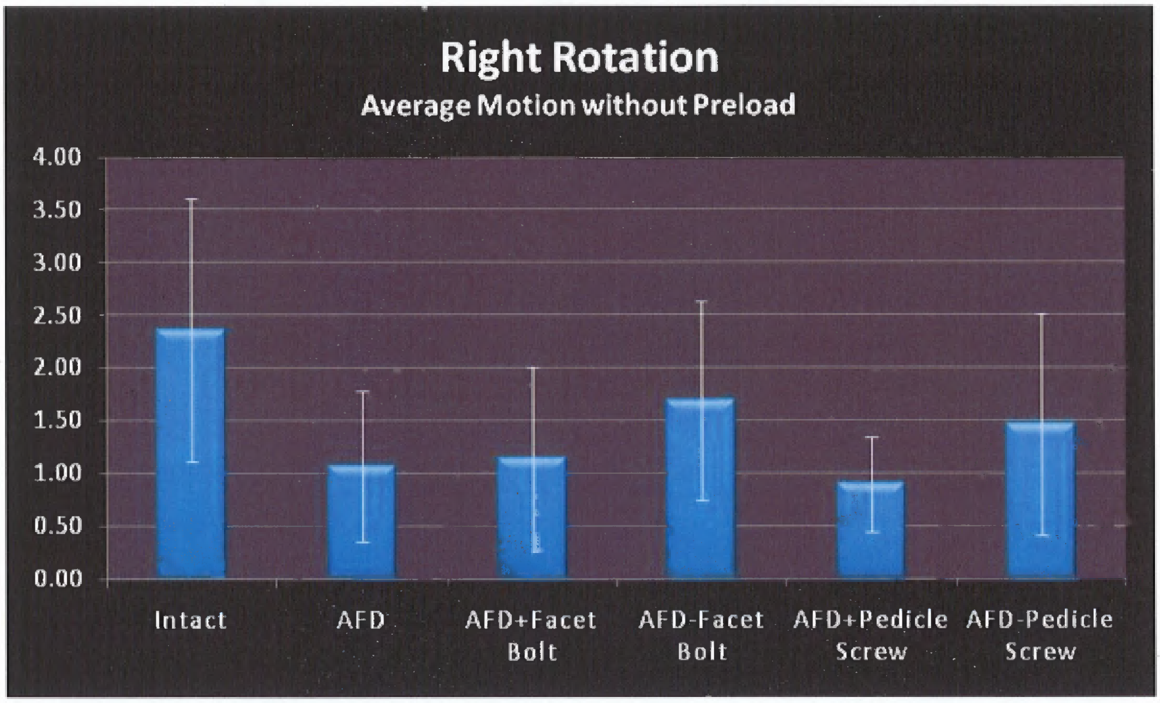


Figure 4.15 Average motion in Right Rotation test mode without preload.

Table 4.19: Right Rotation Test Mode – Average Motion Values without Preload.*

	Intact	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
average	2.36	1.07	1.13	1.69	0.89	1.46
Std	1.25	0.71	0.87	0.94	0.44	1.05

*Values rounded to nearest two decimal places

In right rotation without preload test mode the calculated p-value was 0.0981, which is approximately 90.19% level of significance. This implies that in this test mode no significant difference was found between the treatments. Since the level of significance was lower than 95% (i.e. p-value > 0.05) SNK Post-hoc analysis was not applied.

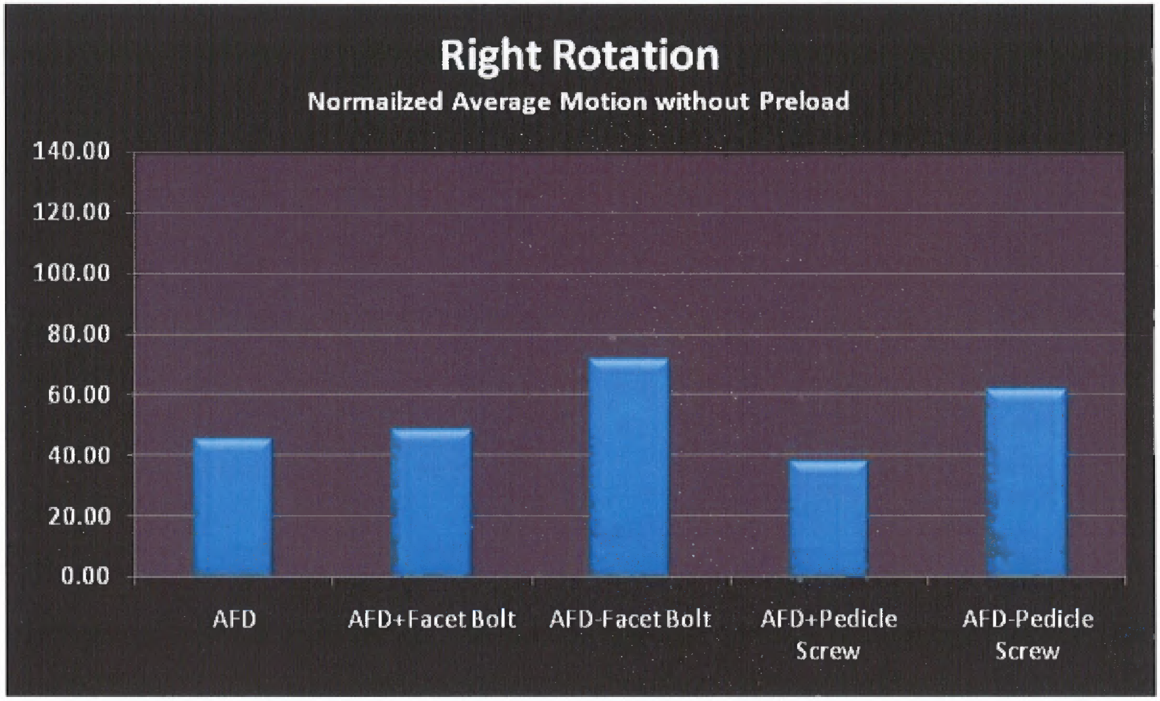


Figure 4.16 Normalized in right rotation mode, average motion without preload.

Table 4.20: Right Rotation Test Mode – Normalized Values without Preload.

	AFD	AFD+ Facet Bolt	AFD- Facet Bolt	AFD+ Pedicle Screw	AFD- Pedicle Screw
% to Intact	45.27	48.12	71.65	37.82	61.79

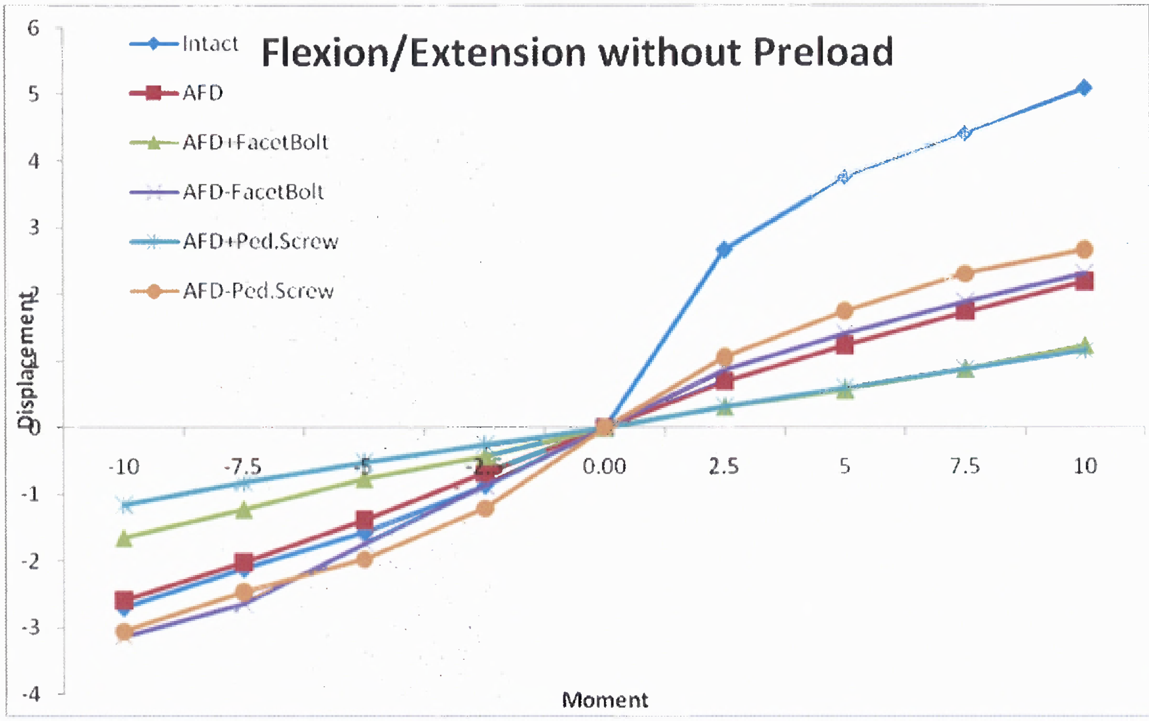


Figure 4.17 Moment vs Displacement of the flexion/extension test mode without preload.

For all specimens, the relative angular motion increased with the increase in the applied load for all six test modes. Figure 4.17 thru 4.20 indicate the average motion of six specimens under increasing loading conditions with reference to the fixed level (L3 in L1-L3 level and S1 in L5-S1 level). In all test modes the intact motion is lot higher than the stabilized implanted modes. Appendix A shows results of all individual specimens.

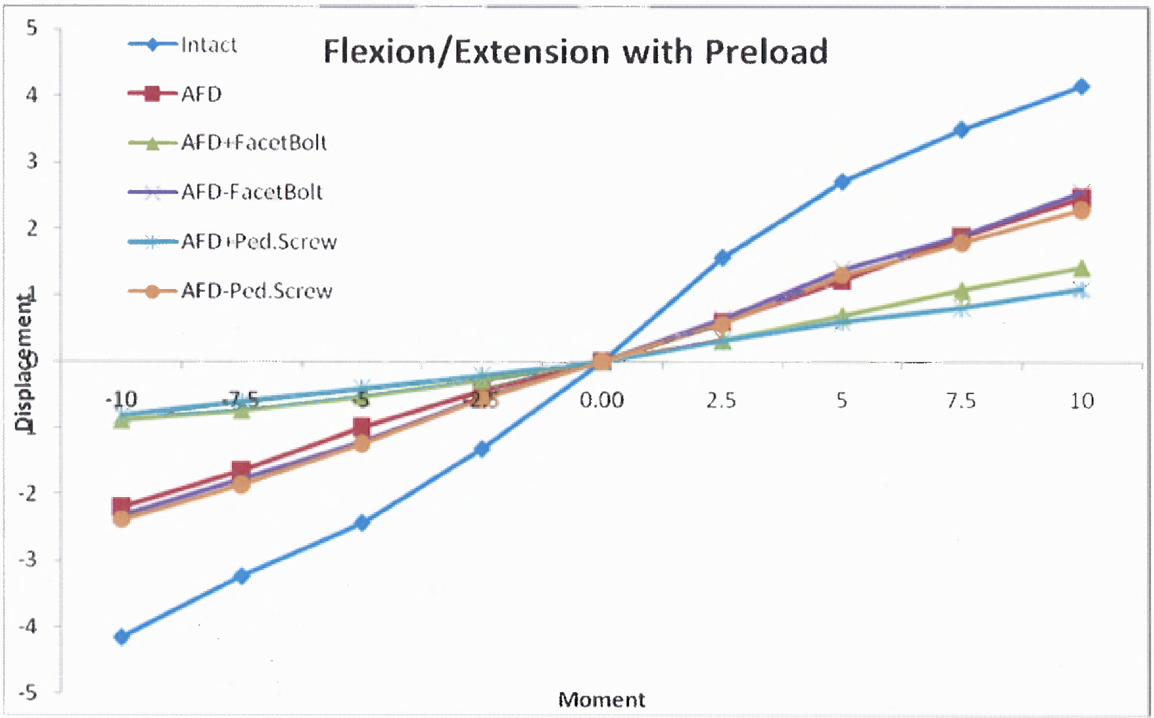


Figure 4.18 Moment vs Displacement of the flexion/extension test mode with 400N preload.

It is important to understand the significance of preload (discussed in section 2.6 of Literature review). In vivo, preload of physiologic magnitude is applied by muscular forces and annular pre-tensioning. Adding a 400N preload clearly reduced the degrees of motion as an average of all specimens in all testing sequences.

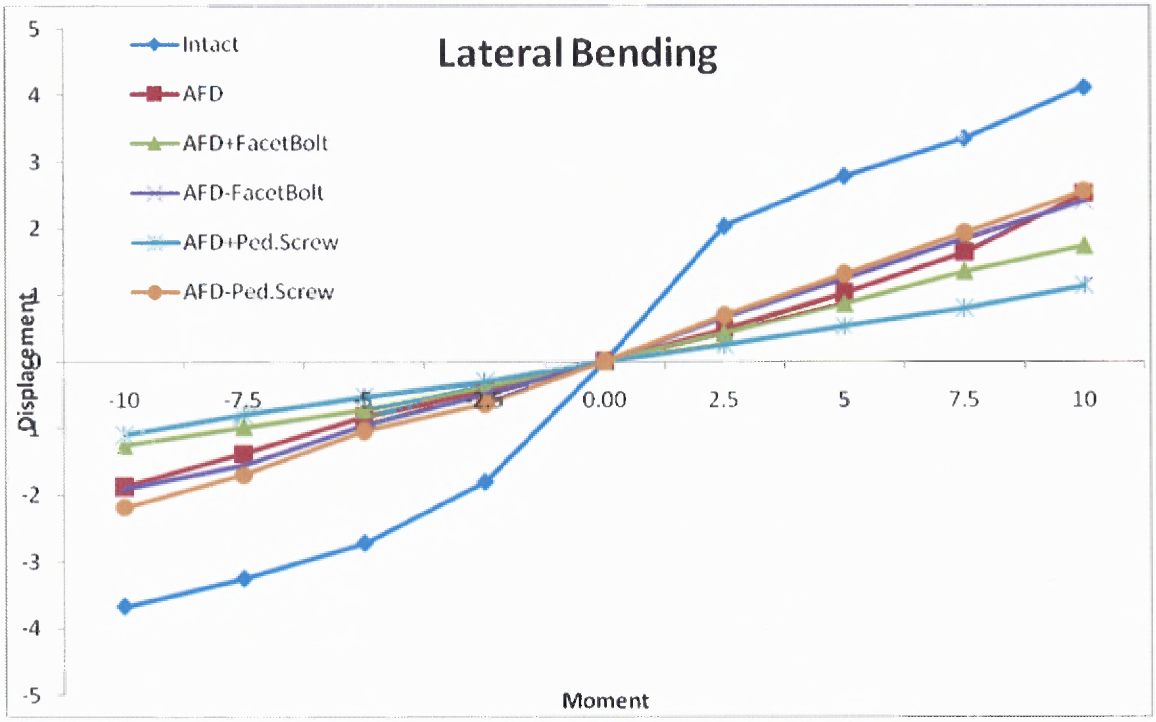


Figure 4.19 Moment vs Displacement of the lateral bending test mode.

Similar to other test modes a clear distinction can be made between intact and other test sequences. After stabilization is applied a noticeable reduction in motion is observed in lateral bending (left and right). According to the graph the AFD + pedicle screws construct has the reduction in motion (with smallest slope). The AFD + facet bolt construct is stiffer compared to AFD alone. After removal of the facet bolts and pedicle screws an increase in motion was observed compared to initial sequence with AFD alone.

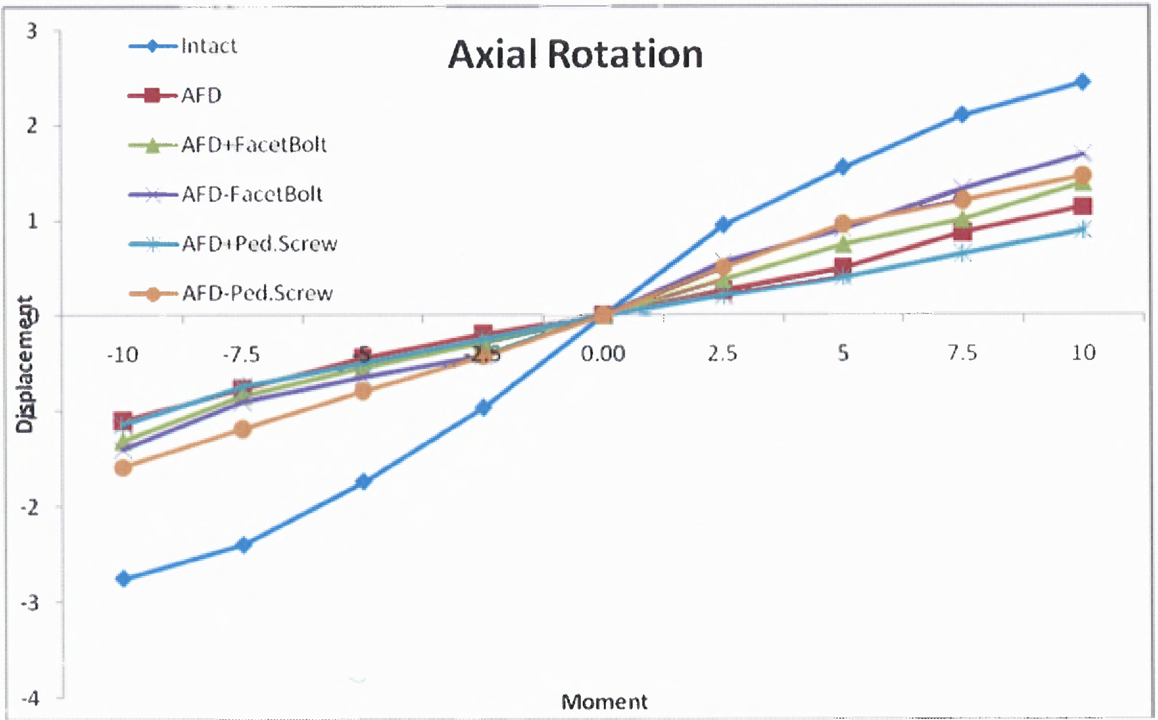


Figure 4.20 Moment vs Displacement of the axial rotation test mode.

Even in axial rotation, the AFD + pedicle screw construct reduced the highest amount of motion. In this test mode, insignificant change in motion was observed between AFD alone and addition of facet bolts.

CHAPTER 5

DISCUSSION

5.1 Overview

The objective of this study was to quantify the change in stiffness occurring in the lumbar spine motion segment after implantation under simulated physiological loading paradigms. The goal was to observe the effects different types of fixation hardware on the FSU stiffness and its range of motion.

In this study a new and unique stand-alone anterior interbody fusion device (AFD) was assessed. The study evaluated the fixation of the AFD with supplemental posterior stabilization to determine if supplemental hardware provided significant additional stability to the interbody fusion site.

This chapter will discuss the results from Chapter 4 categorized based on three degrees of freedom test modes (flexion/extension (with and without preload), lateral bending and axial rotation). It will also explain the statistical significance of each of the test results.

5.2 Discussion of Results

Before discussing the results, it is important to understand the choice of the parameters used in this study. Parameters such as preload, incremental loads, sample size, etc.

The preload of 400 N simulates the average compressive force of physiologic conditions in an upright standing position. This load was only applied in the sagittal plane; i.e., extension and flexion. The reason for applying preload only in sagittal plane is because currently only these test modes have been validated. A study lead by Patwardhan et al.[44,45] investigated the sagittal plane mobility of the whole lumbar spine under different compressive preloads of physiologic magnitude.

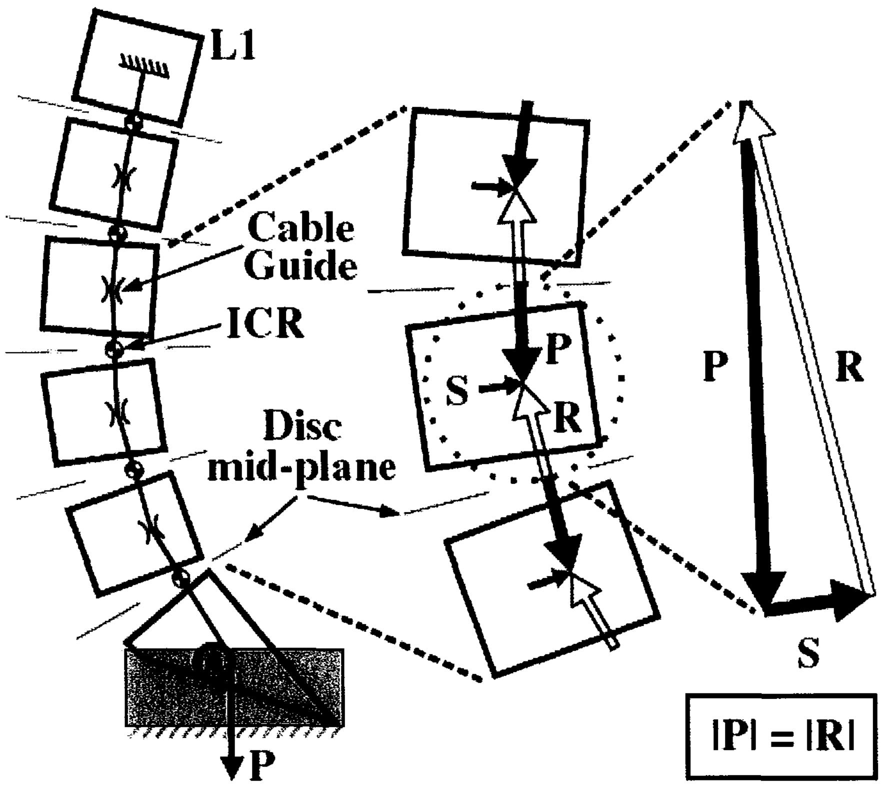


Figure 5.1 A schematic of lumbar spine (L1-Sacrum), subjected to preload.

[45]Source: Patwardhan AG, Havey RM, Carandang G, et al. Effect of compressive follower preload on the flexion-extension response of the human lumbar spine. *J Orthop Res* 2003;21:540-6.

The free body diagram in Figure 5.1 shows equilibrium of intermediate vertebrae under cable force (P), cable guide shear force (S) and internal reaction (R). [44,45] The load vector (P) passes through the flexion-extension Instantaneous Center of Rotation (ICR) of each segment and is perpendicular to the mid-planes of the discs in a given posture of the specimen. The study hypothesized that compressive preloading significantly affects the stability of the ALIF construct. In vivo this instability is balanced by preload of physiologic magnitude, applied by muscular forces and annular pre-tensioning. In conclusion, the publication determined that the external compressive preload significantly affected the stabilization provided by the implant device.[44]

As described in Chapter 3, for each test mode and treatment data was collected with incremental loads being applied. Loads were applied from 2.5 Nm to 10 Nm in increments of 2.5 Nm (i.e. 2.5, 5, 7.5 and 10 Nm). To analyze results only data collected from the highest load applied to the human spine (i.e. 10 Nm) was used.

5.2.1 Extension

5.2.1.1 Extension without preload

During extension without preload test mode, no significant motion reduction was found between treatments when using the average of all specimens. With data normalized to intact specimen, ≈ 8% reduction in motion was observed when AFD was added compared to ≈ 58% with addition of pedicle screws and facet bolts.

5.2.1.2 Extension with preload

With addition of preload, a significant reduction in motion was found between treatments, when taking the average of all six specimens. After applying a SNK Post-hoc analysis, it was determined that there was not a significant reduction in motion with addition of AFD compared to intact. On the other hand a significant difference in motion was observed between intact and AFD +facet bolts and AFD +pedicle screws.

An insignificant reduction in motion was observed when comparing AFD alone to addition of facet bolts and pedicle's screws.

In normalized average motion to intact, there was ≈ 60% reduction in motion between intact and addition of AFD during extension with preload (as compared to only

≈ 8% without preload). With addition facet bolts and pedicle screws to the AFD construct the motion was reduced to ≈ 78% and ≈ 80% respectively.

The stand-alone interbody device was able to significantly reduce more motion in extension with preload compared to without preload. These results directly corroborate the hypothesis by Patwardhan et al. that compressive preloading affects the stability of ALIF construct.[44] Better stability was even observed during addition of posterior fixation, when comparing with and without preload results in extension test mode.

5.2.2 Flexion

5.2.2.1 Flexion without preload

During this test mode on average a significant reduction in motion was found. When the SNK post-hoc analysis was applied, a significant reduction in motion was found between intact and all other treatments. But no significant reduction was found with addition of posterior fixation to the AFD construct.

In flexion, this interbody device was expected to perform well due to its large footprint, oblong shape and flat superior and inferior surfaces.[41] When analyzing the normalized average motion a ≈ 52% reduction in motion was observed with addition of just AFD (compared to ≈ 8% in extension without preload). With addition of facet bolts and pedicle screws to the AFD construct, a reduction of ≈ 75% and ≈77% respectively was observed (when considering intact treatment as 100%).

5.2.2.2 Flexion with preload

On average a significant reduction was also found in flexion with 400N preload. After performing the SNK post-hoc analysis, no significant reduction in motion was found between intact and addition of AFD. But a significant reduction was observed between intact and AFD with posterior fixation. Also, no significant difference in motion was found between AFD and AFD +posterior fixation.

During the normalized average motion ≈57% reduction in motion was observed between intact and AFD. Approximately 66% reduction in motion was observed with AFD +Facet bolts. On the other hand ≈74% motion reduction was seen with AFD +pedicle screws.

When comparing average motion values of intact and AFD, during flexion with and without preload, a higher standard deviation was observed with preload test mode. This seems to be the cause of insignificant reduction in motion, even though the normalized average motion shows increase in reduction of motion (≈57%) with addition of AFD (compared to ≈ 52% without preload).

5.2.3 Left Bending without preload

On average a significant reduction was found in left bending without preload. After performing the SNK post-hoc analysis, no significant reduction in motion was found between intact and addition of AFD. But a significant reduction was observed between intact and AFD with posterior fixation. Also, no significant difference in motion was found between AFD and AFD +posterior fixation.

For normalized average values a 50% reduction was observed with addition of AFD. With addition of facet bolts and pedicle screws to the AFD construct a reduction of ≈66% and ≈70% respectively was observed.

5.2.4 Right bending without preload

During this test mode on average an insignificant reduction of motion was observed between treatments. During the normalized average motion analysis ≈43% reduction was observed with addition of AFD. On the other hand, with addition of facet bolts and pedicle screws ≈58% and 72% reduction in motion was observed respectively.

5.2.5 Left Rotation without preload

During left rotation no significant motion was observed between treatments. Analyzing the normalized average values ≈55% reduction in motion was observed with AFD. The addition of both facet bolts and pedicle screws in this test mode did not lead to significant reduction in motion. A reduction of ≈51% and 55% in motion was observed with addition of facet bolts and pedicle screws to the AFD respectively.

Tremendous amount of standard deviation was observed in this test mode, especially during the AFD +Facet bolt treatment. Looking at individual specimen data, it seems that one specimen had unusual spike in degrees of motion at 10 Nm, when compared to lower loads (i.e. 2.5, 5 and 7.5 Nm). After this observation, the specimen was re-thawed to look for anatomical defects. No defects were visible with naked eye. The reason for such behavior in a certain degree of freedom could very well be an underlining anatomical defect.

5.2.6 Right Rotation without preload

In right rotation no significant difference in motion was found between treatments. Analyzing the normalized average values ≈55% reduction in motion was observed with AFD. In this test mode the addition of both facet bolts and pedicle screws did not lead to significant reduction in motion. A reduction of ≈52% and 62% in motion was observed with addition of facet bolts and pedicle screws to the AFD respectively.

The calculated p-value after running multi-way ANOVA was 0.0981 which is still fairly close to the 0.05. A significant difference was not observed between intact and addition of implants, but the increase in the biomechanical stability is evident. A reason for observation of this insignificance seems to be high standard deviation.

5.3 Summary

Overall our data showed a decrease in motion with increase in stabilization by interbody spacer and additional posterior fixation. Many current studies confirm these findings.[10,11,16,52]

During all test modes removal of facet bolts and pedicle screws on average led to increased motion compared to AFD alone originally. This was caused by the incisions created in the anatomy when implanting the posterior fixation, which upon removal leaves less stable construct behind. Precautions were taken to minimize the effects of pedicle screw insertion and removal on pedicle stiffness. Pedicle screws once inserted were not removed till the completion of testing, only the connecting rods (that provide stiffness to the construct) were removed.

Our data showed no statistical difference in reduction of motion between AFD +Facet Bolts and AFD +Pedicle Screws in all test modes. A study done by Ferrara et al. performed biomechanical tests to observe short term and long term effects of cyclic loading on lumbar motion segments using stability provided by the facet screw fixation and or the pedicle screw fixation. In conclusion the study found facet fixation equivalent to pedicle screw fixation.

The new stand-alone fusion device used in this study has several design advantages. One of which is having very shallow screw angles for fixation to the vertebral bodies.

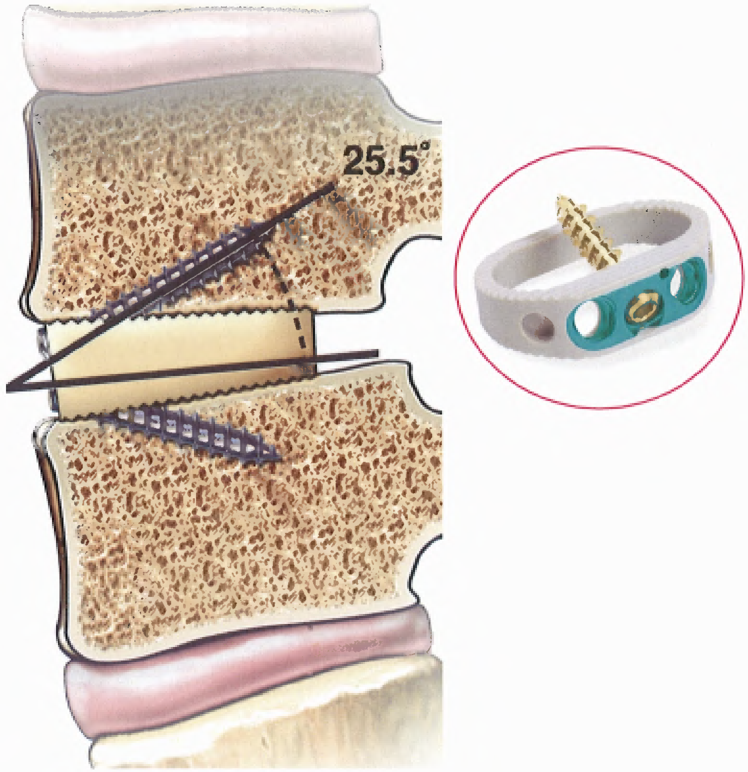


Figure 5.2 AFD low angle screw fixation.

Source: Courtesy Biomet Inc.

The outside of the vertebral body is made up of cortical bone which is much harder, stronger and stiffer compared to cancellous bone inside. Having shallow angle provides stronger fixation by maximizing thread contact with cortical bone compared to having steeper screw angle. This feature also allows for ease of implantation by requiring a small incision to facilitate screw insertion.

The results from flexion/extension test modes match well with the hypothesis by Patwardhan et al. that compressive preloading affects the stability of ALIF construct. In vivo, this instability is balanced by preload of physiologic magnitude, applied by muscular forces and annular pre-tensioning. In conclusion, the publication determined that the external compressive preload significantly affected the stabilization provided by the implant device.[44]

There is no doubt that addition of posterior fixation adds to the stability of a stand-alone construct.[48,57] But the question is whether additional fixation offered by this kind of instrumentation sufficient to ensure fusion success.

A study conducted by Fritzell et al.[22] indicate that the increased fusion rate associated with more extensive surgery was not associated with a clinical benefit. The study recognized an increased incidence in operative complications and postoperative morbidity when more extensive surgical approaches were used. The authors of this study believe a significant factor in the lack of correlation between fusion and clinical success is the morbidity associated with more extensive, technically demanding surgical intervention; specifically, the damage done to posterior muscles, adjacent facet joints, and motion segments caused by the insertion of posterior instrumentation systems.

5.4 Limitations

The current study has several limitations common to *in vitro* biomechanical experiments. First, these results extend only to the immediate postoperative state and do not include the effects of tissue remodeling or long-term viscoelastic response. Its inability to provide lumbar spine musculature stability, muscle tone at resting state and reflex muscular contraction initiated by loads applied under certain conditions.[16] Absence of these anatomical stabilizers puts additional loads onto the test devices.

The physiologic loads in the lumbar spine are not completely known. We applied 10 Nm pure moments in four incremental steps. It is still possible that higher or lower if there is a significant gain in performing a 360° fusion compared to just implanting a stand-alone interbody spacer.

loads arise in vivo. It was shown previously that these loads produce vertebral rotations typical of those measured in vivo.[43]

In this study the entire anterior and lateral annulus was removed, leaving behind only the posterior annulus intact. The anterior longitudinal ligament (ALL) was also removed at the implanted level (Figure 1.6). Removal of these anatomical stabilizers is similar to the clinical setting (variation exists between surgeon approach preferences).

A high standard deviation was observed between mean degrees of motion of specimens. This was considered as a limitation to our study. Human tissue is hard to obtain and there is limited supply available to run studies like this one. Cost and maintenance of these tissues is also a factor in deriving the samples used. Increase in sample size is expected to reduce this standard deviation.

Despite the several limitations common to many biomechanical studies, in vitro testing using human cadaveric material remains the only method suited to measure the stabilizing effect and strength of implant constructs.

5.5 Future work

Additional samples added to the current study are expected to lower the standard deviation observed. As explained in the limitations section there are lot of factors involved with human tissue, such as cost involved in obtaining specimens along with the limited availability of the supply.

An ideal condition to better understand the changes in stability between test devices used in this study would be clinical testing. In testing with clinical setting, not only will there be natural musculature loading but also feedback and reflexes of the muscles after implantation has occurred. A comparison of fusion rates can be done to see

APPENDIX A

MOMENT VS DISPLACEMENT

Figures A.1 to A.24 show results of individual six specimens, representing all six degrees of freedom.

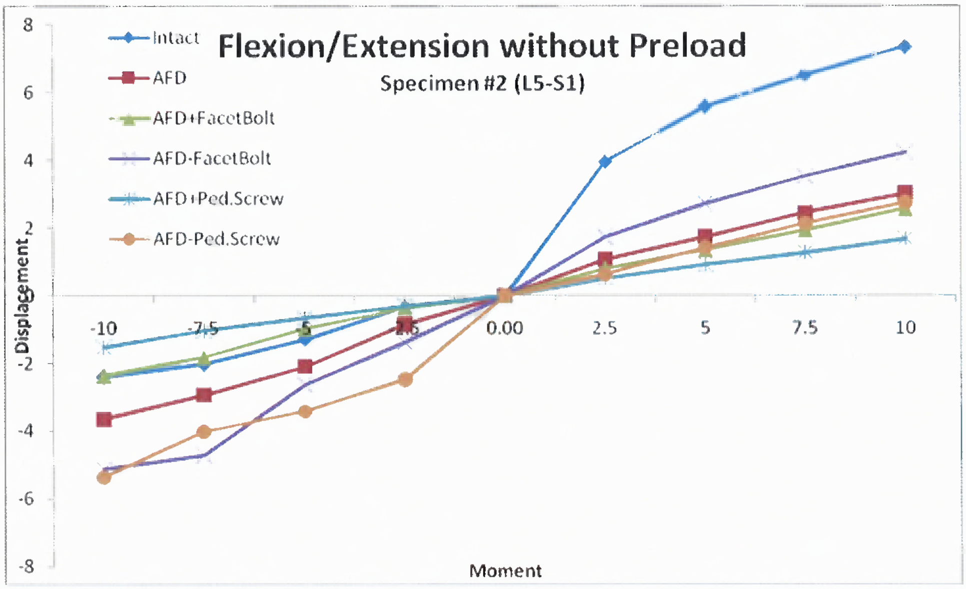


Figure A.1 Specimen #2: Moment vs Displacement of the flexion/extension test mode without preload

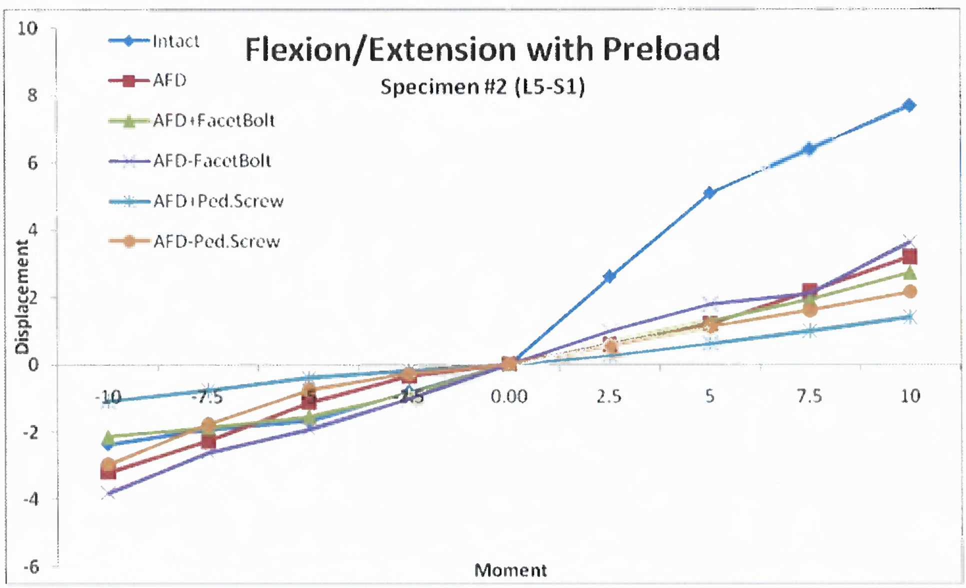


Figure A.2 Specimen #2: Moment vs Displacement of the flexion/extension test mode with 400N preload.

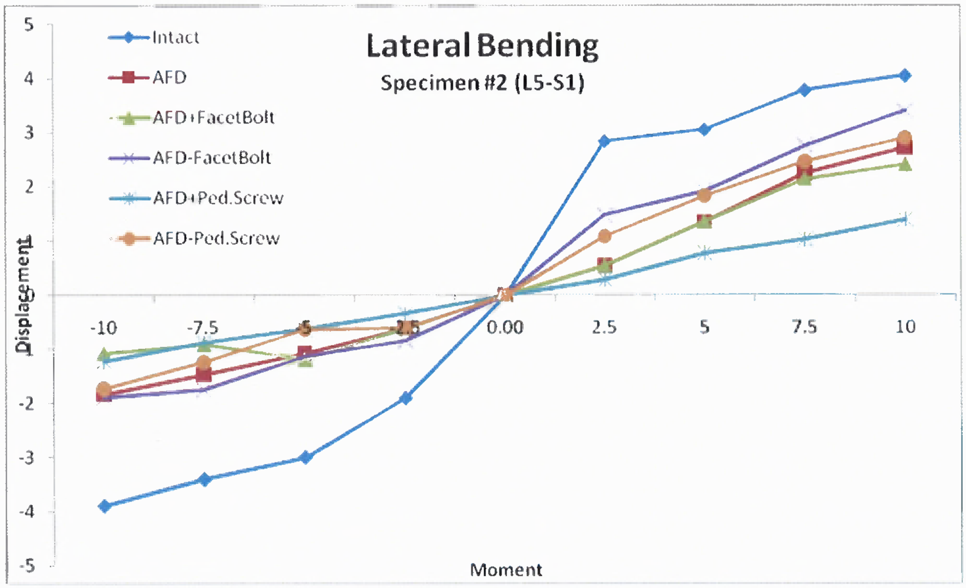


Figure A.3 Specimen #2: Moment vs Displacement of the lateral bending test mode.

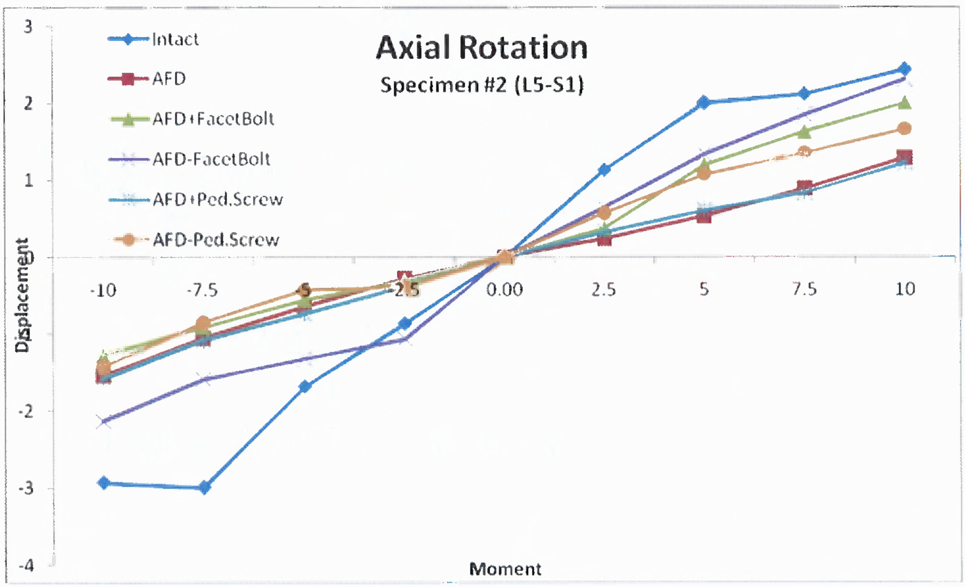


Figure A.4 Specimen #2: Moment vs Displacement of the axial rotation test mode.

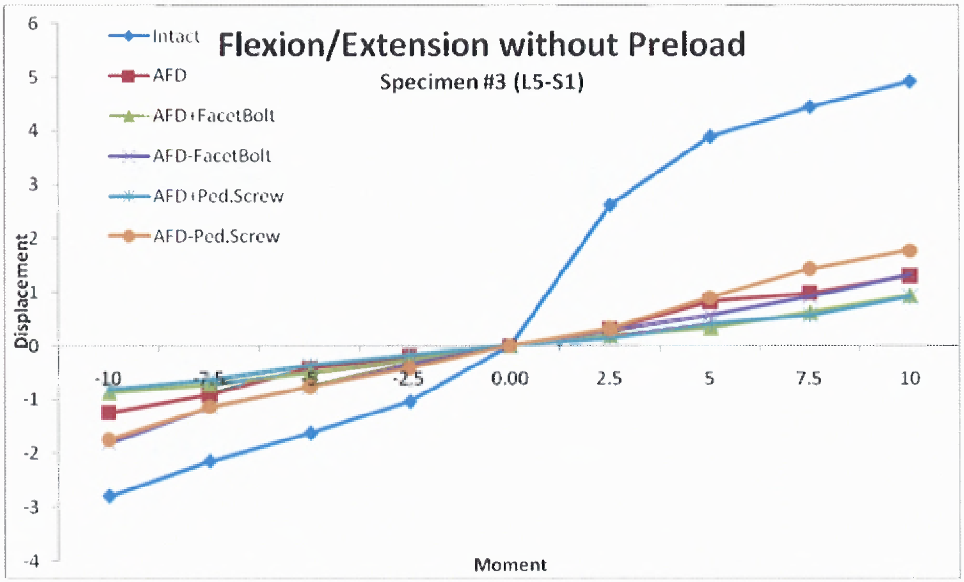


Figure A.5 Specimen #3: Moment vs Displacement of the flexion/extension test mode without preload.

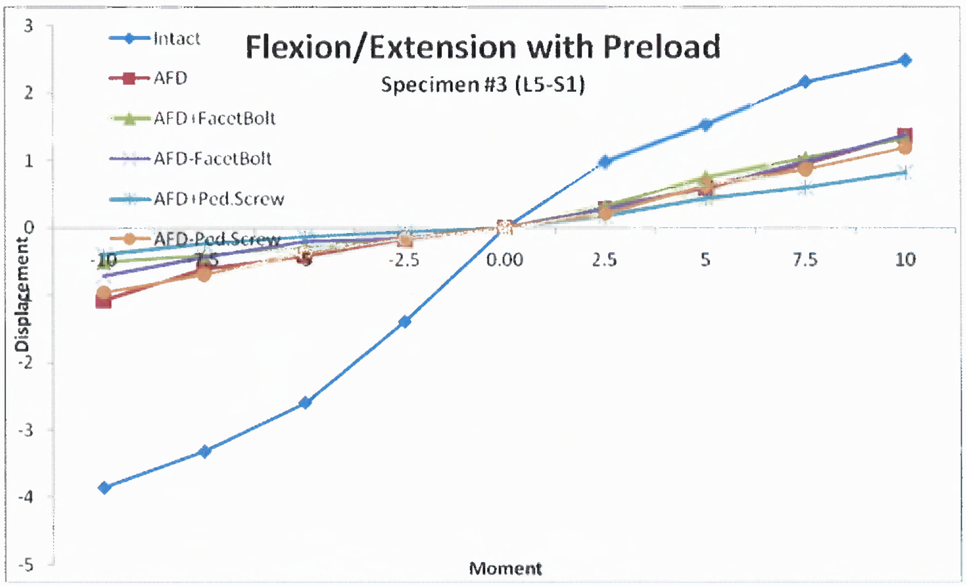


Figure A.6 Specimen #3: Moment vs Displacement of the flexion/extension test mode with 400N preload.

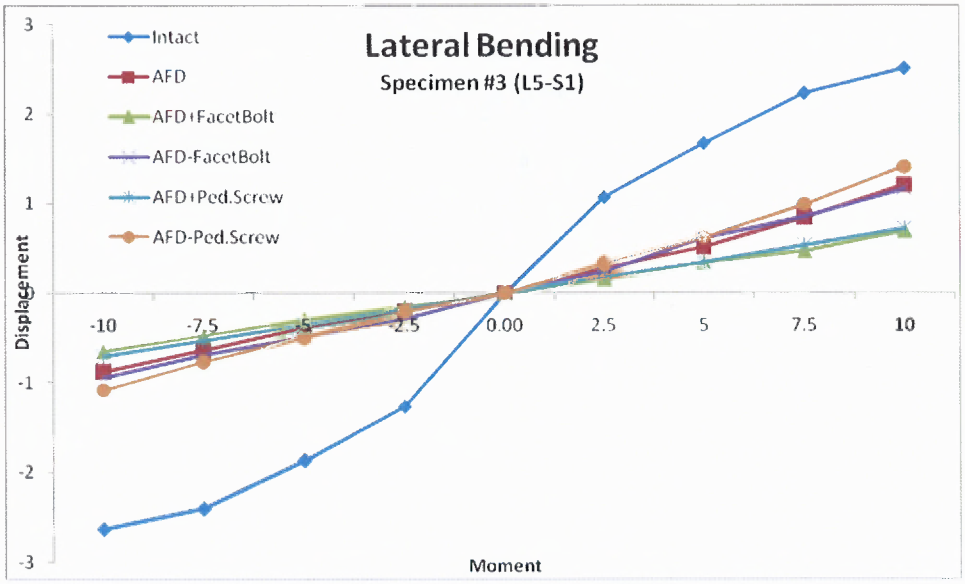


Figure A.7 Specimen #3: Moment vs Displacement of the lateral bending test mode.

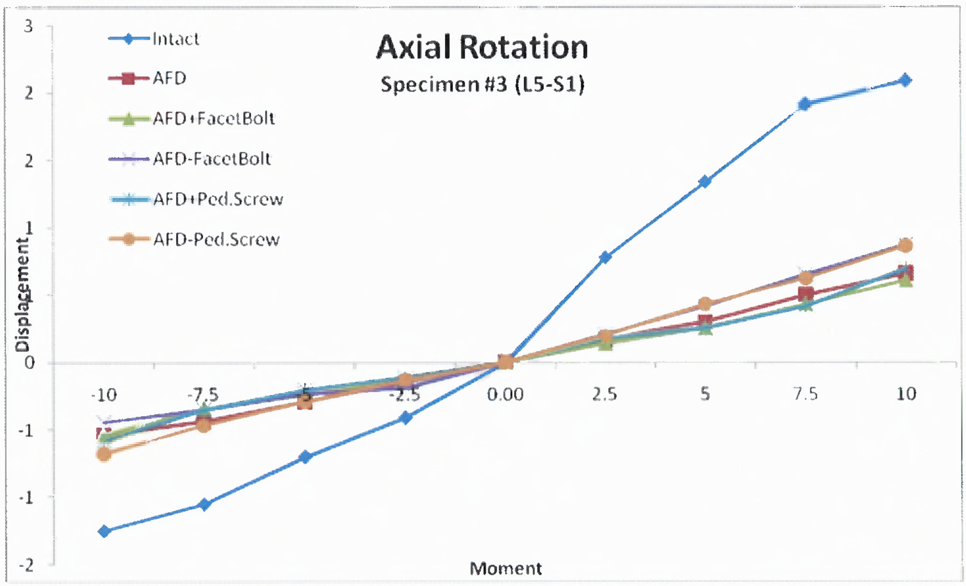


Figure A.8 Specimen #3: Moment vs Displacement of the axial rotation test mode.

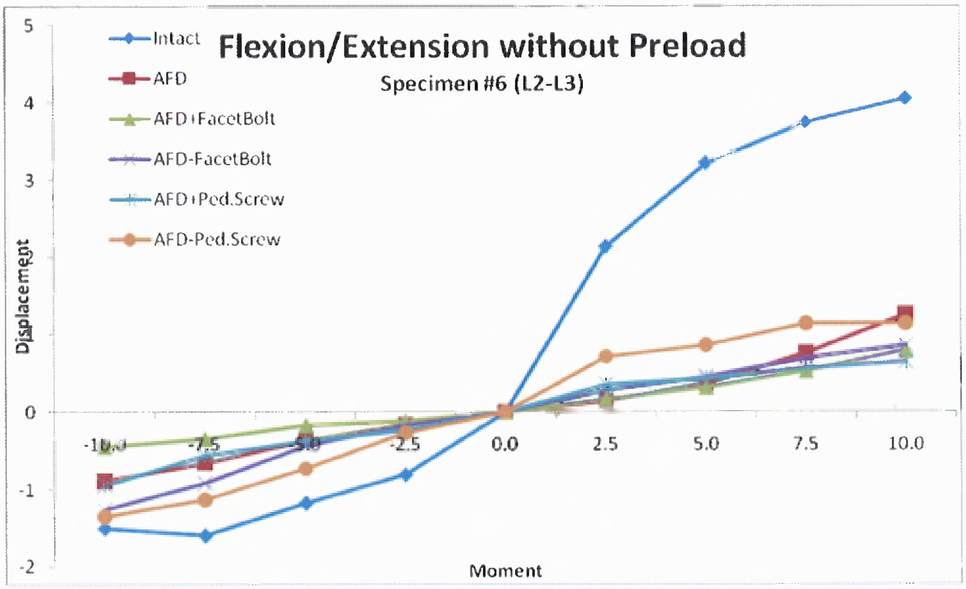


Figure A.9 Specimen #6: Moment vs Displacement of the flexion/extension test mode without preload.

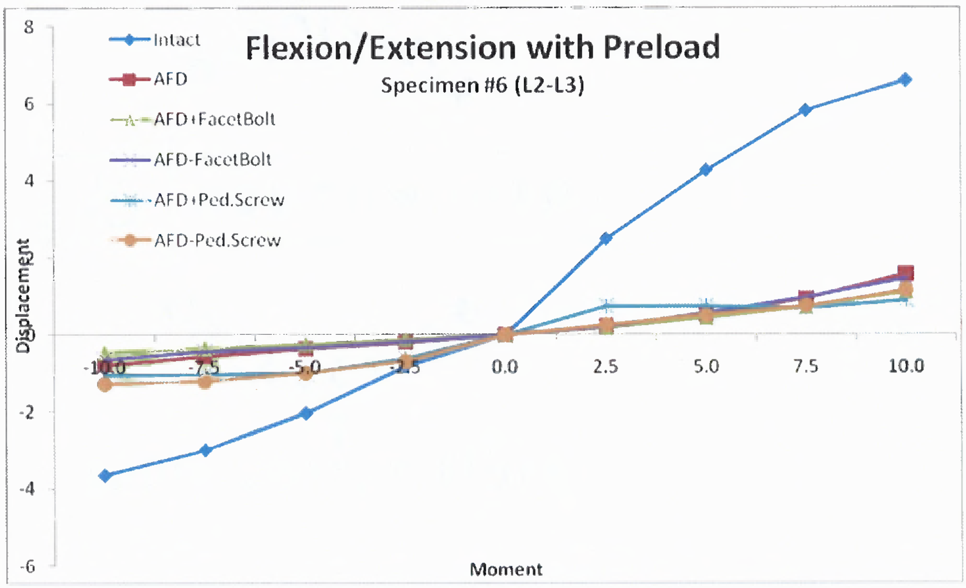


Figure A.10 Specimen #6: Moment vs Displacement of the flexion/extension test mode with 400N preload.

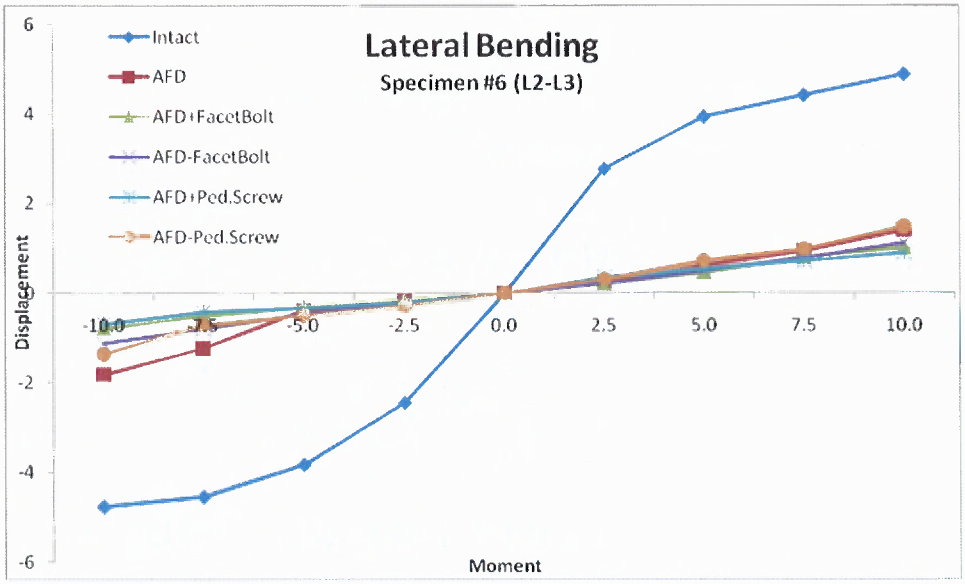


Figure A.11 Specimen #6: Moment vs Displacement of the lateral bending test mode.

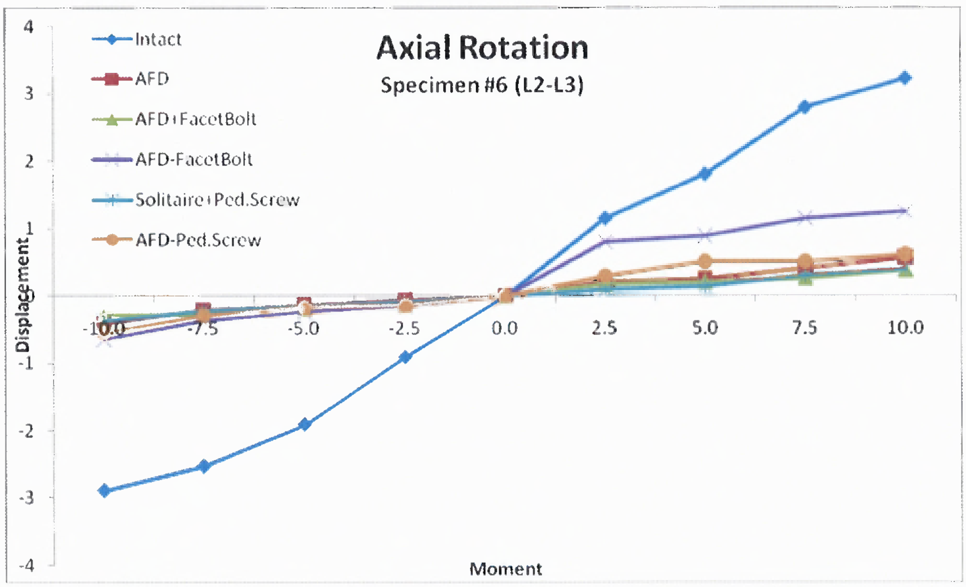


Figure A.12 Specimen #6: Moment vs Displacement of the axial rotation test mode.

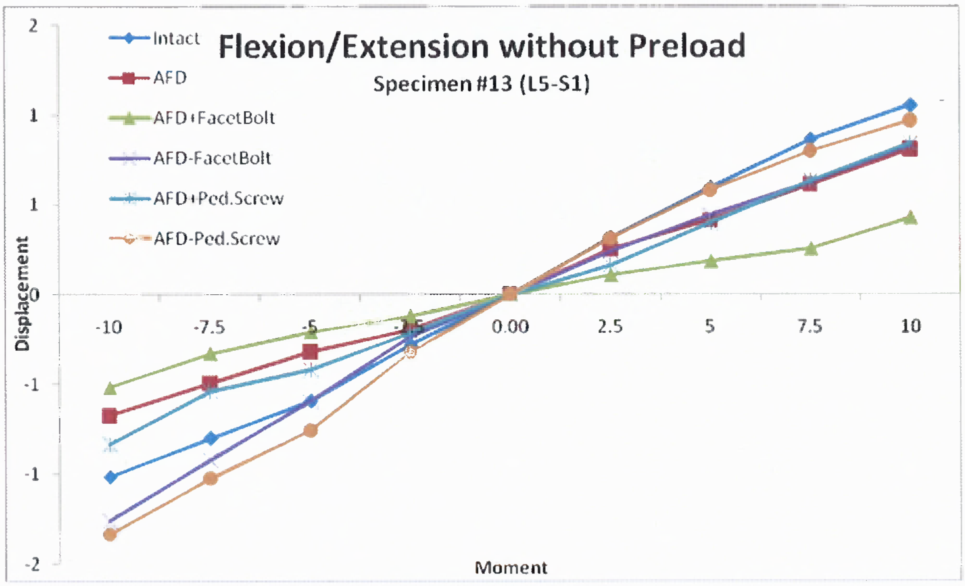


Figure A.13 Specimen #13: Moment vs Displacement of the flexion/extension test mode without preload.

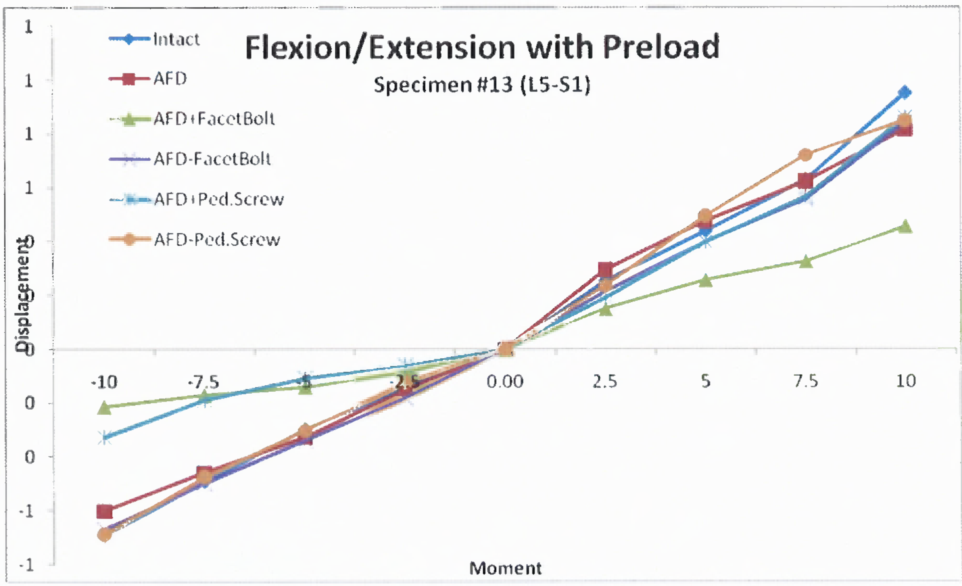


Figure A.14 Specimen #13: Moment vs Displacement of the flexion/extension test mode with 400N preload.

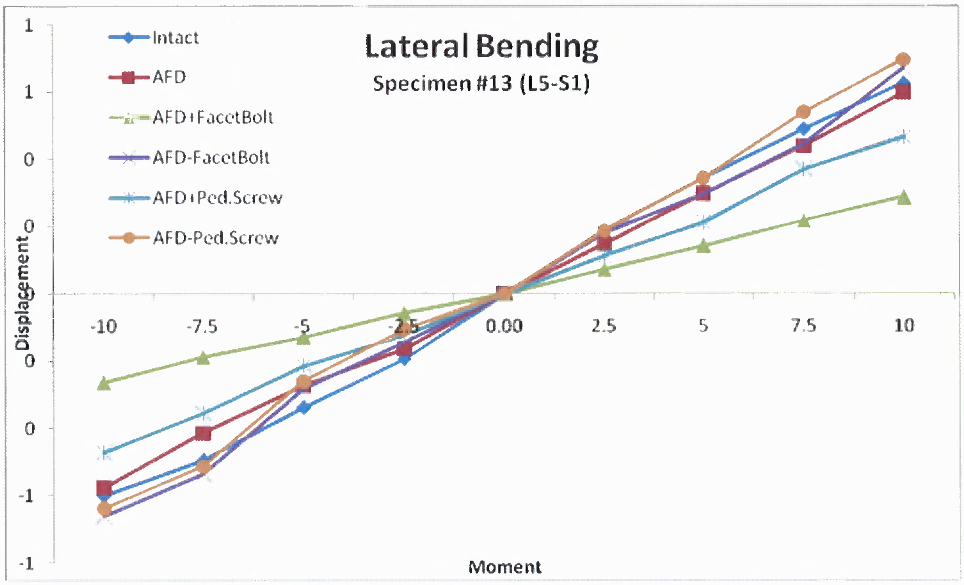


Figure A.15 Specimen #13: Moment vs Displacement of the lateral bending test mode.

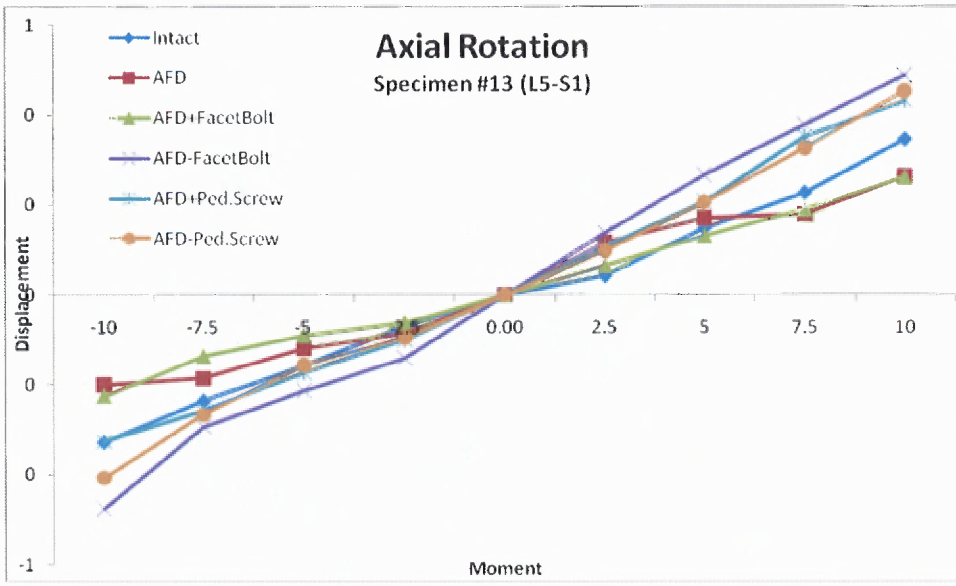


Figure A.16 Specimen #13: Moment vs Displacement of the axial rotation test mode.

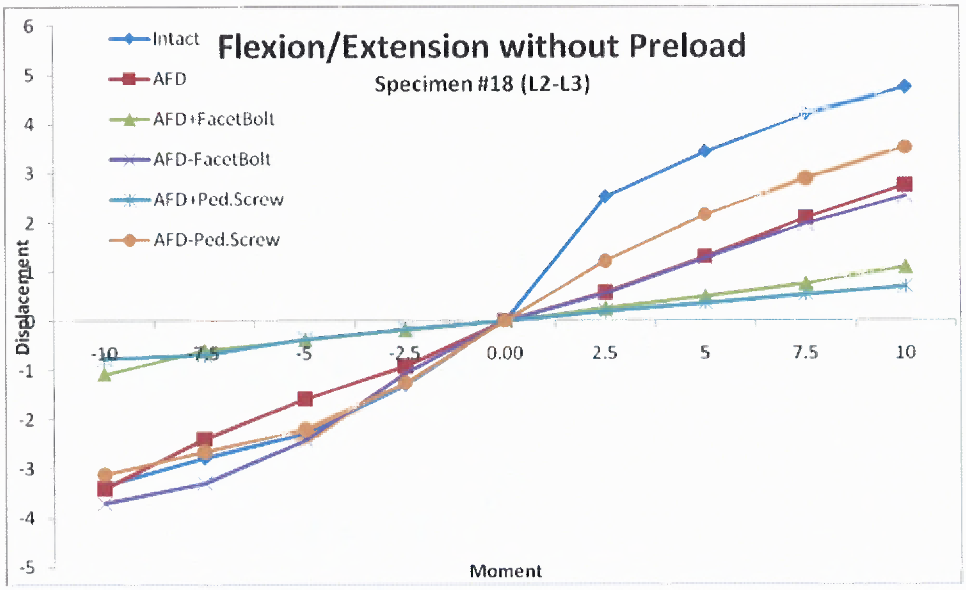


Figure A.17 Specimen #18: Moment vs Displacement of the flexion/extension test mode without preload.

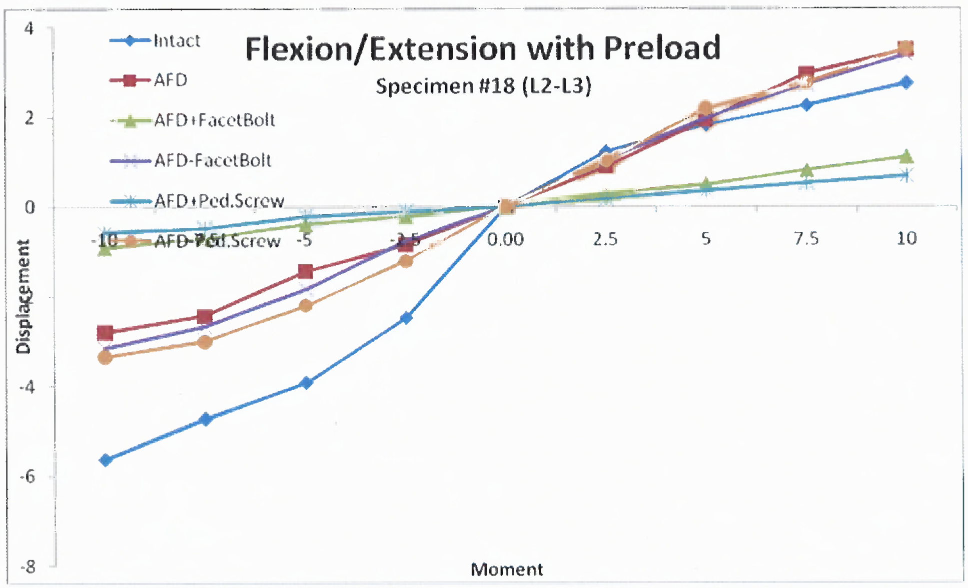


Figure A.18 Specimen #18: Moment vs Displacement of the flexion/extension test mode with 400N preload.

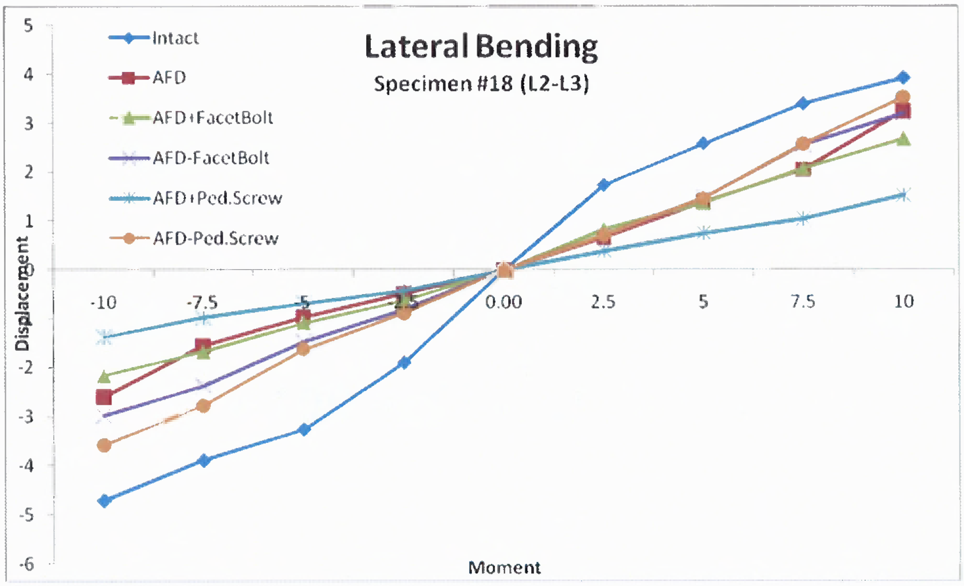


Figure A.19 Specimen #18: Moment vs Displacement of the lateral bending test mode.

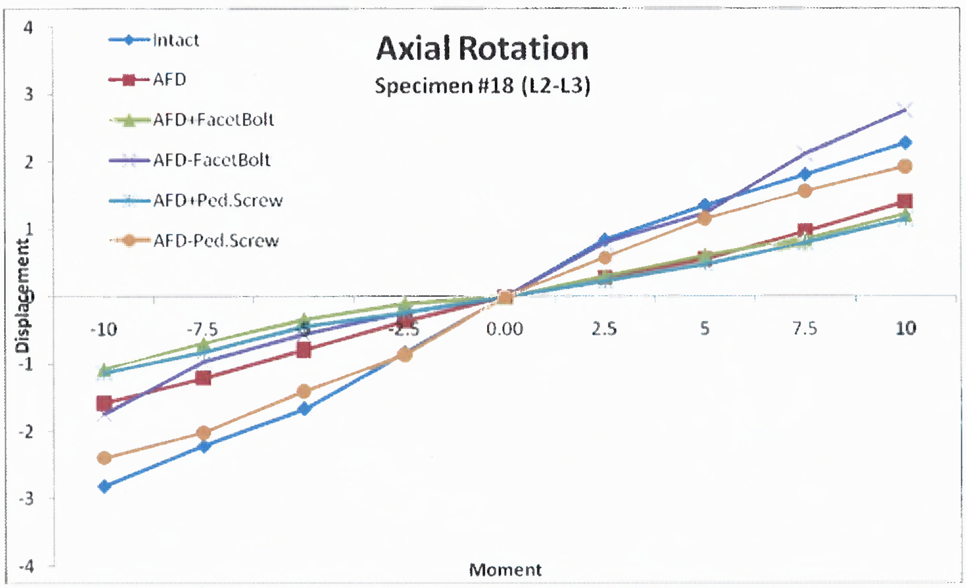


Figure A.20 Specimen #18: Moment vs Displacement of the axial rotation test mode.

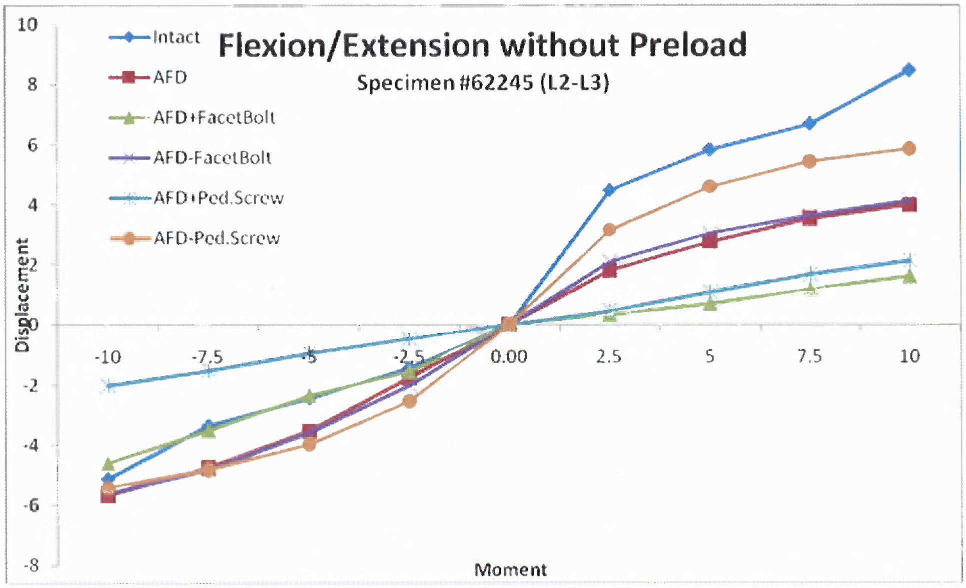


Figure A.21 Specimen #62245: Moment vs Displacement of the flexion/extension test mode without preload.

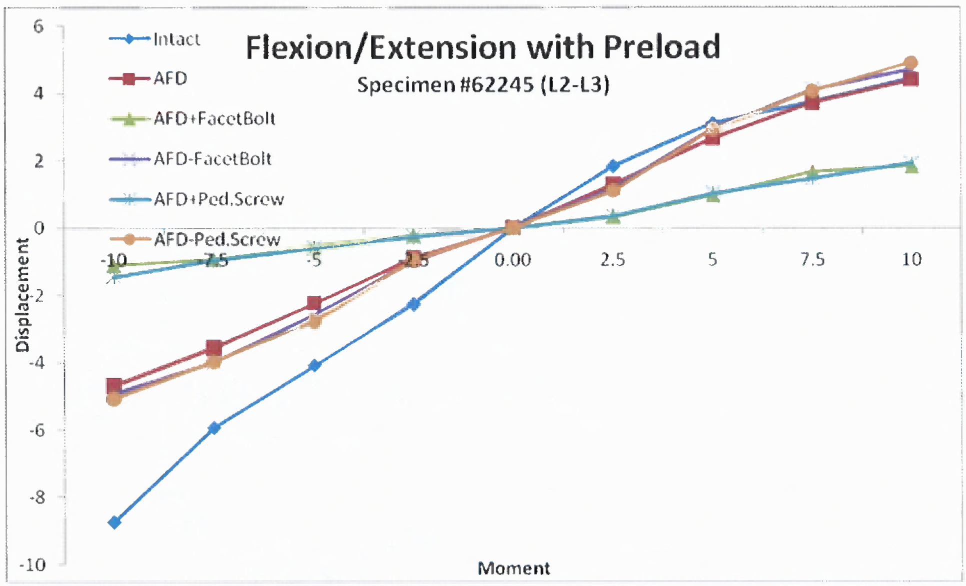


Figure A.22 Specimen #62245: Moment vs Displacement of the flexion/extension test mode with 400N preload.

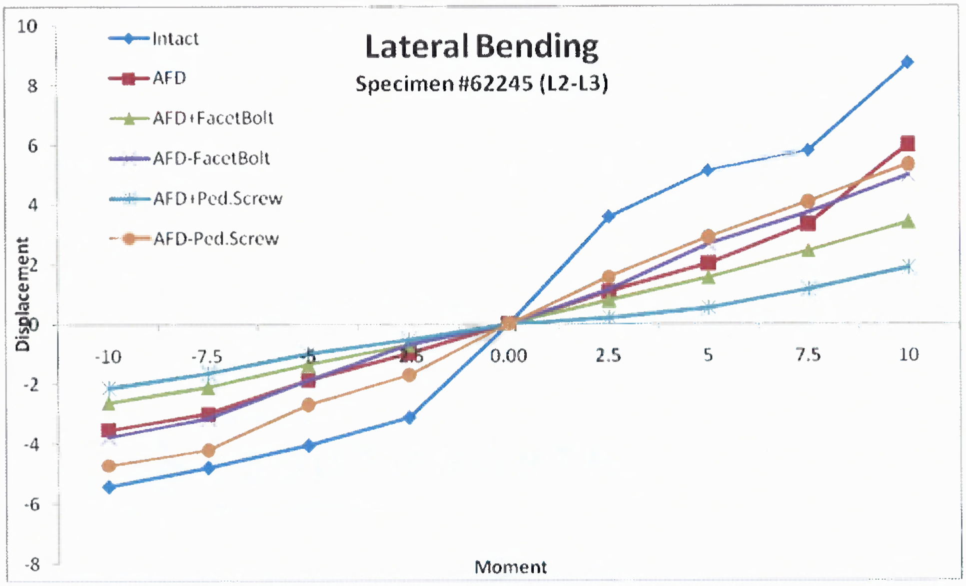


Figure A.23 Specimen #62245: Moment vs Displacement of the lateral bending test mode.

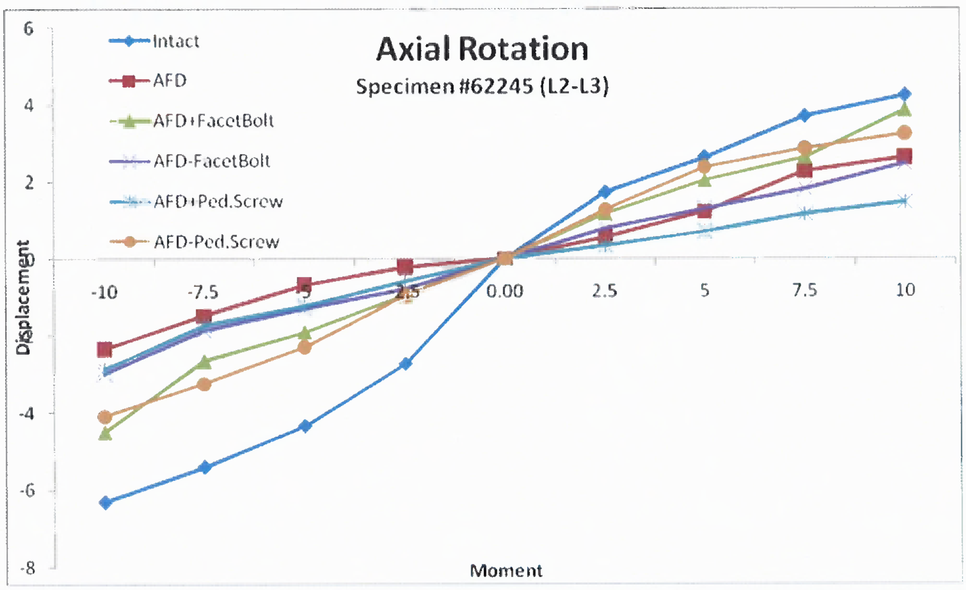


Figure A.24 Specimen #62245: Moment vs Displacement of the axial rotation test mode.

APPENDIX B

ANGULAR DISPLACEMENT

Figures B.1 to B.12 show the changes in angular displacement during all six degrees of freedom for individual specimens.

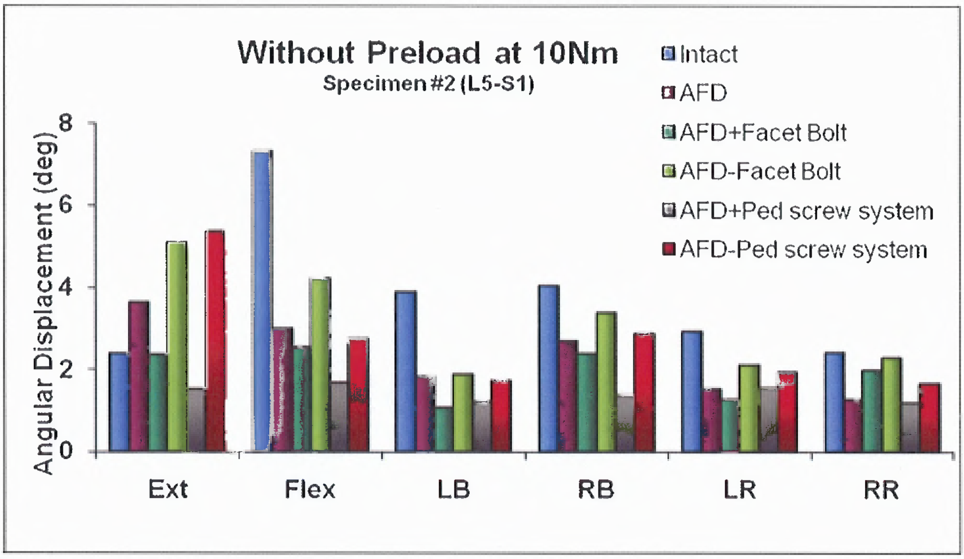


Figure B.1 Specimen #2: Angular displacement without preload at 10 Nm load.

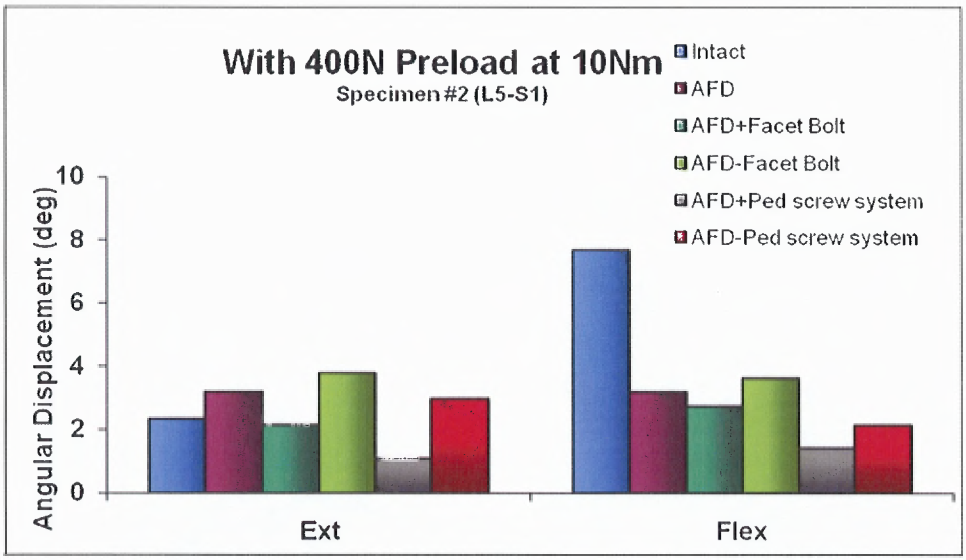


Figure B.2 Specimen #2: Angular displacement with 400N preload at 10 Nm load.

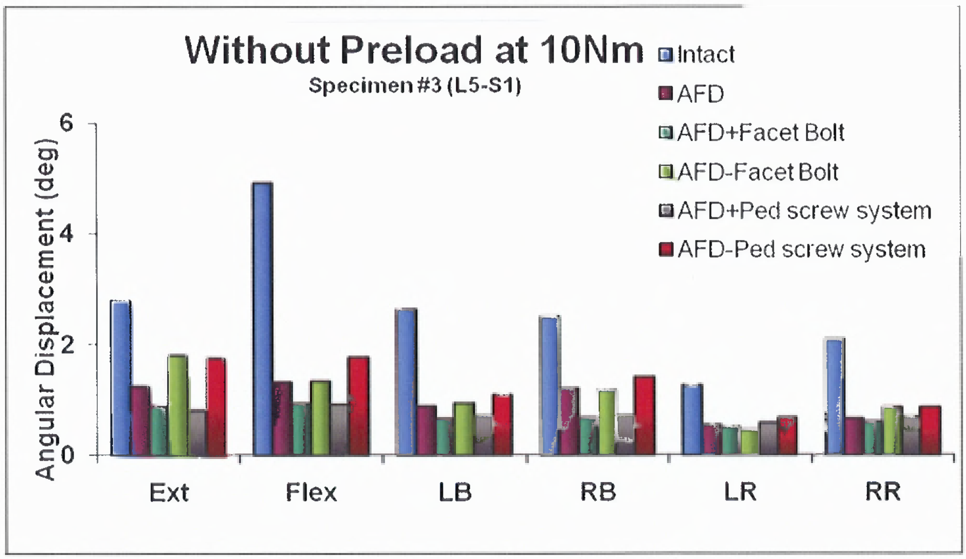


Figure B.3 Specimen #3: Angular displacement without preload at 10 Nm load.

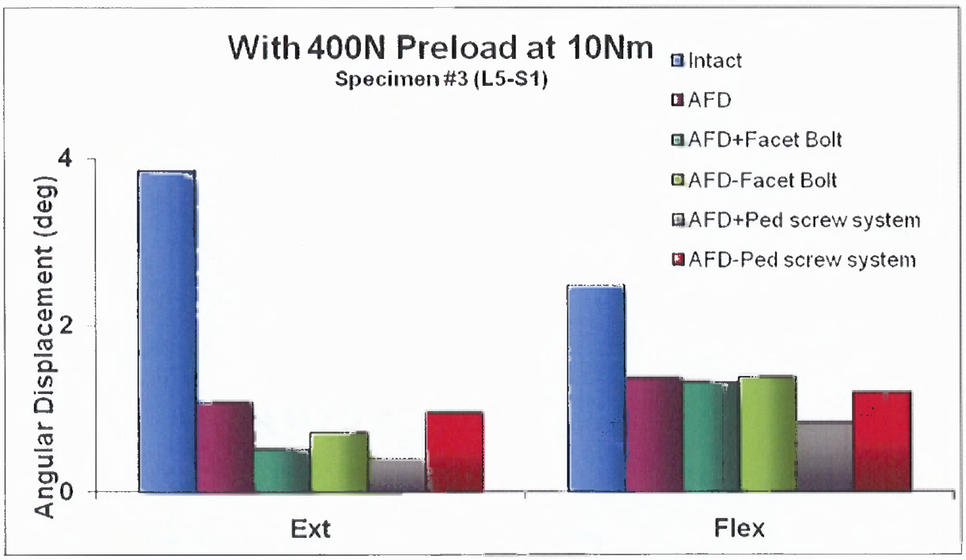


Figure B.4 Specimen #3: Angular displacement with 400N preload at 10 Nm load.

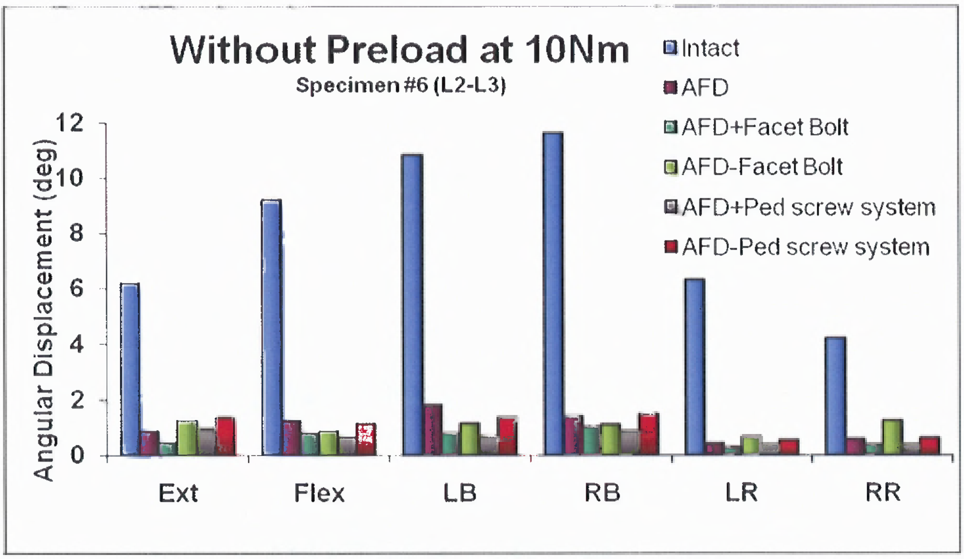


Figure B.5 Specimen #6: Angular displacement without preload at 10 Nm load.

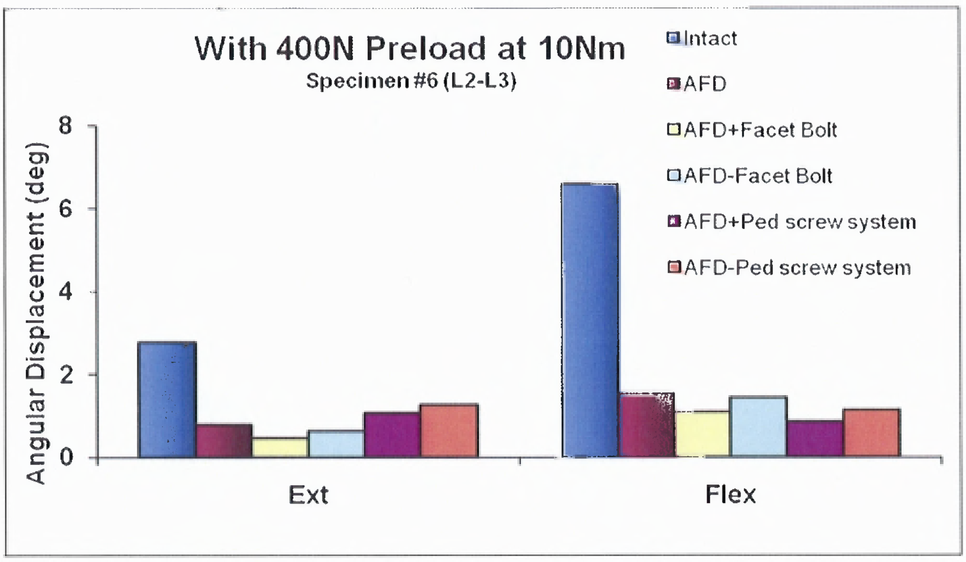


Figure B.6 Specimen #6: Angular displacement with 400N preload at 10 Nm load.

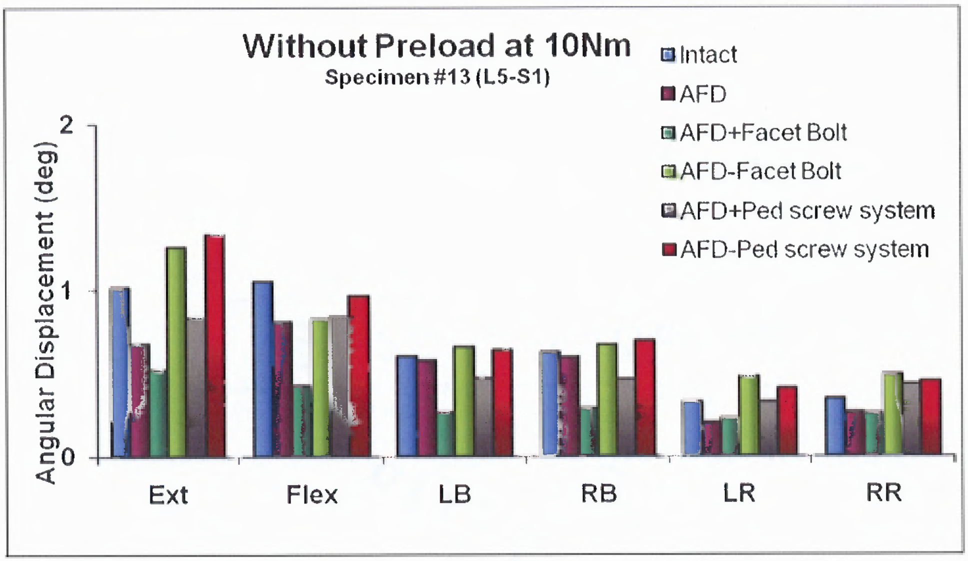


Figure B.7 Specimen #13: Angular displacement without preload at 10 Nm load.

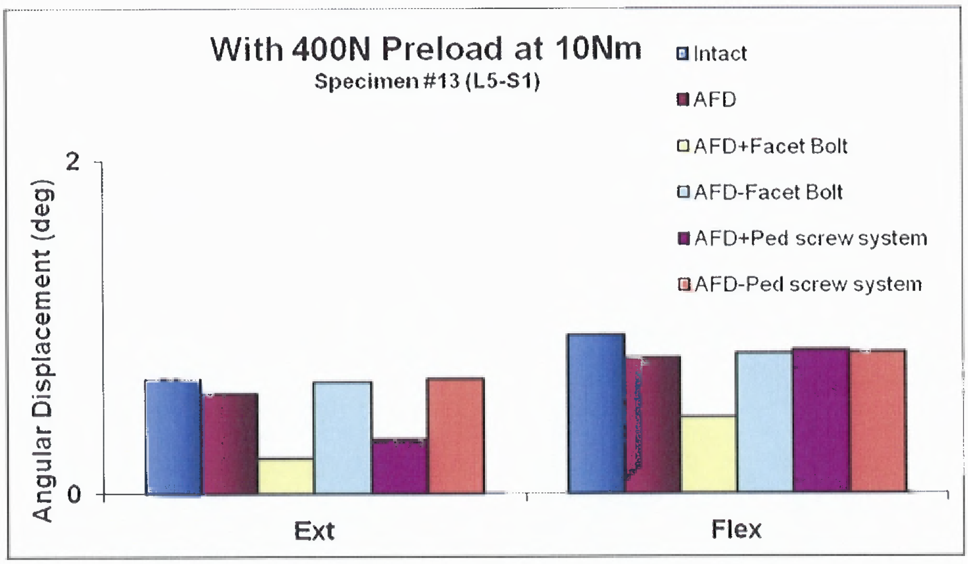


Figure B.8 Specimen #13: Angular displacement with 400N preload at 10 Nm load.

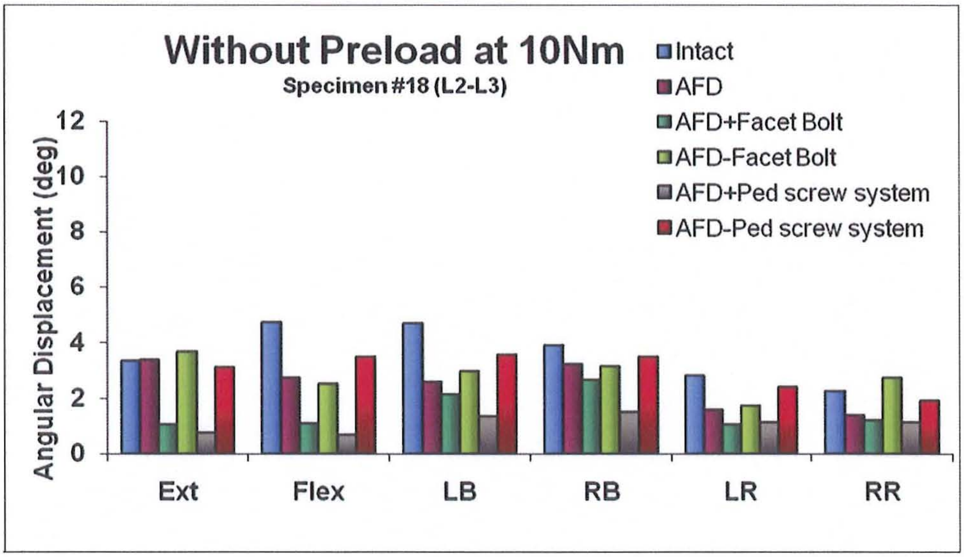


Figure B.9 Specimen #18: Angular displacement without preload at 10 Nm load.

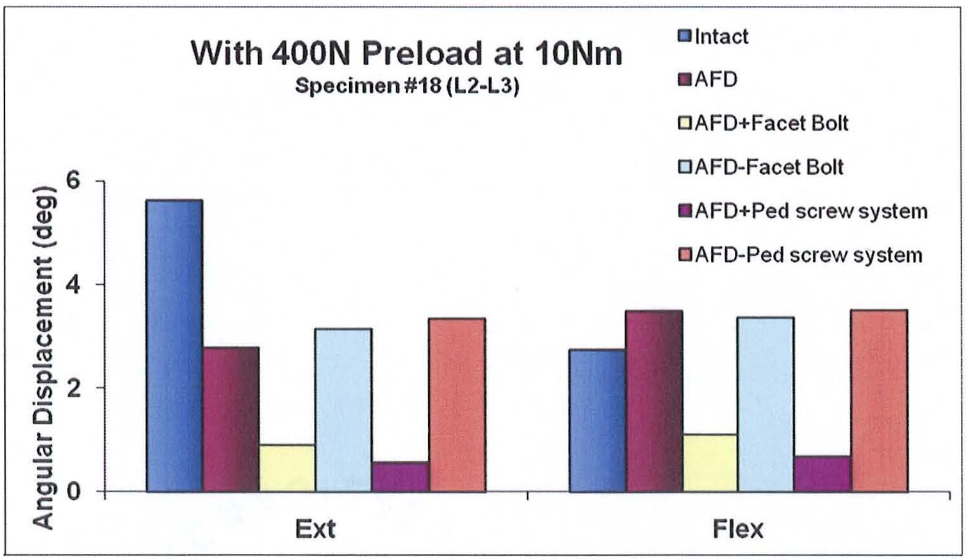


Figure B.10 Specimen #18: Angular displacement with 400N preload at 10 Nm load.

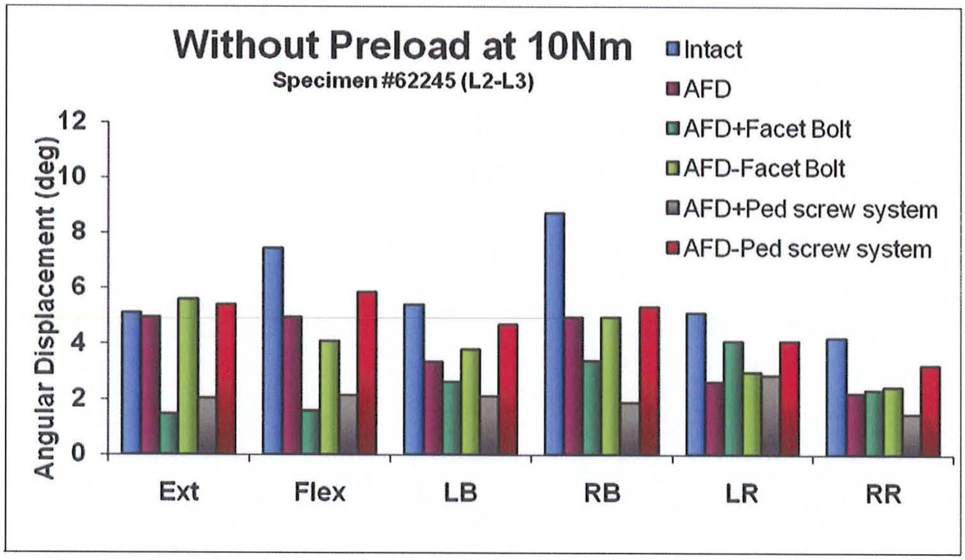


Figure B.11 Specimen #62245: Angular displacement without preload at 10 Nm load.

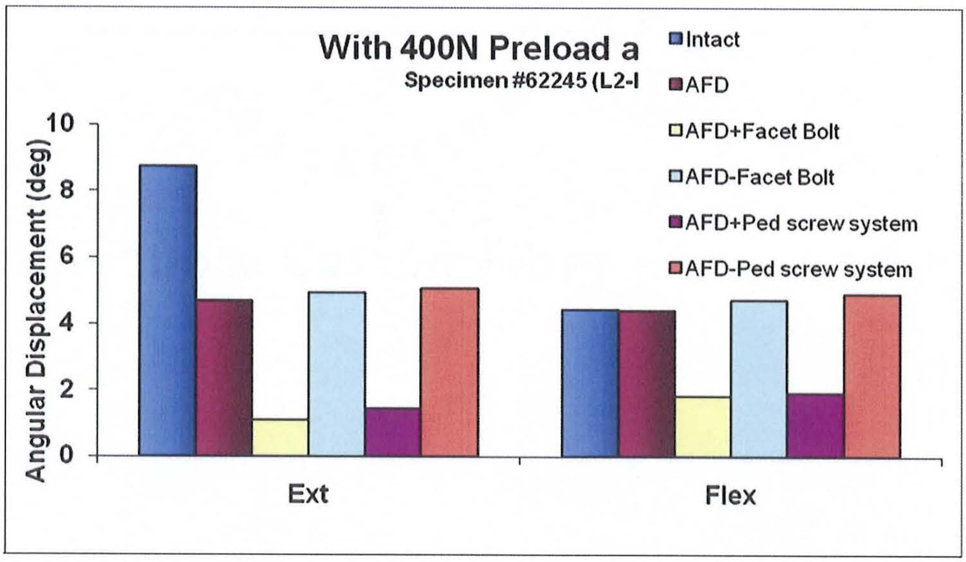


Figure B.12 Specimen #62245: Angular displacement with 400N preload at 10 Nm load.

APPENDIX C

NORMALIZED MOTION

Figures C.1 to C.12 show the normalized data with intact as reference. The data represents for individual specimens loaded in all six degrees of freedom.

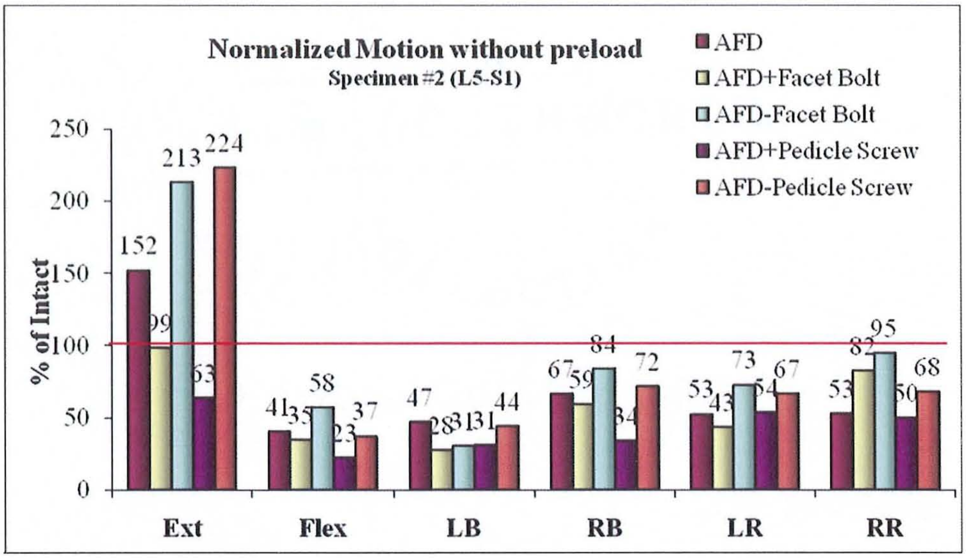


Figure C.1 Specimen #2: Normalized with intact data without preload at 10 Nm load.

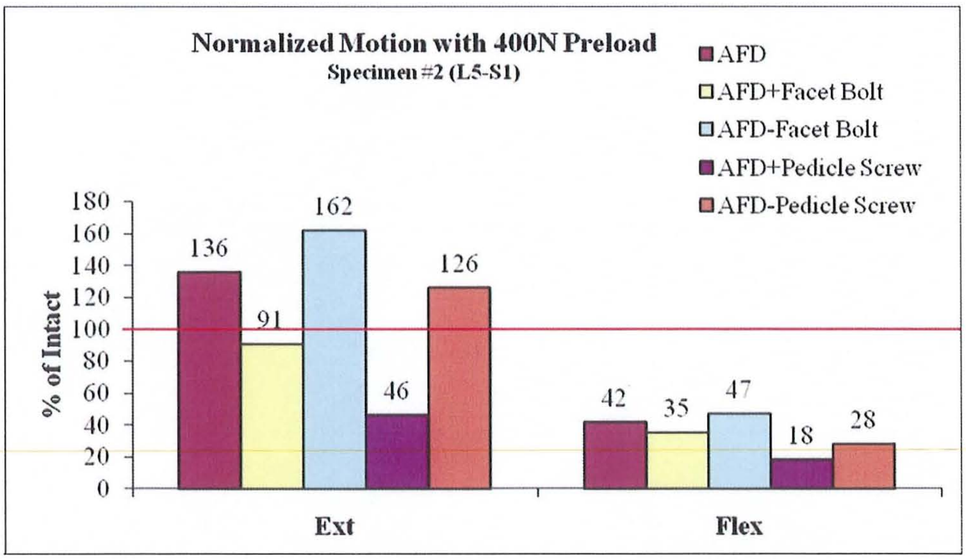


Figure C.2 Specimen #2: Normalized with intact data with 400N preload at 10 Nm load.

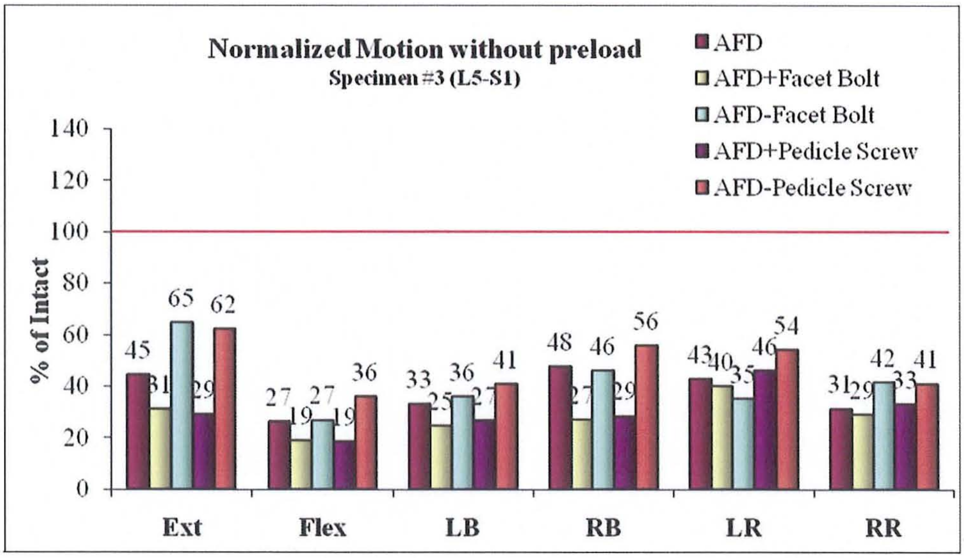


Figure C.3 Specimen #3: Normalized with intact data without preload at 10 Nm load.

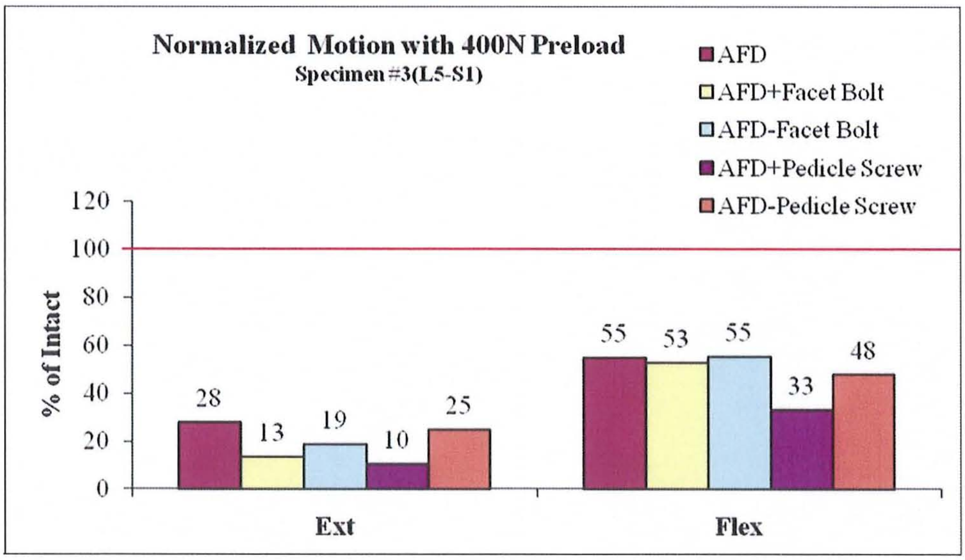


Figure C.4 Specimen #3: Normalized with intact data with 400N preload at 10 Nm load.

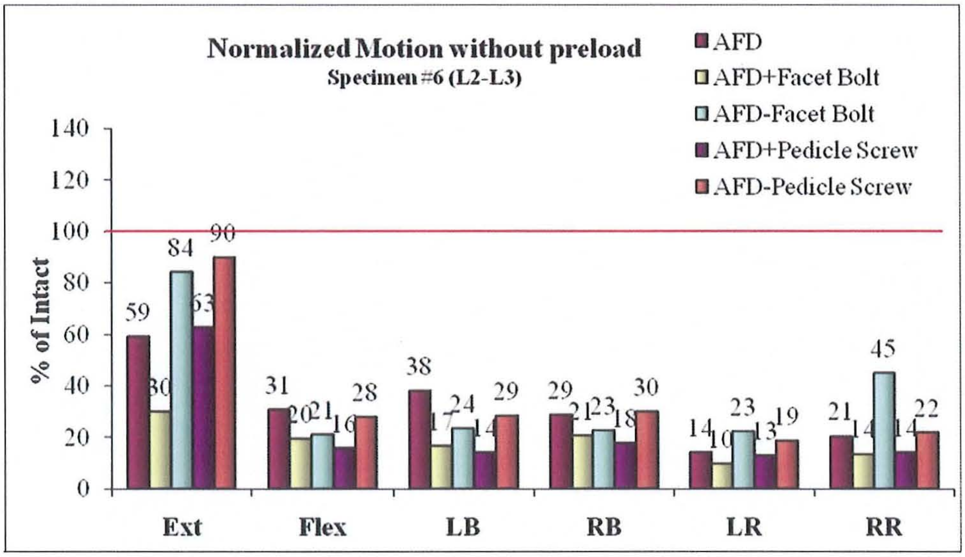


Figure C.5 Specimen #6: Normalized with intact data without preload at 10 Nm load.

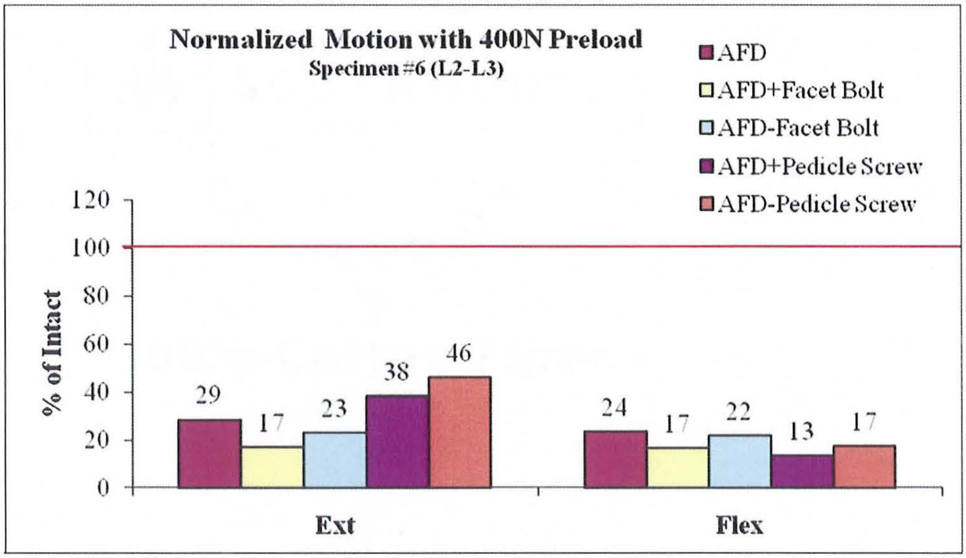


Figure C.6 Specimen #6: Normalized with intact data with 400N preload at 10 Nm load.

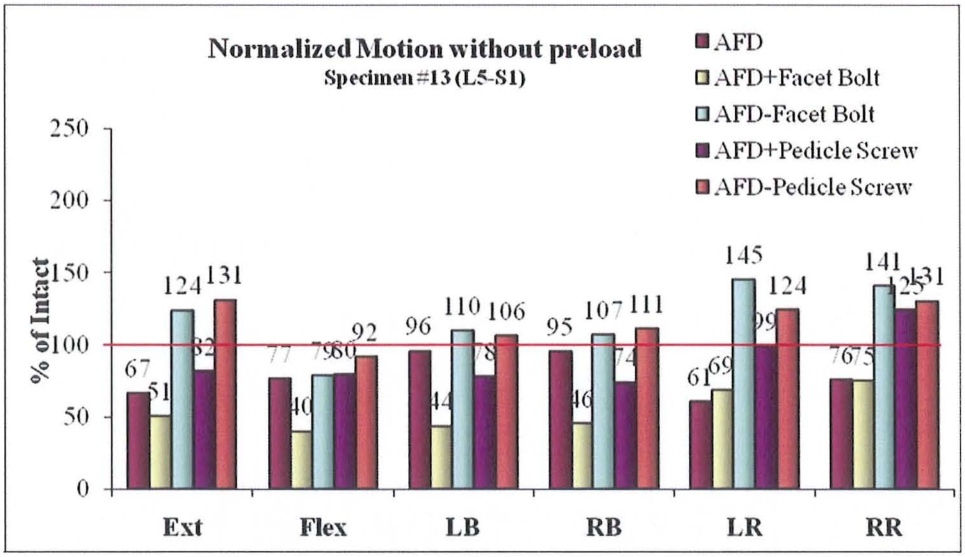


Figure C.7 Specimen #13: Normalized with intact data without preload at 10 Nm load.

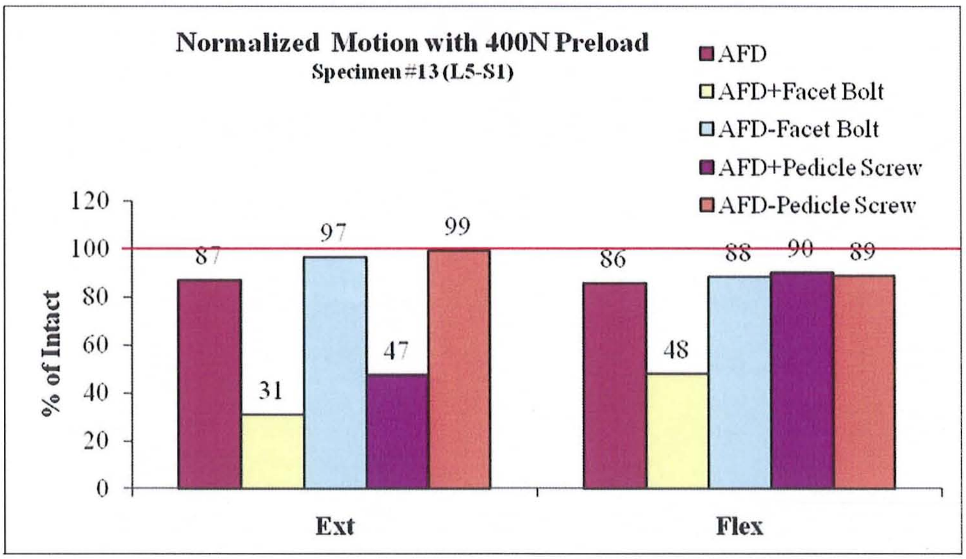


Figure C.8 Specimen #13: Normalized with intact data with 400N preload at 10 Nm load.

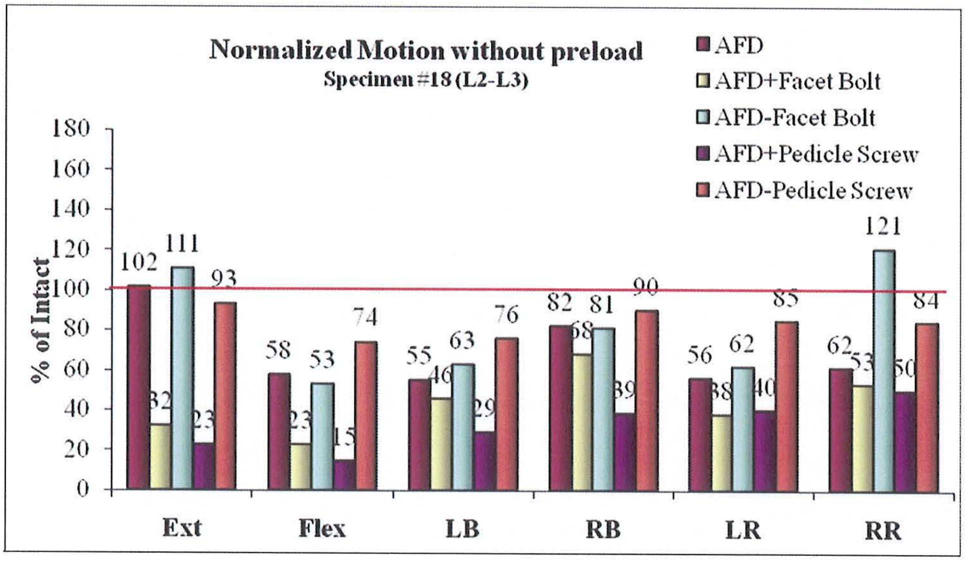


Figure C.9 Specimen #18: Normalized with intact data without preload at 10 Nm load.

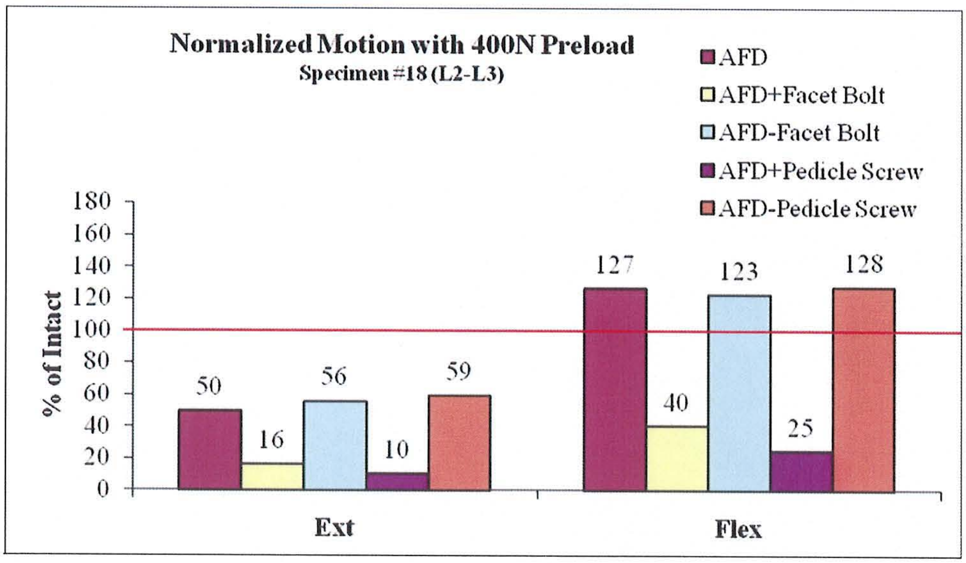


Figure C.10 Specimen #18: Normalized with intact data with 400N preload at 10 Nm load.

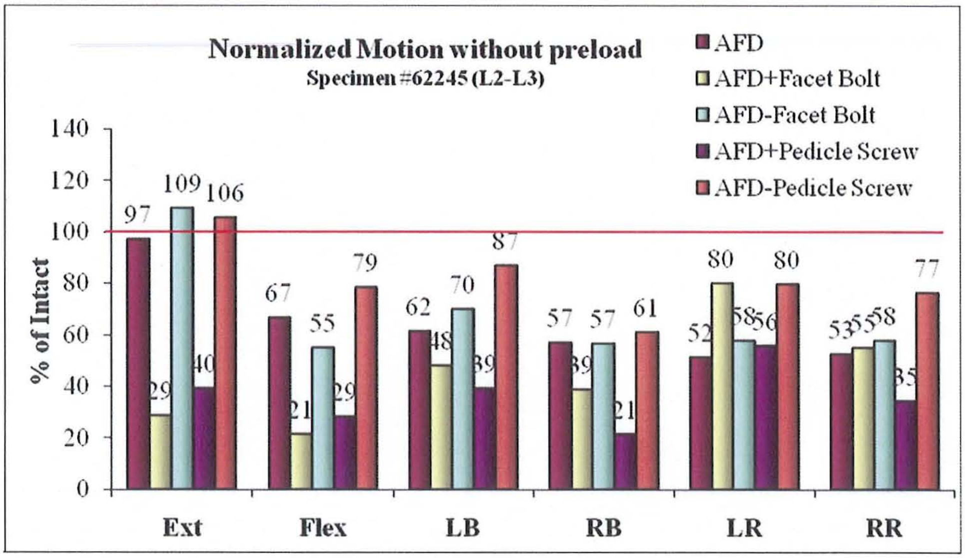


Figure C.11 Specimen #62245: Normalized with intact data without preload at 10 Nm load.

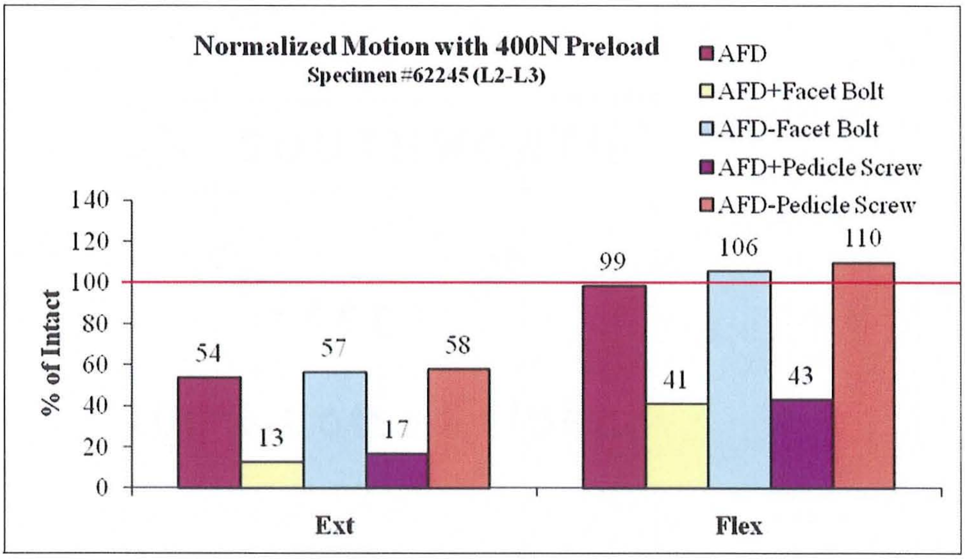


Figure C.12 Specimen #62245: Normalized with intact data with 400N preload at 10 Nm load.

REFERENCES

1. Anatomy of Spine [North American Spine Society (NASS)]. Available from: http://www.spine.org/Pages/ConsumerHealth/SpineConditionsAndTreatments/Anatomy/Default.aspx. Accessed December 10th, 2008.

2. Anatomy of Spine [National Pain Foundation]. 01/12/2009. Available from: http://www.nationalpainfoundation.org/MyTreatment/articles/BackAndNeck_Part_2.asp. Accessed 01/25/2009, 2009.

3. Divisions of Skeleton [Seer's Training Website]. Available from: http://training.seer.cancer.gov/module_anatomy/unit3_5_skeleton_divisions.html#. Accessed 01/25/09, 2009.

4. An introduction to discogenic chronic low back pain [Spinal Restoration]. Available from: http://www.spinalrestoration.com/patients/index.html. Accessed 02/02/2009, 2009.

5. Lumbar Degenerative Disc Disease [eOrthopod®]. September 18th 2002. Available from: http://www.eorthopod.com/public/patient_education/6495/lumbar_degenerative_disc_disease.html. Accessed January 27th, 2009.

6. Motion Preservation [Euro Spine]. April 2007. Available from: http://www.eurospine.org/cm_data/motion_Fig05_en.jpg, 10/05/2008.

7. Pain Management: A Patient's Guide to Facet Joint Injections [eOrthopod®]. July 19th, 2006. Available from: http://www.eorthopod.com/public/patient_education/6633/facet_joint_injections.html. Accessed January 27th, 2009.

8. Solitaire™ Anterior Spinal System [Biomet]. Available from: http://www.biomet.com/spine/products.cfm?pdid=3&majcid=14&prodid=220. Accessed February 15, 2009.

9. Andersson GB. Epidemiological features of chronic low-back pain. *Lancet* 1999;354:581-5.

10. Beaubien BP, Derincek A, Lew WD, et al. In vitro, biomechanical comparison of an anterior lumbar interbody fusion with an anteriorly placed, low-profile lumbar plate and posteriorly placed pedicle screws or translaminar screws. *Spine* 2005;30:1846-51.

11. Beaubien BP, Mehbod AA, Kallemeier PM, et al. Posterior augmentation of an anterior lumbar interbody fusion: minimally invasive fixation versus pedicle screws in vitro. *Spine* 2004;29:E406-12.

12. Bellenir K. Back & Neck Disorder Sourcebook [Omnigraphics, Inc.], 1997. Available from: http://www.back.com/anatomy-lumbar.html. Accessed January 26th, 2009.

13. Bjarke Christensen F, Stender Hansen E, Laursen M, et al. Long-term functional outcome of pedicle screw instrumentation as a support for posterolateral spinal fusion: randomized clinical study with a 5-year follow-up. *Spine* 2002;27:1269-77.

14. Blumenthal SL, Ohnmeiss DD. Intervertebral cages for degenerative spinal diseases. *Spine J* 2003;3:301-9.

15. Boos N, Weissbach S, Rohrbach H, et al. Classification of Age-Related Changes in Lumbar Intervertebral Discs: 2002 Volvo Award in Basic Science. *Spine* 2002;27:2631-44.

16. Cain CM, Schleicher P, Gerlach R, et al. A new stand-alone anterior lumbar interbody fusion device: biomechanical comparison with established fixation techniques. *Spine* 2005;30:2631-6.

17. Cohen SP, Argoff CE, Carragee EJ. Management of low back pain. *BMJ* 2008;337:a2718.

18. Deyo RA, Nachemson A, Mirza SK. Spinal-fusion surgery - the case for restraint. *N Engl J Med* 2004;350:722-6.

19. Deyo RA, Weinstein JN. Low back pain. *N Engl J Med* 2001;344:363-70.

20. Dhillon N, Bass EC, Lotz JC. Effect of frozen storage on the creep behavior of human intervertebral discs. *Spine* 2001;26:883-8.

21. Erstad S. MBA/MPH [WebMD]. February 06, 2008. Available from: http://www.webmd.com/back-pain/spinal-fusion-arthrodesis. Accessed February 6, 2009.

22. Fritzell P, Hagg O, Wessberg P, et al. Chronic low back pain and fusion: a comparison of three surgical techniques: a prospective multicenter randomized study from the Swedish lumbar spine study group. *Spine* 2002;27:1131-41.

23. Glazer PA, Colliou O, Klisch SM, et al. Biomechanical analysis of multilevel fixation methods in the lumbar spine. *Spine* 1997;22:171-82.

24. Goel VK, Monroe BT, Gilbertson LG, et al. Interlaminar shear stresses and laminae separation in a disc. Finite element analysis of the L3-L4 motion segment subjected to axial compressive loads. *Spine* 1995;20:689-98.

25. Goh JC, Wong HK, Thambyah A, et al. Influence of PLIF cage size on lumbar spine stability. *Spine* 2000;25:35-9; discussion 40.

26. Gray H, Clemente CD. *Anatomy of the human body*. 30th American ed. Philadelphia: Lea & Febiger, 1985.

27. Grob D, Humke T. Translaminar screw fixation in the lumbar spine: technique, indications, results. *European Spine Journal* 1998;7:178-86.

28. Hart LG, Deyo RA, Cherkin DC. Physician office visits for low back pain. Frequency, clinical evaluation, and treatment patterns from a U.S. national survey. *Spine* 1995;20:11-9.

29. Katzer A, Marquardt H, Westendorf J, et al. Polyetheretherketone--cytotoxicity and mutagenicity in vitro. *Biomaterials* 2002;23:1749-59.

30. Lee CK, Langrana NA. A review of spinal fusion for degenerative disc disease: need for alternative treatment approach of disc arthroplasty? *Spine J* 2004;4:173S-6S.

31. Lonstein JE, Denis F, Perra JH, et al. Complications associated with pedicle screws. *J Bone Joint Surg Am* 1999;81:1519-28.

32. Lund T, Oxland TR, Jost B, et al. Interbody cage stabilisation in the lumbar spine: biomechanical evaluation of cage design, posterior instrumentation and bone density. *J Bone Joint Surg Br* 1998;80:351-9.

33. Luoma K, Riihimaki H, Luukkonen R, et al. Low back pain in relation to lumbar disc degeneration. *Spine* 2000;25:487-92.

34. Lyons G, Eisenstein SM, Sweet MB. Biochemical changes in intervertebral disc degeneration. *Biochim Biophys Acta* 1981;673:443-53.

35. MILLER JAA, SCHMATZ C, SCHULTZ AB. Lumbar Disc Degeneration: Correlation with Age, Sex, and Spine Level in 600 Autopsy Specimens. *Spine* 1988;13:173-8.

36. Morrison C, Macnair R, MacDonald C, et al. In vitro biocompatibility testing of polymers for orthopaedic implants using cultured fibroblasts and osteoblasts. *Biomaterials* 1995;16:987-92.

37. Mummaneni PV, Haid RW, Rodts GE. Lumbar interbody fusion: state-of-the-art technical advances. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2004. *J Neurosurg Spine* 2004;1:24-30.

38. Myklebust JB, Pintar F, Yoganandan N, et al. Tensile strength of spinal ligaments. *Spine* 1988;13:526-31.

39. O'Brien JP, Holte DC. Simultaneous combined anterior and posterior fusion. *European Spine Journal* 1992;1:2-6.

40. Oxland TR, Hoffer Z, Nydegger T, et al. A comparative biomechanical investigation of anterior lumbar interbody cages: central and bilateral approaches. *J Bone Joint Surg Am* 2000;82:383-93.

41. Oxland TR, Lund T. Biomechanics of stand-alone cages and cages in combination with posterior fixation: a literature review. *Eur Spine J* 2000;9 Suppl 1:S95-101.

42. Panjabi MM, Krag M, Summers D, et al. Biomechanical time-tolerance of fresh cadaveric human spine specimens. *J Orthop Res* 1985;3:292-300.

43. Panjabi MM, Oxland TR, Yamamoto I, et al. Mechanical behavior of the human lumbar and lumbosacral spine as shown by three-dimensional load-displacement curves. *J Bone Joint Surg Am* 1994;76:413-24.

44. Patwardhan AG, Carandang G, Ghanayem AJ, et al. Compressive preload improves the stability of anterior lumbar interbody fusion cage constructs. *J Bone Joint Surg Am* 2003;85-A:1749-56.

45. Patwardhan AG, Havey RM, Carandang G, et al. Effect of compressive follower preload on the flexion-extension response of the human lumbar spine. *J Orthop Res* 2003;21:540-6.

46. Pflaster DS, Krag MH, Johnson CC, et al. Effect of test environment on intervertebral disc hydration. *Spine* 1997;22:133-9.

47. Polly DW, Jr., Cunningham BW, Kuklo TR, et al. Anterior thoracic scoliosis constructs: effect of rod diameter and intervertebral cages on multi-segmental construct stability. *Spine J* 2003;3:213-9.

48. Rathonyi GC, Oxland TR, Gerich U, et al. The role of supplemental translaminar screws in anterior lumbar interbody fixation: a biomechanical study. *Eur Spine J* 1998;7:400-7.

49. Rissanen PM. The surgical anatomy and pathology of the supraspinous and interspinous ligaments of the lumbar spine with special reference to ligament ruptures. *Acta Orthop Scand Suppl* 1960;46:1-100.

50. Stewart G. Eidelson M. Lumbar Spine [Spine Universe]. 01/22/2008. Available from: http://www.spineuniverse.com/displayarticle.php/article1394.html. Accessed 28th January, 2009.

51. Tsantrizos A, Andreou A, Aebi M, et al. Biomechanical stability of five stand-alone anterior lumbar interbody fusion constructs. *Eur Spine J* 2000;9:14-22.

52. Tzermiadianos MN, Mekhail A, Voronov LI, et al. Enhancing the stability of anterior lumbar interbody fusion: a biomechanical comparison of anterior plate versus posterior transpedicular instrumentation. *Spine* 2008;33:E38-43.

53. Ullrich PF. Jr., MD [Spine-Health]. May 3, 2006, 2006. Available from: http://www.spine-health.com/conditions/degenerative-disc-disease/low-back-pain-and-degenerative-disc-disease-treatments. Accessed February 2, 2009.

54. Urban JP, McMullin JF. Swelling pressure of the lumbar intervertebral discs: influence of age, spinal level, composition, and degeneration. *Spine* 1988;13:179-87.

55. Urban JP, Roberts S. Degeneration of the intervertebral disc. *Arthritis Res Ther* 2003;5:120-30.

56. Vadapalli S, Sairyo K, Goel VK, et al. Biomechanical rationale for using polyetheretherketone (PEEK) spacers for lumbar interbody fusion-A finite element study. *Spine* 2006;31:E992-8.

57. Volkman T, Horton WC, Hutton WC. Transfacet screws with lumbar interbody reconstruction: biomechanical study of motion segment stiffness. *J Spinal Disord* 1996;9:425-32.

58. Wang ST, Goel VK, Kubo S, et al. Comparison of stabilities between obliquely and conventionally inserted Bagby and Kuslich cages as posterior lumbar interbody fusion in a cadaver model. *J Chin Med Assoc* 2003;66:676-81.

59. Weiner BK, Fraser RD. Spine update lumbar interbody cages. *Spine* 1998;23:634-40.

60. Wenz LM, Merritt K, Brown SA, et al. In vitro biocompatibility of polyetheretherketone and polysulfone composites. *J Biomed Mater Res* 1990;24:207-15.

61. White AA. *Clinical Biomechanics of Spine*. Second ed: Lippincott, 1978.

62. Wu HC, Yao RF. Mechanical behavior of the human annulus fibrosus. *J Biomech* 1976;9:1-7.

63. Zhong ZC, Wei SH, Wang JP, et al. Finite element analysis of the lumbar spine with a new cage using a topology optimization method. *Med Eng Phys* 2006;28:90-8.