In Vitro Biomechanical Testing and Computational: Modeling in Spine

Mageswaran Prasath
Cleveland State University
IN VITRO BIOMECHANICAL TESTING AND COMPUTATIONAL MODELING IN SPINE

MAGESWARAN PRASATH

BACHELOR OF ENGINEERING
University of Nigeria
May, 2001

MASTER OF ENGINEERING
University of North Carolina Chapel-Hill/North Carolina State University
Biomedical Engineering
May, 2005

Submitted in partial fulfillment of the requirements for the degree

DOCTOR OF ENGINEERING
Applied Biomedical Engineering
at the
CLEVELAND STATE UNIVERSITY

August, 2012
This dissertation has been approved for the
Department of Chemical and Biomedical Engineering
and the College of Graduate Studies by

Dr. R. McLain, Chairperson

Dr. J. Gatica, Member

Dr. S. Duffy, Member

Dr. R. Setser, Member

Dr. J. Lock, Member
ACKNOWLEDGEMENTS

I would like to thank Dr. McLain for all his support and guidance throughout my research. Thank you for taking the time to work with me and share your experiences in research and life in general. I would also like to say thank you to Dr. Benzel for his time, even with a busy schedule, he always made time, his feedback and support was so valuable. I would also like to thank Dr. Gilbertson for giving me the opportunity to take up spine research and for all his help and guidance. To my committee members for their patience, flexibility and advice, thank you for your support.

Many thanks and sincere gratitude to Robb Colbrunn and Tara Bonner for their immense help and contribution, I wouldn’t have done it without your support. Thank you for your time. I would like to also say thanks to Adam Bartsch and Brian Perse for their encouragement and support.

Finally to my family and friends for all their love, encouragement and support throughout my study.
IN VITRO BIOMECHANICAL TESTING AND COMPUTATIONAL MODELING IN SPINE

MAGESWARAN PRASATH

ABSTRACT

Two separate *in vitro* biomechanical studies were conducted on human cadaveric spines (Lumbar) to evaluate the stability following the implantation of two different spinal fixation devices; interspinous fixation device (ISD) and Hybrid dynamic stabilizers. ISD was evaluated as a stand-alone and in combination with unilateral pedicle rod system. The results were compared against the gold standard, spinal fusion (bilateral pedicle rod system). The second study involving the hybrid dynamic system, evaluated the effect on adjacent levels using a hybrid testing protocol. A robotic spine testing system was used to conduct the biomechanical tests. This system has the ability to apply continuous unconstrained pure moments while dynamically optimizing the motion path to minimize off-axis loads during testing. Thus enabling precise control over the loading and boundary conditions of the test. This ensures test reliability and reproducibility.

We found that in flexion-extension, the ISD can provide lumbar stability comparable to spinal fusion. However, it provides minimal rigidity in lateral bending and axial rotation when used as a stand-alone. The ISD with a unilateral pedicle rod system when compared to the spinal fusion construct were shown to provide similar levels of stability in all directions, though the spinal fusion construct showed a trend toward improved stiffness overall.
The results for the dynamic stabilization system showed stability characteristics similar to a solid all metal construct. Its addition to the supra adjacent level (L3- L4) to the fusion (L4- L5) indeed protected the adjacent level from excessive motion. However, it essentially transformed a 1 level into a 2 level lumbar fusion with exponential transfer of motion to the fewer remaining discs (excessive adjacent level motion).

The computational aspect of the study involved the development of a spine model (single segment). The kinematic data from these biomechanical studies (ISD study) was then used to validate a finite element model of the spine.
# TABLE OF CONTENTS

LIST OF TABLES ........................................................................................................... xi

LIST OF FIGURES ......................................................................................................... xii

CHAPTER OVERVIEW ................................................................................................... xv

CHAPTER

I. INTRODUCTION ......................................................................................................... 1

II. BIOMECHANICAL TESTING OF SPINE ................................................................. 4

  2.1 Spinal Anatomy ........................................................................................................ 4

  2.2 Biomechanical Role of the Intervertebral Disc .................................................. 12

  2.3 Spinal Ligaments ..................................................................................................... 13

  2.4 Intervertebral Disc Degeneration .......................................................................... 14

  2.5 Kinematic Parameters for Spine ............................................................................ 15

  2.6 Multi-Segment Spine Testing ................................................................................ 17

    2.6.1 Pure moment testing systems ........................................................................ 17

    2.6.2 Follower load system .................................................................................... 18

  2.7 Specimen Preparation ............................................................................................ 19

  2.8 Custom Spinal Test Fixtures ................................................................................ 20

  2.9 Follower Load Fixtures ........................................................................................ 24

  2.10 Robotic Spine Testing .......................................................................................... 26

  2.11 References ............................................................................................................. 29

III. PROPERTIES OF AN INTERSPINOUS FIXATION DEVICE (ISD) IN LUMBAR FUSION CONSTRUCTS: A BIOMECHANICAL STUDY ........ 32

  3.1 Abstract .................................................................................................................. 32

    3.1.1 Introduction .................................................................................................... 32
4.6 Data and Statistical Analysis ................................................................. 66
4.7 Results ........................................................................................................ 66
  4.7.1 Flexion-extension .................................................................................. 66
  4.7.2 Flexion-extension with follower load .................................................. 67
  4.7.3 Lateral bending ..................................................................................... 68
  4.7.4 Axial rotation ....................................................................................... 68
4.8 Discussion .................................................................................................... 71
4.9 Conclusion .................................................................................................. 74
4.10 References ................................................................................................. 79

V. INTRODUCTION .......................................................................................... 83
  5.1 Role of Finite Element Models of the Spine .......................................... 83
  5.2 Methods ..................................................................................................... 86
    5.2.1 Vertebral bodies ................................................................................. 87
    5.2.2 Intervertebral disc ............................................................................ 88
    5.2.3 Ligaments ......................................................................................... 88
    5.2.4 Spinal instrumentation ..................................................................... 92
    5.2.5 Loading and Boundary Conditions .................................................. 95
  5.3 Results ....................................................................................................... 95
  5.4 Discussion .................................................................................................. 99
    5.4.1 Multi-segment model ....................................................................... 100
  5.5 Future Work .............................................................................................. 102
  5.6 References ................................................................................................. 102

VI. STUDY CONCLUSIONS ................................................................................. 105
LIST OF TABLES

3.1 Shows the Mean Resultant off-axis forces for FE, LB and AR for each of the five test conditions .................................................. 44

3.2 Shows the Mean ROM for FE, LB and AR for each of the five test conditions.................................................................................. 45

4.1 Flexion-Extension (FE): Intervertebral Range of Motion (˚) for Intact, Construct A and Construct B ........................................... 69

4.2 Flexion-Extension with Follower Load (FE-FL): Intervertebral Range of Motion (˚) for Intact, Construct A and Construct B .............. 70

4.3 Lateral bending (LB): Intervertebral Range of Motion (˚) for Intact, Construct A and Construct B ................................................. 70

4.4 Axial Rotation (AR): Intervertebral Range of Motion (˚) for Intact, Construct A and Construct B ...................................................... 71

5.1 Material Properties of FE Spine model ................................................................................................................................. 89
LIST OF FIGURES

Figure 2.1. Anatomy of the Spine [Netters, 2003] ................................................................. 7
Figure 2.2. Cervical Spine [Netters, 2003] ........................................................................... 8
Figure 2.3. Thoracic Spine [Netters, 2003] ........................................................................... 9
Figure 2.4. Lumbar Spine [Netters, 2003] .......................................................................... 10
Figure 2.5. Sacrum and Coccyx [Netters, 2003] ................................................................. 11
Figure 2.6. Intervertebral Disc ............................................................................................. 13
Figure 2.7. Spinal Ligaments [Gray's Anatomy] ................................................................. 14
Figure 2.8. Disc Herniation ................................................................................................... 15
Figure 2.9. Typical Load-Motion curves obtained from biomechanical tests ..... 16
Figure 2.10. Pure Moment System using coupled forces .............................................. 18
Figure 2.11. Pure Moment System using coupled forces .............................................. 19
Figure 2.12. (a) 3D CT scan model, (b) Transverse CT section, (c) & (d) Soft tissue dissection .................................................................................................................. 20
Figure 2.13. Custom Spinal Test Fixtures .............................................................................. 21
Figure 2.14. Placement of Pedicle Screws on cranial vertebra (A) and caudal vertebra (B) for attachment onto Custom Spinal Fixtures .............. 23
Figure 2.15. Placement of Spine onto Stainless Steel Rod .............................................. 23
Figure 2.16. Placement of Wood screws for additional stability ...................................... 24
Figure 2.17. Embedding Wood screws in Liquid metal ...................................................... 24
Figure2.18. Placement of Follower Fixtures onto Spine ...................................................... 25
Figure 2.19. Custom-made Follower Load Fixtures and setup ........................................ 26
Figure 2.20. (a) Robotic Spine Testing Apparatus (b) Force/Torque Sensor ...... 27
<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.21</td>
<td>Mounted Specimen with Custom fixtures on Robot</td>
<td>29</td>
</tr>
<tr>
<td>3.1</td>
<td>Aspen Interspinous Device</td>
<td>36</td>
</tr>
<tr>
<td>3.2</td>
<td>Spine Testing Robot with Infra Red markers attached to spine</td>
<td>38</td>
</tr>
<tr>
<td>3.3</td>
<td>Spine Specimen attached to Custom-fixtures and mounted onto Robot</td>
<td>40</td>
</tr>
<tr>
<td>3.4</td>
<td>Four Surgical Treatment Conditions</td>
<td>42</td>
</tr>
<tr>
<td>3.5</td>
<td>Mean ROM for all test conditions in FE, LB and AR</td>
<td>45</td>
</tr>
<tr>
<td>4.1</td>
<td>Follower Load Fixtures attached to the Lumbar Spine</td>
<td>62</td>
</tr>
<tr>
<td>4.2</td>
<td>(a) Construct A (b) Construct B</td>
<td>63</td>
</tr>
<tr>
<td>4.3</td>
<td>Spine Testing Robot</td>
<td>64</td>
</tr>
<tr>
<td>4.4</td>
<td>Mean ROM for Flexion-Extension</td>
<td>75</td>
</tr>
<tr>
<td>4.5</td>
<td>ALE results for Flexion-Extension</td>
<td>75</td>
</tr>
<tr>
<td>4.6</td>
<td>Flexion-Extension with Follower Load</td>
<td>76</td>
</tr>
<tr>
<td>4.7</td>
<td>ALE results for Flexion-Extension with Follower Load</td>
<td>76</td>
</tr>
<tr>
<td>4.8</td>
<td>Mean ROM for Lateral Bending</td>
<td>77</td>
</tr>
<tr>
<td>4.9</td>
<td>ALE results for Lateral Bending</td>
<td>77</td>
</tr>
<tr>
<td>4.10</td>
<td>Mean ROM for Axial Rotation</td>
<td>78</td>
</tr>
<tr>
<td>4.11</td>
<td>ALE results for Axial Rotation</td>
<td>78</td>
</tr>
<tr>
<td>5.1</td>
<td>Finite element model development flow chart</td>
<td>90</td>
</tr>
<tr>
<td>5.2</td>
<td>Invertebral disc development in CAD</td>
<td>91</td>
</tr>
<tr>
<td>5.3</td>
<td>Fibers implemented as Rebars in ABAQUS</td>
<td>91</td>
</tr>
<tr>
<td>5.4</td>
<td>A finite element model of spine</td>
<td>92</td>
</tr>
<tr>
<td>5.5</td>
<td>Spinal implant CAD and Finite element model</td>
<td>93</td>
</tr>
</tbody>
</table>
Figure 5.6. Spine Finite Element Models with implants ................................................. 94
Figure 5.7. Intact Spine Model results compared against in vitro data .................... 96
Figure 5.8. Results showing ROM for ISD with Interbody in Flexion-Extension.. 97
Figure 5.9. Flexion-Extension plots for Pedicle Screw-Rod system.................... 97
Figure 5.10. Lateral bending plot for ISD system.................................................... 98
Figure 5.11. Lateral bending plot for PS system....................................................... 98
Figure 5.12. Axial Rotation plot for ISD system....................................................... 99
Figure 5.13. Intact Multi-segment Spine FE Model (T12 - Sacrum)................. 101
Figure 5.14. Intact FE (T12 - Sacrum) comparison with in vitro ROM results for
Flexion-Extension ................................................................................................. 101
CHAPTER OVERVIEW

A brief overview regarding spine research and the overall research objectives of the dissertation are stated in the introduction. In chapter 2, an introduction to the basic anatomy of the spine is highlighted. It also contains a detailed explanation of the methodology used in conducting a biomechanical test on spine. It includes description of the basic biomechanical parameters involved as well as the different testing systems currently available and in use. In chapters 3 and 4, the biomechanical testing of a novel interspinous device and the adjacent level effects of hybrid dynamic stabilization are described in detail and the results and conclusions are presented. Chapter 5 describes the development of a finite element spine model and its validation using test data from in vitro biomechanical testing of spine.
CHAPTER I

INTRODUCTION

Low back pain is one of the most common spine disorders. According to the Congress for Neurological Surgeons (CNS), 65 million people in the US annually suffer from low back pain. Treatment costs incurred for back pain exceed 50 billion dollars per year in the United States alone.¹ Studies have also shown that by age 55, about 85 percent of the population exhibits evidence of intervertebral disc degeneration which is an initiator of low back pain. Treatment of back pain upon diagnosis usually involves either a conservative treatment approach (medications, weight-watch, heat treatment, physical therapy etc.) and/or surgery (discectomy for decompression of neural elements, fusion with bone graft and instrumentation for mechanical stabilization).

Spinal fusion is considered the gold standard for the surgical treatment of intervertebral disc degeneration which causes clinical instability in the spine. Currently, there are several spinal fusion devices available for use in surgery. Rapid advancement in basic science research, material science and manufacturing technologies has led to an increase in novel fusion devices being developed and made available for the physicians. There is also a push for the
development of minimally invasive devices which have the appeal of requiring smaller incisions, allow for less blood loss and shorter hospital stay. There is also an increase in the development of motion preserving devices due to the prevalence of accelerated degeneration of adjacent levels following fusion.

With the current influx of new devices into the medical market, it is paramount to effectively and systematically evaluate the biomechanical performance of these new devices and their ability to stabilize the spine. Biomechanical evaluation of spinal devices has been conducted using three main standard tests – Failure, Fatigue and Stability. The first two tests are destructive in nature while the third test is non-destructive in nature. Failure test is used to assess the device’s ability withstand excessive loading while fatigue test is used to assess the device’s longevity of use. The stability test involves multi-directional testing to assess the device’s ability to stabilize the spine. Past studies have recommended the use of pure moment loading condition in stability tests for the evaluation of devices.\(^2\) Pure bending moment when applied properly causes a uniform constant load throughout the entire length of the spinal segment making for more accurate comparison between devices. Several spine testing apparatus (cable-pulley systems, biaxial and multi-axial spine systems) have been developed in the past to conduct biomechanical tests on spines under pure moment loading conditions. Robotic spine testing is a more recent system currently being used in conducting biomechanical tests. It utilizes a multi-axis robotic system which provides a flexible testing environment. The robotic system enables easy changes to be made to the boundary and loading conditions. It also
enables unconstrained motion of the spine during testing thereby mimicking in vivo spinal motion.

The current study is aimed at the development of a methodology for conducting biomechanical testing of the spine using a robotic system and using the data from the test to validate a finite element model of a spine. The robotic system was used to evaluate the performance of two spinal implants - an interspinous device and a dynamic stabilizer. A finite element model of the spine was then developed and validated using the data from the biomechanical testing.
CHAPTER II

BIOMECHANICAL TESTING OF SPINE

2.1 Spinal Anatomy

The human spine (vertebral column) is composed of vertebrae (singular – vertebra) and intervertebral discs. The vertebrae articulate on each other and are supported structurally by spinal ligaments. The main function of the human spine is to protect the neural elements (spinal cord and nerves). Other functions are to support the body weight, provide posture and locomotion. The vertebra mainly consists of the vertebral body (anterior part of the vertebra), vertebral arch (posterior part of the vertebra, consists of two pedicles and lamina), two transverse process, one spinous process and four articulating facets (two superior and two inferior). A functional spinal unit (FSU) is referred to as the smallest segment of the spine that exhibits similar biomechanical characteristics as a whole spine.\(^3\) It basically consists of two adjacent vertebrae, the intervertebral disc and spinal ligaments. Biomechanical testing on the spine typically involves the use of either single FSU or multisegmental spinal units.
The human spine is divided into 5 regions: cervical, thoracic, lumbar, sacral, and coccygeal (Figure 1). The cervical spine is the most superior region and located close to the head (cranial) while coccygeal is the most inferior region that is located closer to the feet (caudal). The anatomical differences between each regions result in differences in their biomechanical characteristics. The orientation of the articulating facet joints, vertebral body size between the regions, all play a considerable role in contributing towards the variation in kinematics of each region.

- **Cervical Spine** – The cervical spine is located between the head (cranium) and the thoracic vertebrae. They are the smallest of the spinal vertebrae. There are a total of seven cervical vertebrae anatomically labeled C1 through to C7. The two superior vertebrae, C1 and C2 are also known as Atlas and Axis. They are anatomically different from the other cervical vertebrae. Atlas has no vertebral body or spinous process while the Axis has a prominent protrusion called the Odontoid process (dens) that projects superiorly from the vertebral body. Figure 2 shows an illustration of the cervical spine. In the sagittal plane, the cervical spine has a convex-shaped curve anteriorly (Lordosis).

- **Thoracic Spine** – The thoracic spine is located in the upper back between the cervical vertebrae and the lumbar vertebrae. There are a total of twelve thoracic vertebrae anatomically labeled T1 to T12. These vertebrae also provide attachments for the ribs and thus
contain costal facets for articulation with the ribs. An identifying anatomic feature is the spinous process typically projects downwards. In the sagittal plane, the thoracic spine has a concave curvature (Kyphosis) anteriorly. Figure 3 shows an illustration of the thoracic spine.

- **Lumbar Spine** – The lumbar spine is located in the lower back between the thoracic spine and sacrum. There are five lumbar vertebrae, anatomically labeled L1 to L5. They have larger vertebral bodies than thoracic or cervical spine. In the sagittal plane, the Lumbar spine has a convex curvature (Lordosis) anteriorly. Figure 4 shows an illustration of the lumbar spine.

- **Sacrum and Coccyx** – The sacrum is located caudal to the lumbar spine. It consists of about five fused vertebrae. The coccyx is located caudal to the sacrum and is made up of four fused vertebrae. Figure 5 shows an illustration of the Sacrum and Coccyx.
Figure 2.1. Anatomy of the Spine [Netters, 2003]
Figure 2.2. Cervical Spine [Netters, 2003]
Figure 2.3. Thoracic Spine [Netters, 2003]
Figure 2.4. Lumbar Spine [Netters, 2003]
Figure 2.5. Sacrum and Coccyx [Netters, 2003]
2.2 Biomechanical Role of the Intervertebral Disc

The intervertebral disc is located between each vertebra (with the exception of C1-2) and serves as a shock absorbing spacer. The intervertebral disc can be divided into three main components: nucleus pulposus, annulus fibrosus, and the cartilaginous end-plates (Figure 6). The nucleus pulposus occupies the central portion of the disc and has a mucus-like appearance. It contains about 70-90% water by wet weight, and about 10-30% of loose translucent network of fibrous strands that lie in a mucoprotein gel made up of mucopolysaccharides.\(^3\) It plays a major role in the disc's compressive properties. The annulus fibrosus is made up of concentric laminated layers of collagen fibers that encase the nucleus pulposus. These fibers are oriented about 30° from the horizontal plane and alternate in direction between adjacent layers (+ 30° in one layer and -30° in the adjacent layer).\(^5\) One of its major functions is to withstand tension\(^6\). The cartilaginous endplate is made of hyaline cartilage. It forms a barrier between the vertebral body and the other two components that make up the intervertebral disc. The cellular elements of the disc obtain their nutrition through diffusion from the endplates.
2.3 Spinal Ligaments

The anterior longitudinal ligament (ALL) is located on the anterior of the vertebral body while the posterior longitudinal ligament (PLL) provides structural support posteriorly. These are broad thin bands of ligaments that extend from the cervical spine (C2, Axis) to the Sacrum. The facet joints are supported by the capsular ligaments. The anterior side of the lamina is supported by the ligamentum flavum extending between adjacent vertebrae. The supraspinous ligaments connect the spinous processes of adjacent levels extending from C7 to the sacrum. The interspinous ligaments are located between the spinous processes of adjacent levels. The intertransverse ligaments are located between
adjacent transverse processes. (Figure, 7). The main functions of these ligaments are to provide structural stability and limit excessive spinal motion.

![Figure 2.7. Spinal Ligaments [Gray’s Anatomy]](image)

### 2.4 Intervertebral Disc Degeneration

Intervertebral disc degeneration is one of the leading causes of spinal instability and low back pain. A number of factors such as trauma, obesity, aging, genetics, etc. have been found to be progenitors of disc degeneration. With aging, the disc loses its water absorbing matrix components, which in turn causes water loss within the disc. This leads to disc dehydration, reduction in disc height, disruption of the concentric lamellae of the annulus and appearance of cracks and fissures.\(^6\)-\(^7\) When the disc begins to lose its biomechanical function as a result of these processes and elicit painful symptoms, the disease is called
degenerative disc disease, DDD. The disease causes the disc to lose its (elasticity, flexibility and shock absorption properties). Disc degeneration can cause disc herniation (abnormal bulging or rupture of the disc) which can lead to nerve root or spinal cord compression (Figure 8). DDD also causes instability between vertebrae. The discs located in the lumbar spine typically at regions L4-L5 and L5-S1 are thought to be more prone to DDD because these regions experience high forces and motions.


Figure 2.8. Disc Herniation

2.5 Kinematic Parameters for Spine

Application of loads to a spine segment results in motion and the relationship between applied load and motion can be described using load-motion curves. These curves are nonlinear in nature. There are specific parameters that are typically used within spine research to describe the
relationship between load and motion. These parameters aid in determining biomechanical stability of the spine.

- **Neutral Zone (NZ):** This is the region of laxity within the spine. It is the zone where spinal motion occurs with minimal loading (Figure 9). Spines having large NZ tend to be more degenerated and unstable.

- **Range of Motion (ROM):** This describes the total motion of the spine in any plane of motion. (Figure 9).

- **Elastic Zone (EZ):** This is the region beyond NZ where the spine tends to show increasing stiffness as the load is increased. (Figure 9).

![Load-Motion curve diagram](image)

*Figure 2.9. Typical Load-Motion curves obtained from biomechanical tests*
2.6 Multi-Segment Spine Testing

Physiological loading of a spine involves a combination of muscle forces, external loads and body weight. Experimentally mimicking these loading conditions is a very complex problem. Several spine testing systems have been developed with the goal to mimic realistic in vivo motion. These systems involve the application of pure moments, follower loads and eccentric loads.

2.6.1 Pure moment testing systems. These systems apply a constant uniform pure moment on spinal segment while ensuring that all off axis forces are minimized (Figure 10). In essence, only a rotational load is applied while compressive, tensile and shear loads are kept at zero. This type of system ensures that every level is subjected to an equal uniform load. Thus, this type of loading is preferred for the evaluation of spinal stability and the comparison between spinal implants. Earlier systems used a combination of pulleys, cables and dead weights to implement pure moment loading. However, more sophisticated systems have been developed to conduct a pure moment test on a spine.
2.6.2 Follower load system. *In vivo* lumbar spine is capable of supporting large compressive loads without buckling because of the presence of active element (muscles) which provide additional stability and increase the overall stiffness of the spine to resist motion. However, under *in vitro* conditions, the spine tends to buckle at low compressive loads. In order to simulate the load-carrying capabilities of *in vivo* lumbar spine for *in vitro* conditions, an experimental technique originally developed and validated by Patwardhan in 1999 was used to apply large compressive loads. It involved the application of a follower compressive load along the lordotic curvature of the lumbar spine.\textsuperscript{14} The compressive follower load is applied using a system of pulleys, cables, eyelets and dead weights. The eyelets are mounted laterally onto each of the vertebral bodies. The cables are attached to the cranial end of the spine and guided
through each of the eyelets. The positions of the eyelets are adjusted to approximate the center of the vertebral bodies and enable the load path to follow the curvature of the lumbar spine.

![Diagram of Pure Moment System using coupled forces](image)

**Figure 2.11. Pure Moment System using coupled forces**

**2.7 Specimen Preparation**

Fresh frozen human cadaveric spines (whole spines or segments) are procured from organ donor sites based on the following exclusion criteria – age group > 75 years, prior spine surgery, spine trauma or defects, heavy smoker, cancer, osteoporosis and not physically active. Before dissection of the non-structural elements such as muscles, soft tissues etc, a radiologic assessment
using Computed Tomography (CT) and a visual inspection were made to exclude any bony defects such as fractures and soft tissue abnormalities.

The specimens were then dissected to remove all non-ligamentous soft tissue (non-structural) while preserving the vertebral bodies, discs, facet joint capsules and the following ligamentous soft tissues (structural) – anterior longitudinal ligament (ALL), posterior longitudinal ligament (PLL), the interspinous and the supraspinous ligament. (Figure 12).

![Figure 2.12. (a) 3D CT scan model, (b) Transverse CT section, (c) & (d) Soft tissue dissection](image)

### 2.8 Custom Spinal Test Fixtures

Custom test fixtures (Figure 13) were designed to secure the spine specimen for biomechanical testing based on anthropometric data. The
custom fixtures were designed to enable four points of fixation on the spine using a combination of pedicle-screws, rods and wood screws embedded in Cerobend, a liquid metal alloy (HiTech Alloys, Squamish, WA). These fixtures were made from aluminum in order to reduce the overall weight on the spine during testing.

In order to mount the specimen onto the custom spinal test fixture, three pedicle screws were inserted into the cranial and caudal vertebra (Sacrum).
(Figure 14). For the cranial vertebra, two screws were placed posteriorly through the pedicles into the vertebral body while the third screw was placed anteriorly through the vertebral body in an anterior-posterior orientation. A similar approach was applied to the caudal vertebral (Sacrum) with two screws placed posteriorly at sites that would ensure maximum bone purchase, and a third screw placed anteriorly through the sacral body. Stainless steel rods from the testing fixtures were then attached to the pedicle screws of each end vertebra and fixed using set screws. (Figure 15). The rods were secured onto the spinal fixture using custom-made holders. It was ensured that before securing the rods onto the spinal fixture, the spine segment was positioned in a neutral posture. The position of the rods and the holders were adjusted depending on the size of the vertebra. For additional stability, four wood screws were placed into the superior endplate of the cranial vertebral body and embedded in Cerobend, a liquid metal alloy (HiTech Alloys, Squamish, WA). (Figures 16 and 17). Similarly, wood screws were inserted onto the inferior part of the sacral body and embedded in liquid metal alloy. The intervening discs were left intact and were not entered by screws or compromised by the potting material.
A. Cranial Vertebra

B. Caudal Vertebra

Figure 2. 14. Placement of Pedicle Screws on cranial vertebra (A) and caudal vertebra (B) for attachment onto Custom Spinal Fixtures

Figure 2.15. Placement of Spine onto Stainless Steel Rod
2.9 Follower Load Fixtures

Custom fixtures were designed and developed based on the follower load model to apply compressive loads during the robotic biomechanical testing. Dead weights were used to apply the compressive load. The follower load fixtures were mounted anteriorly onto the vertebrae using wood screws. (Figure 18) The
fixtures are mounted on all vertebrae except the cranial and caudal vertebra. Eyelets were then placed onto the fixture and adjusted to be approximately in line with the center of rotation of the spine (posterior one-third of the vertebra). A cable fixed on the cranial vertebra is passed through the eyelets to enable the loading to follow the curvature of the spine and attached to the dead weights through a pulley system. (Figure 19).

![Figure 2.18. Placement of Follower Fixtures onto Spine](image)

- Placement of Fixture on anterior part of vertebral body using wood screws
- Eyelets
2.10 Robotic Spine Testing

A six-axis industrial robot (KUKA, KR 16, Augsburg, Germany) was used as the spine testing apparatus (Figure 20a). A six-axis force-moment sensor (GAMMA, ATI, Apex, NC) was used to measure the applied load and provide feedback to the robot (Figure 20b). The sensor also measured the off-axis forces and moments in order to provide feedback to ensure that a pure moment was being applied along the primary axis of motion of the spine. The robot was programmed using custom force-torque software to apply continuous loading and unloading cycles of pure moment in torque control along each of the primary axis of the spine to simulate flexion-extension (FE), lateral bending (LB) and axial rotation (AR). The program was set to minimize loads in all other axes. The relative vertebral motion was captured using an optoelectronic camera system.
(Optotrak, Northern Digital Inc., Waterloo, Ontario, Canada). The camera system measures the vertebral motion by tracking the relative motion between infra-red markers placed on vertebral segments.

The spine is a three dimensional structure having six degrees of freedom – three translations and three rotations. It is therefore important to measure the kinematics of the spinal motion using a suitable coordinate system. The coordinate system definition used for each vertebrae and set of adjacent vertebral bodies is based on the ISB 2002 standard\textsuperscript{15} with one slight modification regarding the definition of the origin. The ISB standard defines the origin as the intersection of the proximal and distal y axes in the reference, neutral position. It requires that the neutral position must be specified, and must be in a position where the vertebral y axes are coplanar. If the y axes are parallel (do not
intersect at the common origin O) the y axes are constrained to be collinear, and the origin O is the mid-point between adjacent endplates. Since the vertebral y axis from one vertebra to another are not guaranteed to be co-planar in a practical neutral position (i.e. zero load condition) a variation of the standard was implemented. The axis intersection point was not used and the mid-point between adjacent endplates was estimated as the midpoint of the two vertebral origins. Though these points are not guaranteed to be the same, they are likely close enough and will allow for multiple vertebral kinematics to be calculated without having to have two origins per vertebra.

The spine specimen with the custom spinal fixture was mounted onto the industrial robot by attaching, first, the caudal spinal fixture to a fixed base pedestal and then the free end, the cranial fixture, is attached to the robotic end effector. (Figure 21). The spine was kept moist using saline solution. Nondestructive flexibility testing was performed on the specimens using the robot to compare various treatments. The specimens are subjected to three cycles of pure bending moment while continuously minimizing off-axis loads. Range of motion (ROM) was determined from the third loading cycle for each specimen. ROM is the total angular rotation between vertebral bodies.

Statistical analysis was performed using Minitab 16 (Minitab Inc., State College, PA) to compare the differences between treatments. A repeated measures analysis of variance was used to analyze the ROM between test conditions with a 95% level of significance. Post-hoc Tukey-Kramer or Bonferroni
analysis (p < 0.05 was considered statistically significant) was used for multiple comparisons of the ROM between conditions.

2.11 References


3.1 Abstract

3.1.1 Introduction. Segmental fixation improves fusion rates and promotes mobility after lumbar surgery. Efforts to obtain stability using less invasive techniques have lead to the advent of new implants and constructs. A new interspinous fixation device (ISD) has been introduced as a minimally invasive method of stabilizing two adjacent interspinous (IS) processes while the fusion occurs. Used to augment an interbody cage in transforaminal interbody fusion, the ISD is intended to replace the standard pedicle screw instrumentation used for posterior fixation. The ISD was evaluated using the standard biomechanical testing methods. The purpose of this study is to compare the rigidity of these implant systems when supplementing an interbody cage as used in transforaminal lumbar interbody fusion (TLIF). The overall goal of this study was to utilize the robotic system to conduct the in vitro tests and assess the stability of the ISD in relation to the spine.
3.1.2 Methods. Seven human cadaver spines (T12 to the sacrum) were mounted in a custom designed testing apparatus, then mounted for biomechanical testing using a multiaxial robotic system. A comparison of segmental stiffness was carried out among four instrumentation constructs: 1) intact spine control, 2) Interbody cage, alone (IBC), 3) Interbody Cage with Interspinous Fixation Device (ISD), 4) Interbody Cage, Interspinous Fixation Device and unilateral pedicle screws (Unilat), 5) Interbody Cage, with bilateral pedicle screws (Bilat). An industrial robot (KUKA, GmbH, Augsburg, Germany) applied a pure moment (±5 Nm) in flexion-extension (FE), lateral bending (LB) and axial rotation (AR) through an anchor to the T12 vertebral body. The relative vertebral motion was captured using an optoelectronic camera system (Optotrak, Northern Digital Inc., Waterloo, ON, Canada). The load sensor and the camera were synchronized. Maximum displacement was measured at each level and stiffness of the implant segments calculated and compared to the intact control. Implant constructs were compared to control and to each other. Statistical analysis was performed using ANOVA.

3.1.3 Results. A comparison between the intact spine and the IBC group showed no significant difference in range of motion (ROM) in FE, LB or AR. After implantation of the ISD to augment the IBC, there was a significant decrease in ROM of 74% in FE (p =0.00), but no significant change in ROM in LB and AR. The addition of unilateral pedicle-screws (Unilat) to the ISD significantly reduced the ROM by 77% compared to FE control, (p=0.00), and by 55% (p=0.002) and 42% (p=0.04) in LB and AR respectively, in comparison to control. The bilateral
pedicle-screw fixation (Bilat) reduced ROM in FE by 77% (p=0.00), and by 77% (p=0.001) in LB and 65% (p=0.001) in AR when compared to the control spine.

There was no statistically significant difference in FE stiffness between the stand alone ISD, ISD with unilateral pedicle screws, and bilateral pedicle screw constructs. However, in both LB and AR the ISD with unilateral screws and the bilateral pedicle screws spines were significantly stiffer than the ISD and IBS combination. The ISD stability in LB and AR was not different from the intact control with no instrumentation at all. There was no statistical difference between the stability of ISD plus unilateral screws and bilateral pedicle screws in any direction. However, LB and AR in the Unilat group produced a mean displacement of 3.83˚± 3.30˚, and 2.33˚± 1.33˚ respectively, compared to the Bilat construct which limited motion to 1.96˚± 1.46˚, and 1.39˚± 0.73˚. There was a trend suggesting that bilateral pedicle screws were the most rigid construct.

3.1.4 Conclusions. In FE the ISD can provide lumbar stability comparably to bilateral pedicle screws. It provides minimal rigidity in LB and AR when used alone to stabilize the segment after a interbody cage placement. ISD with unilateral pedicle screws and the more typical bilateral pedicle screw construct were shown to provide similar levels of stability in all directions after a IBS placement, though the Bilat construct showed a trend toward improved stiffness overall.

3.2 Introduction

Increased stability provided by segmental instrumentation has demonstrated in many studies to improve fusion rates in spine surgery. In recent
years there has also been a constant push to try to accomplish surgical procedures through minimally invasive approaches. Although, to date, most studies of minimally invasive surgery (MIS) are only able to demonstrate short term benefits (like less blood loss and earlier hospital discharge) and, at best, similar long term results when compared to the traditional open procedures.

The increased use and improved application of MIS techniques is driven by the interests of health care professionals, industry and patients.\textsuperscript{1-3} The impetus for improvement in MIS procedures has led to an increase in the development of spinal stabilization devices that require less invasive surgical exposure for their implantation. Such a device is the interspinous fixation device used to clamp adjacent spinous elements in rigid alignment in anticipation of spinal fusion. The clinical indications for the use of non-fusion interspinous fixation devices are for lumbar spinal stenosis and painful facet arthrosis.\textsuperscript{4} With the clinical success of those devices a number of interspinous fixation devices have been tested or introduced into clinical use.

The use of interspinous fixation devices to promote interspinous fusion is not a new idea. Similar implants have been used in the past,\textsuperscript{5-6} but their use has been discontinued when faced with greater stability and better clinical results of more modern instrumentation implants.

The Aspen Interspinous Fixation Device, produced by Lanx (Broomfield, CO) is representative of implants seeking to augment interbody fusion techniques while reducing the need for transpedicular fixation. The device is made of titanium alloy and consists of two components, (Figure 1). Component A
consists of an extruded semi-cylindrical-shaped hollow shaft attached to a lateral plate while component B consists of a lateral plate with a locking screw and an insertion hole for component A. Both lateral plates have spikes at the top and bottom that are meant to pierce into the spinous process during placement of the device, which firmly secures the motion segment. The aim of the implant is to increase segmental stability with the purpose of improving the fusion rate, with the advantage of being inserted in a minimally invasive fashion. The insertion of the implant requires only a small midline incision with no additional lateral exposure. The device is placed between the spinous processes of an unstable segment with only the disruption of the interspinous ligament during implantation while the supraspinous ligament remains intact.

The purpose of this study was to biomechanically test this new interspinous fixation device using an interbody cage model, and compare its ability to stabilize a lumbar motion segment tested in flexion/extension, side-bending, and axial rotation. The interspinous fixation device was tested as a stand-alone device, and in combination with a unilateral pedicle screw fixation, relative to a more traditional fixation construct using bilateral pedicle screw fixation, which is considered the current gold standard of rigid fixation.

Figure 3.1. Aspen Interspinous Device
3.3 Methods

Seven fresh, frozen cadaveric human spines from T12 to Sacrum (5 male, 2 female, mean age, 50 years, range: 26 – 64 years) were used in this study. Each specimen was dissected to remove all non-ligamentous soft tissue while preserving the vertebral bodies, discs, facet joint capsules and the following ligamentous soft tissues – anterior longitudinal ligament (ALL), posterior longitudinal ligament (PLL), the interspinous and the supraspinous ligament. Prior to testing, the specimen was assessed for any significant structural defects or anatomical abnormalities through visual inspection and computer tomography (CT).

An industrial robot (KUKA, GmbH, Augsburg, Germany) was used as the spine testing apparatus (Figure 2). It applied pure moments on the spinal segment. A six-axis force-moment sensor (GAMMA, ATI, Apex, NC) was used to measure the applied load and provide feedback to the robot. The sensor also measured the off-axis forces and moments in order to provide feedback to ensure that a pure moment was being applied along the primary axis of motion of the spine. The robot was programmed using custom force-torque software to apply three continuous loading and unloading cycles of pure moment in torque control along each of the primary axis of the spine to simulate flexion-extension (FE), lateral bending (LB) and axial rotation (AR). The program was set to minimize loads in all other axes. The relative vertebral motion was captured using an optoelectronic camera system (Optotrak, Northern Digital Inc., Waterloo, Ontario, Canada). The camera system measures the vertebral motion
by tracking the relative motion between infra-red markers placed on vertebral segments.

Figure 3.2. Spine Testing Robot with Infra Red markers attached to spine

The coordinate system definition for each vertebrae and set of adjacent vertebral bodies is based on the ISB 2002 standard\(^7\) with one slight modification regarding the definition of the origin. The ISB standard defines the origin as the intersection of the proximal and distal y axes in the reference, neutral position. It requires that the neutral position must be specified, and must be in a position where the vertebral y axes are coplanar. If the y axes are parallel (do not intersect at the common origin O) the y axes are constrained to be collinear, and the origin O is the mid-point between adjacent endplates. Since the vertebral y axis from one vertebra to another are not guaranteed to be co-planar in a practical neutral position (i.e. zero load condition) a variation of the standard was
implemented. The axis intersection point was not used and the mid-point between adjacent endplates was estimated as the midpoint of the two vertebral origins. Though these points are not guaranteed to be the same, they are likely close enough and will allow for multiple vertebral kinematics to be calculated without having to have two origins per vertebra.

Prior to testing, the spine specimens were thawed to room temperature and then attached to custom-designed spinal fixtures which were made to fix the spine securely onto the spine testing apparatus. In order to mount the specimen onto the custom-designed spinal fixture, three pedicle screws were inserted into the cranial (T12) and caudal vertebra (Sacrum). For the cranial vertebra, two screws were placed posteriorly through the pedicles into the vertebral body while the third screw was placed anteriorly through the vertebral body in an anterior-posterior orientation. A similar approach was applied to the caudal vertebral (Sacrum) with two screws placed posteriorly at sites that would ensure maximum bone purchase, and a third screw placed anteriorly through the sacral body. Stainless steel rods from the testing fixtures were then attached to the pedicle screws of each end vertebra and fixed using set screws. The rods were secured onto the spinal fixture using custom-made holders. It was ensured that before securing the rods onto the spinal fixture, the spine segment (T12 – S) was positioned in a neutral posture by horizontally orienting the L3 – L4 disc. The position of the rods and the holders were adjusted depending on the size of the vertebra. For additional stability, four wood screws were placed into the superior endplate of the cranial vertebral body and embedded in Cerobend, a liquid metal
alloy (HiTech Alloys, Squamish, WA). Similarly, wood screws were inserted onto the inferior part of the sacral body and embedded in liquid metal alloy. The intervening discs were left intact and were not entered by screws or compromised by the potting material.

On the day of testing, the specimen with the custom spinal fixture was thawed to room temperature and mounted onto the industrial robot. The caudal spinal fixture was attached to a base pedestal while the cranial fixture was attached to the robotic arm. (Figure 3). The spine was kept moist using saline solution. Nondestructive flexibility testing was performed on the specimens using the robot. The specimens were subjected to three cycles of FE, LB and AR at an applied pure bending moment of ±5Nm while continuously minimizing off-axis loads. Range of motion (ROM) was determined from the third loading cycle for each specimen. ROM was measured in this study as the angular motion between the segments at ± 5 Nm. All surgical instrumentation was provided by Lanx, Broomfield, CO.

![Figure 3. Spine Specimen attached to Custom-fixtures and mounted onto Robot](image)
3.4 Surgical Treatment

The flexibility tests were performed on each specimen sequentially under five different treatment conditions:

1. Intact Control: Intact spine was subjected to *in vitro* flexibility tests to simulate FE, LB and AR motions.

2. Interbody Spacer (IBS): The TLIF surgical approach was simulated at the intervertebral disc between L3 and L4 vertebra and an interbody device was placed at L3 – L4 level (See figure 4a). No posterior instrumentation was used following interbody placement.

3. Interspinous Device (ISD) with IBS: The interbody spacer was supplemented by fixation with an ISD. (See figure 4b). An appropriate size of the ISD was selected to fit the space between the spinous process of L3 and L4 vertebral level. No other fixation was applied.

4. ISD with Unilateral Pedicle Screw/rod (Unilat): Fixation provided by the Interspinous device and the interbody cage was augmented using unilateral pedicle screw/rod fixation. (Figure 4c)

5. IBS with Bilateral Pedicle Screw/rod (Bilat): The ISD was removed and bilateral pedicle screw/rod fixations was added to support the interbody spacer in the “Gold Standard”. (Figure 4d)
Statistical analysis was performed using Minitab 16 (Minitab Inc., State College, PA). A repeated measures analysis of variance was used to analyze the ROM between test conditions with a 95% level of significance. Post-hoc Tukey-Kramer analysis (p < 0.05 was considered statistically significant) was used for multiple comparisons of the ROM between conditions.

3.5 Results

The mean ROM for the intact spine segment was 6.47 ± 2.44° in FE, 8.59 ± 5.23° in LB and 3.99 ± 2.34° in AR. Table 1 shows the minimized mean resultant off-axis forces for FE, LB and AR for each of the five different test conditions. The IBS placement resulted in a 6% and 7% reduction in ROM in FE
and AR, respectively, when compared to the intact control. However the ROM in LB increased by 4% for IBS group when compared to the control. After additional implantation of the ISD, a significant decrease in ROM of 74% was observed in FE. The ISD resulted in a 5% decrease in LB and a 0.4% decrease in AR in comparison to the intact condition.

The addition of unilateral pedicle screw/rod fixation (Unilat) to ISD/IBS offered no incremental improvement in FE stiffness, but greatly improved torsional and side-bending stiffness. The Unilat construct reduced the ROM by 77%, 55% and 42% in FE, LB and AR, respectively, in comparison to intact controls. The removal of the ISD and the insertion of bilateral pedicle screw/rod fixation with IBS resulted in a reduction in ROM of 77% in FE, 77% in LB and 65% in AR when compared to the intact control. Figure 5 shows the mean ROM and standard deviations for the five conditions in the three motion planes, FE, LB and AR. Table 2 shows the ROM values for all conditions for FE, LB and AR.

A statistical comparison (α = 0.05) between intact control and IBS tests showed that there was no significant difference in ROM observed in FE (6.47˚± 2.44˚vs 6.07˚± 3.36˚, p = 0.965), LB (8.59˚± 5.23˚vs 8.96˚± 7.13˚, p = 0.770) and AR (3.99˚± 2.34˚vs 3.69˚± 2.16˚, p = 0.982). Comparing the results of the intact to the ISD group showed that the ISD placement significantly reduced the ROM in FE (6.47˚± 2.44˚vs 1.67˚± 1.77˚, p < 0.001 however, there were no significant change in ROM in LB (8.59˚± 5.23˚vs 8.14˚± 7.33˚, p = 0.998) and AR (3.99˚± 2.34˚vs 3.97˚± 2.58˚, p = 0.982).
Comparison of the ISD group to the Unilat group showed no significant change in the ROM in FE (1.67° ± 1.77° vs 1.49° ± 1.60°, p = 0.998). The comparison results for LB (8.14° ± 7.33° vs 3.83° ± 3.30°, p = 0.049) and AR (3.97° ± 2.58° vs 2.33° ± 1.33°, p = 0.043), showed that the unilateral pedicle screw/rod combination significantly reduced the ROM when compared to the ISD construct alone. A similar trend was observed when comparing the ISD group to bilateral pedicle screw/rod fixation (Bilat): We found no significant change in FE ROM (1.67° ± 1.77° vs 1.51° ± 1.35°, p = 0.998) but a significant reduction in ROM in the Bilat group in LB (8.14° ± 7.33° vs 1.96° ± 1.46°, p = 0.002) and AR (3.97° ± 2.58° vs 1.39° ± 0.73°, p = 0.001) compared to the ISD alone.

Finally, comparing the results of the Unilat construct to those of the Bilat fixation construct found no significant difference in FE ROM (1.49° ± 1.60° vs 1.51° ± 1.35°, p = 1.000), LB (3.83° ± 3.30° vs 1.96° ± 1.46°, p = 0.701) and AR (2.33° ± 1.33° vs 1.39° ± 0.73°, p = 0.442). Nevertheless, the bilateral pedicle screw construct showed a trend to be the most rigid construct of all.

Table 3.1
Shows the Mean Resultant off-axis forces for FE, LB and AR for each of the five test conditions
Table 3.2

Shows the Mean ROM for FE, LB and AR for each of the five test conditions

<table>
<thead>
<tr>
<th></th>
<th>Intact</th>
<th>IBS</th>
<th>ISD</th>
<th>Unilat</th>
<th>Bilat</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(deg)</td>
<td>(deg)</td>
<td>(deg)</td>
<td>(deg)</td>
<td>(deg)</td>
</tr>
<tr>
<td>FE</td>
<td>6.47˚ ± 2.44˚</td>
<td>6.07˚ ± 3.36˚</td>
<td>1.67˚ ± 1.77˚</td>
<td>1.49˚ ± 1.60˚</td>
<td>1.51˚ ± 1.35˚</td>
</tr>
<tr>
<td>LB</td>
<td>8.59˚ ± 5.23˚</td>
<td>8.96˚ ± 7.13˚</td>
<td>8.14˚ ± 7.33˚</td>
<td>3.83˚ ± 3.30˚</td>
<td>1.96˚ ± 1.46˚</td>
</tr>
<tr>
<td>AR</td>
<td>3.99˚ ± 2.34˚</td>
<td>3.69˚ ± 2.16˚</td>
<td>3.97˚ ± 2.58˚</td>
<td>2.33˚ ± 1.33˚</td>
<td>1.39˚ ± 0.73˚</td>
</tr>
</tbody>
</table>

Note: Underlined values indicate significant difference (P < 0.05) when compared to Bilat

Figure 3.5. Mean ROM for all test conditions in FE, LB and AR

See Appendices for data on all specimens tested.
3.6 Discussion

This study investigated the effect of an interspinous fixation device on the kinematic behavior of the lumbar spine. The investigated device was designed for a minimally invasive application involving minimal disruption of structural elements of the lumbar spine during its implantation. The intended goal is to provide supplemental support in a TLIF application, obviating the need for pedicle screw fixation.

The stabilizing effect of the device on the lumbar segment was measured using in vitro flexibility tests and compared against bilateral pedicle screw fixation, which may be considered the current gold standard for segmental fixation of the lumbar spine.\textsuperscript{8-9} Traditional flexibility tests have, in the past, been implemented using pulleys and cables to apply static loads, and vertebral displacements are measured following load application.\textsuperscript{10-12} Flexibility tests have also been conducted using specially made fixtures mounted on standard material testing systems.\textsuperscript{13-14} However, these test systems tend to constrain the motion of the spine. More recent spine testing systems involve the use of multi-axis test systems such as robots which can provide a flexible, repeatable and accurate way of loading and simulating unconstrained spinal motion. For our study, a robotic spine testing system was used to apply continuous, unconstrained, pure moments of $\pm 5$ Nm to the lumbar motion segment to simulate FE, LB and AR. The test system minimized off-axis forces and moments generated during the application of load in the primary axis. The uniqueness of our test system, when compared to other systems in the literature, is in its ability to apply continuous
unconstrained pure moments while dynamically optimizing the motion path to minimize off-axis loads during testing. Our system provides the flexibility to alter both the loading and boundary conditions of the biomechanical test.

In our study we found that the ROM following the IBS placement, with no posterior instrumentation in place, was not measurably different from intact control conditions in any of the motion planes. However, when supplementing the interbody spacer with the ISD, we observed a significant reduction in FE ROM, yet motion in LB and AR were not significantly affected when compared to intact.

These results are consistent with those previously presented in the literature.15-18 Lindsey et al reported that placement of interspinous spacer (X Stop, SFMT, Concord, CA) at L3 – L4 level significantly reduced ROM in FE with no effect on the ROM in AR and LB.15 Wilke et al conducted a biomechanical study on four different interspinous implants and found that all four implants restricted motion in FE only. They concluded that all the tested implants showed a similar effect in stabilization in FE while having no effect in LB and AR.16 Karahalios et al conducted a study using this same ISD (Aspen, Lanx, Broomfield, CO) to supplement an Anterior Lumbar Interbody Fusion (ALIF) procedure at L4 – L5 level and found a similar trend to our study. They concluded that the acquired stability was greatest in FE (25% of intact motion retained) and much less in AR or LB (71% of intact motion was retained for both).17

This study also showed that, in FE, the stability provided by ISD was statistically equivalent to the unilateral pedicle screw/rod, when used in combination with the interbody spacer, while in LB and AR, the unilateral pedicle
screw/rod construct showed significantly greater stability. We found a similar trend with bilateral pedicle screw/rod combination when compared to the ISD alone. In contrast, Karahalios et al found no statistically significant difference in stability between bilateral pedicle screw fixation and the interspinous devices used to supplement ALIF in any of the FE, LB and AR tests.\textsuperscript{17} There are several reasons for this discrepancy in findings, one of which is the surgical procedures performed in their study compared to ours (ALIF vs TLIF). Another difference is in the testing methodology used in their study, the application of load was dynamically optimized (minimize off axis loads) in our study to ensure unconstrained pure moment loading conditions throughout the test.

There are few studies currently in the literature that have assessed the stability provided by unilateral pedicle screw/rod fixation in combination with ISD. Lo et al developed a finite element model to compare the biomechanical differences between an ISD and pedicle screw fixation combined with TLIF against ISD and pedicle screw fixation combined with ALIF. In their study, they found that the TLIF combination was less stable than the ALIF combination.\textsuperscript{19} The results from our study showed that additional augmentation of TLIF with unilateral pedicle screws and ISD was statistically equivalent to TLIF with bilateral pedicle screws in FE, LB and AR, but that ISD alone was not comparable.

Only a few animal studies have emerged regarding this new generation of implants. Bae et al developed a sheep model to assess the interspinous segmental fusion rate when using an interspinous fixation device. They obtained
100% fusion rate when the device was supplemented with bone graft and Bone Morphogenic Protein (BMP) and a 0% rate of fusion when no BMP was associated.\textsuperscript{20} Wang et al compared a small group (21 patients) with interspinous device (Spire SPP, Medtronic, Minneapolis, MN) used to supplement ALIF, to 11 patients with bilateral pedicle screws. They found no complications, no pseudoarthrosis and no hardware failure at approximately 5 months of follow up for both groups.\textsuperscript{21} However, there are associated complications of using interspinous devices reported in the literature.\textsuperscript{22,23} Post-operative spinous process fracture and device dislocations can both occur with interspinous devices.\textsuperscript{22,23}

While the ISD studied here did appear to provide suitable fixation to withstand flexion/extension forces in the patient treated for lumbar fusion, this study looked at acute fixation strength, and issues of loosening or failure with protracted cyclic loading were not assessed. Deficiencies in torsional control and side-bending stiffness are also of concern, as the interbody devices typically used for TLIF application are inherently weak in these axes as well. Application of a unilateral pedicle screw construct appears to provide adequate immediate fixation strength, comparable to the bilateral pedicle screw construct typically considered a standard, but application of pedicle screws along with the ISD may negate much of the cost advantage or time/surgical advantage proposed as the reason for using the interspinous device. Clinical experience to date is limited, but ongoing studies may provide guidance as to whether supplemental screw are routinely warranted in adult lumbar fusions using ISD.
The adjacent level effects resulting from the implantation of this ISD was not investigated in this study and could serve as a future study. Clinical data regarding the use of this ISD is limited and to date no conclusion can be made on their long term efficacy in promoting fusion.

3.7 Conclusions

The current study assessed the biomechanical stability of the lumbar spine following a simulated TLIF procedure with an interbody cage alone, the ISD in combination with the cage, the ISD plus unilateral pedicle screws in combination with the cage, and bilateral pedicle screws with an interbody cage in a typical TLIF configuration. We found that the ISD, used to augment the IBS, was able to provide FE stability comparable to bilateral pedicle screw fixation. However, it provided minimal stability in LB and AR unless further augmented with pedicle screws. This study also found that the combination of the ISD with unilateral pedicle screws was biomechanically equivalent to bilateral pedicle screws, in providing stability in all directions after a TLIF.

3.8 References


CHAPTER IV

HYBRID DYNAMIC STABILIZATION: A BIOMECHANICAL ASSESSMENT OF
ADJACENT AND SUPRA-ADJACENT LEVELS

(Submitted for publication – Journal of Neurosurgery: Spine)

4.1 Abstract

The primary goal of this study was to use the developed biomechanical testing methodology involving the robotic system to access and evaluate a hybrid dynamic stabilization system and its effect on adjacent level motion.

4.1.1 Study design. A human spine cadaveric study accessing the biomechanical effects of pedicle screw based dynamic stabilization of the supra adjacent level to a one level lumbar fusion. Objective: To evaluate the effect of hybrid dynamic stabilization on adjacent levels of lumbar spine.

4.1.2 Summary of background. One of the many proposed indications for dynamic stabilization is its use as transition instrumentation adjacent to a solid fusion to protect that adjacent level from excessive compensating motion / stress and also aid in creating a smoother motion transition to the other levels of the spine. In this model, we accessed the angular range of motion (ROM) of the adjacent levels of the spine after a L4 - L5 instrumented fusion. Subsequently,
we implanted a pedicle screw dynamic stabilization device at L3 - L4 and analyzed biomechanically its protective effects on that level as well as the ROM on the remaining segments of the lumbar spine.

**4.1.3 Methods.** Seven human specimens T12-sacrum were used. The following conditions were implemented: (1) Intact spine, (2) Fusion of L4-5 with bilateral pedicle screws and titanium rods, and (3) Supplementation of the L4-5 fusion with a pedicle screw dynamic stabilization construct (Zimmer, Warsaw, IN) at L3-L4, with the purpose of protecting the L3-4 level from the excessive ROM and also to create a smoother motion transition to the rest of the lumbar spine. The robot applied continuous pure moment (±2 Nm) in flexion-extension (FE) with and without follower load, lateral bending (LB) and axial rotation (AR). Intersegmental rotations of the fused, dynamically stabilized and adjacent levels were measured and compared.

**4.1.4 Results.** The rigid instrumentation at L4 – L5 caused a 78% decrease in the segment’s F/E when compared to the intact specimen. To compensate, it caused an increase in motion at L1 – L2 (45.6%) and L2 – L3 (23.2%) (P = 0.00). No statistically significant increase in the ROM was seen at T12-1, L3-4 or L5-S1. The placement of the dynamic construct at L3 – L4, decreased the operated level’s motion by 80.4% (same stability as the fusion at L4-5) and caused a significant increase in motion at all tested adjacent levels: T12 – L1 (73.4%), L1 – L2 (85.0%), L2 – L3 (49.9%) and L5 – S1 (20.8%).

In FE with follower load, instrumentation at L4 – L5 showed no significant change in motion at all adjacent levels except L5 – S1 which showed a significant
increase in motion of 52.0%. There was a significant reduction in motion at the operated level, L4 – L5 (76.4%). The addition of a dynamic construct caused a significant decrease in motion at the operated level, L3 – L4 (76.7% - very similar stability found at the adjacent lower fused level), while the adjacent levels, T12 – L1 (44.9%), L1 – L2 (57.3%) and L5 – S1 (83.9%) all showed a significant increase in motion. The only exception was L2 – L3 with no significant change in ROM.

In LB, instrumentation at L4 – L5, showed no significant change in motion in all the adjacent levels except T12 – L1 (increase of 22.8%). The operated level, L4 – L5, showed a decrease in motion of 83.6% when compared to intact. The placement of the dynamic construct at L3 – L4 after the L4 - L5 fusion caused an increase in motion at T12 – L1 (69.9%), L1 – L2 (59.4%), L2 – L3 (44.7%), L5 – S1 (43.7%) and a significant decrease in motion of 80.7% at the operated level, L3 – L4.

In AR, there were no significant changes in motion at the adjacent levels after L4 – L5 fusion. The operated level, L4 – L5 showed a decrease in motion of 46.1%. The placement of dynamic construct at L3 – L4 after the L4-5 fusion caused a significant increase in motion of the adjacent levels, L2 – L3 (25.1%) and L5 – S1 (31.4%). There was a significant decrease in motion of 38% at the operated level, L3 – L4.

4.1.5 Conclusion. The dynamic stabilization system had the same stability as a solid all metal construct. Its addition to the supra adjacent level (L3- L4) to the fusion (L4- L5) in deed protected the adjacent level from excessive
motion. However, it essentially transformed a 1 level into a 2 level lumbar fusion with exponential transfer of motion to the fewer remaining discs.

4.2 Introduction

Intervertebral fusion is considered the gold standard for the treatment of lumbar segmental instability which is typically caused by degeneration of the intervertebral disc, zygapophysial joints and ligaments [1-2]. However, studies have shown that fusion causes accelerated degeneration at adjacent levels. [3-13]. This has led to the development of motion-preserving treatment options as an alternative to fusion. [2,14]. One of such options is Dynamic stabilization. It involves the use of a semi-rigid implant design to stabilize a dysfunctional lumbar spinal segment. It is intended to mitigate accelerated adjacent level degeneration and limit abnormal motion which contributes to disc and ligamentous degeneration. Dynamic stabilization may be implemented as a stand-alone technique or as a hybrid technique. In a stand-alone application, the injured or degenerated segment is instrumented posteriorly only with a dynamic system, in the hope that the system’s stabilizing properties will be sufficient to prevent dysfunctional segmental motion; no fusion is performed, reducing the risk of subsequent degeneration at adjacent levels. In the hybrid application, a fusion is performed at the injured or degenerated segment using rigid implants applied posteriorly, with dynamic stabilization extended to levels above or below the segment to be fused (Topping off). The goal of a hybrid application is to prophylactically limit stress at the level above or below the fusion and prevent the development of adjacent level disease.
Several clinical studies have focused on dynamic stabilization as a stand-alone alternative to traditional fusion. Kim et al. conducted a 3 year follow-up post-op study on 21 patients who underwent lumbar spinal stabilization with dynamic stabilization and found a significant decrease in range of motion (ROM) at the operated level and a significant increase in motion at the adjacent levels.[15]. Cakir et al performed an in vivo study of 26 patients with degenerative instability who underwent decompression and stand-alone dynamic stabilization versus decompression and standard fusion. Patients who underwent fusion demonstrated decreased global and segmental ROM, while patients who underwent dynamic stabilization demonstrated preserved global and segmental ROM. In both groups, adjacent level ROM was unchanged when compared with the pre-operative state. [16]. Kumar et al performed dynamic stabilization in 32 patients, using both stand-alone (20 patients) and hybrid (12 patients) procedures. Follow-up was performed with 2 year post-op MRI scans; clinical outcomes were not assessed. In patients who received a hybrid procedure, the unfused, dynamically-stabilized segments demonstrated evidence of additional degeneration in 25% of patients, and the segment above the dynamically stabilized segment demonstrated additional degeneration in 8%. However, interpretation of these hybrid results is limited by the small number of patients involved and the subjective nature of the primary outcome measure. [17].

Presently, there is a lack of biomechanical data supporting the hybrid application of dynamic systems. In particular, there is a lack of information regarding the effect of hybrid stabilization on the levels above the dynamically
stabilized level. It is possible that dynamic stabilization above a fusion will simply transmit stresses created by the fusion to the motion segment above the dynamic stabilization, accelerating degeneration over a longer segment of the spine. The aim of this study was to analyze the effect of the hybrid dynamic stabilization system on the ROM of the lumbar segments, adjacent to the operated level.

4.3 Materials and Methods

4.3.1 Specimen Preparation. Seven fresh, frozen cadaveric human spines from T12 to Sacrum (6 male, 1 female, mean age, 60 years, range: 37 – 69 years) were used in this study. Each specimen was dissected to remove all non-ligamentous soft tissue while preserving the vertebral bodies, discs, facet joint capsules and the following ligamentous soft tissues – anterior longitudinal ligament (ALL), posterior longitudinal ligament (PLL), the interspinous and the supraspinous ligament. The spine was then frozen at -20˚ C until testing. Prior to testing, the specimen was assessed for any significant structural defects or anatomical abnormalities through visual inspection and computer tomography (CT).

The spine was thawed to room temperature overnight prior to test day and it was ensured that the spine was kept moist during testing by lightly spraying exposed tissues using saline solution. Custom-designed spinal fixtures were made to fix the spine securely onto the spine testing apparatus. In order to mount the specimen onto the spinal fixture, three pedicle screws were inserted into the cranial (T12) and caudal vertebra (Sacrum).
For the cranial vertebra, two screws were placed posteriorly through the pedicles into the vertebral body while the third screw was placed anteriorly through the vertebral body in an anterior-posterior orientation. A similar approach was applied to the caudal vertebral (Sacrum) with two screws placed posteriorly at sites that would ensure maximum bone purchase, and a third screw placed anteriorly through the sacral body. Stainless steel rods from the testing fixtures were then attached to the pedicle screws of each end vertebra and fixed using set screws. The rods were secured onto the spinal fixture using custom-made holders. It was ensured that before securing the rods onto the spinal fixture, the spine segment (T12 – S) was positioned in a neutral posture by horizontally orienting the L3 – L4 disc. The position of the rods and the holders were adjusted depending on the size of the vertebra. For additional stability, four wood screws were placed into the superior endplate of the cranial vertebral body and embedded in Cerobend, a liquid metal alloy (HiTech Alloys, Squamish, WA). Similarly, wood screws were inserted onto the inferior part of the sacral body and embedded in liquid metal alloy. The intervening discs were left intact and were not entered by screws or compromised by the potting material. Follower load fixtures were then mounted onto each of the vertebral bodies (L1 – L5). (See Figure 1)
4.4 Surgical Treatment

Each spine underwent a single-level posterior pedicle screw and rod instrumentation without intervertebral instrumentation using bilateral polyaxial screws and a solid rod at L4 – L5 (Construct A, Figure 2a). Specimens underwent subsequent extension of the construct, using a dynamic system to L3 – L4 (Construct B, Figure 2b). This was achieved using a hybrid construct (Zimmer Optima System, Zimmer Inc. Warsaw, IN) with a rigid rod at L4 – L5 and a dynamic rod at L3 – L4 which consists of polycarbonate urethane (PCU) spacers placed over polyethylene terephthalate (PET) cords also mounted on pedicle screws. The spacers withstand compression and extension, while the tensioned cords provide stability in flexion and distraction. Construct A represents a standard treatment for a single-level lower lumbar disc degeneration.
disease, using bilateral pedicle screws and a rigid, titanium rod. Construct B represents an extension of that basic construct with a system that is not rigid at the adjacent level, but which may mitigate stresses seen at that level after L4 – L5 fusion. This construct has been proposed as a means of preserving motion at the adjacent levels but is only approved as system for segmental fixation for spinal fusion.

4.5 Experimental Procedure

An industrial robot (KUKA, GmbH, Augsburg, Germany) capable of motion in six axis was used as the spine testing apparatus for implementing in vitro flexibility tests. (Figure 3). It was used to apply pure moments on the spinal segment through the custom designed mounting fixtures. A six-axis force-
moment sensor (GAMMA, ATI, Apex, NC) was used to measure the applied load and provide feedback for the robot. The sensor was also used to measure the off-axis forces and moments in order to provide feedback to ensure that a pure moment was being applied along the primary axis of motion of the spine.

The robot was programmed using its custom force-torque software to apply three continuous loading and unloading cycles of pure moment in force control along each of the primary axis of the spine to simulate flexion-extension (FE), flexion-extension with a follower load of 600 N (FE-FL), lateral bending (LB)
and Axial rotation (AR). Throughout the test, kinematics and kinetics of the refined center of rotation point are recorded at 83Hz. The specimens were preconditioned to eliminate any viscoelastic effects. ROM was determined from the third loading cycle for each specimen under each of the test conditions (intact, construct A, construct B). The relative vertebral motion was captured using an optoelectronic camera system (Optotrak, Northern Digital Inc., Waterloo, Ontario, Canada). The camera system measures the vertebral motion by tracking the relative motion between infra-red markers placed on each vertebral segment, T12 – S.

The hybrid test protocol originally developed by Panjabi et al was used to assess the effect of the placement of Construct A and Construct B on the adjacent level segments. [8 – 11]. The protocol was a two part process;

1. An intact flexibility test was conducted to determine the ROM of the intact specimen under pure moments of ± 2 Nm in FE, FL-FE, LB and AR.

2. Following the placement of the constructs, the specimen was subjected to pure moments until the ROM of the constructs equaled the intact ROM for FE, FE-FL, LB and AR. A unique feature of the robotic system was in its ability to follow the same rotational trajectory obtained from the intact test above, in other words, following the placement of the constructs, the spine was forced to follow the same rotational trajectory as the intact in reaching the intact ROM.
4.6 Data and Statistical Analysis

In order to study the effect of both Construct A and Construct B treatments on the adjacent levels, a nondimensional parameter, adjacent level effects (ALE), was determined (Panjabi et. al, 2007). ALE can be defined as the normalized (Intact) percentage difference between ROM following treatment and ROM at intact. The ALE at each adjacent level was given by the formula:

\[ \text{ALE} (\%) = 100 \times \frac{(iROM_{\text{treatment}} - iROM_{\text{intact}})}{iROM_{\text{intact}}} \]

where \( iROM_{\text{treatment}} = \) intervertebral motion after Construct A or Construct B placement

\( iROM_{\text{intact}} = \) intact intervertebral motion

Statistical analysis was performed using Minitab 16 (Minitab Inc., State College, PA). A repeated measures analysis of variance was used to compare the segmental ROM after surgical treatment with the intact segmental ROM. Post-hoc Tukey-Kramer analysis (\( P < 0.05 \) was considered statistically significant) was used for multiple comparisons.

4.7 Results

4.7.1 Flexion-extension. Table 1 shows the intervertebral range of motion for the intact, Construct A and Construct B treatment conditions for flexion-extension. Figure 4 shows the average intervertebral range of motion for Intact, Construct A and Construct B for flexion-extension. In flexion-extension, Construct A at L4 – L5 caused no significant change in motion at the following adjacent levels when compared to intact: L3 – L4 (\( P = 0.36 \)) and L5 – S (\( P = 0.76 \)). However, there was a 30.9% increase in motion at T12 – L1 (\( P = 0.05 \)),
45.6% increase in motion at L1 – L2 (P < 0.001) and a 23.2% increase in motion at L2 – L3 (P = 0.03). There was a significant decrease in motion of 78% when compared to intact at L4 – L5 following placement of Construct A. (P < 0.001). The placement of Construct B at L3 – L4, decreased the motion by -80.4% at the operated level and caused a significant increase in motion at the adjacent levels, T12 – L1 (73.4%), L1 – L2 (85.0%), L2 – L3 (49.9%) and L5 – S (20.8%). There was no significant change in motion at L4 – L5 (1.03 ± 0.51 vs 1.24 ± 0.83, P = 0.92) with the addition of Construct B. The graphical representation of the distribution of motion (ALE) to the adjacent levels after Construct A and Construct B placement can be clearly seen for flexion-extension (Figure 5). The results show that placement of both Construct A and Construct B causes a substantial increase in ALE of non-operated levels with Construct B producing the larger increase of the two constructs.

**4.7.2 Flexion-extension with follower load.** Table 2 shows the intervertebral range of motion for the intact, Construct A and Construct B for flexion-extension with follower load. Figure 6 shows the average intervertebral range of motion for Intact, Construct A and Construct B for flexion-extension with follower load. In flexion-extension with follower load, placement of Construct A at L4 – L5 showed no significant change in motion at T12 – L1 (P = 0.08), L1 – L2 (P = 0.34), L2 – L3 (P = 0.11) and L3 – L4 (P = 0.87) when compared to intact. However, there was a significant increase in motion of 52.0% at L5 – S (P < 0.001) when compared to intact. There was a significant reduction in motion at the operated level, L4 – L5 (-76.4%) following Construct A placement. (P =
The placement of Construct B, caused a significant decrease in motion at the operated level, L3 – L4 (-76.7%) while the adjacent levels, T12 – L1 (44.9%), L1 – L2 (57.3%) and L5 – S (83.9%) all showed a significant increase in motion except L2 – L3 which showed no significant change in motion. (P = 0.11). The ALE results for flexion-extension with follower load are shown in Figure 7. The addition of Construct A and Construct B resulted in a larger increase in ALE to the sub-adjacent non-operated level (L5 – S) when compared to flexion-extension.

**4.7.3 Lateral bending.** Table 3 shows the intervertebral range of motion for the intact, Construct A and Construct B for lateral bending. Figure 8 shows the average intervertebral range of motion for Intact, Construct A and Construct B for Lateral Bending. In lateral bending, for Construct A at L4 – L5, the results showed that there was no significant change in motion in all the adjacent levels except T12 – L1 which showed an increase in motion of 22.8%. The L4 – L5 level (Construct A), showed a decrease in motion of -83.6% when compared to intact. The placement of the Construct B at L3 – L4 caused an increase in motion at T12 – L1 (69.9%), L1 – L2 (59.4%), L2 – L3 (44.7%) and L5 – S (43.7%). There was a significant decrease in motion of -80.7% at L3 – L4 after Construct B placement. A visual representation of ALE is shown in Figure 9 for lateral bending with Construct B causing a larger change in ALE on the non-operated levels compared to Construct A.

**4.7.4 Axial rotation.** Table 4 shows the intervertebral range of motion for the intact, fusion Construct A and Construct B for axial rotation. Figure 10 shows
the average intervertebral range of motion for Intact, Construct A and Construct B for Axial Rotation. In axial rotation, there were no significant changes in motion at the adjacent levels after Construct A at L4 – L5. However, there was a significant decrease in motion of -46.1% at the operated level, L4 – L5 (Construct A). The placement of Construct B at L3 – L4 caused a significant increase in motion to the adjacent levels, L2 – L3 (25.1%) and L5 – S (31.4%). There was a significant decrease in motion of -38% at the operated level, L3 – L4 (Construct B). Figure 11 shows the ALE results for axial rotation with Construct B showing greater influence on ALE when compared to Construct A.

Table 4.1
Flexion-Extension (FE): Intervertebral Range of Motion (˚) for Intact, Construct A and Construct B

<table>
<thead>
<tr>
<th></th>
<th>T12-L1 (˚)</th>
<th>L1 - L2 (˚)</th>
<th>L2 - L3 (˚)</th>
<th>L3 - L4 (˚)</th>
<th>L4 - L5 (˚)</th>
<th>L5 - S1 (˚)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>1.49±0.87</td>
<td>1.55±0.73</td>
<td>2.13±1.43</td>
<td>2.08±1.53</td>
<td>2.93±1.62</td>
<td>1.88±1.02</td>
</tr>
<tr>
<td>Construct A</td>
<td>1.89±1.09</td>
<td>1.96±1.21</td>
<td>2.41±1.80</td>
<td>2.36±2.02</td>
<td>0.69±0.30</td>
<td>2.85±1.56</td>
</tr>
<tr>
<td>Construct B</td>
<td>2.16±1.36</td>
<td>2.44±1.66</td>
<td>2.93±2.42</td>
<td>0.48±0.18</td>
<td>0.62±0.33</td>
<td>3.45±1.52</td>
</tr>
</tbody>
</table>

Underlined values indicate significant difference (P < 0.05) between the intervertebral range of motion after surgical treatment and its corresponding range of motion at intact.
Table 4.2

Flexion-Extension with Follower Load (FE-FL): Intervertebral Range of Motion (˚) for Intact, Construct A and Construct B

<table>
<thead>
<tr>
<th></th>
<th>T12-L1 (˚)</th>
<th>L1-L2 (˚)</th>
<th>L2-L3 (˚)</th>
<th>L3-L4 (˚)</th>
<th>L4-L5 (˚)</th>
<th>L5-S1 (˚)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intact</strong></td>
<td>1.78±0.76</td>
<td>1.94±1.02</td>
<td>3.20±1.54</td>
<td>4.06±1.87</td>
<td>4.70±2.39</td>
<td>5.47±1.76</td>
</tr>
<tr>
<td><strong>Construct A</strong></td>
<td>2.33±0.66</td>
<td><strong>2.83±1.01</strong></td>
<td>3.94±1.73</td>
<td>4.82±2.20</td>
<td><strong>1.03±0.51</strong></td>
<td>5.73±1.48</td>
</tr>
<tr>
<td><strong>Construct B</strong></td>
<td>3.09±0.98</td>
<td>3.60±1.07</td>
<td>4.80±2.17</td>
<td>0.79±0.43</td>
<td>1.24±0.83</td>
<td>6.62±1.79</td>
</tr>
</tbody>
</table>

Underlined values indicate significant difference (P < 0.05) between the intervertebral range of motion after surgical treatment and its corresponding intact range of motion.

Table 4.3

Lateral bending (LB): Intervertebral Range of Motion (˚) for Intact, Construct A and Construct B

<table>
<thead>
<tr>
<th></th>
<th>T12-L1 (˚)</th>
<th>L1-L2 (˚)</th>
<th>L2-L3 (˚)</th>
<th>L3-L4 (˚)</th>
<th>L4-L5 (˚)</th>
<th>L5-S1 (˚)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intact</strong></td>
<td>2.01±1.03</td>
<td>2.95±1.56</td>
<td>4.70±2.22</td>
<td>6.41±2.66</td>
<td>4.95±2.65</td>
<td>2.97±1.60</td>
</tr>
<tr>
<td><strong>Construct A</strong></td>
<td><strong>2.47±1.21</strong></td>
<td>3.40±1.90</td>
<td>5.52±2.60</td>
<td>6.91±2.77</td>
<td><strong>0.81±0.41</strong></td>
<td>3.20±1.35</td>
</tr>
<tr>
<td><strong>Construct B</strong></td>
<td>3.42±1.52</td>
<td>.70±1.84</td>
<td>6.80±3.16</td>
<td>1.24±0.56</td>
<td>0.69±0.41</td>
<td>4.26±1.27</td>
</tr>
</tbody>
</table>

Underlined values indicate significant difference (P < 0.05) between the intervertebral range of motion after surgical treatment and its corresponding range of motion at intact.
Table 4.4

Axial Rotation (AR): Intervertebral Range of Motion (˚) for Intact, Construct A and Construct B

<table>
<thead>
<tr>
<th>AR</th>
<th>T12-L1 ˚</th>
<th>L1 - L2 ˚</th>
<th>L2 - L3 ˚</th>
<th>L3 - L4 ˚</th>
<th>L4 - L5 ˚</th>
<th>L5 - S1 ˚</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>0.48±0.19</td>
<td>0.68±0.37</td>
<td>1.07±0.49</td>
<td>1.88±1.54</td>
<td>1.02±0.57</td>
<td>1.07±0.50</td>
</tr>
<tr>
<td>Construct A</td>
<td>0.48±0.12</td>
<td>0.57±0.25</td>
<td>1.16±0.64</td>
<td>2.03±1.51</td>
<td>0.55±0.31</td>
<td>1.17±0.55</td>
</tr>
<tr>
<td>Construct B</td>
<td>0.51±0.16</td>
<td>0.68±0.30</td>
<td>1.34±0.71</td>
<td>1.16±0.89</td>
<td>0.67±0.36</td>
<td>1.40±0.72</td>
</tr>
</tbody>
</table>

Underlined values indicate significant difference (P < 0.05) between the intervertebral range of motion after surgical treatment and its corresponding range of motion at intact.

4.8 Discussion

The prevalent increase in accelerated adjacent-level degeneration following spinal fusion has served as an impetus for the development of motion preserving devices such as dynamic stabilizers. These devices are currently being used as an alternative to fusion. Despite the numerous biomechanical studies on dynamic stabilizers, there is very little information on their hybrid application which utilizes both semi-rigid and rigid implants. This study was designed to look precisely at the effect of hybrid stabilization on the kinematic motion at the adjacent levels of the lumbar spine using a hybrid test protocol [8 – 11]. The hybrid test protocol was developed to specifically assess the redistribution of motion to adjacent levels following surgery. For our study, we compared the biomechanical effects of two different constructs – Construct A (single-level fusion with no intervertebral disc instrumentation at L4 – L5) and
Construct B (Stabilization of adjacent level, L3 – L4 using hybrid dynamic stabilization with no intervertebral disc instrumentation) on the adjacent non-operated levels.

Traditional flexibility tests, have in the past, been implemented using pulleys and cables to apply the loads and generally vertebral motion measurements are taken statically following load application [18 - 20]. For our study, in implementing the hybrid test protocol, a robotic spine testing system was used to apply continuous unconstrained pure moment of ± 2 Nm on the lumbar motion segment to simulate FE, LB and AR. The test system minimized off-axis forces and moments generated during the application of load in the primary axis. The uniqueness of our test system, when compared to other systems in the literature is in its ability to apply continuous unconstrained pure moment while dynamically optimizing the motion path to minimize off axis loads during testing. The test system enables precise control over the loading and boundary conditions of the test over the entire test duration, thus ensuring test reliability and reproducibility. In implementing the hybrid test, our system also has the unique feature of enabling the treated spine to follow the same rotational trajectory obtained from the intact spine.

In our study, we found that placement of Construct B caused an overall higher increase in ALE than Construct A in all the test conditions (flexion-extension, flexion-extension with follower-load, lateral bending and axial rotation). In assessing the effect of each construct separately on the adjacent levels for flexion-extension, we found that Construct A caused no significant increase in
ALE to its nearest cranial (L3 – L4) and caudal (L5 – S) adjacent levels. However, there was a significant effect on ALE at the supra-adjacent levels (L1-L2 and L2 – L3) in flexion-extension. The placement of Construct B on the other hand showed significant effect on ALE on all the adjacent levels in flexion-extension. Additionally, we found that in flexion-extension with follower-load, both constructs seemed to increase the ALE of the sub-adjacent non-operated level (L5 – S) than the supra-adjacent non-operated levels only. Our study showed comparable results between both constructs in stabilizing and significantly restricting motion in the operated levels.

Comparison of our results to previous literature looking specifically at the operated levels showed a consistent trend to past studies. [2, 21, 22, 23]. Schulte et. al. conducted an in vitro biomechanical study on dynamic semi-rigid implants and found an overall reduction in ROM at the operated level when compared to intact specimens. [2]. Niosi et al demonstrated that implantation of a dynamic stabilization system in an injury model of the lumbar spine caused a decrease in the range of motion (ROM) in flexion-extension, lateral bending and axial rotation when compared to intact specimens. [21] Gedet et al compared two different dynamic stabilization systems and found that both systems significantly reduced the overall ROM in flexion-extension and lateral bending but axial rotation showed no significant difference with intact state. [22]. Schmoelz et al. also reported reduction in ROM at the operated level, however, in their study, the levels adjacent to the dynamically stabilized level did not change significantly when compared to their intact state.[23]. Cheng et al. also reported similar results.
on the adjacent levels following a single-level hybrid construct. [24]. This contrast in findings for the latter two studies with our study may be attributed to the test methodology used for assessing adjacent level effects. In our study we used the well known and validated hybrid test protocol [8 – 11] while the latter two studies used only pure moment flexibility tests with no hybrid control which doesn’t assess the adjacent level effects. The pure moment flexibility test is not an appropriate test to evaluate ALE because the application of a pure moment results in a uniform constant moment at all the spinal levels. Thus following a surgical treatment such as fusion, the non-operated levels and adjacent levels remain unaffected. [8].

4.9 Conclusion

In conclusion, placement of a posterior rigid fixation (Construct A) significantly reduced motion at the operated level and did not affect the ALE at the adjacent levels cranial and caudal to the operated level. However, the supra-adjacent levels showed increased motion following Construct A placement. The hybrid dynamic stabilization (Construct B) while significantly limiting motion on the operated levels caused a significant increase in motion at both the sub-adjacent and supra-adjacent levels. It also essentially transformed a single-level posterior fixation to a two-level posterior fixation with increased motion occurring at the remaining non-operated adjacent levels. Both constructs showed a higher effect on the sub-adjacent level than the supra-adjacent levels under flexion-extension with follower load, implying that under an in vivo scenario, with muscle attachments and compressive loads acting on the spine, placement of either
construct would to a certain degree affect the sub-adjacent level more than the supra-adjacent level.

Figure 4.4. Mean ROM for Flexion-Extension

Figure 4.5. ALE results for Flexion-Extension
Figure 4.6. Flexion-Extension with Follower Load

Figure 4.7. ALE results for Flexion-Extension with Follower Load
Figure 4.8. Mean ROM for Lateral Bending

Figure 4.9. ALE results for Lateral Bending
Figure 4.10. Mean ROM for Axial Rotation

Figure 4.11. ALE results for Axial Rotation
4.10 References


CHAPTER V

INTRODUCTION

The previous chapters explained in detail in vitro biomechanical testing and its implementation in evaluating spinal implants. Two different spinal implants were evaluated and their effect on the spine was analyzed. This chapter explains in detail the development of a finite element model and its validation using the in vitro test data.

5.1 Role of Finite Element Models of the Spine

Finite element modeling is a numerical method used for analyzing complex structures. The application of finite element modeling in spine has been primarily used to study the behavior of the spine under varying boundary and loading conditions. Advancements in numerical techniques, medical imaging and computer technology facilitate the acquisition of detailed quantitative geometric information of anatomical structures – which in turn facilitates both research and patient care. Patient-specific models can be developed quickly to aid clinicians in their decision making process regarding the management of spinal ailments. These models can be used to simulate and evaluate various clinical scenarios such as the extent of degeneration, the biomechanical efficacy of surgical
procedures (e.g. laminectomy and fusion), and the placement of implants for stabilization, etc.

A finite element model of the spine has the advantage of not only providing useful information about a model’s response to an external load, but it also has the ability to predict and approximate the internal stresses/strains that occur within the modeled structure\(^3\)-\(^4\). Finite element spine models can be used for conducting comparative analysis of spinal implants through the evaluation of their respective effects on the stability of the spine. In essence, a spine model can serve as a valuable cost effective tool for the modification of existing or the design of new spinal implants. Spinal stability following the placement of various implants can be simulated and analyzed, providing the clinician with valuable insight into the potential performance of specific implants, before the actual surgery. These analytical models can provide the flexibility of precisely controlling a variety of parameters and then studying the effects of these changes on the behavior of the modeled structure.

Current physical testing methods (both in vivo and in vitro) of the spine, are fraught with flaws. Such techniques include the testing of animal or human cadaveric specimens in a mechanical testing machine. Such testing strategies are expensive and very time consumptive. In addition, in vivo studies are associated with ethical concerns, the accuracy of data and the interpretation /correlation of results to the human situation\(^1\)-\(^2\). In both in vivio and in vitro studies, difficulty exists regarding the determination of the internal stresses and strains within segments. Normal healthy human spines are not readily available
for in vitro testing. Loads and muscle forces that are active in normal spine motion cannot be effectively replicated and the internal stress/strain distribution within specific tissue components cannot be accurately measured during such studies. These and more factors create a substantial impetus for improving existing testing methods through virtual modeling and the further development of sophisticated three dimensional (3D) finite element models of the spine.

In recent years, there has also been a constant push to try to accomplish surgical procedures through minimally invasive surgery (MIS) due to their demonstrated benefits (like less blood loss and earlier hospital discharge) when compared to the traditional open procedures. The increased use and improved application of MIS techniques is driven by the interests of health care professionals, industry and patients. The impetus for improvement in MIS procedures has led to an increase in the development of spinal stabilization devices that require less invasive surgical exposure for their implantation. Such a device is the interspinous fixation device (ISD) used to clamp adjacent spinous elements in rigid alignment in anticipation of spinal fusion. The clinical indications for the use of non-fusion interspinous fixation devices are for lumbar spinal stenosis and painful facet arthrosis. With the clinical success of those devices a number of interspinous fixation devices have been tested or introduced into clinical use.

The use of ISDs to promote interspinous fusion is not a new idea. Similar implants have been used in the past, but their use has been discontinued when faced with greater stability and better clinical results of more modern
instrumentation implants. The Aspen ISD, produced by Lanx (Broomfield, CO) is representative of implants seeking to augment interbody fusion techniques while reducing the need for transpedicular fixation. The aim of the implant is to increase segmental stability with the purpose of improving the fusion rate; the advantage being a minimally invasive surgery. The insertion of the implant requires only a small midline incision with no additional lateral exposure. The device is placed between the spinous processes of an unstable segment with only the disruption of the interspinous ligament during implantation while the supraspinous ligament remains intact.

The purpose of this study was to develop a finite element model of a lumbar spinal segment and evaluate the effect of placing the new interspinous fixation device with an interbody spacer model on kinematics of the lumbar spine motion. The finite element model was used to compare the device’s ability to stabilize the motion of a lumbar segment in flexion-extension, lateral bending, and axial rotation. The ISD was modeled as a stand-alone device, and in combination with a unilateral pedicle screw fixation, relative to a more traditional fixation construct using bilateral pedicle screw fixation, which is considered the current gold standard of rigid fixation.

5.2 Methods

A three-dimensional finite element model was developed using CT images obtained from an intact L3-L4 cadaveric spinal motion segment. The CT images had a resolution of 0.75 mm.
5.2.1 Vertebral bodies. The CT image processing to develop a three-dimensional model of the vertebrae was done using the commercially available software, MIMICS 9.0 (Materialise, MI, USA). A series of image segmentation and region-growing operations were carried out on the CT images. These operations were done to isolate the bony tissue from the soft tissue and to extract the desired geometrical information of the spinal motion segment. The segmented CT images were then converted to a three-dimensional surface model using a set of interpolation and smoothening functions available in MIMICS. The STL+ module found within MIMICS was then used to convert the model into a triangular surface mesh. The FE module also found in MIMICS was used to improve the quality of the triangular mesh through a series of optimization algorithms. The optimized surface mesh model made up of triangular elements was converted to a solid mesh model made of tetrahedral elements. The solid model was then exported into a commercially available finite element program, ABAQUS (Simulia Corporation, RI, USA). A flow chart of all the operations required to develop a finite element model is shown in Figure 1. In ABAQUS, the all the exterior elements of the vertebrae were modeled as cortical bone while all the interior elements were modeled as cancellous bone. Isotropic material properties were assigned to the elements. (Table 1). Offset elements were created from the element faces of the facet joints and assigned cartilaginous properties. In Abaqus, a hard contact surface to surface algorithm was implemented between the facets with a frictionless tangential contact property.
5.2.2 Intervertebral disc. The poor soft tissue image quality in CT prevented the development of a surface model of the disc using MIMICS. The intervertebral disc model was developed using a CAD program, Pro Engineer (Pro Engineer, Wildfire III, USA). The three-dimensional vertebral bodies developed in MIMICS were imported into the CAD program and a set of sagittal planes were created. The cross sections of the vertebral bodies were then traced onto the planes as shown in Figure 2. Using these sections, curves were then sketched to fit the upper and lower sections of the endplates. Surfaces were then fitted onto these sketches and a solid model was extruded from the upper surface to the lower surface. The solid model was then exported as an Elysium file into ABAQUS for further preprocessing operations such as partitioning, element-embedding and meshing. The nucleus pulposus (NP) was modeled using solid hexahedral elements while the annulus fibrosus (AF) was modeled using solid hexahedral elements to represent the ground substance with embedded rebar layers representing collagen fibers. Four concentric rings of rebar layers were created in ABAQUS and each ring contained two evenly spaced rebars (tension-only fibers) oriented at ±30° to the horizontal. (Figure 3). The fiber thickness and stiffness were assigned to increase in the radial direction. Both nucleus pulposus and the annulus fibrosus were assigned isotropic material properties. (Table 1). All the superior and inferior elements of the disc were tied to the vertebral model endplates in ABAQUS.

5.2.3 Ligaments. The spinal motion segment is made up of a number of ligaments serving as connective tissues between the vertebral bodies. These
ligaments were modeled using three-dimensional tension-only truss elements. Isotropic material properties were assigned to these ligaments. The following ligaments were incorporated into the model: Anterior Longitudinal Ligament (ALL), Posterior Longitudinal Ligament (PLL), Supraspinous ligaments (SL), Interspinous Ligaments (ISL), Transverse Spinous Ligaments (TSL) and Capsular Ligaments (CL). The developed model with the vertebral bodies, disc and ligaments are shown in Figure 4.

Table 5.1

Material Properties of FE Spine model

<table>
<thead>
<tr>
<th>FE Spine Model</th>
<th>Young’s Modulus (MPa)</th>
<th>Poisson’s Ratio</th>
<th>Cross-sectional Area (mm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cortical Bone</td>
<td>12000</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Cancellous Bone</td>
<td>100</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Endplates</td>
<td>600</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Intervertebral Disc</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NP</td>
<td>Non-Linear Hyperelastic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AF</td>
<td>Non-Linear Hyperelastic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibers</td>
<td>357.5 - 550</td>
<td>0.3</td>
<td>0.00601 – 0.00884</td>
</tr>
<tr>
<td>Ligaments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALL</td>
<td>20</td>
<td>0.3</td>
<td>74</td>
</tr>
<tr>
<td>PLL</td>
<td>70</td>
<td>0.3</td>
<td>14.4</td>
</tr>
<tr>
<td>ISL</td>
<td>28</td>
<td>0.3</td>
<td>30</td>
</tr>
<tr>
<td>SL</td>
<td>28</td>
<td>0.3</td>
<td>30</td>
</tr>
<tr>
<td>TSL</td>
<td>50</td>
<td>0.3</td>
<td>1.8</td>
</tr>
<tr>
<td>CL</td>
<td>20</td>
<td>0.3</td>
<td>34</td>
</tr>
</tbody>
</table>
Figure 5.1. Finite element model development flow chart
Cross Sectional Sketches

Upper Surface fitted onto the sketches

Export to ABAQUS

Figure 5.2. Invertebral disc development in CAD

Figure 5.3. Fibers implemented as Rebars in ABAQUS
5.2.4 Spinal instrumentation. The following spinal instruments: pedicle screws, interspinous fixation device (ISD), interbody cage and rods were created in CAD. All spinal instruments were made of titanium (Ti) alloy except the interbody cage which was made from Polyetheretherketone (PEEK). (Figure 5). A 3D modeling software, 3matic (Materialise, MI, USA) was used to position and...
orient the implants within the spine model similar to an actual surgical procedure. Three surgical cases were developed (a) Pedicle Screw – Rod system (PS) mimicking standard fusion with interbody cage, (b) ISD with Interbody alone (ISD) and (c) Unilateral Pedicle Screw – Rod with ISD and interbody. Cases a, b and c, required the removal of a portion of the intervertebral disc while cases b and c required additional removal of a ligament (ISL) during actual surgery, thus, for these models the portions of the disc and the ISL were not incorporated. For each model, both the instruments and the spine model were merged together before exporting to an FE solver, ABAQUS for FE analysis (Figure 6). In ABAQUS, the instruments were assigned isotropic properties from the literature. Ti was assigned a Young's modulus of 110000MPa and a Poisson's ratio of 0.3 while PEEK's modulus was 3100MPa with a Poisson's ratio of 0.3. All instruments were modeled using tetrahedral elements. Tie constraints were created between bone and implant.

Figure 5.5. Spinal implant CAD and Finite element model
Figure 5.6. Spine Finite Element Models with implants
5.2.5 Loading and Boundary Conditions. The model’s boundary conditions were implemented to mimic in-house in vitro testing of a spine using pure moment loading conditions. The inferior endplate of the caudal vertebra was rigidly fixed in all directions. A coupling constraint was created between the nodes of the superior endplate of the rostral vertebra and the center of the intervertebral disc. Pure moment of ± 5 Nm was applied about the center of the intervertebral disc to simulate Flexion-Extension (FE), Lateral Bending (LB) and Axial Rotation (AR) similar to in vitro spine testing. Loading was applied in 8 steps to obtain convergence.

5.3 Results

Intact model validation was performed by comparing the kinematic output of the simulation for FE, LB and AR against the results from in vitro testing of intact spines. The mean ROM (L3 - L4) and standard deviation for the in vitro tests in FE, LB and AR were used for comparison with the predicted results. The in vitro test data from in-house testing as well as from literature\textsuperscript{12-14} was used to compare against the predicted values for FE, LB and AR as shown in Figure 7. The results for LB and AR showed fairly good agreement with in vitro data. The predicted value for ROM fell within the standard deviation of the in vitro data for both LB and AR. The results for FE, however, showed a lower predicted value than the in vitro test data.

Both the placement of ISD (Figure 8) and PS systems (Figure 9) showed a reduction in motion for FE. However, for both cases the predicted values were much lower than in vitro results. (0.63° vs 1.67°, 0.53° vs 1.51°). In LB, the
results showed that following placement of the PS system (Figure 10), there was a reduction in motion from 6.9° to 0.73°. Similarly we found that ISD (Figure 11) reduced motion from 6.9° to 0.99°. In AR, we found that motion decreased to 0.58° from intact state (5.7°) following the placement of ISD (Figure 12) while PS system (Figure 13) caused a decrease in motion from intact (5.7°) to 0.91°.

**Figure 5.7.** Intact Spine Model results compared against in vitro data
Figure 5.8. Results showing ROM for ISD with Interbody in Flexion-Extension

Figure 5.9. Flexion-Extension plots for Pedicle Screw-Rod system
Figure 5.10. Lateral bending plot for ISD system

Figure 5.11. Lateral bending plot for PS system
Figure 5.12. Axial Rotation plot for ISD system

5.4 Discussion

The main goal of the present study was to develop a finite element model of a single functional unit and validate against in vitro data. The validated model
was then used to predict kinematic motion following the surgical placement of an ISD and a PS system. The models predicted a similar trend to actual test data however the predicted values were lower than the results from the in vitro tests. There are several reasons for this discrepancy; one reason is the assumption of complete osteointegration between the surgical implants and bone. Thus, during model development, all the nodes of the devices that were in contact with the spine were completely tied. Another reason is that the devices were placed in the spine to mimic the actual procedure; however, these orientations were not exactly the same.

5.4.1 Multi-segment model. Using similar methodologies as a single functional segment, a multi-segment model, T12 - S1 was developed from CT images. Soft tissues (Intervertebral discs and ligaments) were incorporated following the generation of the vertebral models. (Figure 13). Loading and boundary conditions were established similar to the single functional segment model. We found that the Initial simulation results for the overall ROM in FE motion showed a similar trend when compared to in-house in vitro test data. (Figure 14). However, further validation is required to improve the predictive accuracy of the model in other planes of motion. Moreover, it is important to conduct multilevel comparison and determine how well the model can predict motion at each level.
Figure 5.13. Intact Multi-segment Spine FE Model (T12 - Sacrum)

Figure 5.14. Intact FE (T12 - Sacrum) comparison with in vitro ROM results for Flexion-Extension
5.5 Future Work

This study involved the development of a single functional spinal unit. It can be used for comparative analysis following surgical intervention. Future work would entail an elaborate validation of the multi-segment model. It should be noted that with increasing model detail and complexity, the computational cost will also increase. This model can be used to provide valuable insights into adjacent level kinematics. It can be used in the simulation and evaluation of multilevel surgical interventions.

5.6 References


Chapter VI

STUDY CONCLUSIONS

In vitro biomechanical test methodology was successfully developed for testing spinal constructs. Two unique implants were evaluated and their test results were presented. The current setup using a robotic system can be modified to study not only the lumbar spine but other spinal regions such as cervical and thoracic. The fixtures were custom designed and can match the different vertebral sizes. The custom force-torque program used in running the robot can be used to apply known physiological loads on the spine in a reproducible and accurate manner. The robotic system enables easier manipulation of both boundary and loading conditions during testing when compared to older static pure moment systems from the literature.

The finite element model of a single FSU, L3-4, was developed using CT image data from one of the test specimens used in the in vitro study. The model was then validated using the in vitro test data of the ISD study. A multi-segment model, T12- Sacrum was also developed and evaluated using in vitro test data.
APPENDICES
**APPENDIX A**

**LIST OF ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Expansion</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSU</td>
<td>Functional Spinal Unit</td>
</tr>
<tr>
<td>ISD</td>
<td>Interspinous Fixation Device</td>
</tr>
<tr>
<td>IS</td>
<td>Interspinous</td>
</tr>
<tr>
<td>CNS</td>
<td>Congress for Neurological Surgeons</td>
</tr>
<tr>
<td>ALL</td>
<td>Anterior longitudinal ligament</td>
</tr>
<tr>
<td>PLL</td>
<td>Posterior longitudinal ligament</td>
</tr>
<tr>
<td>DDD</td>
<td>Degenerative disc disease</td>
</tr>
<tr>
<td>NZ</td>
<td>Neutral Zone</td>
</tr>
<tr>
<td>ROM</td>
<td>Range of Motion</td>
</tr>
<tr>
<td>EZ</td>
<td>Elastic Zone</td>
</tr>
<tr>
<td>CT</td>
<td>Computed Tomography</td>
</tr>
<tr>
<td>FE</td>
<td>Flexion-extension</td>
</tr>
<tr>
<td>LB</td>
<td>Lateral bending</td>
</tr>
<tr>
<td>AR</td>
<td>Axial rotation</td>
</tr>
<tr>
<td>FE-FL</td>
<td>Flexion-extension with follower load</td>
</tr>
<tr>
<td>TLIF</td>
<td>Transforaminal lumbar interbody fusion</td>
</tr>
<tr>
<td>IBS</td>
<td>Interbody Spacer</td>
</tr>
<tr>
<td>Unilat</td>
<td>Interspinous Fixation Device and unilateral pedicle screws</td>
</tr>
<tr>
<td>Bilat</td>
<td>Interbody spacer with bilateral pedicle screws</td>
</tr>
<tr>
<td>MIS</td>
<td>Minimally invasive surgery</td>
</tr>
<tr>
<td>ALIF</td>
<td>Anterior Lumbar Interbody Fusion</td>
</tr>
<tr>
<td>Term</td>
<td>Abbreviation</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Supraspinous ligaments</td>
<td>SSL</td>
</tr>
<tr>
<td>Interspinous Ligaments</td>
<td>ISL</td>
</tr>
<tr>
<td>Intertransverse Spinous Ligaments</td>
<td>TSL</td>
</tr>
<tr>
<td>Capsular Ligaments</td>
<td>CL</td>
</tr>
<tr>
<td>Bone Morphogenic Protein</td>
<td>BMP</td>
</tr>
<tr>
<td>Polycarbonate urethane</td>
<td>PCU</td>
</tr>
<tr>
<td>Polyethylene terephthalate</td>
<td>PET</td>
</tr>
<tr>
<td>Adjacent level effects</td>
<td>ALE</td>
</tr>
<tr>
<td>Nucleus pulposus</td>
<td>NP</td>
</tr>
<tr>
<td>Annulus Fibrosus</td>
<td>AF</td>
</tr>
<tr>
<td>Polyetheretherketone</td>
<td>PEEK</td>
</tr>
</tbody>
</table>
APPENDIX B

STATISTICAL ANALYSIS ON INTERSPINOUS FIXATION DEVICE

FE
Descriptive Statistics: Intact, Interbody, Aspen, Unilateral, Bilateral
Total

<table>
<thead>
<tr>
<th>Variable</th>
<th>Count</th>
<th>Mean</th>
<th>StDev</th>
<th>Minimum</th>
<th>Median</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>6.467</td>
<td>2.439</td>
<td>3.042</td>
<td>6.553</td>
<td>10.597</td>
</tr>
<tr>
<td>Interbody</td>
<td>7</td>
<td>6.07</td>
<td>3.36</td>
<td>1.68</td>
<td>5.46</td>
<td>12.40</td>
</tr>
<tr>
<td>Aspen</td>
<td>7</td>
<td>1.672</td>
<td>1.766</td>
<td>0.528</td>
<td>1.056</td>
<td>5.564</td>
</tr>
<tr>
<td>Unilateral</td>
<td>7</td>
<td>1.488</td>
<td>1.596</td>
<td>0.459</td>
<td>0.844</td>
<td>4.966</td>
</tr>
<tr>
<td>Bilateral</td>
<td>7</td>
<td>1.508</td>
<td>1.348</td>
<td>0.479</td>
<td>0.965</td>
<td>4.335</td>
</tr>
</tbody>
</table>

Results for: Flex-Ext-Stacked.MTW

General Linear Model: Response versus Treatment, Subjects

<table>
<thead>
<tr>
<th>Factor</th>
<th>Type</th>
<th>Levels</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>fixed</td>
<td>5</td>
<td>Aspen, BiLateral, Intact, Interbody, UniLateral</td>
</tr>
<tr>
<td>Subjects</td>
<td>fixed</td>
<td>7</td>
<td>1, 2, 3, 4, 5, 6, 7</td>
</tr>
</tbody>
</table>

Analysis of Variance for Response, using Adjusted SS for Tests

<table>
<thead>
<tr>
<th>Source</th>
<th>DF</th>
<th>Seq SS</th>
<th>Adj SS</th>
<th>Adj MS</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>4</td>
<td>187.073</td>
<td>187.073</td>
<td>46.768</td>
<td>35.38</td>
<td>0.000</td>
</tr>
<tr>
<td>Subjects</td>
<td>6</td>
<td>116.465</td>
<td>116.465</td>
<td>19.411</td>
<td>14.68</td>
<td>0.000</td>
</tr>
<tr>
<td>Error</td>
<td>24</td>
<td>31.727</td>
<td>31.727</td>
<td>1.322</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>34</td>
<td>335.265</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S</td>
<td>1.14976</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R-Sq</td>
<td>90.54%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R-Sq(adj)</td>
<td>86.59%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Unusual Observations for Response

<table>
<thead>
<tr>
<th>Obs</th>
<th>Response</th>
<th>Fit</th>
<th>SE Fit</th>
<th>Residual</th>
<th>St Resid</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>12.3982</td>
<td>10.1978</td>
<td>0.6446</td>
<td>2.2004</td>
<td>2.31 R</td>
</tr>
<tr>
<td>11</td>
<td>1.6759</td>
<td>3.9402</td>
<td>0.6446</td>
<td>-2.2643</td>
<td>-2.38 R</td>
</tr>
</tbody>
</table>

R denotes an observation with a large standardized residual.
Descriptive Statistics: Intact, Interbody, Aspen, Unilateral, Bilateral

<table>
<thead>
<tr>
<th>Variable</th>
<th>Count</th>
<th>Mean</th>
<th>StDev</th>
<th>Minimum</th>
<th>Median</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>8.59</td>
<td>5.23</td>
<td>1.39</td>
<td>8.55</td>
<td>18.36</td>
</tr>
<tr>
<td>Interbody</td>
<td>7</td>
<td>8.96</td>
<td>7.13</td>
<td>1.09</td>
<td>7.30</td>
<td>23.94</td>
</tr>
<tr>
<td>Aspen</td>
<td>7</td>
<td>8.14</td>
<td>7.33</td>
<td>1.16</td>
<td>5.89</td>
<td>23.92</td>
</tr>
<tr>
<td>Unilateral</td>
<td>7</td>
<td>3.83</td>
<td>3.30</td>
<td>1.07</td>
<td>3.18</td>
<td>11.03</td>
</tr>
<tr>
<td>Bilateral</td>
<td>7</td>
<td>1.960</td>
<td>1.457</td>
<td>0.943</td>
<td>1.623</td>
<td>5.155</td>
</tr>
</tbody>
</table>

Results for: Lat-Bend-Stacked.MTW
General Linear Model: Response versus Treatment, Subjects

<table>
<thead>
<tr>
<th>Factor</th>
<th>Type</th>
<th>Levels</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>fixed</td>
<td>5</td>
<td>Aspen, BiLateral, Intact, Interbody, UniLateral</td>
</tr>
<tr>
<td>Subjects</td>
<td>fixed</td>
<td>7</td>
<td>1, 2, 3, 4, 5, 6, 7</td>
</tr>
</tbody>
</table>

Analysis of Variance for Response, using Adjusted SS for Tests

<table>
<thead>
<tr>
<th>Source</th>
<th>DF</th>
<th>Seq SS</th>
<th>Adj SS</th>
<th>Adj MS</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>4</td>
<td>284.326</td>
<td>284.326</td>
<td>71.082</td>
<td>9.59</td>
<td>0.000</td>
</tr>
<tr>
<td>Subjects</td>
<td>6</td>
<td>691.913</td>
<td>691.913</td>
<td>115.319</td>
<td>15.56</td>
<td>0.000</td>
</tr>
<tr>
<td>Error</td>
<td>24</td>
<td>177.871</td>
<td>177.871</td>
<td>7.411</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>34</td>
<td>1154.110</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

S = 2.72237  R-Sq = 84.59%  R-Sq(adj) = 78.17%

Unusual Observations for Response

<table>
<thead>
<tr>
<th>Obs</th>
<th>Response</th>
<th>Fit</th>
<th>SE Fit</th>
<th>Residual</th>
<th>St Resid</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>23.9408</td>
<td>19.1394</td>
<td>1.5262</td>
<td>4.8014</td>
<td>2.13 R</td>
</tr>
<tr>
<td>15</td>
<td>23.9172</td>
<td>18.3223</td>
<td>1.5262</td>
<td>5.5949</td>
<td>2.48 R</td>
</tr>
<tr>
<td>29</td>
<td>5.1552</td>
<td>12.1436</td>
<td>1.5262</td>
<td>-6.9884</td>
<td>-3.10 R</td>
</tr>
</tbody>
</table>

R denotes an observation with a large standardized residual.
Descriptive Statistics: Intact, Interbody, Aspen, Unilateral, Bilateral

<table>
<thead>
<tr>
<th>Total Variable</th>
<th>Count</th>
<th>Mean</th>
<th>StDev</th>
<th>Minimum</th>
<th>Median</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>3.986</td>
<td>2.341</td>
<td>0.699</td>
<td>3.959</td>
<td>7.443</td>
</tr>
<tr>
<td>Interbody</td>
<td>7</td>
<td>3.693</td>
<td>2.160</td>
<td>0.892</td>
<td>3.507</td>
<td>6.875</td>
</tr>
<tr>
<td>Aspen</td>
<td>7</td>
<td>3.967</td>
<td>2.577</td>
<td>0.781</td>
<td>3.372</td>
<td>7.968</td>
</tr>
<tr>
<td>Unilateral</td>
<td>7</td>
<td>2.328</td>
<td>1.330</td>
<td>0.651</td>
<td>2.387</td>
<td>4.653</td>
</tr>
<tr>
<td>Bilateral</td>
<td>7</td>
<td>1.394</td>
<td>0.731</td>
<td>0.604</td>
<td>1.406</td>
<td>2.843</td>
</tr>
</tbody>
</table>

Results for: Axial-Rot-Stacked.MTW

General Linear Model: Response versus Treatment, Subjects

Factor     Type Levels Values
Treatment  fixed      5  Aspen, BiLateral, Intact, Interbody, UniLateral
Subjects   fixed      7  1, 2, 3, 4, 5, 6, 7

Analysis of Variance for Response, using Adjusted SS for Tests

<table>
<thead>
<tr>
<th>Source</th>
<th>DF</th>
<th>Seq SS</th>
<th>Adj SS</th>
<th>Adj MS</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>4</td>
<td>37.749</td>
<td>37.749</td>
<td>9.437</td>
<td>9.12</td>
<td>0.000</td>
</tr>
<tr>
<td>Subjects</td>
<td>6</td>
<td>89.681</td>
<td>89.681</td>
<td>14.947</td>
<td>14.44</td>
<td>0.000</td>
</tr>
<tr>
<td>Error</td>
<td>24</td>
<td>24.843</td>
<td>24.843</td>
<td>1.035</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>34</td>
<td>152.274</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

S = 1.01742  R-Sq = 83.68%  R-Sq(adj) = 76.89%

Unusual Observations for Response

<table>
<thead>
<tr>
<th>Obs</th>
<th>Response</th>
<th>Fit</th>
<th>SE Fit</th>
<th>Residual</th>
<th>St Resid</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>7.96795</td>
<td>6.18949</td>
<td>0.57038</td>
<td>1.77846</td>
<td>2.11 R</td>
</tr>
<tr>
<td>30</td>
<td>1.41579</td>
<td>3.46735</td>
<td>0.57038</td>
<td>-2.05156</td>
<td>-2.44 R</td>
</tr>
</tbody>
</table>

R denotes an observation with a large standardized residual.

Results for: Flex-Ext.MTW

Paired T-Test and CI: Aspen, Unilateral

Paired T for Aspen - Unilateral
<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspen</td>
<td>7</td>
<td>1.672</td>
<td>1.766</td>
<td>0.668</td>
</tr>
<tr>
<td>Unilateral</td>
<td>7</td>
<td>1.488</td>
<td>1.596</td>
<td>0.603</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>0.1839</td>
<td>0.1937</td>
<td>0.0732</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (0.0048, 0.3631)
T-Test of mean difference = 0 (vs not = 0): T-Value = 2.51  P-Value = 0.046

Paired T-Test and CI: Aspen, Bilateral

Paired T for Aspen - Bilateral

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspen</td>
<td>7</td>
<td>1.672</td>
<td>1.766</td>
<td>0.668</td>
</tr>
<tr>
<td>Bilateral</td>
<td>7</td>
<td>1.508</td>
<td>1.348</td>
<td>0.509</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>0.164</td>
<td>0.490</td>
<td>0.185</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (-0.290, 0.617)
T-Test of mean difference = 0 (vs not = 0): T-Value = 0.88  P-Value = 0.411

Paired T-Test and CI: Unilateral, Bilateral

Paired T for Unilateral - Bilateral

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unilateral</td>
<td>7</td>
<td>1.488</td>
<td>1.596</td>
<td>0.603</td>
</tr>
<tr>
<td>Bilateral</td>
<td>7</td>
<td>1.508</td>
<td>1.348</td>
<td>0.509</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>-0.020</td>
<td>0.319</td>
<td>0.121</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (-0.316, 0.275)
T-Test of mean difference = 0 (vs not = 0): T-Value = -0.17  P-Value = 0.873

Results for: Lat-Bend.MTW

Paired T-Test and CI: Aspen, Unilateral

Paired T for Aspen - Unilateral

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspen</td>
<td>7</td>
<td>8.14</td>
<td>7.33</td>
<td>2.77</td>
</tr>
<tr>
<td>Unilateral</td>
<td>7</td>
<td>3.83</td>
<td>3.30</td>
<td>1.25</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>4.31</td>
<td>4.16</td>
<td>1.57</td>
</tr>
</tbody>
</table>
95% CI for mean difference: (0.45, 8.16)
T-Test of mean difference = 0 (vs not = 0): T-Value = 2.74  P-Value = 0.034

Paired T-Test and CI: Aspen, Bilateral

Paired T for Aspen - Bilateral

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspen</td>
<td>7</td>
<td>8.14</td>
<td>7.33</td>
<td>2.77</td>
</tr>
<tr>
<td>Bilateral</td>
<td>7</td>
<td>1.96</td>
<td>1.46</td>
<td>0.55</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>6.18</td>
<td>5.94</td>
<td>2.24</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (0.69, 11.67)
T-Test of mean difference = 0 (vs not = 0): T-Value = 2.75  P-Value = 0.033

Paired T-Test and CI: Unilateral, Bilateral

Paired T for Unilateral - Bilateral

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unilateral</td>
<td>7</td>
<td>3.83</td>
<td>3.30</td>
<td>1.25</td>
</tr>
<tr>
<td>Bilateral</td>
<td>7</td>
<td>1.96</td>
<td>1.46</td>
<td>0.55</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>1.874</td>
<td>1.849</td>
<td>0.699</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (0.164, 3.583)
T-Test of mean difference = 0 (vs not = 0): T-Value = 2.68  P-Value = 0.036

Results for: Axial-Rot.MTW

Paired T-Test and CI: Aspen, Unilateral

Paired T for Aspen - Unilateral

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspen</td>
<td>7</td>
<td>3.967</td>
<td>2.577</td>
<td>0.974</td>
</tr>
<tr>
<td>Unilateral</td>
<td>7</td>
<td>2.328</td>
<td>1.330</td>
<td>0.503</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>1.639</td>
<td>1.349</td>
<td>0.510</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (0.391, 2.886)
T-Test of mean difference = 0 (vs not = 0): T-Value = 3.21  P-Value = 0.018

Paired T-Test and CI: Aspen, Bilateral

Paired T for Aspen - Bilateral
N  Mean  StDev  SE Mean  
Aspen    7  3.967  2.577    0.974  
Bilateral 7  1.394  0.731    0.276  
Difference 7  2.574  1.982    0.749  

95% CI for mean difference: (0.741, 4.407)  
T-Test of mean difference = 0 (vs not = 0): T-Value = 3.44  P-Value = 0.014

Paired T-Test and CI: Unilateral, Bilateral

Paired T for Unilateral - Bilateral

N  Mean  StDev  SE Mean  
Unilateral 7  2.328  1.330    0.503  
Bilateral 7  1.394  0.731    0.276  
Difference 7  0.935  0.661    0.250  

95% CI for mean difference: (0.323, 1.546)  
T-Test of mean difference = 0 (vs not = 0): T-Value = 3.74  P-Value = 0.010

Results for: Flex-Ext.MTW

Paired T-Test and CI: Intact, Interbody

Paired T for Intact - Interbody

N  Mean  StDev  SE Mean  
Intact  7  6.47  2.44     0.92  
Interbody 7  6.07  3.36     1.27  
Difference 7  0.401  1.979    0.748  

95% CI for mean difference: (-1.430, 2.232)  
T-Test of mean difference = 0 (vs not = 0): T-Value = 0.54  P-Value = 0.611

Paired T-Test and CI: Intact, Aspen

Paired T for Intact - Aspen

N  Mean  StDev  SE Mean  
Intact  7  6.467  2.439    0.922  
Aspen  7  1.672  1.766    0.668  
Difference 7  4.795  1.703    0.644  

95% CI for mean difference: (3.220, 6.369)  
T-Test of mean difference = 0 (vs not = 0): T-Value = 7.45  P-Value = 0.000
Paired T-Test and CI: Intact, Unilateral

Paired T for Intact - Unilateral

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>6.467</td>
<td>2.439</td>
<td>0.922</td>
</tr>
<tr>
<td>Unilateral</td>
<td>7</td>
<td>1.488</td>
<td>1.596</td>
<td>0.603</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>4.979</td>
<td>1.746</td>
<td>0.660</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (3.364, 6.593)
T-Test of mean difference = 0 (vs not = 0): T-Value = 7.55  P-Value = 0.000

Paired T-Test and CI: Intact, Bilateral

Paired T for Intact - Bilateral

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>6.467</td>
<td>2.439</td>
<td>0.922</td>
</tr>
<tr>
<td>Bilateral</td>
<td>7</td>
<td>1.508</td>
<td>1.348</td>
<td>0.509</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>4.959</td>
<td>1.851</td>
<td>0.700</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (3.247, 6.671)
T-Test of mean difference = 0 (vs not = 0): T-Value = 7.09  P-Value = 0.000

Results for: Lat-Bend.MTW

Paired T-Test and CI: Intact, Interbody

Paired T for Intact - Interbody

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>8.59</td>
<td>5.23</td>
<td>1.98</td>
</tr>
<tr>
<td>Interbody</td>
<td>7</td>
<td>8.96</td>
<td>7.13</td>
<td>2.70</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>0.36</td>
<td>3.13</td>
<td>1.18</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (-3.25, 2.53)
T-Test of mean difference = 0 (vs not = 0): T-Value = -0.31  P-Value = 0.770

Paired T-Test and CI: Intact, Aspen

Paired T for Intact - Aspen
<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>8.59</td>
<td>5.23</td>
<td>1.98</td>
</tr>
<tr>
<td>Aspen</td>
<td>7</td>
<td>8.14</td>
<td>7.33</td>
<td>2.77</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>0.46</td>
<td>3.17</td>
<td>1.20</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (-2.48, 3.39)
T-Test of mean difference = 0 (vs not = 0): T-Value = 0.38  P-Value = 0.717

Paired T-Test and CI: Intact, Unilateral

Paired T for Intact - Unilateral

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>8.59</td>
<td>5.23</td>
<td>1.98</td>
</tr>
<tr>
<td>Unilateral</td>
<td>7</td>
<td>3.83</td>
<td>3.30</td>
<td>1.25</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>4.761</td>
<td>2.405</td>
<td>0.909</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (2.536, 6.985)
T-Test of mean difference = 0 (vs not = 0): T-Value = 5.24  P-Value = 0.002

Paired T-Test and CI: Intact, Bilateral

Paired T for Intact - Bilateral

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>8.59</td>
<td>5.23</td>
<td>1.98</td>
</tr>
<tr>
<td>Bilateral</td>
<td>7</td>
<td>1.96</td>
<td>1.46</td>
<td>0.55</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>6.63</td>
<td>3.93</td>
<td>1.48</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (3.00, 10.27)
T-Test of mean difference = 0 (vs not = 0): T-Value = 4.47  P-Value = 0.004

Results for: Axial-Rot.MTW

Paired T-Test and CI: Intact, Interbody

Paired T for Intact - Interbody

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>3.986</td>
<td>2.341</td>
<td>0.885</td>
</tr>
<tr>
<td>Interbody</td>
<td>7</td>
<td>3.693</td>
<td>2.160</td>
<td>0.816</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>0.293</td>
<td>0.738</td>
<td>0.279</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (-0.390, 0.975)
T-Test of mean difference = 0 (vs not = 0): T-Value = 1.05  P-Value = 0.334
Paired T-Test and CI: Intact, Aspen

Paired T for Intact - Aspen

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>3.986</td>
<td>2.341</td>
<td>0.885</td>
</tr>
<tr>
<td>Aspen</td>
<td>7</td>
<td>3.967</td>
<td>2.577</td>
<td>0.974</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>0.019</td>
<td>1.527</td>
<td>0.577</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (-1.394, 1.431)
T-Test of mean difference = 0 (vs not = 0): T-Value = 0.03  P-Value = 0.975

Paired T-Test and CI: Intact, Unilateral

Paired T for Intact - Unilateral

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>3.986</td>
<td>2.341</td>
<td>0.885</td>
</tr>
<tr>
<td>Unilateral</td>
<td>7</td>
<td>2.328</td>
<td>1.330</td>
<td>0.503</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>1.658</td>
<td>1.592</td>
<td>0.602</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (0.185, 3.130)
T-Test of mean difference = 0 (vs not = 0): T-Value = 2.75  P-Value = 0.033

Paired T-Test and CI: Intact, Bilateral

Paired T for Intact - Bilateral

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>7</td>
<td>3.986</td>
<td>2.341</td>
<td>0.885</td>
</tr>
<tr>
<td>Bilateral</td>
<td>7</td>
<td>1.394</td>
<td>0.731</td>
<td>0.276</td>
</tr>
<tr>
<td>Difference</td>
<td>7</td>
<td>2.592</td>
<td>1.988</td>
<td>0.751</td>
</tr>
</tbody>
</table>

95% CI for mean difference: (0.754, 4.431)
T-Test of mean difference = 0 (vs not = 0): T-Value = 3.45  P-Value = 0.014
Range of Motion (ROM) Flexion/Extension L4-L5

![Bar chart showing the range of motion for Flexion/Extension L4-L5 for different conditions.]

Range of Motion (ROM) Lateral Bending L4-L5

![Bar chart showing the range of motion for Lateral Bending L4-L5 for different conditions.]

Test Number

Range of Motion (ROM) (deg)

- Intact
- Interbody
- Interbody+Aspen
- Interbody+Aspen+Unilateral Pedicle Screw
- Interbody+Bilateral Pedicle Screw
Range of Motion (ROM) Axial Rotation L4-L5

Test Number

Range of Motion (ROM) (deg)

Intact
Interbody
Interbody+Aspen
Interbody+Aspen+Unilateral Pedicle Screw
Interbody+Bilateral Pedicle Screw
Hybrid Dynamic Stabilization

Range of Motion of T12 - S1 (deg)

Maximum Extension Moment (Nm)
Maximum Positive Lateral Bending Moment (Nm)

Maximum Negative Lateral Bending Moment (Nm)