Biomechanical evaluation of posterior dynamic stabilization systems in lumbar spine

Bharath K. Parepalli
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A Thesis

Entitled

Biomechanical Evaluation of Posterior Dynamic Stabilization Systems in Lumbar Spine

by

Bharath K Parepalli

Submitted as partial fulfillment of the requirements for

the Master of Science Degree in Bioengineering

Adviser: Dr. Vijay K. Goel

College of Graduate Studies

The University of Toledo

December 2009
The University of Toledo
College of Engineering

I HEREBY RECOMMEND THAT THE THESIS PREPARED UNDER MY SUPERVISION BY Bharath K Parepalli

ENTITLED: Biomechanical Evaluation of Posterior Dynamic Stabilization Systems in Lumbar Spine

BE ACCEPTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR
THE DEGREE OF Master of Science in Bioengineering

Advisor: Dr. Vijay K. Goel

Recommendation concurred by Committee

__________________________ On
Dr. Scott C. Molitor Final Examination

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Dr. Ashok Biyani

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Dean, College of Engineering
Abstract of

Biomechanical Evaluation of Posterior Dynamic Stabilization Systems in the Lumbar Spine

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Bharath K Parepalli

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The University of Toledo
December 2009

Fusion has been the gold standard treatment for treating the disc degeneration. Fusion surgeries restrict the motion at the implanted level thereby imposing additional load at the adjacent levels. Many clinical studies have showed that adjacent segment degeneration was observed in patients over time. In order to overcome problems with fusion devices, dynamic stabilization systems are being used to treat disc degeneration related problems. These implants restore intersegmental motion across the implanted level with minimal effects on the adjacent levels.

In vitro cadaveric testing was conducted on seven harvested sheep spines using established protocols. Axient was implanted in the spines 3 months prior to sacrificing. Main aim of this testing is to see if the performance is altered by the presence of surrounding muscle tissue. The specimens were prepared and tested under load control protocol. All six loading modes were tested by applying a pure moment of 10Nm (in
steps of 2.5Nm) and angular displacement was calculated for the following cases: 1) Intact spine + Axient with surrounding muscle tissue, 2) Intact spine + Axient with muscle tissue removed, 3) Intact spine (with implant removed). Relative motion of L4 vertebra with respect to L5 was calculated. Statistical analysis was performed (on the implanted level data) to see if there is a statistical significance between cases 1 and 2. Biomechanical testing was also performed on 4 human cadavers to observe the trend with Axient compared to FE results.

A validated 3-D non linear finite element model of the L3-S1 lumbar spine was used to evaluate biomechanics of various dynamic stabilization systems in comparison with traditional rigid rod system. The model was modified at L4-L5 level to simulate three different dynamic stabilization systems (DSFM-1, DSFM-2 and Axient, Innovative Spinal Technologies Inc., Mansfield, MA). Grade I was simulated at L4-L5 level. Follower preload of 400N and a 10Nm bending moment was applied to simulate physiological flexion, extension, lateral bending and axial rotation. Range of motion (ROM), intra discal pressure (IDP) and facet loads were calculated for all the models. Implant with better performance was then compared with fusion system in both grade I and grade II degenerated spines.

In vitro results showed that there is no significant difference in the performance of the Axient with and without surrounding muscle tissue in terms of range of motion. Coming to FE results, Axient performed better over the other two implants (DSFM-1 and DSFM-2). Axient device was able to restore the motion at the implanted level compared to fusion device. Higher motions were observed at the adjacent level (L5-S1) with fusion
device compared to intact and injured models. Both devices were able to stabilize the
diseased spine and unload the treated disc.
Acknowledgement

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CHAPTER I
INTRODUCTION

1.1 Overview
The following chapter discusses the main reasons for studying the lumbar spine. This is followed by a brief introduction about the significance of low back pain. Mechanisms of disc degeneration will be discussed in brief with a description of current treatments. Finally the scope of the study is defined.

1.2 Background
The spine is divided into 4 regions: Cervical, Thoracic, Lumbar and Sacral region (Figure 1). Spine, also known as vertebral column, plays an important role in control, mobility mechanisms and provides mechanical stability and housing for spinal cord and spinal nerves.
1.3 Lumbar spine

Lumbar spine consists of 5 vertebrae, L1 through L5 (Figure 1.2). This part of the spine is subjected to highest forces during physiological motions. This causes intervertebral disc to degenerate because of the mechanical demand placed on it over time. Chemical composition of the disc changes with age and thereby altering the mechanical properties of the disc (in other words loading carrying capacity) changes [1]. Overall water content and proteoglycans decreases (mostly in the nucleus). The relation between intervertebral disc degeneration and mechanical loading was studied in literature [2, 3]. Disc degeneration alters the kinematics (segmental instability) of the spine [4, 5].

Figure 1.1 Vertebral column (Source: http://www.spine1.com/)
1.4 Significance of low back pain

Low back pain is a major health problem worldwide at an elderly age. More than 31 million Americans suffer with low back pain at any given time [6]. Intervertebral disc is the important source of pain and facet joints often causes back pain [7-9]. It is estimated that around $50 billion is being spent per annum in treating the back pain in the United States alone [8]. Hence there is a need to understand the importance and development of low back pain treatment techniques.

Intervertebral disc is an important part for load carrying as well as providing segmental stability. Acute and continuous loading may result in disc degeneration [2, 9]. Degenerated disc loses the height and hydration which might pinch the existing nerve root and that may result in pain. Disc height reduction is followed by annulus bulging which eventually causes narrowing of the spinal canal. This is also called spinal stenosis. The generation of low back pain has been traditionally attributed to the abnormal motion at the degenerative joint. Often surgeons relieve the pain by removing pain causing
structures (Decompression surgery). In this type of surgery, a small part of the bone above the nerve root, facets (facetectomy), ligaments, nucleus and/or part of the disc below the nerve root is removed to give more space for the nerves \cite{10}.

Three main components in reducing the pain includes: decompression, stabilization and correction of deformity. In the initial stages of the low back pain (LBP), the doctors choose conservative treatments like traction, exercise, heat therapy or the mobilization of the joint. Surgery is recommended for the patient to whom the back pain limits their daily activities. Treatment options may vary from conservative treatment to fusion \cite{11,12}.

Fusion is a traditional technique that has been following for stabilization till today. Fusion without instrumentation (using a graft bone) is used for temporary pain relief at the degenerative level. Fusion surgeries are not completely successful in terms of adjacent segment degeneration \cite{10,13}. Motion at the index level is completely restricted with the fusion device which puts additional burden on the levels above and below the index level. This causes increase in adjacent level degeneration over time \cite{14,15}. A long term follow up on lumbar fusion patients by Lehmann et al showed that degeneration at the adjacent level was noticed in 45\% of their patients \cite{10}. Fusion technique found to be decreasing the lumbar lordosis over the time \cite{16,17}.

Various non fusion technologies have been evolved to replace the conventional fusion techniques and are mainly intended to restore inter segmental motion. Mainly they are intended to provide physiological motion at the treated level and the adjacent level. New techniques include artificial discs, nucleus replacement techniques and dynamic stabilization devices. Dynamic stabilization devices have many advantages over other
techniques: surgical procedure is very easy, minimally invasive (preserves the spinal structures) and better load sharing between the spinal elements. They aim at preserving the motion at the implanted level thereby minimizing the adjacent level degeneration.

1.5 Scope of the study

This study is divided into 3 parts:

1. In vitro biomechanical testing of Axient™ device in human spines and harvested sheep spines.

2. Finite element analysis of the three dynamic stabilization systems in degenerated lumbar spine.

3. Comparing the better dynamic implant of the three with the traditional fusion system.

One of the main problems with dynamic stabilization systems is the tissue growth into the implant parts. First part of the study was conducted on the harvested sheep spines to see if the surrounding muscle tissue alters the performance of the implant. In vitro cadaveric testing was conducted as explained in chapter 3. This involves measurement of range of motion (ROM) of the implanted segment. The goal is to see if the ROM (of the implanted segment) is altered by the presence of surrounding muscular tissue. The hypothesis of the study was that the performance of Axient™ will not be altered by the presence of soft tissue.

In the next part of the study, we have used validated finite element model of the lumbar spine to analyze the biomechanical effects of degenerated lumbar spine implanted with
posterior dynamic stabilization system (Axient™ SC, Innovative Spinal Technologies Inc., Mansfield, MA) and traditional rigid stabilization.
CHAPTER II
LITERATURE REVIEW

2.1 Overview
Low back pain is a major health problem worldwide at an elderly age. More than 31 million Americans suffer with low back pain at any given time \[^6\]. Back pain arising from the degenerative disease could be discogenic or may be directly due to diseased facet joints. Various causes for the low back pain include:

1. Herniated discs are produced as the disc starts to degenerate and this causes the posterior disc to bulge out and decreases in height. Bulged disc starts to impinge the nerve roots which might cause low back pain.
2. Spinal stenosis is a condition in which area of the spinal canal is reduced. This might create nerve root impingement with the normal loads during daily activities.
3. Disc degeneration is a condition in which height of the disc reduces, disc bulges out and eventually spinal canal area decreases. This causes the compression of the nerves.

It is found that disc degeneration is one of main reasons for the low back pain \[^8\].

2.2 Deformities in the spinal structures
Disc herniation, spondylolisthesis, spondylosis, and spinal stenosis may follow these degenerative changes in the segment. Pathological narrowing of the spinal canal or foramen is called Spinal stenosis and may occur simultaneously in multiple locations.
This may occur with aging due to the thickening of ligaments (ligamentum flavum), disc degeneration, posterior osteophyte projection into the spinal canal and facet hypertrophy. The other diseases of the lumbar spine can be congenital (e.g., spinal bifida), tumors or can be caused due to a traumatic injury.

2.3 Disc degeneration

Intervertebral discs are the main load sharing components of the spine. They act like a shock absorbing systems which protect the vertebrae and spinal cord. Intervertebral discs transfer the loads from one vertebra to the other across the spinal column. Disc is composed of annulus fibrosis and nucleus pulposus. In a healthy disc, annulus is isotropic and made up of concentric collagen fibers connected to vertebral endplates. Nucleus is composed of water, proteoglycans and collagen. It has hydrated gel like matter that resists the compression.

Figure 2.1: a) Progression of disc herniation b) Picture showing radiculopathy
(Source: www.spineuniverse.com)
With degeneration, disc starts losing water content which causes disc herniation. Disc degeneration is accompanied by decrease in the disc height, change in the shape and its chemical composition. Reduction in the disc height is due to the decrease in tensile strength of the annulus. This will result in narrowing of the disc space and thus decrease in the spinal canal area causing compression of the nerve roots \(^{18}\). Clefts and slits are observed at the center of the disc and cartilage end plates. These eventually lead to fissures through the annulus which may lead to separation of annulus from the vertebral body \(^{19}\). These structural changes cause change in the overall behavior of the disc and alters kinematics of the spine \(^{20}\). Figure 2.2 shows disc degeneration.

![Degenerated Disc vs Healthy Disc](image)

**Figure 2.2**: Figure showing difference between dehydrated (degenerated) disc and rehydrated disc.

In a healthy spine, load distribution across the spinal structures is given below.

- Vertebra + Disc = 55-60%
- Cortical shell = 10%
- Posterior ligaments = 10%
- Facets = 20-25%

Where as in a degenerated spine, load sharing across the spinal structures is given by:
- Vertebra + Disc = 40%
- Cortical shell = 10%
- Posterior ligaments = 10%
- Facets = 40%

Loads on the facets were increased from 25% to 40% in degeneration spine which means the facets are overloaded. The change in the load sharing among the spinal structures causes abnormal spinal motion which leads to adjacent level degeneration over time. Flexion-extension axis is in the disc space in normal case. In case of disc degeneration, this axis (in other words COR) shifts posterior and moves erratically. Thus load sharing moves posteriorly and the facets are overloaded [21]. This eventually causes facet degeneration.

2.4 Treatment Options

There are several techniques available for the treatment of low back pain. They include conservative treatment, different surgical techniques.

2.5 Conservative Treatment

This is a non-invasive technique which is used to treat the abnormalities of the back. They include medications, exercise, muscle toning and muscle manipulation. Surgical treatment is recommended for a patient if the pain persists even after 6-12 months of conservative treatment.
2.6 Surgical Treatment

These treatments are followed by removal of pain causing structures. Various types include decompression with fusion or different types of non-fusion devices.

2.7 Decompression Surgery

Neural impingement is caused by disc herniation, facet hypertrophy, isthmic spondylolisthesis, and degenerative spondylolisthesis. This surgical procedure is performed to relieve the pain. In this type of surgery, a small part of the bone above the nerve root, facets (facetectomy), ligaments, nucleus and/or part of the disc below the nerve root is removed to give more room for the nerves. This provides better environment for its healing. It is successful in treating the spinal stenosis [22]. Spinal stenosis is a condition in which lateral spinal canal area decreases which starts pinching the nerve roots. Out of the decompression techniques (unilateral facetectomy, unilateral laminectomy, bilateral facetectomy and bilateral laminectomy), bilateral facetectomy would cause the most instability to the spine [23].

2.8 Fusion

Fusion surgeries are performed to limit the motion across the injured motion segment and stabilize the joint. They are intended to relieve the pain. In case of disc related problems, a part of the disc is removed and is filled with a cage or bone graft which restores the height of the disc [24]. This bone graft grows into the adjacent bone over the time thereby limit the motion at that segment to prevent further degeneration.

Fusion causes limited or no motion at the implanted level causing adjacent levels to degenerate because of the mechanical demand placed on it over the time [24-26].
Postoperative complications were higher with fusion compared to without fusion \[27, 28\]. Operating costs, discharge time were more for fusion. Traditional interbody fusion surgeries have utilized either autograft or fibular allograft. Many complications related to graft expulsion and migration, donor site morbidity; pseudarthrosis were reported in the literature \[29, 30\]. Risk of disease transmission, poor osteoconductive and osteoinductive properties of graft bone \[29, 30\] lead to invention of interbody cages.

Deyo et al \[27\] conducted a 4 year follow-up study on 27,111 patients who had spinal surgeries in Washington state. Of whom, 5.6% patients had fusions. They said that complication rates were higher for patients undergoing fusion and postoperative mortality rates were 2 times higher compared to without fusion. There was no improvement in reoperation after 4 years. Cost of the treatment and postoperative care was higher.

In one of the finite element based studies done by Chen et al., \[24\] fusion was done at various levels (single and multilevel) and they found that the stresses in the disc adjacent to fused levels was more than the intact. It means that there is a possibility of adjacent level degeneration post surgery \[25\]. The more levels we fuse the sooner will be the adjacent level degeneration \[14\]. It is not clear, if the adjacent segment degeneration is due to the iatrogenic production of a rigid motion segment or due to the progression of the natural history of the underlying degenerative disease \[26, 31-33\]. It is also well known that implantation of a rigid internal fixation construct without achieving fusion of the bridged segment may cause fatigue failure of the implanted system \[34, 35\].

Lai et al., 2004, conducted a retrospective study of 101 patients who had undergone posterolateral lumbar fusion, to analyze the association between adjacent instability and
the extent of laminectomy before fusion. They found that 74% of patients with laminectomy and, 6.5% of patients without laminectomy developed instability. They concluded that the extent of laminectomy was directly related to adjacent segment instability.[36].

To overcome the problems mentioned above (adjacent segments degeneration, lower success rates, operating costs, postoperative complications, reoperation), new alternative treatments are investigated by the researchers.

2.9 Non-Fusion Systems

Non-Fusion devices are intended to restore the intersegmental motion unlike the fusion devices which restrict the motion at the implanted level. Various non fusion systems like disc and facet replacement devices, dynamic stabilization and interspinous devices will be explained in detail.

2.9.1 Total Disc replacement (TDR) and Facet replacement devices

The main aim of the disc replacement devices is to maintain the disc height and restore the mobility across the disc. Symptoms for this type of surgery include: degenerative disc disease with disc space collapse, back pain and leg pain that are unresponsive to non-operative treatments. There are two types of disc replacement devices available in the market. 1. Total disc replacement devices (both annulus and nucleus) 2. Nucleus substitute.

Nucleus replacement technique requires manufacturing of the materials that mimic function of the natural disc. Artificial devices should restore the height of the disc so that
annulus fibers return to their natural length. Restoring the natural loading distribution across the disc allow healing of the annulus. The design considerations include: it should mimic the natural disc dynamics, withstand long term compressive creep, careful selection of the materials to minimize the wear and biocompatibility.

Guilhem et al [37] studied the kinematics of two level degenerative lumbar spine using artificial disc and fusion device using FE analysis. Instrumentation is placed in the upper disc. Fusion decreased the motion in all degrees freedom by 44% compared to intact and the motion was increased by 52% with artificial disc. Motion at the adjacent level increased greatly with TDR. Facet pressures have increased beyond ultimate strength of articular cartilage. This may result in degeneration of facet joints over the time. Overall results showed that TDR showed greater risk of spinal instability and further degeneration. Disc may subside into the endplate which is above and below it.

Cinotti et al reported on 46 patients implanted with the SB Charite III at an average follow-up time of 3.2 years [38]. Roughly half of these patients were previously diagnosed with disc degeneration and the other half with failed disc excision. In terms of overall satisfaction, 63% of patients had satisfactory results and 67% returned to preoperative work. Dislocation occurred in 2% and subsidence in 9% [38]. If grouped by operative condition, success occurred in 69% of patients with isolated disc replacement and 77% in patients with no previous back injuries. Average sagittal plane rotation range was 9° for the implanted level and 16° for the adjacent. Greater mobility was found in patients who started exercises 1 week after surgery in comparison to those who wore a brace. Placing the disc posteriorly as opposed to anteriorly also increased the range of motion. The
authors attributed a large portion of the unsatisfactory results to the surgical learning curve and misdiagnoses.

### 2.9.2 Dynamic Stabilization systems

Dynamic stabilization devices are used under the hypothesis that they would alter favorably the movement and physiological load transmission of a spinal motion segment; prevent further degeneration at the implanted and adjacent levels \(^{39, 40}\). Dynamic stabilization devices are intended to restore or maintain the intersegmental motion close to the intact and have no effect on the level adjacent to the implanted level.

The advantages of the dynamic stabilization devices over the fusion and disc replacement devices are:

1. They can be used along with other non-fusion devices like disc replacement devices and nucleus replacement systems.
2. Load sharing among the spinal structures is better compared to fusion devices.
3. Can be performed posteriorly.

The main aim of the dynamic stabilization devices is to maintain the intersegmental motion across the implanted level and adjacent levels and prevent adjacent level degeneration. The main two functions of a dynamic stabilization system are; (i) It has to permit motion across different segments, (ii) Share load with the disc and the facets. The load sharing should be more or less uniform during the entire range of motion. This implies that the kinematics of the dynamic stabilization system should be similar to that of the intact spine during all loads of motion. After implanting the dynamic stabilization...
systems it was hypothesized that the damaged disc may repair itself if degeneration is not advanced.

There are two types of dynamic stabilizations systems are currently available.

1. Pedicle screw based

2. Interspinous based

2.9.3 Interspinous based dynamic stabilization systems

The posterior interspinous devices were designed as an alternative treatment for neurogenic claudication and the pain attributed to facet joint disease. These implants are inserted between two adjacent spinous processes of the lumbar spine in a slightly flexed position. This allows nerves to get decompressed thus providing relief from the pain. Main intention of these implants is to limit the motion in extension. But these implants have higher attrition rates $^{[41, 42]}$.

Verhoof et al., 2008 conducted an in vitro study on 12 patients treated with X-STOP interspinous spacer. Percentage of pre-operative degenerative spondylolisthesis is less than 30%. Results showed that 8 out of 12 patients showed improvement after a follow up of 12 months. Remaining patients showed no improvement post operatively. Post operative MRI showed improvement in percentage of degeneration $^{[43]}$.

Swanson KE et al, 2003 conducted a biomechanical investigation using eight cadaver lumbar specimens (L2-L5). The specimens were loaded in flexion, neutral, and extension. A pressure transducer was used to measure the intradiscal pressure and annular stresses during each of the three positions at each of the three disc levels. An appropriately sized
interspinous implant (X-stop) was placed at L3-L4, and the pressure measurements were repeated. They found that the implant does not significantly change the intradiscal pressures at the adjacent levels, yet it significantly unloads the intervertebral disc at the instrumented level in the neutral and extended positions \cite{39}.

A follow up study on 37 consecutive patients was conducted by Floman et al \cite{44} on 2007. The patients had either low back pain or voluminous disc herniation. Discectomy was performed at the index level and Wallis implant was placed. A follow-up period of 1yr was used in this study. Post operative Oswestry score and VAS (visual analog scale) decreased tremendously. Five patients had leg pain persisting after 9 months and 2 of them underwent additional discectomy and fusion. The study concluded that Wallis implant was not able to perform better for patients with disc herniation.

In a finite element based study of L3-S1 spine \cite{45}, DIAM dynamic stabilization device was studied. In this study, DIAM was placed at L4-L5 level after removing the interspinous ligament. A moment of 10Nm was applied both in intact and instrumented cases. Results showed that motion at the implanted level decreased by 17% and 43% in flexion and extension respectively. There was no change in motion at the adjacent level. Intra discal pressure at the index level was decreased by 27% in flexion, by 51% in extension and by 6% in axial rotation respectively. Adjacent level disc were unloaded by 26% and 8% at L3-L4 and L5-S1 level respectively. Overall the device performed well in unloading the treated and adjacent discs. Motion at the implanted level decreased and no significant increase in motion at the adjacent segment was observed.
2.9.4. Pedicle screw based implants:

The main advantage of using pedicle screw based dynamic stabilization devices is that they control the motion of the spine in all three dimensions of space. These screws are threaded and inserted into the pedicles. They are mainly designed to strengthen and reinforce the spine while preserving range of motion.

Dynesys:

Dynesys (Dynamic NEtralization SYStem) was introduced by Gilles and Miller. The system consists of mainly three components (Figure 2.3). 1. Polycarbonate Urethane Spacers (PCU), 2. Polyethylene Terephthalate cord, 3. Pedicle screws

Spacers are inserted bilaterally between pedicle screw heads in order to withstand the compressive loads. Cylinder between the screw heads determines the degree of lordosis. Dynesys is mainly used for spondylolisthesis, spinal stenosis, mono multi segmental stenosis, functional instability.
Philips et al. conducted an in-vitro testing on 6 human lumbar spines to see the effect of dynamic stabilization system on motion at the implanted level. Their device was effective in stabilizing the unstable motion segment. Facetectomy and discectomy were performed for surgery. Motion with the implant was almost close to the intact for flexion-extension. Implant insertion did not reduce the increased motion for lateral bending and axial rotation induced by discectomy \[46\].

Goel et al evaluated a 360 motion preservation device that was implanted in the degenerated spine and was used to compare the biomechanical changes in the implanted spine versus intact in a FE study. The dynamic device in this study included a pair of posterior dynamic stabilizer (PDS) plus posterior disc. The device was implanted to the
spine following bilateral facetectomy. The 360 dynamic system (PDS+Disc) and stand alone PDS restored the motion at implanted level to normal \[^{39}\].

Rohlmann et al. studied the intersegmental rotations and intra discal pressures in a degenerated disc after implanting the posterior dynamic implant in a finite element based study \[^{47}\]. They found that motion at the implanted level decreased and slightly increased at the adjacent level. Intra discal pressure was also decreased at the injured level with the implant. There is no much effect on IDP at the adjacent level with the implant \[^{47}\].

A clinical study of 83 patients investigated by Stoll TM, 2002, concluded that dynamic neutralization system proved to be a safe and effective alternative in the treatment of unstable lumbar conditions. However, screw loosening was observed in seven cases, early surgical intervention was needed in four cases, and late surgery was needed in five cases in the same segment and in seven cases for the adjacent segments \[^{48}\].

Kunwoo et al studied the effect of dynamic stabilization device over the fusion device on the degeneration at the implanted and adjacent levels. Total range of motion was restored to intact with dynamic implant and more than the rigid system. Also, the intra discal pressure of the spine at various levels implanted with dynamic device was close to the intact \[^{49}\].

Freudiger et al. studied the implementation of Dynesys system on four human cadaveric spine specimens. These specimens were tested in a spine simulator that provides simultaneous application of compressive and shear loads as well as bending moments. Results showed that Dynesys significantly restricted extension and flexion \[^{50}\].
2.10 Conclusions

Fusion has been the gold standard treatment for number of years to treat low back pain. There have been several complications reported in the literature regarding adjacent segment degeneration, lower success rates and higher re-operation rates. Fusion surgeries utilizing bone graft have many problems related graft expulsion and migration, donor site morbidity. Non-fusion systems have been developed to avoid problems mentioned above. Dynamic stabilization systems showed better results over the fusion devices in the recent past. They restore the intersegmental motion at the implanted level and lower the incidence of adjacent segment degeneration unlike the fusion implants.
CHAPTER III
MATERIALS AND METHODS

3.1 Overview:
This chapter will describe first the finite element model used in the analysis. Description of the intact lumbar spine model, the boundary conditions and the loads applied will be explained. Various posterior stabilization systems have been illustrated in this chapter. Finally the chapter concludes with in vitro investigation on the cadaveric specimens to validate the finite element models. Finite element study and an in vitro investigation were conducted to compare the biomechanical effects of posterior stabilization systems on the lumbar spine. Biomechanical study of harvested sheep spine is studied to see the effect of surrounding tissue on the performance of the implant.

3.2 In vitro testing on harvested sheep specimens
Seven harvested sheep spines were obtained for this study. Axient™ was implanted in the sheep spine 3 months before sacrifice. Spines were cut into segments of interest. They sealed in a double zip lock bags and frozen until the day of testing. The spines were thawed to room temperature (one day before testing) and soft tissue (muscle and adipose tissue) were cleaned from the specimen. Care was taken to retain the ligaments, bony structures or the disc. Desired spine segment was obtained from the total spine by cutting through the disc at the level above and at a level below (if we need L3-L5, we cut the whole spine at L2-L3 disc and disc below L5) using hack-saw. After cleaning, each
specimen was then potted using Bondo (a 2-part epoxy resin). Lower vertebra was potted by inserting three #12 wood screws into the vertebral body as anchors and then by pouring the resin into a mold designed to create a base that would bolt to the loading frame. Upper vertebra was potted by inserting ¼-20 all thread through the vertebral body and then pouring resin into a mold designed to mate to rods that can impart a moment on the spine. The spine was refrozen until the day of the test.

Figure 3.1: Potted sheep specimen (a) intact spine with implant surrounded by muscle tissue (b) intact spine with implant and surrounding tissue was removed (c) intact spine without implant
Spine was taken out of the freezer on the day before the testing and was thawed overnight to room temperature. Once thawed, the base was bolted to a test frame situated in the field of measurement of an Optotrak active marker optical measuring system. The Optotrak measured angular rotations during load testing. This system utilizes infrared cameras to track the motion of three light-emitting diodes affixed to the each vertebral body (Figure 3.20). The positions of the light emitting diodes affixed to the vertebral bodies were transformed into angular rotations referenced to the base plate. With the help of in built Optotrak software, the recorded data was converted into degrees. The angular rotations across the L4-L5 disc space were derived from the L4 and L5 angular rotations. Applied moment Vs angular rotation curves were plotted.

Pure moments were applied in opposite directions to the loading frame using a system of pulleys and weights. The moment was applied in steps of 2.5Nm till 10Nm in all the loading modes (flexion, extension, lateral bending and axial rotation). To overcome the spine’s viscoelastic effect, the spines were ranged maximally in all directions before data collection. After each load application, the system was allowed to stabilize for 30 seconds to minimize creep. The specimens were kept moist by spraying saline throughout the experiment.

The in vitro testing that we do in the lab either on MTS machine or kinematic profiler do not tell us how the implant will perform inside the body or in vivo. One of the main questions among the researchers is that:

1. How is the performance of an implant after it is implanted in the body?
2. Does the performance altered by the presence of muscle tissue around it?
The main purpose of this study was to see whether the implant performance will be altered by the presence of the soft tissue around the implant over the time once it is implanted in human body or not.

In vitro testing was performed on seven sheep harvested specimens that were of 3 months old. Axient™ was implanted in the real sheep and then were sacrificed for the testing after 3 months of implantation. Implanted levels were different from specimen to specimen. The potting methodology was same as explained above. The only difference here was: the specimens were potted as a motion segment. Implant was placed in the lower vertebra of the motion segment. Care was taken while potting to make sure that implant was not covered in bondo.

The specimens were tested in three different cases.

1. Intact specimen + Implant + soft tissue around
2. Intact specimen + Implant - soft tissue
3. Intact specimen – Implant - soft tissue were

Pure moment was applied in steps of 0, 1.5, 3, 5, 7.5 and 10Nm. Motion data was recorded throughout the testing. Specimens were tested with a follower load of 400N only in flexion and extension and all the loading cases were tested without the preload. The specimens were kept moist by spraying saline throughout the experiment. The recorded data was processed using Optotrak inbuilt software and another excel code.

We had compared the motion data from different cases to see if there was any difference in motion data from step 1 to step 2.
3.3 Finite Element Analysis (FEA)

FE analysis plays an important role in understanding the biological systems. Various biomechanical parameters can be calculated accurately for different implant geometries, materials. FE simulations give full information about stresses, strains that are impossible to obtain through experimental analysis. FEA has become a tool for predicting the failure due to unknown stresses by showing problem causing areas in a material and allowing designers to see all of the theoretical stresses within.

3.3.1 Intact Finite Element Model

The intact FE model of ligamentous lumbar spine model first developed in our lab consisted of two motion segments (L3-L5). The geometric data of the L3-L5 motion segment was obtained from computed tomographic (CT) scans (transverse slices 1.5mm thick) of a cadaveric ligamentous spine specimen. The model consisted of 13,339 elements and 16,240 nodes. To the existing L3-L5 model, the L5-S1 disc and the S1 vertebral body were added. The intact refined L3-S1 model is shown in Figure 3.1. A total lordotic curve of approximately 27° was simulated across the L3-S1 level with the mid L3-L4 disc kept horizontal. The present L3-S1 model has a total of 27,540 elements and 32,946 nodes. Table 3.1 shows the number of elements and the material properties of the intact L3-S1 model. Various structures in the spine were shown in figure 3.2.
Figure 3.2: Finite element model of the intact L3-S1 spine.

Figure 3.3: Mid-sagittal view of L3-S1 spine showing various anatomical features.
**Vertebral body and Posterior bone modeling**

Vertebral body is designed as outer cortical (0.5mm thick) and cancellous bone. Material properties were assigned separately to different regions. Both vertebral body and posterior bony regions were modeled as three dimensional hexagonal elements. Each element is made out of eight nodes and each node has six degrees of freedom.

**Intervertebral Disc**

Disc is composed of annulus and nucleus pulposus. The intervertebral disc was modeled as a composite of a solid matrix with embedded fibers in concentric rings around a pseudofluid nucleus. Fibers were modeled using REBAR option in ABAQUS. Ground substance was made of 3D hexagonal elements. Fiber thickness and stiffness increased in the radial direction and fibers were oriented at ±30 with the horizontal. No Compression option was used for annulus fibers so that they could transmit only tension. The hydrostatic properties of the nucleus were simulated with C3D8 hexagonal elements assigned a very low stiffness (1 MPa) and near incompressibility (n=0.4999).

**Apophyseal (Facet) joint**

Modeling of facets is very crucial as they control the motion of the spine. Anatomically, facets were covered with thin layer of cartilage. Lumbar facets were oriented at 72° with the horizontal. Initial gap of 0.5mm was defined between the inferior and superior facets based on the CT images of the cadaveric specimens. Thin layer was simulated via GAPUNI in ABAQUS. Each facet joint was simulated using 36 gap elements. These elements transfer the load between the nodes in one direction as a specified gap closes. The cartilaginous layer between the facet surfaces was simulated by ABAQUS “softened
contact” parameter, which exponentially adjusted force transfer across the joint depending on the size of the gap. The joint assumed the same stiffness as the surrounding bone at full closure.

**Ligaments**

All the 7 major ligaments (Interspinous, supraspinous, intertransverse, capsular, posterior longitudinal, anterior longitudinal ligaments and ligamentum flavum) were defined in the intact finite element model. They were constructed using 3-dimensional two node truss elements. Non linear material properties and cross sectional areas were assigned to the ligaments based on the literature [35]. Hypoelastic material property was assigned for all the ligaments to simulate the naturally changing ligament thickness (less stiff at low strain rate and stiffness increases as the strain rate increases).

**Assigning the material properties**

The material properties assigned in the model were assumed to be homogeneous and isotropic. These material properties were selected in agreement with the literature. The material properties are condensed in table 3.1.
3.3.2 Boundary and the Loading Conditions

Inferior surface of S1 (including the posterior elements) is constrained in all degrees of freedom. A follower preload of 400N was applied using springs. Springs were placed on both sides across each motion segment and iteratively placed in such a way that load in the spring did not induce any relative rotational motion across the motion segment. Follower preload was applied using two springs (one on either side) which are pretensioned to 200N each together producing 400N preload. A bending moment of 10Nm was applied on the top of L3 to simulate physiological flexion, extension, lateral bending and axial rotation. The lumbar FE model is symmetric about the mid sagittal plane hence

Table 3.1: Element types and material properties for the intact L3-S1 finite element spine model

30
results were computed for left rotation and left bending only. For all practical purposes, results calculated in left bending and rotation, are equal and reversed for right bending and rotation.

![Figure 3.4: Figure showing all six loading modes (Flexion, extension, left bending, right bending, left rotation and right rotation).](image)

### 3.3.3 Application of follower preload

In a healthy human body, the spine is stabilized by all the surrounding muscles and upper body weight. To simulate the upper body weight, the follower preload concept was invented by Dr. Avinash Patwardhan [52]. To mimic the in vivo scenario, A follower preload of 400N applied using two springs one on either side of the spine.

The characteristics of these springs were given by:

1. Zero stiffness was defined for these springs
2. These springs were pre tensioned to 200N each.
3. Non linear curve was defined for the springs.

The follower load path was optimized for the neutral posture which produces minimal deflection (produces pure compression). The springs were passed through each of the vertebral bodies and made sure that the specimen doesn’t into flexion or extension.

Figure 3.5: Application of follower preload using two springs one on either side.

3.4 Simulating the disc degeneration:

In this study, we have simulated 2 grades of disc degeneration (Grade I and Grade II) at L4-L5 level. The properties of the disc were modified to create the degeneration in FE model.

Grade I and II degeneration:

Initially 15% (for grade I degeneration) and 21% (for grade II degeneration) radial tears were created in the annulus respectively and the property of the nucleus was modified
(from gel to fibrous structure) at L4-L5 level. Load was applied on L4-L5 disc (lower endplate of L4-L5 is fixed) till the desired disc height reduction was obtained and then a new model was created using the new coordinates of the nodes obtained from this simulation. New models (with 14% and 30% Disc Height Reductions) were used for implanted cases.

Figure 3.6: Radial tears and Disc height reduction at L4-L5 level.
Figure 3.7: The loading scenario for simulating disc degeneration at L4-L5 level.

Injury

The intact L3-S1 FE model was modified to simulate the posterior instrumentation placement by creating both disc degeneration and facetectomy at L4-L5 level.

*Grade I disc degeneration:* 15% radial tears were created in L4-L5 annulus and 14% disc height reduction, 50% medial bilateral facetectomy at the same level (Figure 3.10).

*Grade II disc degeneration:* 21% radial tears were created in L4-L5 annulus, 30% disc height reduction and 100% medial bilateral facetectomy at the same level (Figure 3.11).
Figure 3.8: 50% Bilateral Medial Facetectomy at L4-L5 level.

Figure 3.9: 100% Bilateral Medial Facetectomy at L4-L5 level.
Figure 3.10: L3-S1 spine with intact disc and intact facets at L4-L5 level.
Figure 3.11: L3-S1 spine with grade I degenerated disc at L4-L5 level.
Figure 3.12: L3-S1 spine with grade II degenerated disc at L4-L5 level.

3.5 Finite element formulation of the intact spine with instrumentation

The 3D solid drawings of the various implants were created in Solidworks, and exported in the STEP format. These drawings were imported and meshed in ABAQUS/Standard™ version 6.7 (Simulia, Inc. Rhode Island, USA). The intact L3-S1 model was modified to simulate the various posterior devices at L4-L5 level. The details of simulation of each of the devices are given below:
Initially we had three different types of posterior dynamic stabilization devices (Axient™, DSFM-1 and DSFM-2). These implants were implanted in the grade I degenerated spine. Motion, intra discal pressure and facet loads were calculated for the three designs. First phase of the study is to see which one of these three implants performs better over the other two. Then grade II degeneration is analyzed with one implant. Of the three designs, Axient™ had given better results. So we did all the remaining finite element analysis and in vitro cadaveric testing on Axient. Grade II degeneration was simulated in the FEM and Axient was implanted in the degenerated spine. Axient device was compared with the fusion device for both grade I and II degenerated spines.

3.5.1 DSFM-1 and DSFM-2

Both the designs have hinge joints and look almost the same (Figure 3.13 and 3.15). These hinge joints control the motion of the spine in flexion and extension.

3.5.2 Axient™ (Posterior dynamic stabilization system)

Axient is a pedicle screw based dynamic stabilization system (Figure 3.17). The Axient™ (DSMM) includes a curved sliding male-female part attached to a hinge joint mounted on an angular adjustable screw head at each end. The device has a “bumper” between male and female parts that will limit the motion in extension. The length of the arc and thus the allowable motion before the collar of the male component hits the end of the female housing are designed to provide the desired motion values in flexion and extension. The COR of the implant is aligned with the spine. All of the implant components are made of Titanium and cobalt-chrome alloy (Table 3.2).
3.5.3 Rigid screw and rod system

Fusion device was designed in Solidworks and imported into Abaqus (Figure 3.18). The implantation was bilateral. Surfaces were created at each interface. The interaction between the screw shaft and bone, screw head and rod were simulated using the ‘coupling’ constraint. The ‘coupling’ is a type of constraint which imposes constraints on the involving surfaces such that there is no relative motion between them. Threads in the pedicle screw were ignored. Screw and the rod were simulated as elastic material and titanium material property was assigned to them (Table 3.2).

<table>
<thead>
<tr>
<th></th>
<th>Young's Modulus (MPa)</th>
<th>Poisson's Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rigid screw system</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pedicle screw (Titanium)</td>
<td>115000</td>
<td>0.3</td>
</tr>
<tr>
<td>Rigid rod (Titanium)</td>
<td>115000</td>
<td>0.3</td>
</tr>
<tr>
<td><strong>Axient™</strong></td>
<td></td>
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</tr>
<tr>
<td>All the parts except bumper (Titanium)</td>
<td>115000</td>
<td>0.3</td>
</tr>
<tr>
<td>Bumper (Bionate)</td>
<td>7.584</td>
<td>0.4</td>
</tr>
</tbody>
</table>

*Table 3.2:* Material properties used for the different posterior stabilization systems
**Figure 3.13:** Different parts in the DSFM-1 implant.

**Figure 3.14:** DSFM-1 implant placed at L4-5 in the L3-S1 lumbar spine model.
**Figure 3.15:** Different parts in the DSFM-2 implant.

![Diagram of DSFM-2 implant parts](image)

**Figure 3.16:** DSFM-2 implant placed at L4-5 in the L3-S1 lumbar spine model.

![Diagram of DSFM-2 implant in lumbar spine model](image)
**Figure 3.17:** Different parts in the Axient implant.

**Figure 3.18:** Axient implant placed at L4-5 in the L3-S1 lumbar spine model.
3.6 Simulating bone-screw interface:

Bone screw interface is very important in a finite element analysis. Better contact surface gives better load transfer from spine to the implant. For this, we have created four holes in the pedicles (at L4 and L5 levels) of length equal to the length of the pedicle screw. A cylinder of same dimensions (as the pedicle holes) and inserted it in pedicle holes. Cortical bone properties were assigned this cylinder. All the four pedicle screws were aligned with four holes in the pedicles and inserted up to desired depth. When the screws are in the proper place, “coupling” is defined between bone (cylinder) and the screw which restricts any relative motion between the two.

Figure 3.19: Rigid screw system (Fusion) at L4-5 in the L3-S1 lumbar spine model.
3.7 Implant Misalignment:

Axient is placed in the spine with the help of a guide which aligns COR of the implant with COR of spine (approximately). It is important to see the affect of implant misalignment on the performance of spine. In our FE model, COR of the implant was moved 4mm lateral and 4mm distal to the COR of the spine and then we calculated range of motion, intra discal pressure and facet loads.

3.8 Finite Element Model Validation

**Human cadaveric testing:**

For the validation of the finite element models and understanding of posterior dynamic stabilization design Axient™, DSMM (Innovative Spinal Technologies Inc., Mansfield, MA), a cadaveric study was performed on four human specimens. Among these four specimens, three were L3-S1 level and the other one is T12-L2. Two types of injury (50% facetectomy on two specimens and 100% facetectomy on the other two) were performed on the specimens. The data from the in vitro study was used to validate the FE model. Because the specimens were of different levels, only the trend was compared with that of intact.

For simplicity, two injuries were represented as follows:

*Injury 1:* 50% medial bilateral facetectomy

*Injury 2:* 100% medial bilateral facetectomy

In vitro testing was performed as follows:

- Intact
- Injured (50% or 100% bilateral medial facetectomy)
- Injured with Axient
Once the specimens are tested in intact, an injury was created (50% or 100% bilateral medial facetectomy) with the help of a surgeon. Injured specimens were then tested as explained above. In the next step, Axient was implanted using guided instrumentation (to place the implant at a desired angle) and the specimens were tested again.

3.9 Statistical Analysis:
Statistical analysis was performed in sheep testing data using SAS software. For the analysis, motion at the highest load (10Nm) was only used. ANOVA (Analysis of Variance) was used to analyze the different sequences run at each test mode. ANOVA in its simplest definition is a statistical method for simultaneous for making simultaneous comparisons between two or more means. It is a method that yields values (P-values) that can be tested to determine whether a significant relationship exists between variables.

Null hypothesis $H_0 = \text{There is a significant different between the two treatment groups}$ $(p<0.05)$.

Alternate hypothesis $H_0 = \text{There is no significant different between the two treatment groups}$ $(p>0.05)$.

Seven sheep spines were tested in this study. Each specimen was tested in all six degrees of motions (ext, flexion, lateral bending and axial rotation). Specimens were grouped according to the loading mode and each mode was analyzed separately. Each motion contains intact with surrounding tissue and intact without surrounding tissue which serve as treatments.
CHAPTER IV

RESULTS

Firstly this chapter discusses in vitro harvested sheep testing and then the results from various finite element studies explained in the chapter III. Angular motion, Intra discal pressure, facet loads, intervertebral stresses and implant peak stresses will be provided. In each case the results were compared with the intact. This chapter ends with validation of the finite element model results with in vitro results.

4.1 In vitro testing on harvested sheep specimens

One of the main questions with the dynamic implant is: Does the performance of the implant is altered by the presence of surrounding muscle tissue. We have tested 7 sheep specimens and the graph below shows the mean and standard deviation of all the specimens.
**Figure 4.1:** Relative motions (degrees) at the implanted level of the sheep lumbar spine at 10Nm. (P>0.05 between with tissue and without tissue)

<table>
<thead>
<tr>
<th></th>
<th>Extension</th>
<th>Flexion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>Intact without tissue</td>
<td>Intact without tissue</td>
</tr>
<tr>
<td>2.8766</td>
<td>4.484</td>
<td></td>
</tr>
<tr>
<td>2.5586</td>
<td>3.86</td>
<td></td>
</tr>
<tr>
<td>p&gt;0.61</td>
<td>p&gt;0.73</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Left Bending</th>
<th>Right Bending</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>Intact without tissue</td>
<td>Intact without tissue</td>
</tr>
<tr>
<td>5.487</td>
<td>7.68</td>
<td></td>
</tr>
<tr>
<td>5.369</td>
<td>6.6</td>
<td></td>
</tr>
<tr>
<td>p&gt;0.93</td>
<td>p&gt;0.62</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Left Rotation</th>
<th>Right Rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>Intact without tissue</td>
<td>Intact without tissue</td>
</tr>
<tr>
<td>2.9714</td>
<td>4.229</td>
<td></td>
</tr>
<tr>
<td>2.71</td>
<td>3.417</td>
<td></td>
</tr>
<tr>
<td>p&gt;0.75</td>
<td>p&gt;0.46</td>
<td></td>
</tr>
</tbody>
</table>

**Table 4.1:** Statistical analysis for various treatments in six degrees of motion

*Table interpretation:*

ANOVA (Analysis of Variance) was using SAS. In extension, intact without tissue has a mean of 2.88 and mean for intact with tissue was 2.56. P-values in all loading modes were greater than 0.05, which means there was no significant difference between the intact with tissue and intact without tissue treatments (as explained in chapter 3). For all
the remaining motions, there was no significant difference between the two treatments (p>0.05). Two treatments share that same group letter (A) and the mean values were very close.

From the data in table 4.1, we can say that implant performance was not significantly altered by the presence of the soft tissue.

4.2 Results for Grade I degenerated spine

4.2.1 ROM for injured spine with different implants in load control protocol:

Grade I degeneration (14 % DHR + 50% bilateral facetectomy) was simulated at L4-L5 level in the first phase of the study. Angular displacements were calculated for intact, injured and dynamic stabilization systems and were compared with intact as shown in Figures 4.1a, b and c loading conditions were 400N follower load and 10Nm bending moment. Normalized angular displacements (with intact) for various treatment groups were given in Table 4.1a, b and c.

![Figure 4.2a](image)

**Figure 4.2a:** Range of motion (degrees) at L3-L4 level of the lumbar spine for injured and different instrumentation systems with 400N follower load and 10Nm.
<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>DSFM-1 (L4-L5)</th>
<th>DSFM-2 (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>-0.13</td>
<td>7.21</td>
<td>9.00</td>
<td>6.03</td>
</tr>
<tr>
<td>Extension</td>
<td>-0.27</td>
<td>34.63</td>
<td>7.32</td>
<td>4.18</td>
</tr>
<tr>
<td>Lateral Bending</td>
<td>-0.63</td>
<td>1.86</td>
<td>1.77</td>
<td>1.45</td>
</tr>
<tr>
<td>Axial Rotation</td>
<td>-1.83</td>
<td>-1.30</td>
<td>-1.51</td>
<td>-1.62</td>
</tr>
</tbody>
</table>

**Table 4.2a:** Percentage change in motion (ROM) at L3-L4 level for injured and different implant groups compared to intact.

**Figure 4.2b:** Range of motion (degrees) at L4-L5 level of the lumbar spine for injured and different instrumentation systems with 400N follower load and 10Nm.

<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>DSFM-1 (L4-L5)</th>
<th>DSFM-2 (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>0.00</td>
<td>-6.77</td>
<td>-55.35</td>
<td>-9.28</td>
</tr>
<tr>
<td>Extension</td>
<td>1.81</td>
<td>26.41</td>
<td>-54.87</td>
<td>-35.48</td>
</tr>
<tr>
<td>Lateral Bending</td>
<td>7.29</td>
<td>-45.20</td>
<td>-55.68</td>
<td>-43.88</td>
</tr>
<tr>
<td>Axial Rotation</td>
<td>3.37</td>
<td>-38.53</td>
<td>-45.73</td>
<td>-49.23</td>
</tr>
</tbody>
</table>

**Table 4.2b:** Percentage change in motion (ROM) at L4-L5 level for injured and different implant groups compared to intact.
Figure 4.2c: Range of motion (degrees) at L5-S1 level of the lumbar spine for injured and different instrumentation systems with 400N follower load and 10Nm.

<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>DSFM-1 (L4-L5)</th>
<th>DSFM-2 (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>2.30</td>
<td>-4.96</td>
<td>-27.72</td>
<td>-36.58</td>
</tr>
<tr>
<td>Extension</td>
<td>-11.81</td>
<td>-43.18</td>
<td>-34.65</td>
<td>-38.15</td>
</tr>
<tr>
<td>Lateral Bending</td>
<td>3.61</td>
<td>-46.58</td>
<td>-43.55</td>
<td>-48.94</td>
</tr>
<tr>
<td>Axial Rotation</td>
<td>-0.83</td>
<td>-32.13</td>
<td>-30.69</td>
<td>-32.21</td>
</tr>
</tbody>
</table>

Table 4.2c: Percentage change in motion (ROM) at L5-S1 level for injured and different implant groups compared to intact.
4.2.2 Intradiscal pressure (IDP) at different levels:

**Figure 4.3a:** Intradiscal pressure (MPa) at L3-L4 in response to 400N follower load and 10Nm moment for injured with different instrumentation models.

**Table 4.3a:** Percentage change in intradiscal pressure at L3-L4 level for injured and different implant groups compared to intact.
**Figure 4.3b:** Intra discal pressure (MPa) at L4-L5 in response to 400N follower load and 10Nm moment for injured with different instrumentation models.

**Table 4.3b:** Percentage change in intra discal pressure at L4-L5 level for injured and different implants compared to intact.
**Figure 4.3c:** Intra discal pressure (MPa) at L5-S1 in response to 400N follower load and 10Nm moment for injured with different instrumentation models.

**Table 4.3c:** Percentage change in intra discal pressure at L5-S1 level for injured and different implants compared to intact.
4.2.3 Facet Loads under load control protocol

**Facet loads at L3-L4**
(400N Follower Load+10Nm Bending)
Grade I degeneration at L4-L5

---

**Figure 4.4a:** Total facet loads (N) at L3-L4 in response to 400N follower load and 10Nm moment for injured and different instrumentation models.

<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>DSFM-1 (L4-L5)</th>
<th>DSFM-2 (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Left Facets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ext</td>
<td>6.43</td>
<td>5.00</td>
<td>2.89</td>
<td>2.08</td>
</tr>
<tr>
<td>LB</td>
<td>25.68</td>
<td>27.28</td>
<td>158.27</td>
<td>30.42</td>
</tr>
<tr>
<td>LR</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Right Facets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ext</td>
<td>6.43</td>
<td>5.00</td>
<td>2.90</td>
<td>1.50</td>
</tr>
<tr>
<td>LB</td>
<td>242.87</td>
<td>207.09</td>
<td>501.24</td>
<td>196.13</td>
</tr>
<tr>
<td>LR</td>
<td>4.12</td>
<td>5.32</td>
<td>110.31</td>
<td>5.07</td>
</tr>
</tbody>
</table>

**Table 4.4a:** Percentage change in total facet loads at L3-L4 level for injured and different implant compared to intact.
Figure 4.4b: Total facet loads (N) at L4-L5 in response to 400N follower load and 10Nm moment for injured and different instrumentation models.

<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>DSFM-1 (L4-L5)</th>
<th>DSFM-2 (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Left Facets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ext</td>
<td>11.72</td>
<td>41.46</td>
<td>-21.87</td>
<td>20.52</td>
</tr>
<tr>
<td>LB</td>
<td>207.90</td>
<td>430.11</td>
<td>964.01</td>
<td>398.43</td>
</tr>
<tr>
<td>LR</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Right Facets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ext</td>
<td>11.72</td>
<td>41.46</td>
<td>-21.82</td>
<td>20.52</td>
</tr>
<tr>
<td>LB</td>
<td>-74.53</td>
<td>-49.76</td>
<td>35.08</td>
<td>-35.45</td>
</tr>
<tr>
<td>LR</td>
<td>0.95</td>
<td>17.21</td>
<td>130.20</td>
<td>32.82</td>
</tr>
</tbody>
</table>

Table 4.4b: Percentage change in total facet loads at L4-L5 level for injured and different implants compared to intact.
**Figure 4.4c:** Total facet loads (N) at L5-S1 in response to 400N follower load and 10Nm moment for injured and different instrumentation models.

**Table 4.4c:** Percentage change in total facet loads at L5-S1 level for injured and different implant groups compared to intact.
4.3 FE Analysis of Axient and Rigid fusion system:

4.3.1 Range of motion (ROM):

**Figure 4.5a:** Relative motions (degrees) at L3-L4 level of the lumbar spine for injured and instrumentation systems in 400N follower load and 10Nm flexion.

<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>Fusion (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>-0.13</td>
<td>12.60</td>
<td>6.03</td>
</tr>
<tr>
<td>Extension</td>
<td>-0.27</td>
<td>18.26</td>
<td>4.18</td>
</tr>
<tr>
<td>Lateral Bending</td>
<td>-0.63</td>
<td>1.42</td>
<td>1.45</td>
</tr>
<tr>
<td>Axial Rotation</td>
<td>-1.83</td>
<td>-1.49</td>
<td>-1.62</td>
</tr>
</tbody>
</table>

**Table 4.5a:** Percentage change in motion (ROM) at L3-L4 level for injured and different implants compared to intact.
Motion at L4-L5
(400N Follower Load+10Nm Bending)
Grade I degeneration at L4-L5

Figure 4.5b: Relative motions (degrees) at L4-L5 level of the lumbar spine for injured and instrumentation systems in 400N follower load and 10Nm flexion.

Table 4.5b: Percentage change in motion (ROM) at L4-L5 level for injured and different implants compared to intact.
**Figure 4.5c:** Relative motions (degrees) at L5-S1 level of the lumbar spine for injured and instrumentation systems in 400N follower load and 10Nm flexion.

**Table 4.5c:** Percentage change in motion (ROM) at L5-S1 level for injured and different implants compared to intact.
4.3.2. *Facet loads for injured with instrumentation models*

Facet loads for each were calculated at 400N follower load and 10Nm bending moment and were compared to the intact. Comparison is shown in Figures 4.5a, 4.5b, 4.6c. Facet loads in flexion were very less hence were not reported. Table 4.5a, b and c shows the percentage decrease in facet loads in each case compared to intact at the same loading conditions.

![Facet loads at L3-L4](image)

**Figure 4.6a:** Total facet loads (N) at L3-L4 level of the lumbar spine in response to 400N follower load and 10Nm moment in extension for injured with instrumentation models.

<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>Fusion (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Left Facets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ext</td>
<td>6.4</td>
<td>4.5</td>
<td>2.08</td>
</tr>
<tr>
<td>LB</td>
<td>25.6</td>
<td>40</td>
<td>30.4</td>
</tr>
<tr>
<td>LR</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Right Facets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ext</td>
<td>6.4</td>
<td>3.9</td>
<td>1.50</td>
</tr>
<tr>
<td>LB</td>
<td>242</td>
<td>234.1</td>
<td>196.1</td>
</tr>
<tr>
<td>LR</td>
<td>4.1</td>
<td>5.6</td>
<td>5.1</td>
</tr>
</tbody>
</table>

**Table 4.6a:** Percentage change in total facet loads at L3-L4 level for injured and different implant groups compared to intact.
**Figure 4.6b:** Total facet loads (N) at L4-L5 level of the lumbar spine in response to 400N follower load and 10Nm moment in extension for injured with instrumentation models.

**Table 4.6b:** Percentage change in total facet loads at L4-L5 level for injured and different implant groups compared to intact.
Figure 4.6c: Total facet loads (N) at L5-S1 level of the lumbar spine in response to 400N follower load and 10Nm moment in extension for injured with instrumentation models.

Table 4.6c: Percentage change in total facet loads at L5-S1 level for injured and different implant groups compared to intact.
4.3.3 *Intra discal pressure for injured with instrumentation models*

IDP was calculated at three levels for all the loading modes in all the cases and was compared to the intact. Comparison data was shown in figure 4.6a, b, and c. IDP at the index level was less in both fusion and Axient case. IDP at the adjacent levels was restored to intact with Axient which means the device will not overload the adjacent levels over the time. Fusion caused increase in the intra discal pressure at the adjacent levels in all the loading cases.

![IDP at L3-L4](image)

*Figure 4.7a:* Intra discal pressure (MPa) at L3-L4 level of the lumbar spine in response to 400N follower load and 10Nm for injured and different implant systems.

<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>Fusion (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flex</td>
<td>1.00</td>
<td>9.99</td>
<td>1.97</td>
</tr>
<tr>
<td>Ext</td>
<td>7.89</td>
<td>25.26</td>
<td>10.79</td>
</tr>
<tr>
<td>LB</td>
<td>1.76</td>
<td>-0.08</td>
<td>0.58</td>
</tr>
<tr>
<td>LR</td>
<td>5.22</td>
<td>5.92</td>
<td>5.65</td>
</tr>
</tbody>
</table>

*Table 4.7a:* Percentage change in intra discal pressure at L3-L4 level for injured and different implants compared to intact.
Figure 4.7b: Intra discal pressure (MPa) at L4-L5 level of the lumbar spine in response to 400N follower load and 10Nm for injured and different implant systems.

Table 4.7b: Percentage change in intra discal pressure at L4-L5 level for injured and different implants compared to intact.
**IDP at L5-S1**
(400N Follower Load+10Nm Bending)
Grade I degeneration at L4-L5

Figure 4.7c: Intra discal pressure (MPa) at L5-S1 level of the lumbar spine in response to 400N follower load and 10Nm for injured and different implant systems.

<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>Fusion (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flex</td>
<td>1.94</td>
<td>-23.77</td>
<td>-31.63</td>
</tr>
<tr>
<td>Ext</td>
<td>-2.57</td>
<td>-13.25</td>
<td>-18.37</td>
</tr>
<tr>
<td>LB</td>
<td>0.00</td>
<td>-38.38</td>
<td>-47.93</td>
</tr>
<tr>
<td>LR</td>
<td>1.79</td>
<td>-13.86</td>
<td>-15.62</td>
</tr>
</tbody>
</table>

Table 4.7c: Percentage change in intra discal pressure at L5-S1 level for injured and different implants compared to intact.
4.4 Peak Implant stresses for injured with implanted models

Peak von mises stresses at the bone screw interface were calculated for all the models. As the implant was symmetrical on both sides, stresses in left bending and right rotation are calculated. The peak Von mises stress values in both L4 and L5 pedicle screws were more for fusion device than Axient (figure 4.7). Stress contours are shown in figures 4.8a, 4.8b and 4.8c.

**Figure 4.8:** Peak Von Mises stress values (MPa) occurring at the pedicle screws of the rigid system and Axient in a grade I degenerated spine.
**Figure 4.9a:** Von Mises stress plots for the pedicle screws in the Axient with the injured model using 400N follower preload and 10Nm pure moment in extension.

**Figure 4.9b:** Von Mises stress plots for the pedicle screws in the Axient with the injured model using 400N follower preload and 10Nm pure moment in flexion.
Figure 4.9c: Von Mises stress plots for the pedicle screws in the Axient with the injured model using 400N follower preload and 10Nm pure moment in lateral bending.

Figure 4.9d: Von Mises stress plots for the pedicle screws in the Axient with the injured model using 400N follower preload and 10Nm pure moment in axial rotation.
4.5 Grade II degeneration results:

Injury: 30% disc height reduction + Total facetectomy at L4-L5 level.

4.5.1 Range of motion

<table>
<thead>
<tr>
<th>Motion at L3-L4</th>
<th>400N Follower Load+10Nm Bending</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade II degeneration at L4-L5</td>
<td></td>
</tr>
</tbody>
</table>

Figure 4.10a: Relative motions (degrees) at L3-L4 level for injured and instrumentation models in response to 400N follower load and 10Nm moment

<table>
<thead>
<tr>
<th>Angular Displacement (Deg)</th>
<th>Intact</th>
<th>Injured</th>
<th>Fusion (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flex</td>
<td>4.1</td>
<td>-1.1</td>
<td>2.7</td>
<td>0.5</td>
</tr>
<tr>
<td>Extension</td>
<td>9.0</td>
<td>9.0</td>
<td>-0.5</td>
<td>-6.2</td>
</tr>
<tr>
<td>Lateral Bending</td>
<td>-28.6</td>
<td>2.3</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>Axial Rotation</td>
<td>-5.7</td>
<td>-5.7</td>
<td>-1.5</td>
<td>-3.0</td>
</tr>
</tbody>
</table>

Table 4.8a: Percentage change in motion at L3-L4 level for injured (grade II degenerated) and different implanted models compared to intact.
Figure 4.10b: Relative motions (degrees) at L4-L5 level for injured and instrumentation models in response to 400N follower load and 10Nm moment

Table 4.8b: Percentage change in motion at L4-L5 level for injured (grade II degenerated) and different implanted models compared to intact.
Figure 4.10c: Relative motions (degrees) at L5-S1 level for injured and instrumentation models in response to 400N follower load and 10Nm moment

<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>Fusion (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>-14.3</td>
<td>24.0</td>
<td>-12.4</td>
</tr>
<tr>
<td>Extension</td>
<td>-21.2</td>
<td>-24.1</td>
<td>-23.2</td>
</tr>
<tr>
<td>Lateral Bending</td>
<td>-44.3</td>
<td>65.6</td>
<td>-13.7</td>
</tr>
<tr>
<td>Axial Rotation</td>
<td>-21.6</td>
<td>38.6</td>
<td>-14.3</td>
</tr>
</tbody>
</table>

Table 4.8c: Percentage change in motion at L5-S1 level for injured (grade II degenerated) and different implanted models compared to intact.
4.5.2 Intra discal pressure for injured with instrumentation models

IDP was calculated at three levels for all the loading modes in all the cases and was compared with intact. Comparison data was shown in figure 4.10a, b, and c. IDP at the index level was less in both fusion and Axient case. But IDP at the adjacent levels was not changed much with Axient or fusion device.

Figure 4.11a: Intra discal pressure (MPa) at L3-L4 in response to 400N follower load and 10Nm moment for injured and instrumentation models.

<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>Fusion (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>-0.659</td>
<td>-1.398</td>
<td>-1.048</td>
</tr>
<tr>
<td>Extension</td>
<td>20.530</td>
<td>9.233</td>
<td>6.913</td>
</tr>
<tr>
<td>Lateral Bending</td>
<td>-28.044</td>
<td>0.818</td>
<td>2.116</td>
</tr>
<tr>
<td>Axial Rotation</td>
<td>10.669</td>
<td>6.777</td>
<td>12.440</td>
</tr>
</tbody>
</table>

Table 4.9a: Percentage change in intra discal pressure at L3-L4 level for injured (grade II degenerated) and different implanted models compared to intact.
Figure 4.11b: Intra discal pressure (MPa) in response to 400N follower load and 10Nm moment in extension for injured with instrumentation models.

Table 4.9b: Percentage change in intra discal pressure at L4-L5 level for injured (grade II degenerated) and different implanted models compared to intact.
**Figure 4.11c:** Intra discal pressure (MPa) in response to 400N follower load and 10Nm moment in lateral bending for injured with instrumentation models.

**Table 4.9c:** Percentage change in intra discal pressure at L5-S1 level for injured (grade II degenerated) and different implanted models compared to intact.
4.5.3 Facet loads for injured with instrumentation models

100% facetectomy was performed at L4-L5 to simulate grade II degeneration. Facet loads for each model were calculated at 400N follower load and 10Nm bending moment and were compared to the intact. Comparison is shown in Figures 4.11a, b, c. Facet loads in flexion were very less hence was not reported.

![Facet loads at L3-L4](image)

**Figure 4.12a:** Total facet loads (N) at L3-L4 level in response to 400N follower load and 10Nm moment in extension for injured with instrumentation models.

<table>
<thead>
<tr>
<th>Left Facets</th>
<th>Injured</th>
<th>Fusion (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ext</td>
<td>128.0</td>
<td>5.6</td>
<td>8.4</td>
</tr>
<tr>
<td>LB</td>
<td>90.9</td>
<td>21.4</td>
<td>125.6</td>
</tr>
<tr>
<td>LR</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Right Facets</th>
<th>Injured</th>
<th>Fusion (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ext</td>
<td>128.0</td>
<td>5.6</td>
<td>8.5</td>
</tr>
<tr>
<td>LB</td>
<td>696.5</td>
<td>209.4</td>
<td>549.5</td>
</tr>
<tr>
<td>LR</td>
<td>125.7</td>
<td>8.4</td>
<td>122.2</td>
</tr>
</tbody>
</table>

**Table 4.10a:** Percentage change in total facet loads at L3-L4 level for injured and different implant groups compared to intact.
Figure 4.12b: Total facet loads (N) in response to 400N follower load and 10Nm moment in lateral bending for injured with instrumentation models.

<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>Fusion (L4-L5)</th>
<th>Axient (L4-L5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ext</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>LB</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>LR</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ext</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>LB</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>LR</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 4.10b: Percentage change in total facet loads at L4-L5 level for injured and different implant groups compared to intact.
Figure 4.12c: Total facet loads (N) in response to 400N follower load and 10Nm moment in axial rotation for injured with instrumentation models.

Table 4.10c: Percentage change in total facet loads at L5-S1 level for injured and different implant groups compared to intact.
4.6 Peak Implant stresses for injured with implanted models

Peak von mises stresses at the bone screw interface were calculated for all the models. As the implant was symmetrical on both sides, stresses in left bending and right rotation are calculated. The peak von mises stress values in both L4 and L5 pedicle screws were more for fusion device than Axient. Stress contours are shown in figure 4.12.

**Figure 4.13:** Peak von Mises stress values (MPa) occurring at the pedicle screws of the rigid system and Axient\textsuperscript{TM} in a grade II degenerated spine.
4.7 Implant misalignment results:

**Extension Motion Data**

10Nm+400N Preload

<table>
<thead>
<tr>
<th>Displacement (Deg)</th>
<th>L3-L4</th>
<th>L4-L5</th>
<th>L5-S1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>2.0</td>
<td>2.5</td>
<td>3.5</td>
</tr>
<tr>
<td>Properly Aligned</td>
<td>1.5</td>
<td>1.7</td>
<td>1.8</td>
</tr>
<tr>
<td>4mm Lateral</td>
<td>1.2</td>
<td>1.4</td>
<td>1.6</td>
</tr>
<tr>
<td>4mm Distal</td>
<td>0.8</td>
<td>1.0</td>
<td>1.2</td>
</tr>
</tbody>
</table>

**Flexion Motion Data**

10Nm+400N Preload

<table>
<thead>
<tr>
<th>Displacement (Deg)</th>
<th>L3-L4</th>
<th>L4-L5</th>
<th>L5-S1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>3.0</td>
<td>3.5</td>
<td>4.0</td>
</tr>
<tr>
<td>Properly Aligned</td>
<td>2.5</td>
<td>3.0</td>
<td>3.5</td>
</tr>
<tr>
<td>4mm Lateral</td>
<td>2.0</td>
<td>2.5</td>
<td>3.0</td>
</tr>
<tr>
<td>4mm Distal</td>
<td>1.5</td>
<td>2.0</td>
<td>2.5</td>
</tr>
</tbody>
</table>

Figure 4.14: Range of motion (degrees) of the spine in extension and flexion for different alignments of implant
Figure 4.15: Intra discal pressure at different levels in extension and flexion for different alignments of implant.
**Figure 4.16:** Facet loads (N) at different levels of the spine in extension and flexion for different alignments of implant

### 4.8 Results from in vitro human cadaveric study

As mentioned earlier, 50% medial bilateral facetectomy was performed on 2 specimens and 100% on the other two. We did not test the first two specimens in intact as the original specimens were implanted with Axient by a professional surgeon, and we did not get the chance to test them in intact case. Only the results from injured and implanted cases were measured and compared.

*Injury 1: 50% medial bilateral facetectomy

*Injury 2: 100% medial bilateral facetectomy*
Figure 4.17a: Relative motions (degrees) at the implanted level for injured and instrumentation models in response to 400N follower load and 10Nm moment.

Figure 4.17b: Relative motions (degrees) at the adjacent level for injured and instrumentation models in response to 400N follower load and 10Nm moment.
Figure 4.17c: Total flexion-extension motion for injured and instrumentation models in response to 400N follower load and 10Nm moment.
4.9 Model validation:

Validation of the FE model was done by comparing the FE data with the experimental data. As explained in chapter III, in vitro testing was conducted on four human specimens. We performed two types of injuries (50% bilateral medial facetectomy on the two and total bilateral facetectomy on the other) on the specimens. We have simulated the same injury in finite element analysis as we did in the in vitro testing. Motion data from both cases were calculated and compared (Figures 4.13a, b and c). As the specimens were of different levels, only the trend was compared. In vitro human cadaveric testing results were in agreement with the finite element results.

**Figure 4.18a:** Comparison of in vitro and finite element results for the implanted level of the lumbar spine with 50% medial bilateral facetectomy under 400N follower load and 10Nm moment.
Figure 4.18b: Comparison of in vitro and finite element results for the adjacent levels of the lumbar spine with 50% bilateral facetectomy under 400N follower load and 10Nm moment.

Figure 4.18c: Comparison of in vitro and finite element analysis range of motion results in flexion-extension at the implanted and adjacent levels of the lumbar spine with 100% bilateral facetectomy under 400N follower load and 10Nm.
Discussion

The results section is divided into 4 parts:

1. Evaluating better system of the three implants (Axient, DSFM-1 and DSFM-2) through finite element studies.
2. Comparing Axient™, dynamic stabilization system with traditional posterior pedicle screw fusion system using finite element analysis.
4. Validation of the finite element model using cadaveric data.

In this study, we have used validated finite element model of the lumbar spine. Two types of injuries were implemented in the study (Grade I and II disc degeneration). Initially, the performance of three separate implants on grade I degenerated spine will be discussed in this chapter. Implant with better performance was considered for further evaluation through both FE and cadaveric studies (on harvested spines).

Comparison of three posterior stabilization systems:

Intact spine was tested in all degrees of motion and ranges of motion at the implanted and adjacent levels were measured. Then grade I degeneration was simulated at L4-L5 level. Three different implants (DSFM-1, DSFM-2 and Axient) were placed at L4-L5 level. The implanted spine was re-tested with three different implants. Range of motion of instrumented cases was compared to the intact to see if there is any difference in performance between different implants.
There is no significant difference between the effects of three implants on the adjacent level (L3-L4). Motion at L4-L5 (implanted level) and L5-S1 levels is lower than intact in all instrumented cases except with DSFM-1 in extension (Table 4.1). Intradiscal pressure did not vary much between three implant types at all levels (Table 4.2). Facet Loads are much lower for Axient compared to DSFM-1 and DSFM-2 (Table 4.3). This indicates that additional load is being placed on the facets with two DSFM implants. This may cause facet degeneration over time both at the adjacent and implanted levels. Because of the better performance of Axient over the other two devices, all the remaining study was performed on Axient™.

**Stability of the Axient™ compared to rigid rod system**

Due to the better performance of Axient™ over other two implants, the remaining part of the study utilized only Axient™. In the next step, rigid rod (fusion) system was compared with Axient. Intact FE model was modified to accommodate pedicle screw based fusion system (rigid rod device). ROM, IDP and facet loads of the implanted and adjacent level of both instrumentation groups were compared to intact.

Results presented in chapter IV (Figures 4.5, 4.6, 4.7, 4.9, 4.10 and 4.11) show that Axient™ restored kinematics of the degenerated spine close to normal than with the fusion device (for grade I and grade II degenerated spine). Axient was able to restore the kinematics of degenerated spine at the adjacent levels where as fusion increased segmental motion beyond the intact. Intra discal pressure in the adjacent disc showed that the risk of degeneration was reduced by using dynamic system. Also the motion at L4-L5 in extension with Axient was less than the intact and this was due to the presence of
bumper which restricted the motion. As the disc degeneration is followed by disc height reduction which may cause pinching of the spinal cord and associated structures, bumpers were designed in such a way that they are free from other spinal structures during physiological extension. Unlike most spring based dynamic stabilization devices, Axient™ preserves the stability of implanted segment in all loading conditions.

Stresses in pedicle screws were more for rigid system compared to the AXIENT system. This implies that the risk of screw breakage is lower for a dynamic stabilization device than for a rigid one over time.

Both Axient™ and fusion devices unloaded the disc at the treated level. They did not have much effect on the adjacent level. This showed some positive findings with the results provided in other studies by Rohlmann et al [47] and Schmoelz et al [53] in vitro study where they compared the effect of dynamic device and rigid system on intra-discal pressures.

Implant misalignment did not have significant affect on the motion and the intra-discal pressure at the implanted level and adjacent levels; however the facet loads at the implanted and adjacent levels changed slightly.

Dynamic stabilization devices are intended to provide motion at the implanted level unlike the fusion devices. The main aim of dynamic stabilization devices is to stabilize the injured motion segment and prevent further degeneration while minimizing the adjacent segment degeneration. Overall motion was restored to normal with the AXIENT compared to the fusion device and this was consistent with the data from the literature.
where fusion caused a significant decrease in the motion of the implanted segment [47].

**In vitro study**

**Harvested sheep testing**

Statistical analysis showed that there was no significant difference (p>0.05) between two treatments (with and without tissue) in all loading modes. Based on statistical analysis, the implant performance was not significantly altered by the presence of muscle tissue.

**Human cadaveric testing**

Number of specimens was very less for in vitro study. We could not perform the statistical analysis as we need a minimum of 6 specimens to consider for statistical significance. Because the implanted level was different from specimen to specimen, only trend was compared in figure 4.13a and b.

**Study limitations:**

Due to the limited availability and high cost of the human cadavers, we have tested only 4 specimens. This is a very small number from statistics point of view. These 4 specimens were divided into 2 groups (each group received separate injury). It’s hard to analyze the implant performance with two specimens. There should be at least 6 specimens in each group statistically to see the effect of an implant on the spine.

In this study we used *in vitro* cadaveric testing and finite element (FE) techniques to assess the biomechanics of the spine following replacement of a novel posterior dynamic stabilization device. The finite element analysis and *in vitro* cadaveric testing are complementary techniques, and thus are appropriate methods to investigate the complex
biomechanical behavior of the spine. The finite element modeling, like the cadaveric testing has several limitations including not being able to account for variations in geometry of the specimens such as facet orientations and material properties that vary from specimen to specimen as well as the prediction of the long term behavior of the implant such as stress distribution pattern at the screw-bone interface. However in FE simulations, for a given intact model dimensions, the predicted data in terms of kinematics are in reasonable agreement with the results from the in vitro studies. Hence the application of a computational technique like FE modeling in spine biomechanics can provide very useful information. These studies can predict many variables including the occurrence of degeneration at the adjacent segment which take years/decades to define clinically. Finite element technique is an inexpensive method which allows for evaluation of motion and load changes across the spinal segments which can be anticipated and help predict the potential effects of clinical scenarios and acts and optimization tool for the design and development of the implant from its concept to prototype for further investigations.
References:


29. Lu, D.C., V. Wang, and D. Chou, *The use of allograft or autograft and expandable titanium cages for the treatment of vertebral osteomyelitis*.

30. Pollock, R., et al., *Donor site morbidity following iliac crest bone harvesting for cervical fusion: a comparison between minimally invasive and open techniques*.

31. Park, P., et al., *Adjacent segment disease after lumbar or lumbosacral fusion: review of the literature*.


34. Nockels, R.P., *Dynamic stabilization in the surgical management of painful lumbar spinal disorders*.

    The University of Toledo: Toledo.


Appendix A

Functional Anatomy of Spine

The spine is comprised of 33 small bones that extend from the neck to the pelvis. Anatomically they can be classified into 4 regions called cervical, thoracic, lumbar and sacrum.

- The top seven vertebrae starting from the neck are called cervical spine and are labeled C1-C7. C1 is called atlas and C2 is called axis.
- Thoracic spine is made up of 12 vertebrae and is labeled T1-T12.
- The lower back or the lumbar spine is made up of 5 vertebrae, labeled L1-L5.
- The sacrum and the coccyx are made up of 9 vertebrae that are fused together.

Each region contains several bony vertebrae separated by flexible intervertebral discs. Any two vertebrae are separated by disc in between and associated ligaments, muscle and joints together called a motion segment. Whole spine is meant to support the upper body structures and protect the spinal cord which passes through the spinal canal.

The cervical and lumbar regions are lordotic, and the thoracic is kyphotic. These curvatures are produced by the wedge like shape of the intervertebral discs and to some degree the shape of the vertebrae themselves [35].

Vertebral body

Each vertebra has anterior and posterior arch which form a hole called foramen through which spinal cord passes. Anterior arch is called the vertebral body. Vertebral body is made of cancellous bone which is surrounded by a thin layer of cortical bone. Thin layer
of surfaces above and below the cortical bone are called endplates. Load is transferred from one vertebra to the other through the intervertebral disc. The shape of the vertebra is almost similar from C3-L5 but the size and mass increases from cervical to lumbar.

**Intervertebral disc**

Intervertebral disc constitutes 20-33% of the entire height of the spinal column. Intervertebral disc is soft, gel like structure between the vertebral bodies. It is made of outer annulus fibrosis and inner jelly like nucleus pulposus.

*Annulus fibrosis* is composed of collagen, protein and water which make it almost incompressible. Annulus fibrosis consists of many annulus fibers oriented in different directions provides flexibility to the spine and anchor to the vertebral bodies. Given these functions, it should be able to transfer the compression, bending, shear forces and torsion between the vertebrae. It is said that an intervertebral disc can carry as much as 3 times the weight of the trunk in sitting position \(^{[54]}\).

*Nucleus pulposus* is located in the central portion of the disc. It is composed of proteoglycans and mostly water about 70-90% by its volume. Nucleus occupies 30-50% of the total disc space. It acts like an air bag under loading and swells under pressure. However swelling is restricted by the superior, inferior endplates and annulus which encloses the nucleus.

*Endplate* is made of hyaline cartilage and separates intervertebral disc from the vertebrae.
Ligaments

There seven major ligaments in the spine: anterior longitudinal (ALL), posterior longitudinal (PLL), supraspinous, facet capsular ligaments, interspinous, ligamentum flavum and intertransverse ligaments. They allow adequate physiological motion between the vertebrae while limiting the excessive motion [54]. Anterior and posterior longitudinal ligaments run along the anterior and posterior part of the vertebral body and are attached to both vertebral body and the disc. They are most effective in carrying loads along the direction of the fibers. Anterior longitudinal ligaments play an important role in limiting the motion in extension. The posterior longitudinal ligament traverses the posterior surface of the entire spine, lining the vertebral foramen. Supraspinous ligament runs along the posterior edge of the spinous process and provides stability in flexion [55]. The interspinous ligament is attached to adjacent spinous processes in the sagittal plane and also helps resist flexion. The ligamentum flavum is the most elastic ligament, helps protect the spinal cord, and connects to adjacent laminae [56]. The intertransverse ligament attaches to neighboring transverse processes and restricts motion in bending and axial rotation. The facet capsular ligaments surround the facet joint and the fibers are oriented perpendicular to the facet surface helping to provide stability in flexion [56].

Facet joints

Facet joints are located on the posterior part of the vertebral body. Each vertebra has two facet joints. The one facing upwards is called superior articular facet and facing downwards is the inferior articular facet. Superior facet of a vertebra articulates with inferior facet of the vertebrae above it and inferior facet articulates with superior facet of
the vertebrae below it. Facet joints are synovial type and are covered with hyaline cartilage which gives them smooth movement. Orientation of the facets varies between cervical, thoracic and lumbar. Facet joints play a major role in stabilizing the spine \cite{55}. They are major source of pain \cite{56}. These facet joints allow small degrees of flexion and extension and limit the rotation and ultimately protect the intervertebral disc from translational shear stresses.