A Thesis

entitled

Biomechanical Evaluation of a Lumbar Interspinous Spacer

by

Avanthi Chikka

Submitted to the Graduate Faculty as partial fulfillment of the requirements

for the Master of Science Degree in Bioengineering

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The University of Toledo
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An Abstract of

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Lumbar interspinous spacers have recently become popular as an alternative treatment for low back pain. These devices are primarily used to treat spinal stenosis and facet arthritis and are intended to unload the facet joints, restore foraminal height and provide stability mainly in extension while allowing normal range of motion in other loading modes. The goals of this study were three fold: (i) to evaluate the biomechanical stability provided by the Superion Interspinous Spacer (ISS) (Vertiflex®, San Clemente, CA) implanted in the lumbar spine; (ii) to study the effect of transection of supraspinous ligament (SSL) on the lumbar spine implanted with ISS; and (iii) to investigate the effect of graded facetectomies (50%, 75%, 100% facetectomies for both unilateral and bilateral cases) following the placement of ISS in the lumbar spine.
This study is basically divided into two parts: an *in vitro* investigation and finite element analysis. The *in vitro* biomechanical study was conducted on six human lumbar motion segments (3 L2-L3 and 3 L4-L5) in the following test sequence: (i) intact, (ii) implanted (SSL intact), (iii) SSL dilated longitudinally at the center (with ISS), (iv) 50% resection of SSL (with ISS), (v) 100% resection of SSL (with ISS) (vi) injured (ISS removed). A finite element (FE) analysis was performed for the same test cases and also to investigate the effect of graded facetectomies using an experimentally validated 3D L3-S1 model. A bending moment of 10 Nm was applied in all loading modes (flexion-extension, right/left lateral bending, and right/left axial rotation) while a bending moment of 10 Nm with 400N compressive follower load was applied only in flexion-extension. Range of motion (ROM) was recorded for each of the test constructs. In addition to ROM, intradiscal pressure (IDP), facet loads and stress contour plots for these test constructs were obtained from the FE model. Repeated measures one way ANOVA was used to perform statistical analysis to determine the statistically significant differences between different test constructs for the *in vitro* data.

The *in vitro* results showed that the mean ROM was significantly (p<0.05) reduced in extension post-implantation. There was a minimal decrease in mean ROM in flexion as well, but it was not significant (p>0.05). ROM in lateral bending and axial rotation were not affected. Also, there was no significant difference in ROM in any of the loading modes for the instrumented cases with and without SSL. The FE results were in agreement with the *in vitro* results except in flexion. Unlike the *in vitro* results, the flexion ROM increased slightly with progressive transection of SSL. From the FE data, it was observed that there was a significant reduction in IDP and facet loads in extension
following the placement of ISS. However, there was no considerable difference in IDP and facet loads for the implanted cases with partial or complete transection of SSL. ROM, IDP and facet loads were not affected at the adjacent levels in any of the loading modes for any of the test constructs. It was also observed that there was an effect of graded facetectomies (50%, 75% and 100%) on the instrumented spine with a significant increase in ROM in flexion in case of both unilateral and bilateral facetectomies.

The ISS provided an increased stability in extension while preserving motion comparable to intact in the other loading modes. Also, it can be inferred that SSL plays an insignificant role in segmental stability in extension, lateral bending and axial rotation and has nominal effect in flexion. In addition, the results suggest that ISS may not be used in combination with graded facetectomies for both unilateral and bilateral cases.
I would like to dedicate this work to my dearest and loving

Parents - Krishnaiah Chikka and Rajamani Chikka (late)

Husband - Naveen Kumar Ale

Sister - Anusha Chikka
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Chapter 1

Introduction

This chapter discusses the significance of studying low back pain and the various stabilization systems employed for its treatment. The biomechanics of different stabilization systems and the advantages of non-fusion systems over conventional fusion systems will be discussed. Finally, the purpose and scope of the study will be defined.

1.1 Lumbar Spine Anatomy

The spine is a musculoskeletal structure with complex biomechanical behavior. It consists of discrete bony elements (vertebrae) joined by ligamentous structures, kept separated by intervertebral discs and articulating joints, and dynamically controlled by muscular activity. The spine is broadly divided into 5 regions: the cervical spine, the thoracic spine, the lumbar spine, the sacrum, and the coccyx. It consists of 33 vertebrae, with seven vertebrae in cervical region, twelve vertebrae in thoracic region, five in lumbar region, five (fused) in sacrum and four (fused) in coccyx. The main functions of the spine are to provide structural support, flexibility or motion and protect spinal cord.

Each vertebra of the lumbar spine consists of an anterior vertebral body and the posterior neural arch. The superior and inferior surfaces of the vertebral bodies consist of cartilaginous endplates to which the intervertebral discs are affixed. The posterior neural
arch begins bilaterally with the pedicles which form a junction with the laminae, the superior and inferior facets, and the transverse processes. The laminae join at the most posterior aspect, from which the spinous process extends. The spinal cord is protected by the neural arch. A functional spinal unit (FSU) is comprised of a superior vertebra, intervertebral disc, inferior vertebra and the corresponding ligamentous structures.

The spinal motion is majorly due to the flexibility of the intervertebral disc. The disc has a unique structure with central nucleus pulposus, surrounded by annulus fibrosus. The nucleus pulposus is made of collagen, proteoglycans and water content whereas the annulus fibrosus is composed of fibrocartilage and collagen. The disc acts as shock absorber with the annulus fibrosus resisting the tensile stresses and the nucleus pulposus resisting the compressive stresses. Also, they play a role in creating the spinal curves (lordosis and kyphosis) which assist in distributing the weight and the applied loads throughout the body. The articulating facets serve to limit motion and transmit direct compressive loads and bears compressive forces from bending and rotation.

There are seven ligaments supporting the FSU - anterior longitudinal, posterior longitudinal, ligamentum flavum, capsular, interspinous, supraspinous and intertransverse ligaments, which serve to protect the neural structures by limiting the motion of the FSU.

1.2 Low Back Pain

Low back pain (LBP) is a common musculoskeletal disorder and is a widespread problem in modern society both in economics and prevalence. Between 70% and 80% of the world’s population experiences low back pain at some point of their lives. The incidence of low back pain in western industrialized society has been reported to range from a high
of 20% of adults in any given 2 week period to a low of 10% in a 2 year period [1].
Direct and indirect costs for US payers for the treatment of LBP are estimated in the tens of billions of dollars [2]. Hence, there is a necessity to study the origin of pain associated with the lumbar spine and investigate for simple, cost effective, and safe treatment options.

Anatomically, many tissues can produce LBP symptoms; however, the degeneration of the intervertebral disc is the primary source of LBP. Degenerative disc disease mainly results from the dehydration of the nucleus pulposus. As a result, the ability of nucleus to bear compressive loads is reduced and consequently more loads are transferred to the peripheral regions of the disc and annulus. In addition, disc degeneration results in the loss of disc height which results in the increase of axial compressive loads to the posterior elements, potentially accelerating facet arthrosis.

Disc degeneration leads to many potential spinal disorders such as disc herniation, spinal stenosis, spondylolisthesis etc. Facet degeneration which may be a consequence of disc degeneration may lead to facet tropism, hypertrophy, arthritis, and spinal stenosis. All these pathologies induce pain due to the compression of spinal nerves, exiting the spinal canal at the intervertebral foramen, or due to the direct compression of the spinal cord.

### 1.3 Treatment Measures

The conservative method of treatment is followed in the initial stages. This includes rest, medications, physical therapy, orthotics and braces. These are followed for a period of 6 months. Upon the failure of conservative measures, surgical treatment is recommended.
The optimal method of surgical treatment for a particular spinal disorder is decided by the surgeon. However, fusion has been the gold standard technique to treat various spinal pathologies. This is based on the theory that the spinal instability (abnormal motion under physiologic loads) is the cause of the mechanical low back pain. However, this concept is still unclear and controversial. Fusion procedure intends to completely limit the abnormal pathologic motion by fusing the vertebral components. It has been successful in providing temporary relief of symptoms to the patient. However, this procedure alters the load transmission to the adjacent segments leading to increased motion and stresses causing degenerative changes to occur. One of the most common findings observed adjacent to fused segment was disc degeneration. Spondylolisthesis, instability, hypertrophic facet joint arthritis, herniated nucleus pulposus and stenosis were also reported frequently [3]. In addition, pseudarthrosis, bone resorption and osteophyte formation may occur and lead to poor clinical outcomes [4]. Also, successful fusion rate could not be correlated to mixed clinical outcomes. Other complications included pain at the bone harvesting site and also resulted in revision surgeries [5, 6]. Thus, the limitations of fusion lead to the development of alternative treatments with non-fusion devices.

The goal of the non-fusion devices is to restore the normal biomechanics of the spine i.e. normal kinematics and loading pattern, resulting in normal function of the spine. This would relieve pain and prevent adjacent segment degeneration. These devices include disc arthroplasty, nucleus replacement, facet replacement and posterior dynamic stabilization (PDS) systems. However, it is to be noted that these devices are intended to stay anchored in the spine for entire patient’s life to maintain normal function.
Disc arthroplasty, nucleus replacement, facet replacement are indicated for severe cases of degeneration of the disc and facet joints respectively. These devices replace the degenerated disc and facet components of the spine and restore the normal biomechanical behavior of the spine by acting as load bearing device. As these devices undergo constant mechanical relative motion of the components due to the physiologic loads, there is a potential risk of implant failure and osteolysis, due to wearing properties of the device.

Dynamic stabilization technology is indicated for younger patients with disc degeneration in more than one segment and for whom adjacent level disc degeneration is a possibility in long term follow up. These devices preserve the natural anatomy of the spine and restore the normal biomechanics by acting as load-sharing device. Biomechanically, PDS unload the intervertebral disk evenly with a predictable load distribution. It controls physiologic 3D motion, maintains/restores sagittal balance and anatomic alignment. The unloading of the disc allows optimum amount of physiologic load transmission through the degenerated disc which may aid in regeneration of the disc. It is also advantageous as the surgical procedure involved is minimally invasive and allows for easier revision surgeries.

Interspinous Spacer Decompression has been an emerging technology which is based on dynamic stabilization concept. This has been used as a viable treatment for spinal stenosis and facet arthritis. In general, these devices are free-floating and act as a spacer placed between the spinous processes at a symptomatic level. Biomechanically, their presence acts to limit extension with no effect on flexion, axial rotation, and lateral bending [7].
this study, a novel interspinous spacer, Superion Interspinous Spacer (ISS) (Vertiflex®, San Clemente, CA), currently under clinical trials has been biomechanically evaluated.

1.4 Purpose of the study

The purpose of this study was to evaluate the biomechanics of the lumbar spine implanted with Superion Interspinous Spacer at L4-L5 segment. The study is divided into two parts; an *in vitro* investigation on six lumbar motion segments (L2-L3/L4-L5) followed by finite element analyses using L4-L5 motion segment model and L3-S1 model.

The hypotheses of the study and the rationale for these hypotheses are as follows:

1. There is no effect of transection of supraspinous ligament on the lumbar spine implanted with ISS.
   During the surgical procedure to place the ISS in between the adjacent spinous processes, a posterior incision is made to access the interspinous space through dilation of the supraspinous ligaments followed by the transection of the interspinous ligaments. However, there is a potential risk that SSL may be resected in error as it is very small. Hence this study was performed to determine if there is any biomechanical effect of transection of SSL on the lumbar spine implanted with ISS.

2. There is no effect of graded facetectomies on the lumbar spine implanted with ISS.
   In degenerative lumbar spinal canal stenosis, the nerve roots are compressed mainly in the lateral part of the spinal canal. Medial facetectomy, unroofing of the lateral recess, is commonly performed for decompression of the nerve root [8, 9].
Furthermore, total facetectomy is sometimes performed for the excision of the intraforaminal herniated disc, spinal tumor at the posterior parts, etc. In patients with severe stenosis at multilevel, decompressive surgeries such as different grades of facetectomy in combination with posterior stabilization systems such as Interspinous Spacers may alleviate the symptoms related to LBP and provide the increased stability. In this study, the ISS was biomechanically evaluated in combination with graded facetectomies (50%, 75% and 100%) for both unilateral and bilateral cases. However, it is to be noted that the use of this device is not indicated with concomitant lumbar surgery according to the developers of the device.
Chapter 2

Literature Review

This chapter provides a review of literature on low back pain, its causes and the treatment options. The biomechanical factors contributing to low back pain and the various stabilization devices employed to treat the spinal instabilities will be discussed.

2.1 Introduction

Traditionally, low back pain is associated with the degenerative changes occurring in the spine with the age. The intervertebral and facet joints play a crucial role in the transfer of physiologic biomechanical loads through the spinal segments producing normal kinematic pattern. With the advancing age, repetitive loading may initiate degenerative changes in these structures causing various spinal disorders such as disc degeneration, disc herniation, facet arthritis, spinal stenosis etc. Degeneration of the vertebral body and ligaments may also lead to spinal pathologies.

2.2 Intervertebral Disc Degeneration

Degenerative disc disease is one of the major causes of low back pain and its associated symptoms. Aging is the main cause of the degenerative changes in the spine. Other factors include smoking, obesity, gender, previous trauma to the spine. Primary
degeneration of the disc has been recognized as the initiating factor resulting in secondary degeneration of facets, ligaments and muscles. Disc degeneration depends on the failure of cellular activity in charge of producing a normal extracellular matrix which in turn depends on various factors: genetic, nutritional and mechanical [10]. The main nutrient supply to the disc is provided by the adjacent cartilaginous vertebral end plate. With the advancing age, there is a decrease in the permeability of endplate as they become calcified, leading to its resorption and subsequent replacement by bone. This causes reduction in the blood supply to the disc which eventually leads to the breakdown of disc tissues, altering the composition of the avascular disc starting in the nucleus, including a decrease of its proteoglycan content and hydration as well as an increase of collagen fibers [11]. Concentric fissuring and radial tears begin to appear in the annulus fibrosis. All these changes result in a loss of disc height. Loss of proteoglycans and fluid, lowering of osmotic pressure in the nucleus, as well as alterations of the collagen network, affect the normal absorption and dissipation of the movement forces applied to the normal viscoelastic hydrostatic nature of the disc [12]. These biochemical changes alter the overall biomechanical behavior (kinematics and kinetics) of the disc. The segmental motion increases with increasing severity of disc degeneration up to grade IV but decreases thereafter as it advances to grade V. The degenerative changes in the disc may result in the following spinal disorders.

### 2.3 Disc Herniation

The degenerative changes in the disc can cause the rupture of the annulus fibrosus which allows the nucleus pulposus to escape out. This may push into the spinal canal and cause
the compression of the spinal nerves passing out through the foraminal space. Sometimes, there may also be direct compression of the spinal cord.

![Herniated Disc](image)

Figure 2-1: Herniated disc causing compression of a nerve at the site of intervertebral foramen (Source: www.spineuniverse.com)

2.4 Spinal Stenosis

Spinal Stenosis is a pathological condition in which there is narrowing of the midline sagittal spinal canal (central) and/or narrowing between the facet superior articulating process, the posterior vertebral margin (lateral recess), and the nerve root canal (foraminal). As a consequence, there is compression of the spinal nerves which are in the spinal canal and/or exiting through foraminal space. This may be caused due to disc degeneration, thickening of the ligament (ligamentum flavum) and enlarged facet joints due to arthritis.
2.5 Spondylolisthesis

This is one of the degenerative spinal disorders in which there is forward slippage of one vertebral body over the one below. This may be caused due to the high loads and/or repetitive excessive strains acting on the spine which makes it to rotate in multiple directions while carrying the body weight.
Figure 2-3: Spondylolisthesis showing forward slippage of vertebra with respect to inferior stable vertebra (Source: http://www.richmondchiro.net/health-conditions/spondylolisthesis/)
Figure 2-4: Various disc pathologies shown which develop as a consequence of disc degeneration (Source: http://www.spineuniverse.com/conditions/degenerative-disc/what-degenerative-disc-disease)

2.6 Vertebral Body Degeneration

The vertebral body is composed of highly porous trabecular bone, surrounded by solid cortical shell. The individual trabeculae are oriented along the paths of principal forces and play a vital role in the transfer of the compressive forces along the spine [10]. With the age, the central cancellous portion of the vertebra undergoes many changes which include loss of bone mineral density, trabecular thinning, increased intratrabecular spacing, and loss of connectivity between trabeculae leading to Osteoporosis. Hence, there is a decrease in the load-bearing capacity of the vertebral body which may result in
increased risk of vertebral fracture [13]. The vertebral endplate evenly distributes the applied loads to the underlying cancellous bone and the cortex of the vertebra. With aging, thinning of the endplate coupled with the loss of bone mineral density increases the risk of endplate fracture. Also, ossification of the endplate may decrease the nutritional supply and hydration of the intervertebral disc leading to disc degeneration.

2.7 Posterior Element Degeneration

The posterior paravertebral elements include facet joints, ligamentum flavum, interspinous ligaments, supraspinous ligaments, and paraspinous muscle structures. These structures have a large number of innervations. The facet joints are one of the main structures for the stability of the spinal motion segment. It protects the spine from high extension rotations and large shear displacements in the anterior direction. The high facet loads resulting from these rotations give rise to high stresses in the facets at the areas of contact. With the advancing age, high facet stresses may give rise to facet osteoarthritis and hypertrophy resulting in osteophyte formation at the articular margins and enlargement of articular surfaces. This may lead to spinal stenosis. As the facet joint capsules are innervated by spinal nerves, the degenerative changes cause pain. The supraspinous and interspinous ligaments play a significant stabilizing role in flexion and their failure results in unstable flexion rotations and spondylolisthesis. In general, ligament laxity affects the overall stability of the spine.
2.8 Treatment Options for Low Back Pain

Low back pain in the initial stages is treated with conservative measures such as rest, medications, exercises, physical therapy, spinal orthotics and braces. If the conservative treatment fails, surgical treatment is recommended.

2.9 Surgical Treatment of Low Back Pain

Surgical treatments involve removal of pain causing structures such as herniated disc, protruded disc, hypertrophic facets, osteophytes impinging the neural structures either in the spinal canal or intervertebral foramina. Various operative procedures include decompression with fusion or different types of non-fusion devices. The following sections describe decompression surgery and the various stabilization systems.

2.10 Decompression Surgery

Low back pain caused by neural impingement is often treated by decompression surgery. Neural impingement (compression of the nerves) can be caused due to disc herniation, facet hypertrophy, spinal stenosis, spondylolisthesis or a spinal tumor. Decompression surgery involves removal of small portion of the bone over the nerve root and/or disc material from under the nerve root to relieve the pressure on the nerve root and allow it to heal, thus alleviating the pain. Various methods of decompression include unilateral laminectomy, bilateral laminectomy, unilateral facetectomy, bilateral facetectomy and microdiscectomy. Following the decompression surgery, the stability of the spine is restored with the fixation devices such as fusion devices or posterior dynamic stabilization devices.
2.11 Fusion

Lumbar spinal fusion procedure has been the gold standard technique for the treatment of multitude of spinal disorders. Lumbar spine conditions that can be managed by fusion are isthmic spondylolisthesis, degenerative spondylolisthesis, spinal stenosis, degenerative scoliosis, segmental instability (degenerative and iatrogenic), disc related syndromes, lumbar disc herniation, disc related low back pain and failed previous surgery (The indications for lumbar spine fusion with and without instrumentation). This procedure involves fusing two or more bones, limiting the motion at these joints. This is done by partial removal of the disc and/or facets depending on the severity of deformity. This results in a destabilized spinal segment(s) which is stabilized by the instrumentation devices incorporating a bone graft between vertebral bodies to be fused. The concept of fusion is based on Wolff’s law, according to which, mechanical stimuli elicits an osteogenic response in bone, causing bone to form in regions of increased stress. It is evident that an optimal range of applied stress to bone will induce bone formation while extreme outliers to this stress can result in bone resorption. Thus, rate of fusion depends on the load sharing properties of the stabilization devices.

There are various types of approaches to perform spinal fusion surgery, described as below:

- **Posterior Lumbar Interbody Fusion (PLIF)** - the procedure is done from the back and is a complicated approach as it requires accessing intervertebral disc by moving around the spinal cord. This procedure involves removing the disc between two vertebrae and inserting bone graft with cages placed bilaterally. A bilateral
facetectomy may be performed for a better access to the anterior compartment of the spinal segment. In case of facetectomy, the segment is stabilized with rigid fixation system with transpedicular screws and rods posteriorly. The major advantage of this type of surgery is that all procedures can be performed in one surgery.

- **Transverse Lumbar Interbody Fusion (TLIF)** - It is same as that of the PLIF except that it is unilateral approach (of placing the bone graft) with the advantage of avoiding trauma to the spinal cord and the nerves.

- **Anterior Lumbar Interbody Fusion (ALIF)** - the procedure is done from the front and involves transperitoneal or retroperitoneal approach i.e. by moving the abdominal organs, vascular and neural structures to a side to access the anterior compartment of the spinal segment. The intervertebral disc is removed and inserted with bone graft. It is often supplemented with anterior plate fixation or with posterior pedicle screw fixation to increase the stability of the spine. However, this involves a second incision for posterior approach.

- **Posterolateral fusion** - the procedure is done from the back. The transverse processes are fused by placing bone graft. The disc is left intact after the removal of herniated tissue.

- **Extreme Lateral Interbody Fusion (XLIF)** - It is a relatively new technique whereby access to the disc space is achieved through a minimally invasive lateral, retroperitoneal, trans-psoas approach. It is dependent upon real-time electromyographic monitoring. This approach to the anterior disc space allows for complete discectomy, distraction, and interbody fusion without the need for an approach surgeon when compared to that of ALIF.
Novel interbody fusion cage designs made of different materials (metallic/polymeric) have become popular. The compressive stresses produced by the anterior column due to weight-bearing, contribute to the bone healing acting at the fusion site. These cages are used to increase the disc height, which is necessary to restore the normal distribution of forces within the spinal unit and in combination with bone grafts speeds up the fusion process. Since the anterior interbody procedures involve loss of anterior longitudinal ligament, dissection of paraspinal muscle with partial denervation, it further contributes to destabilization of the spinal segment and can lead to implant migration. Biomechanically, interbody fusion provides anterior column support and in combination with posterior fixation will aid in restoring the load balance along the spinal column. The addition of posterior fixation has increased success of fusion. Posterior spinal fixation devices incorporate distraction, tension band and three point bending mechanisms in order to stabilize the spinal segments. The instrumentation consists of pedicle screws and rods, wires, hooks etc. and they further immobilize the fusion site during healing. The spinal alignment and load balance is crucial for posterior fixation as any residual imbalance in the load transfer may result in increased stresses on the vertebral components resulting in phenomena such as pseudoarthrosis [14], bone resorption and osteophyte formation which may lead to poor clinical outcomes [15, 16].

Degeneration of the adjacent segments of the fused level has been the greatest concern with the lumbar spinal fusion. It may also result in mechanical breakdown of these motion segments, with recurrence of pain and sometimes even neurologic symptoms. As the fusion incorporates, the segment becomes immobilized and the stresses during bending and rotation moments of the spine are transferred to the adjacent vertebral
endplates and surrounding intact spinal segments, which may eventually lead to the degeneration of these segments. Disc degeneration (loss of disc height, disc space narrowing), listhesis (anterolisthesis, retrolisthesis), instability, herniated nucleus pulposus, stenosis, hypertrophic facet arthritis, osteophyte formation, scoliosis and vertebral compression fracture were reported as abnormal processes observed at the adjacent segment after spinal fusion [3].

Biomechanical studies have shown that there is an increased motion at the adjacent segments to a fusion site [17]. However, patients with fusion surgery will continue to achieve the same range of motion as that of intact, healthy spine. The motion is significantly reduced at the fused segment with the adjacent spinal segments absorbing the transferred stresses with motion. Chow et al, measured segmental mobility and intradiscal pressure in six cadaveric lumbar spine specimens before and after, single level L4-5 and double level L4-5-S1 anterior interbody fusions. They found that there was an increased motion at the adjacent levels. However, they found no evidence that the loads at the adjacent segments increased.

Goto et al. using finite element models analyzed the degeneration of the adjacent segments of the fused level of the lumbar spine. He compared intact, L4/5 posterolateral lumbar fusion (PLF), and L4/5 posterior lumbar interbody fusion (PLIF) models. The findings of this study demonstrate that with lumbar fusion, stresses on the vertebral end-plate and the annulus fibrosus were high adjacent to the fusion level; furthermore, stresses were higher in the PLIF model than in the PLF model. These high stresses may damage the annulus fibrosis and vertebral endplates adjacent to the fusion level [18]. In
an *in vitro* biomechanical testing on human lumbar spines, the effects of spinal destabilization and instrumentation on lumbar intradiscal pressure were analyzed. They found that in response to destabilization and instrumentation, adjacent disc pressures increased as much as 45%, and at the fused levels decreased by about 41-55% in cases of flexion and extension. However, it is still unclear to some extent whether the radiographic and clinical findings of adjacent segment instability and degeneration are a direct outcome of iatrogenic production of a rigid motion segment with spinal fusion, or these represent the progression of the natural history of the underlying degenerative disease [3, 19].

With recent developments of the fusion techniques, successful fusion rate has approached nearly 100% but this has failed to reflect a comparable increase in successful clinical outcomes [20]. In a retrospective study, 149 patients who had undergone a one-level or multilevel instrumented posterolateral lumbar fusion for intractable pain related to degenerative conditions of the spine were considered for the study. Follow-up period was 2-15 years. 41% of the patients developed transitional segment alterations, and 20% needed a secondary operation for extension of the fusion [21]. Arnold et al, conducted a clinical study on patients who underwent Posterior Lumbar Interbody Fusion with Allograft Spacer. After one year follow-up, he reported 98% fusion rate with 86% patients reporting decreased pain and disability. The overall complication rate was 1.61% [22]. Glassman et al, conducted a retrospective study on older patients (65 years above) who had undergone posterolateral lumbar decompression and fusion surgery and reported positive clinical outcomes [23]. A review of prospective clinical trials through the
Cochrane database shows that there is no significant improvement of the natural history of low back pain by spinal fusion [24].

In spite of the mixed results on clinical outcomes of lumbar fusion, the drawbacks of this procedure namely adjacent segment degeneration, tedious surgical procedure, post operative complications, long recovery period and revision surgeries have led to the development of other alternative treatments which aim at restoring the normal biomechanics of not only the operated segments but also the adjacent segments.

2.12 Non-Fusion Systems

The non-fusion systems intend to maintain or restore the intersegmental motions to magnitudes of the intact spine and prevent the degeneration of the adjacent segments to the stabilized one. It is advantageous for young patient population as fusion is an over-treatment for such groups. There are various non-fusion systems such as total disc replacement, facet replacement and dynamic stabilization systems. However, it is to be noted that these non-fusion systems are supposed to retain in the body for the patient’s entire life in order to maintain normal function of the spine.

2.13 Total Disc Replacement and Nucleus Replacement

Total disc replacement arthroplasty and nucleus replacement serve as an efficient surgical treatment of intervertebral disc pathology. As an alternative to interbody arthrodesis, an artificial disc serves to replace the symptomatic degenerated disc, restore the functional biomechanical properties of the motion segment, and protect neurovascular structures. The implanted device should promote osseointegration at the bone–metal interface,
restore the disc height, reestablish kinematics to the functional spinal unit, and provide an anterior–posterior column load-sharing environment. Painful degenerative disc disease, failed disc syndrome, and transition zone syndrome are clinical indications for total disc arthroplasty [25]. The nucleus replacement device is designed to replace only the inner portion of the disc i.e. nucleus while the annulus fibrosus is in intact condition.

Cunningham et al, in an in vitro biomechanical study, compared the kinematics and the position of the center of intervertebral rotation of total disc arthroplasty (using SB Charite disc) versus conventional fusion stabilization techniques. The SB Charite’ restored motion to the level of the intact segment in flexion-extension and lateral bending while an increased motion in axial rotation by 44% . Motion at the adjacent segment levels was also same as that of intact for SB Charite when compared to the increased motion in case of fusion systems. Also, the mapping of intervertebral COR at the operative and proximal adjacent levels were in the posterior one-third of the intervertebral disc bordering the superior endplate of the inferior vertebral level for SB Charite’ which was very close to that of intact [26].

Rohlmann et al, using a 3 dimensional non-linear finite element model studied the mechanical behavior of lumbar spine implanted with ProDisc prosthesis at L3-L4 level. They found that position of the device strongly influences intersegmental rotation for the loading cases of flexion and standing. A disc height 2 mm in excess of the normal disc space increases intersegmental rotation at implant level during standing and extension. Optimal height and correct position of the implant; preserving lateral portions of the
annulus and reconstruction of anterior longitudinal ligament play a key role in restoring normal biomechanics of the operated level as well as the adjacent segments.[27]

The biomechanical analysis of Prodisc L®, Maverick®, and SB Charite III®, using L1-S1 three dimensional finite element models, showed that all the models implanted with artificial discs demonstrated spinal motions similar to those of the intact model during flexion. However, during extension, there was an increased motion at the operated site (L4-5) in comparison to the intact model, which led to an increase in the facet contact load. The increased facet load may result in facet degeneration. In addition, Prodisc L® had stress greater than yield stress under the flexion load, which may expose the disc to injury [28].

Biomechanically, the artificial disc behaves as a load bearing structure and shares the kinematics with the other spinal joints. Due to the constant motion of the disc, there is a possibility of wear of the implant which may eventually lead to mechanical failure of the device.

2.14 Facet Replacement

Facet degeneration eventually leads to facet tropism, hypertrophy, arthritic or degenerated facet joints, and spinal stenosis causing low back pain. Partial or full laminectomy with facetectomy surgeries may be necessary to relieve pain. Facet replacement technology has been used as an alternative treatment as it preserves stability and restores normal spinal motion at the implanted levels. Some of the facet replacement
systems available are Anatomic Facet Replacement System (Facet Solutions Inc, Logan, Utah), Total Facet Arthroplasty System (TFAS) (Archus Orthopedics, Inc).

Goel et al. conducted an *in vitro* investigation and finite element study to compare the biomechanical effects of an artificial facet system to the intact spine. The cadaveric study showed that the artificial facet system was able to restore the motion to intact values. On average, motion with the device was only 18% less than intact motion in extension, 3% more in flexion, 18% less in lateral bending, and 15% less in axial rotation. The finite element model simulated motions in all modes were similar to the mean experimental values. The artificial facet system was able to reduce the intradiscal pressure back to the intact values in all the modes [29].

Figure 2-5: Total Facet Arthroplasty System
2.15 Dynamic Stabilization Systems

These systems are designed to stabilize the spinal segments by preserving the natural anatomy of the spine in comparison to disc and facet replacement technologies. The principle of dynamic stabilization is that the control of spinal instability (abnormal motion under physiological loads), and restoring normal physiological loading pattern through the spinal elements would alleviate pain and prevent degeneration of the adjacent segments [30, 31].

The three basic biomechanical requirements for an ideal posterior dynamic stabilization device are:

- Unload the intervertebral disc evenly with optimum load sharing
- Control physiologic 3D motion (ROM - Range of Motion and location of mean AR - Axis of Rotation)
- Maintain/restore sagittal balance and anatomic alignment

These devices are broadly classified into two categories

- Pedicle screw based systems
- Interspinous process spacers

**Loading pattern**

Abnormal load distribution over the degenerated disc is a significant source of mechanical low back pain. Additionally, it results in reduction of disc height, transferring excessive abnormal forces to the posterior elements, potentially accelerating facet arthrosis. Dynamic stabilization systems have been designed as load-sharing devices to unload the degenerated disc and minimize load transfer to the posterior facets. The decreased pressure on the degenerated disc and facets may reduce mechanical pain associated with these structures.

**Kinematics**

The relationship between spinal instability and low back pain is still a controversial concept. However, most of the studies attribute low back pain to the abnormal physiologic motion of the spine. PDS provide spinal stability by controlling range of motion in flexion-extension, lateral bending and axial rotation which may result in relief of pain associated with instability. Ideal functioning of such system can be achieved when the location of the optimum instantaneous axis of rotation (IAR) of the system lies close to that of motion segment during entire range of motion. For pedicle screw based PDS, COR lies posterior to the physiologic COR. This may result in overloading of the
disc in certain positions of the spine. Any discrepancy in the kinematics of the spinal segment and the system leads to abnormal loading pattern. The increased loads on the system may lead to fatigue failure of the implant or implant-bone junction.

**Alignment/Posture**

Restoration of sagittal balance is of paramount importance in order to achieve normal loading pattern through the spinal elements. Most PDS systems provide a certain degree of posterior distraction to unload posterior annulus and facet joints and widen intervertebral foramen potentially resulting in relief of radicular and discogenic pain. However posterior distraction may also lead to focal kyphosis and subsequently increased adjacent level stresses. The design of the PDS should be able to overcome these limitations by controlling the shear forces produced in lordotic spines.

**Implant longevity and adjacent level**

As these systems stay anchored to the bone to maintain normal range of intervertebral motion, there is a potential risk of mechanical failure of the implants due to repeated motion of the integral components of the device, such as screw loosening and breakage, implant migration and dislocation. Adjacent level stresses were found to be comparatively less in comparison to fusion.

**2.16 Pedicle screw based dynamic stabilization systems**

The pedicle screw based dynamic stabilization devices allow controlled range of motion of the spine in all three dimensions. The instrumentation includes screws which are inserted into the pedicles while the rods are designed as flexible components to allow
controlled motion. This system provides the compressive forces required for the mechanical stability of the spine.

**Graf Ligament System**

The Graf ligament was one of the first posterior dynamic devices used clinically. Under applied compressive load, the non-elastic bands connected to the pedicle screws are preloaded to place the intervertebral segment in extension, allowing immobilization of the instrumented segment in lordosis. Strauss et al. conducted a biomechanical *in vitro* study to evaluate the impact of Graf ligament implantation on intervertebral motion. The balance point (defined as the loading point on the upper plate of the vertebra causing rotation less than 0.03°) of the injured segments was significantly displaced anteriorly whereas stabilized segments demonstrated a balance point more similar to intact spines. It unloads the painful anterior disc and transfers the load to the posterior annulus. Instrumented spines demonstrated significant reduction of ROM in flexion-extension and lateral bending compared to intact spines, and an increased intervertebral motion in axial rotation and translation of the vertebra in all 3 directions [32].

Figure 2-7: The Graf Ligament System [33]
Dynesys (Dynamic Neutralization System)

This system consists of titanium alloy pedicle screws, polyethylene terephthalate (PET) cords and polycarbonate urethane (PCU) spacers. The hollow spacer fits between the pedicle screw heads while the cords connect the pedicle screw heads through the spacer. It is designed such that the stabilizing cords carry tensile forces controlling flexion while the spacers resist compressive forces limiting extension.

![Figure 2-8: The Dynesys System [33]](image)

Niosi et al. described a biomechanical study assessing the three-dimensional kinematic behavior of the Dynesys device with varying polymer spacer lengths to analyze the quality of motion with a special focus on the NZ and on the 3D helical axis of motion (HAM). Ten cadaveric specimens were tested by applying a pure moment of 7.5 Nm in five different testing conditions: intact, injured (section of posterior ligaments and facet joint capsules, posterolateral nucleotomy), stabilized with Dynesys (normal spacer, long spacer (+2 mm), and short spacer (-2 mm)). Implantation of the Dynesys device, compared to the intact and injured spines, resulted in significantly decreased ROM in all three loading directions. In flexion-extension and lateral bending, ROM decreased to
26% and 33% of the intact spine respectively, and axial rotation was approximately 76% of the intact spine. As expected, *in vitro* destabilization increased the NZ; however, implantation of the Dynesys restored the NZ to a magnitude less than that of the intact spine. In addition, the authors observed a significant posterior shift in the location of the HAM in flexion-extension and axial rotation after Dynesys implantation. Spacer length also affected intervertebral motion with the long spacers allowing the largest ROM in all loading conditions, whereas the short spacers resulted in a significant reduction of ROM compared to a standard spacer length. The authors hypothesized that the increased ROM associated with the long spacer may be related to the reduction of segmental compression with a less preloaded FSU as a consequence [34].

Schmoelz et al. conducted an *in vitro* study to understand the dynamic stabilization provided by Dynesys on lumbar spine and its effect on adjacent segments in comparison to the internal fixator. The DYNESYS and fixator both reduced the ROM and NZ below the magnitude of the intact spine for lateral bending and flexion. In extension the ROM for the DYNESYS was in the range of the intact spine, while the fixator showed a decreased ROM. In axial rotation the fixator stabilized the segment to a ROM below the magnitude of the intact spine, whereas the DYNESYS stabilized the defect but showed an increased ROM compared with the intact spine. There were no significant differences in the intersegmental motion of the regions adjacent to the bridged one for both tested fixation systems [35].

Cheng et al. conducted another biomechanical cadaveric study comparing the effect of Dynesys versus rigid fixation stabilization on ROM. Their results showed that following
Dynesys at L3-4, ROM decreased to 25% of intact ROM in flexion-extension, 40% in lateral bending and increased to 102% in axial rotation, whereas rigid instrumentation resulted in 32%, 39% and 78% of intact ROM, respectively [36].

2.17 Interspinous Distraction Devices

These are free floating devices i.e. not rigidly anchored to the vertebrae, placed between the spinous processes. The mechanical goal of these devices is distraction between adjacent spinous processes in order to decompress the nerve roots exiting the spinal canal at intervertebral foramen. They result in reduced extension at that level, which in turn unloads the disc and facets. The indications for their use include lumbar canal stenosis, Grade I degenerative spondylolisthesis, discogenic low back pain, nontraumatic instability, lumbar disc herniation and facet syndrome. However, the evidence for such widespread use is lacking currently.

There are four common interspinous implants namely Coflex (Paradigm Spine, Wurmlingen, Germany), Diam (Medtronic Sofamor Danek, Paris, France), Wallis (Abbott Laboratories, Bordeaux, France) and X-Stop (St Francis Medical Technologies, Alameda, USA). Coflex is a “U” shaped implant made of titanium. It has four lateral wings which are crimped to the spinous processes to secure the implant in place following resection of interspinous and supraspinous ligaments. Diam implant is composed of silicone, covered with a polyethylene coat. It has two ligatures to secure it in place. For the placement of this device, only interspinous ligaments are resected while supraspinous ligaments are left intact [37, 38]. Wallis implant is made of polyetheretherketone. It is secured in place with two ligatures wrapped around the
adjacent spinous processes. Both interspinous and supraspinous ligaments have to be resected for the placement of the device. However, post-implantation, supraspinous ligaments will be refixed in place with sutures. X-Stop is an oval titanium implant secured in place with two lateral wings which prevent migration. Only the interspinous ligaments are pierced (creating a small opening) in order to implant the device.

Wilke et al conducted an *in vitro* study on four different lumbar interspinous implants to compare the flexibility (range of motion) and intradiscal pressure. Twenty four human lumbar spinal motion segments (12 L2-L3, 12 L4-L5) were used for this study and were divided into four groups based on the device implanted. The destabilization of the specimens was created by performing bilateral hemifacetectomy. This defect caused a slightly kyphotic deformation of the specimens. The specimens were tested intact, destabilized and then followed by the stabilization with the four implants. The defect increased the range motion by 8% in lateral bending and 18% in axial rotation. Following the implantation with the four implants, there was a decrease in extension by 50% of the intact motion while flexion, lateral bending and axial rotation were almost same as that of the defect state. Intradiscal pressure was same as that of the intact specimens in flexion, lateral bending and axial rotation but greatly reduced in case of extension. The segmental tilt (kyphotic deformation) varied following the implantation of the four implants [39].

Lindsey et al, conducted a cadaver study to assess the effect of the X-Stop interspinous implant on the kinematics of the lumbar spine at the instrumented and adjacent levels. They observed that at the implanted level, ROM was significantly reduced in flexion-extension, while the other directions were not affected. The results of this study also
showed that the kinematics of the adjacent levels during flexion–extension, axial rotation, and lateral bending were not significantly affected with one exception; at the caudal L4–L5 level, the ROM from the neutral to extended positions was reduced by 0.8° which was not clinically significant. They also showed that the sagittal angle was affected by the implantation i.e. the specimens were in a more flexed i.e. kyphotic position. These results demonstrated a 2° decrease in lordosis from L2 to L5, having no effect on the kinematics at the adjacent levels [40].

Richards et al quantified the effect of the X-Stop Interspinous Spacer on the dimensions of the spinal canal and neural foramina during flexion and extension. Eight L2-L5 specimens were positioned to 15 degrees of flexion followed by 15 degrees of extension for each of the specimens to be magnetic resonance imaged with and without an interspinous implant (X STOP) placed in the L3-L4 interspinous space. Canal and foramina dimensions were compared between the intact and implanted specimens. In extension, the implant significantly increased the canal area by 18%, the subarticular diameter by 50%, the canal diameter by 10%, the foraminal area by 25%, and the foraminal width by 41%. This shows that X-Stop implant prevents narrowing of the spinal canal and neural foramina during extension [41].

Zucherman et al. conducted a clinical study comprising of 191 neurogenic intermittent claudication (NIC) patients, with 100 in the X STOP group and 91 in the control group. Clinical outcomes were measured using Zurich Claudication Questionnaire, a validated instrument for NIC, completed by the patients. At a follow-up period of 2 years, the X STOP patients showed an improvement of 45.4% over the mean baseline Symptom
Severity score compared with 7.4% in the control group; 44.3% mean improvement in the Physical Function domain in comparison to 0.4% in the control group. 73.1% patients of X-stop group, were satisfied with the treatment compared with 35.9% of control patients [42].

Lafage et al, conducted a combined in vitro and finite-element analysis to assess the biomechanical effect of Wallis implant on the lumbar spine. Six human cadaver lumbar L3-S1 spines were tested. Injury was created by performing a nucleotomy at L4-L5 through an incision in the left lateral annulus. The specimens were tested intact, injured with instrumentation and injured with the removal of instrumentation. A finite element analysis of L3-L5 model was simulated same as that of experimental conditions. They concluded that the effect of interspinous implant appears only in flexion-extension. In this load case, experimental results showed a reduced ROM while FEM analysis indicated decrease of disc stresses and increase of loads transmitted through the spinous processes [43].

Trautwein et al did a study to determine the in vivo posterior loading environment of the Coflex. The average loads exerted by the Coflex implant on the spinous process and lamina were 11.3% and 7.0% of their respective static failure load. As the implant fatigue strength is significantly higher than the measured median force, they concluded that Coflex fatigue failure is extremely rare [44].

Kettler et al. performed a biomechanical study on a new version of the Coflex interspinous implant, called Coflex rivet, tested for flexibility and load transfer and compared to the original Coflex implant. The aim was to evaluate whether Coflex rivet
was able to prevent instability also in axial rotation and lateral bending while still allowing the intervertebral disc to transmit some load. It was observed that the new spacer was able to compensate the destabilizing effect of the defect created in all loading directions. It strongly stabilized in extension and flexion and to a small degree in lateral bending and axial rotation. However, the original implant provided stability only in extension. The bending moments transferred through the implants were highest in extension and flexion. The authors believed that the biomechanical characteristics of this new implant might even make it suitable as an adjunct to fusion, which would be a new indication for this type of device [45].

Figure 2-9: Coflex Interspinous Spacer [45]
Figure 2-10: Wallis Interspinous Spacer [43]

Figure 2-11: X-STOP Interspinous Spacer [46]
2.18 Conclusion

Fusion has been the gold standard procedure to treat LBP for several years. However, it has drawbacks that have presented complications in long term. In an effort to overcome the limitations of fusion, motion preservation systems have been developed. These systems have many advantages over rigid fusion devices. However, this concept came into existence recently and the long term studies are in progress. Among the motion preservation systems, Interspinous Spacers technology has been emerging with the evidence based good clinical outcomes and biomechanical studies. There are several such devices with different design variables which may be placed in the spine using different surgical approaches. Hence, there is a need for a more detailed study to evaluate the biomechanical performance of these devices and surgical techniques as well. In this study, a novel device, Superion Interspinous Spacer has been biomechanically evaluated and the corresponding surgical technique has been quantified.
Chapter 3

Materials and Methods

This chapter discusses biomechanical evaluation of the Interspinous Spacer System using *in vitro* testing and finite element analysis. The finite element analysis was conducted as close to the *in vitro* test conditions in order to compare and validate the biomechanical parameters obtained.

3.1 *In vitro* Study

Human cadaveric lumbar spine specimens (L1-S1 < 70 years of age) were considered for this study. Each specimen was radiographed to ensure the absence of major anatomical abnormalities. Any specimen exhibiting significant degeneration, osteophytic bridging, narrowed disc space, signs of metastatic disease, or exhibiting any previous surgery that was either instrumented or non-instrumented were excluded from the study. Three specimens were cleaned of all surrounding musculature and adipose tissue, leaving the vertebrae, discs and ligaments intact. The three specimens were dissected into L2-L3 and L4-L5 motion segments, yielding 6 lumbar motion segments for testing. These specimens were stored at -20° c until the day of testing. The spinal motion segments were thawed to room temperature a day before testing.
3.1.1 Test Set-up

Each of the specimens was potted using a mixture of Bondo and Polyester resin (a 2-part epoxy resin) with a hardener additive. The motion segment was anchored superiorly at L2/L4 level and inferiorly at L3/L5. Screws were placed in the caudal/cephalad vertebra prior to potting to add strength to the contact between the vertebrae and bondo, and also to balance the specimen while the mixture hardened. Care was taken to ensure that the L2-3/L3-4 disc was parallel to the transverse plane. Rods were threaded through the L2/L4 vertebral body parallel to the plane of the L2-3 or L4-5 disc before the mixture was poured for the proximal end. These rods were used to apply bending moments on the motion segment to simulate physiologic range of motion. The specimen was fixed to the loading frame at the caudal end and the loads were applied on the proximal end which was free to move in any plane. During the testing, the specimens were wrapped in saline soaked gauze periodically to prevent dehydration of the soft tissues. All tests were performed at room temperature. The Optotrak® motion tracking system (Northern Digital, Waterloo, Canada) was used to record the angular rotations of the motion segment for each loading condition. This is based on rigid body dynamics i.e. evaluating relative motion of one rigid body with respect to another rigid body. The Optotrak® system uses markers which are made of infrared light emitting diodes to record the position coordinates (X, Y, Z) of the markers. Three markers are required to create a local coordinate system in order to track the position of a rigid body in space. Thus, three markers were placed on a metal plate in an “L” shape which was then screwed to the front of each vertebral body. However, in this case, marker plates were attached to the
bondo frames as these were fixed to the vertebral bodies i.e. L3 and L4 vertebrae. The experimental setup is shown in Figure 3-1.

### 3.1.2 Loading Conditions

Unconstrained pure moments were applied to the motion segment using the loading frame on opposite sides using system of pulleys and weights in order to simulate 6 degrees of motion i.e. flexion, extension, right/left lateral bending and right/left axial rotation. Loads were applied up to 10 Nm in increments of 1.5 Nm on the intact and injured segments while a hybrid protocol was followed for instrumented cases [47]. Hybrid protocol measures the moment required to achieve intact range of motion for instrumented cases. The hybrid moments were obtained by applying additional loads beyond that of intact i.e. up to 12 Nm. If the hybrid moment was not achieved within this limit, it was extrapolated from the data at which the intact motion was achieved. A 400N follower load was also applied but only in case of flexion and extension. Addition of a compressive follower load simulates torso weight and musculature as explained by Patwardhan et al. [48]. Range of motion (ROM) data was obtained for all the test constructs (described in the next section) in all loading modes i.e. flexion, extension, lateral bending (right and left) and axial rotation (right and left).
3.1.3 Test Constructs

Each of the spines was initially tested in the intact state. Once the appropriate size of the spacer to be implanted was determined by the surgeon, surgery was performed according to the recommended technique. The novel interspinous spacer using oblique approach (Vertiflex®, San Clemente, CA) was then implanted in between L2-L3/L4-L5 spinous process with only transection of interspinous ligaments (ISL) (Obs). Following this, supraspinous ligaments (SSL) were dilated at the center through a longitudinal incision. This is followed by 50% resection of SSL i.e. SSL transected on one side of dilation of SSL and then SSL was completely (100%) transected. Finally, the device was removed.

The test constructs included:

1. Intact
2. ObS - ISL transected + ISS
3. DS+ISS - (ObS) + Longitudinal dilation of SSL at the center.
4. 50%S+ISS - (DS+ISS ) + 50% Resection of SSL
5. 100%S+ISS - (50%S+ISS ) + 100% Resection of SSL
6. Injured - ISL and SSL resected + ISS removed

![Figure 3-2: L4-L5 cadaver spinal motion segment implanted with ISS](image)

### 3.1.4 Data Acquisition

The three dimensional intervertebral rotation was obtained from the motion analysis data files in the form of Euler angles (degrees) about the X, Y and Z axes. $R_x$ / $R_x$, $R_y$ / $-R_y$ and $R_z$ / $-R_z$ denoting range of motion (ROM) in flexion-extension, right rotation-left rotation, and right bending-left bending respectively. The position coordinates of the markers obtained using Optotrak® motion tracking system were transformed into range of
motion parameters by using Havey program in Microsoft Excel. Previously published studies from our lab have explained it in detail [49]. Hybrid moments were also obtained using the same program. Mean motion and standard deviation were reported for all the test constructs.

3.1.5 Statistical Analysis

A repeated measures one way analysis of variance (ANOVA) was performed to compare the range of motion in flexion, extension, lateral bending and axial rotation (at 10 Nm bending moment with and without preload) of the implanted test constructs with that of intact in order to evaluate the statistical significant differences between them. The effect of transection of supraspinous ligament was evaluated by comparing the test cases: Dilation of SSL + ISS, 50% Transection of SSL + ISS, 100% Transection of SSL + ISS, with that of SSL Intact + ISS. The p-values were computed for all the statistical comparisons performed between the different test constructs. All the statistical analyses were performed using SPSS software (version 17.0).

3.2 Finite Element Analysis

Finite element (FE) analysis is a valuable tool for understanding the biomechanics of the biological systems. Various biomechanical parameters can be analyzed for different geometries and materials of the orthopaedic implants. Its major advantage is that it provides comprehensive stress-strain analysis, which is difficult to obtain through experimental models. Using FE analysis, prototype designs can be evaluated and the right design can be determined based on the study outcomes. Thus, FE plays a major role in
the design and analysis of orthopaedic implants to determine the biomechanical behavior and load characteristics of the biological tissues as well as that of instrumentation.

3.2.1 Intact Finite Element Model

The intact FE model comprised of 3D geometry of vertebral body, intervertebral disc and the corresponding ligaments of the lumbar spine. The original model consisted of two motion segments L3-L5. The geometric data was obtained from 1.5 mm thick CT scans (transverse slices) of a healthy cadaveric spine specimen. Each CT scan was digitized using nodes. The four nodes characterizing a particular element were digitized to obtain their X and Y coordinates with respect to the global axes system. The Z coordinate equaled the depth of the corresponding transverse slice on the CT image. Due to the symmetry of the transverse cross-section of the lumbar spine about the mid-sagittal plane, only half of the model was digitized while the other half was reflected using ABAQUS. The digitized element layers were assembled sequentially to generate 3D mesh of L3-L5 model. To the existing L3-L5 model, L5-S1 disc and S1 vertebral body were added. The mid L3-L4 disc was kept horizontal with a total lordotic curve of approximately 27° across the L3-S1 level. For the FEA study, described in this chapter, L3-S1 as well as L4-L5 motion segment models were used. The L4-L5 model was created from the existing L3-S1 model. It consists of L4 vertebra, L5 vertebra, L4-L5 disc and the corresponding ligaments. This model was used in order to make an exact comparison of FE results with that of in vitro data.
3.2.1.1 Vertebral Body and Posterior Bone

Vertebral body and posterior bony regions were defined using 3D hexagonal elements and were made with solid continuum elements with eight nodes. The vertebral body has been modeled as cancellous (porous) bone core surrounded by a 0.5 mm thick cortical shell. Appropriate isotropic material properties were defined for the respective regions.

3.2.1.2 Intervertebral Disc

The intervertebral disc consisting of nucleus pulposus (core) surrounded by outer annulus fibrosis, was modeled as a composite structure. The annulus fibrosis was modeled as a solid ground substance, reinforced with embedded fibers. The ground substance was made up of 3-D solid hexagonal elements. REBAR option was used to define the fibers which were oriented at alternating angles ±30° to the horizontal. The “No Compression” option was used for the REBAR elements such that they could transmit only tension; also the fiber thickness and stiffness increased in the radial direction. An overall collagenous fiber content of 16% of the annular volume was distributed in the annulus. The nucleus pulposus was modeled with C3D8 hexagonal elements. Isotropic material property with stiffness of 1 MPa and near incompressibility simulated with a Poisson’s ratio of 0.4999 was assigned to the nucleus to simulate its hydrostatic characteristics.
3.2.1.3 Facet (Apophyseal) Joint

Facet joints were modeled with the superior and inferior articulating surfaces and the capsular ligaments. In the present FE model, the facet joint was simulated using 3-D gap elements (GAPUNI). The facets were oriented at an inclination of $72^\circ$ from the horizontal plane. An initial gap of 0.5 mm was specified between these elements. Force is transmitted by using the ABAQUS “softened contact” which exponentially adjusts the force transfer as the gap is closed. At full closure, the joint assumes the same stiffness as the posterior bone.

3.2.1.4 Ligaments

All the seven major ligaments, interspinous, supraspinous, intertransverse, capsular, posterior longitudinal, anterior longitudinal and ligamentum flavum were simulated in the model. The ligaments were modeled using 3-D two node truss elements (T3D2) with a specific cross-sectional area defined. Hypoelastic material properties were assigned to each of these ligaments and the material properties were taken from the literature. The hypoelastic material definition was given by specifying varying Young’s modulus and Poisson’s ratio along with the strain invariants at the specified strain rate. These elements were defined such that they are aligned along the respective ligament fiber orientation. Although the ligamentum flavum and the longitudinal ligaments experience a pre-stress at rest, all ligaments were assumed to be unstressed initially. Modeling the ligaments causes nonlinearity in the spine model.
3.2.1.5 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.

Table 3.1: Material properties assigned to various spinal components in the finite element model

<table>
<thead>
<tr>
<th>Element Set</th>
<th>Element Type</th>
<th># Elements</th>
<th>Youngs Modulus</th>
<th>Poisson's Ratio</th>
<th>Cross Sectional Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bony Sections</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vertebral Cancellous Bone</td>
<td>C3D8</td>
<td>12064</td>
<td>100</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Vertebral Cortical Bone</td>
<td>C3D8</td>
<td>3536</td>
<td>12000</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Posterior Cancellous Bone</td>
<td>C3D8</td>
<td>1846</td>
<td>100</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Posterior Cortical Bone</td>
<td>C3D8</td>
<td>3631</td>
<td>12000</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Joints</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apophyseal Joint</td>
<td>GAPUNI</td>
<td>216</td>
<td>Softened, 12000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervertebral Disc</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nucleus Pulposus</td>
<td>C3D8</td>
<td>2688</td>
<td>1</td>
<td>0.499</td>
<td></td>
</tr>
<tr>
<td>Annulus Fibres</td>
<td>REBAR</td>
<td>5040</td>
<td>175</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Annulus (GROUND)</td>
<td>C3D8</td>
<td>5376</td>
<td>4.2</td>
<td>0.45</td>
<td></td>
</tr>
<tr>
<td>Ligaments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterior Longitudinal</td>
<td>T3D2</td>
<td>144</td>
<td>10.0(&lt;11%), 20.0&gt;(11%)</td>
<td>0.3</td>
<td>2.4</td>
</tr>
<tr>
<td>Anterior Longitudinal</td>
<td>T3D2</td>
<td>240</td>
<td>7.5(&lt;12%),20&gt;(12%)</td>
<td>0.3</td>
<td>7.4</td>
</tr>
<tr>
<td>Ligamentum Flavum</td>
<td>T3D2</td>
<td>24</td>
<td>15.0(&lt;6.2%),19.5&gt;(6.2%)</td>
<td>0.3</td>
<td>5</td>
</tr>
<tr>
<td>Capsular Ligaments</td>
<td>T3D2</td>
<td>84</td>
<td>7.5(&lt;25%),32.9&gt;(25%)</td>
<td>0.3</td>
<td>3.27</td>
</tr>
<tr>
<td>Intervertebral</td>
<td>T3D2</td>
<td>30</td>
<td>10.0(&lt;18%),53.7&gt;(18%)</td>
<td>0.3</td>
<td>0.36</td>
</tr>
<tr>
<td>Interspinous</td>
<td>T3D2</td>
<td>42</td>
<td>10.0(&lt;14%),11.6&gt;(14%)</td>
<td>0.3</td>
<td>2.857</td>
</tr>
<tr>
<td>Susraspineus</td>
<td>T3D2</td>
<td>12</td>
<td>8.0(&lt;20%),15.0&gt;(20%)</td>
<td>0.3</td>
<td>7.5</td>
</tr>
</tbody>
</table>
3.2.1.6 Boundary and Loading Conditions

The inferior surface of S1 vertebra and the posterior elements (inferior articulating surfaces of the facets and the spinous process) was fixed in all six degrees of freedom. Two different loading modes were employed to simulate the following.

(i) Pure bending moments without compression: Bending moments were applied on L3 vertebra at a node which was coupled to the top surface of the L3 vertebra.

(ii) Pure bending moments with a follower preload: The loading was applied in two steps. In the first step, compressive/follower load was applied on the spine at each connector elements across each disc level. The load applied was 200N at each connector element on either sides resulting in a 400N follower load at each segment level. The connectors were oriented such that the load followed the lordotic curve of the spine and not introduce any rotational motion across the segment. In the second step, pure bending moments were applied at a node which was coupled to the top surface of the L3 vertebra. A bending moment of 10 Nm was applied to simulate flexion, extension, lateral bending and axial rotation.
Figure 3-3: Three-dimensional finite element model of the ligamentous L3-S1 segment: (a) intact model, and (b) mid-sagittal cross-section of the model showing important anatomical features.
Figure 3-4: Six loading modes i.e. Flexion-Extension in sagittal plane, Left/ Right Bending in frontal plane and Left/Right Rotation in Transverse plane applied on the spine are shown.

3.2.2 Instrumented Models

Three dimensional solid models of the Interspinous Spinous Spacer were created in SOLIDWORKS software by Vertiflex and exported as parasolid files. These models were imported in ABAQUS/Standard™ version 6.9 (Simulia, Inc. Rhode Island, USA). The device consisted of three parts - Superior Cam Lobe, Body and Inferior Cam Lobe as shown in Figure 3-5 (a). Initially, the spacer is inserted in its undeployed form and then fixed in the interspinous space in its deployed form. The body consisted of several individual small parts which helped in deploying it using surgical instruments during
surgical procedure. Prior to the analysis, these small parts have been merged to form as a single part in ABAQUS, to reduce the complexity of the design. However, it is to be noted that this would not affect the overall analysis of the system. These solid models were then partitioned and meshed in tetrahedral (C3D4) geometry of elements. The intact L4-L5 model was modified to simulate the implantation of spacer. The intact L3-S1 model was also modified to simulate the spacer. L4-L5 model was used to make an exact comparison of biomechanical parameters with the in vitro results while L3-S1 model was used to study biomechanical effects on the adjacent segments.

3.2.2.1 Design Features of Superion Interspinous Spacer

- Single component with deployable, anatomically correct superior and inferior cam lobes to prevent lateral and anterior migration.
- Composed of high-strength biocompatible titanium alloy.
- Available in 5 sizes (8mm-16mm) to support varying anatomy and optimize the bone-implant interface.
- Anatomically contoured cam lobes for optimal bone implant interface.
  
  This helps to reduce stresses at the bone-implant interface and allows uniform distribution of loads. Also, bone resection is not necessary.

- Device is deployed within the interspinous space providing controlled distraction thus:
  
  - Broadening foraminal and spinal canal area
  - Limiting extension
- Reducing stress on facet joints
- Reducing disc pressure anteriorly & posteriorly

Figure 3-5: (a) Superion Interspinous Spacer (ISS) and its components
(b) Undeployed position of ISS during insertion
(c) Fully deployed position of ISS in the interspinous space
3.2.2.2 Simulation of L4-L5 FE Model Implanted with Spacer

The experimentally validated ligamentous L4-L5 motion segment FE model (described previously) was used for the analysis. The spacer was placed in the interspinous space following the removal of interspinous ligaments. Material properties of the spacer were as follows: Titanium-Young’s modulus - 115 GPa, Poisson’s ratio - 0.32.

The nodes of the superior and inferior spinous processes were modified to match the contour of the spacer. A tie was defined between the bottom surface of the spacer and the L5 spinous process. A sliding hard contact with a coefficient of friction of 0.1 was defined between the wings of the spacer and the spinous processes at L4 and L5 levels and the same interaction was also defined between the top surface of the spacer and the L4 spinous process. All the test cases performed in *in vitro* study were simulated with one
exception. The test case involving dilation of SSL with ISS implanted was not performed as it is not feasible to simulate in ABAQUS.

Figure 3-7: (a) L4-L5 motion segment implanted with ISS
(b) Contact constraints defined between the implant and the spinous processes
3.2.2.3 Simulation of L3-S1 FE Model Implanted with Spacer

An experimentally validated L3-S1 model was modified in a similar manner as that of L4-L5 model (described in the previous section) for the placement of ISS at L4-L5 interspinous space. This modified FE model was used to study the following:

1. The biomechanical effect of transection of SSL on the lumbar spine implanted with Superion Interspinous Spacer (ISS). The test cases were simulated same as that of *in vitro* study. It is to be noted that FE analysis was performed for the same test cases using L4-L5 model to make an exact comparison with the *in vitro* results. However, using L3-S1 model, the same study was performed in order to evaluate the effect of ISS on the adjacent segments.

2. The effect of graded facetectomies on the lumbar spine implanted with ISS. The following cases were analyzed.
   - 50% unilateral facetectomy
   - 50% bilateral facetectomy
   - 75% unilateral facetectomy
   - 75% bilateral facetectomy
   - Total unilateral facetectomy
   - Total bilateral facetectomy
3.2.2.4 Data Analysis

The following biomechanical parameters were analyzed from the output finite element models of different test cases.

Figure 3-8: Different grades of facetectomy i.e. 50%, 75% and total facetectomies are shown
Range of Motion

The angular displacements of each of the segments were calculated using the deformations of a constant set of nodes at each segment level. This was obtained by writing an output file consisting of spatial coordinates (U1, U2, and U3). The deflection of each of the co-ordinates was measured from ABAQUS and the angle was determined using Microsoft Excel Macro. These measurements were taken in the sagittal plane for flexion-extension, frontal plane for lateral bending and the transverse plane for axial rotation.

Intradiscal Pressure

The intradiscal pressures were obtained for nucleus pulposus of discs at each of the segments. This was done by writing output file for peak Von Mises Stresses at the region of centroid. The peak Von Mises stresses were recorded for implant and also for bone-implant interface.

Facet Loads

The facet loads were obtained by writing output file for Von Mises Stresses at centroid for the gap elements which form the contact between the superior and inferior articulating surfaces of the facets. Since the gap elements have a unit cross sectional area, the output is represented as total facet loads.
Chapter 4

Results

The results of the *in vitro* and finite element (FE) studies described in the previous chapter will be presented here. *In vitro* results demonstrating the effect of partial or complete transection of SSL on the lumbar spine implanted with ISS will be compared with that of FE results. The effects of graded facetectomies using an experimentally validated 3D L3-S1 model are also presented here. *In vitro* results include range of motion while FE results comprise range of motion, intradiscal pressure, and facet loads. In addition, FE results also include peak Von Mises stresses and stress distribution plots of the implant.

4.1 *In vitro* Study

4.1.1 Range of Motion

The constructs were examined after testing and showed no visible signs of damage, loosening, or breaking. The mean range of motion and standard deviation of six specimens in all loading modes i.e. flexion (Flex), extension (Ext), left bending (LB), right bending (RB), left rotation (LR) and right rotation (RR) are reported. The test constructs compared were (i) Intact, (ii) Instrumented with ISS (ObS) (ISS placed in an oblique approach), (iii) Dilation of supraspinous ligament (SSL), with ISS (DS + ISS),
(iv) 50% transection of SSL with ISS (50%S + ISS), (v) 100% transection of SSL with ISS (100%S + ISS) and (vi) Injured (ISS removed).

The comparative ROM values for different surgical constructs are shown in Figure 4-1. Following instrumentation of ISS, the ROM in extension was significantly reduced by 24% compared to intact condition. Similarly with the dilation of SSL, the ROM significantly reduced by 24% compared to intact state. After 50% and 100% transection of SSL with ISS, the ROM significantly reduced by 31% and 26% compared to intact condition, respectively. The ROM in flexion was also decreased compared to that of intact for tested constructs but was not significant. As expected, in lateral bending and axial rotation, all the instrumented constructs exhibited comparable ROM to that of intact state.

![Graphical representation of L4-L5 mean ROM for different surgical constructs at 10 Nm without follower load.](image)

Figure 4-1: Graphical representation of L4-L5 mean ROM for different surgical constructs at 10 Nm without follower load.
Table 4.1: Percentage change in range of motion at L4-L5 for different surgical constructs compared to intact motion at 10 Nm without follower load

<table>
<thead>
<tr>
<th>L4-L5 Motion</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Ext</th>
<th>Flex</th>
<th>LB</th>
<th>RB</th>
<th>LR</th>
<th>RR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObS+ISS</td>
<td>-23.84</td>
<td>-13.81</td>
<td>-4.58</td>
<td>-4.76</td>
<td>-5.78</td>
<td>-1.73</td>
<td></td>
</tr>
<tr>
<td>DS+ISS</td>
<td>-24.03</td>
<td>-12.36</td>
<td>8.38</td>
<td>-0.03</td>
<td>-4.50</td>
<td>11.34</td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>-30.56</td>
<td>-13.34</td>
<td>4.51</td>
<td>1.57</td>
<td>-2.26</td>
<td>-4.20</td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>-26.35</td>
<td>-12.31</td>
<td>5.88</td>
<td>1.72</td>
<td>-0.01</td>
<td>-0.89</td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>25.80</td>
<td>27.37</td>
<td>14.58</td>
<td>12.72</td>
<td>24.38</td>
<td>17.53</td>
<td></td>
</tr>
</tbody>
</table>

Statistical analysis was conducted after removing outliers. Repeated measures one way ANOVA has been performed on range of motion data for all the test constructs including intact values obtained from Optotrak as described in the previous chapter and the resultant p-values are reported in Table 4.2. Statistical significance was determined at p<0.05. The p-values showed that there was statistically significant change only in extension for intact versus instrumented cases with SSL intact, dilated, 50% resected and 100% resected. No statistically significant changes for other loading modes in comparison to intact motion were observed. Also, the p-values established that there were no significant changes between the instrumented cases with SSL intact and with different grades of SSL transection (i.e. dilated, 50% resected and 100% resected).
A hybrid protocol was used for instrumented cases, in which the moments were applied until the motion achieved was same as that of intact. The hybrid moments are presented below in the Figure 4-2. Moments required to achieve the intact motion for various cases of instrumentation was higher in extension, as compared to other loading modes. Hybrid moment for flexion was slightly greater than that of intact. Moment required for the total SSL transection with no device (injury case) reduced, as expected.
Figure 4-2: Hybrid moments obtained for the instrumented specimens at L4-L5 for different surgical constructs without follower load

4.1.2 Range of Motion with 400 N Follower Load

A 400N compressive follower load was applied and the motion was evaluated only in cases of flexion and extension. Figure 4-3 shows mean motion and standard deviation for all the test constructs. From Table 4.3, it can be observed that the overall motion has reduced in case of extension to a great extent for the instrumented cases with SSL intact, dilated, 50% resected and 100% resected in comparison to intact. There was a slight decrease in flexion as well for the same test cases but not statistically significant.
Figure 4-3: L4-L5 mean ROM for different surgical constructs at 10 Nm with 400N follower load

Table 4.3: Percentage change in range of motion at L4-L5 for different surgical constructs compared to intact motion at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>L4-L5 Motion</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Ext</th>
<th>Flex</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObS+ISS</td>
<td>-53.79</td>
<td>-29.17</td>
<td></td>
</tr>
<tr>
<td>DS+ISS</td>
<td>-55.35</td>
<td>-25.94</td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>-56.67</td>
<td>-24.58</td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>-62.47</td>
<td>-15.74</td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>26.16</td>
<td>20.88</td>
<td></td>
</tr>
</tbody>
</table>
Table 4.4: p-values of repeated measures one way ANOVA of L4-L5 motion at 10 Nm with 400N follower load for six specimens. Statistically significant values (p<0.05) have been highlighted in bold.

<table>
<thead>
<tr>
<th></th>
<th>Ext</th>
<th>Flex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact Vs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ObS+ISS</td>
<td>0.035</td>
<td>0.687</td>
</tr>
<tr>
<td>DS+ISS</td>
<td>0.016</td>
<td>0.778</td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>0.044</td>
<td>0.972</td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>0.003</td>
<td>0.999</td>
</tr>
<tr>
<td>ObS+ISS Vs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DS+ISS</td>
<td>0.999</td>
<td>0.998</td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>0.985</td>
<td>0.999</td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>0.904</td>
<td>0.743</td>
</tr>
<tr>
<td>DS+ISS Vs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>0.999</td>
<td>0.999</td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>0.703</td>
<td>0.967</td>
</tr>
<tr>
<td>50%S+ISS Vs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>0.996</td>
<td>0.074</td>
</tr>
</tbody>
</table>

P-values reported showed that there was statistically significant change in extension for intact versus instrumented cases as described in the Table 4.4. The other loading modes did not have a significant effect on the range of motion in flexion, lateral bending and axial rotation in any of the test cases.

With the application of 400 N follower load, hybrid moment measured for extension was greater for all instrumented cases when compared to intact, which corresponds to decreased extension. Similarly, in flexion, slightly greater hybrid moments correspond to decreased motion. However, the decrease of motion in flexion was not statistically significant.
Figure 4-4: Hybrid moments obtained for the instrumented specimens at L4-L5 for different surgical constructs with 400N follower load

4.2 Finite Element Analysis

This section presents the results of the finite element studies discussed in the previous chapter. Angular displacements in three planes, intradiscal pressure, facet loads and peak stresses in the implant are presented. The range of motion results obtained using L4-L5 finite element (FE) model at the load of 10 Nm in extension, flexion, lateral bending and axial rotation, and also with a follower load of 400 N in extension and flexion are compared to the *in vitro* results. Using L3-S1 FE model, the same parameters are reported at load of 10 Nm with a follower load of 400 N and the hypotheses detailed in the first chapter were tested.
4.2.1 Finite Element Analysis using L4-L5 Model

The results obtained using L4-L5 FE models are presented below. The test constructs similar to that of in vitro study are examined. All the test cases were simulated except for dilation of SSL with ISS as it was not feasible in ABAQUS.

4.2.1.1 Range of Motion

The range of motion was reduced in extension for the instrumented cases with SSL intact, 50% transected and 100% transected, when compared to intact ROM by 64% for all the cases. However, there was no difference in ROM in extension comparing these instrumented cases. Also, flexion was increased following the placement of the implant for all the cases i.e. with and without SSL. Further increase in flexion was observed with the increasing degree of SSL instability [Table 4.5]. The other loading modes i.e. lateral bending and axial rotation were not affected by the implantation and also by resection of SSL.
Figure 4-5: L4-L5 range of motion for different surgical constructs at 10 Nm without follower load

Table 4.5: Percentage change in range of motion at L4-L5 for different surgical constructs compared to intact motion at 10 Nm without follower load

<table>
<thead>
<tr>
<th>L4-L5 Motion</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObS+ISS</td>
<td>13.30 / -64.45</td>
<td>0.04</td>
<td>-3.06</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>29.79 / -64.45</td>
<td>0.07</td>
<td>-2.28</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>36.59 / -64.45</td>
<td>0.07</td>
<td>-2.49</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>37.10 / -0.02</td>
<td>-0.61</td>
<td>1.36</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 4-6: L4-L5 range of motion for different surgical constructs at 10 Nm with 400N follower load

Table 4.6: Percentage change in range of motion at L4-L5 for different surgical constructs compared to intact motion at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>L4-L5 Motion</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Ext</th>
<th>Flex</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObS+ISS</td>
<td>-76.86</td>
<td>11.23</td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>-76.86</td>
<td>17.76</td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>-76.86</td>
<td>32.93</td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>44.40</td>
<td>35.04</td>
<td></td>
</tr>
</tbody>
</table>

With the application of 400N follower load, extension was greatly reduced by 77% in all the implanted cases with SSL intact, 50% transected and 100% transected when compared to intact. Flexion was increased with increasing degree of resection of SSL [Table 4.6].
4.2.1.2 Intradiscal Pressure (IDP)

IDP was reduced in extension for the implanted cases with SSL intact, 50% resected and 100% resected while it increased in flexion with the increasing degree of resection of SSL. The other loading modes were not affected. These observations were made for both cases of without and with application of preload (of 400N) [Table 4.7 and 4.8].

![IDP at L4-L5 (10Nm Bending Moment)](image)

Figure 4-7: L4-L5 Intradiscal pressure for different surgical constructs at 10 Nm without follower load

Table 4.7: Percentage change in intradiscal pressure at L4-L5 for different surgical constructs compared to intact IDP at 10 Nm without follower load

<table>
<thead>
<tr>
<th>IDP at L4-L5</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObS+ISS</td>
<td>13.71</td>
<td>-48.77</td>
<td>0.11</td>
<td>-2.00</td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>32.56</td>
<td>-48.77</td>
<td>0.14</td>
<td>-1.60</td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>40.05</td>
<td>-48.77</td>
<td>0.14</td>
<td>-1.79</td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>40.72</td>
<td>-0.14</td>
<td>-0.23</td>
<td>-0.44</td>
<td></td>
</tr>
</tbody>
</table>
Figure 4-8: L4-L5 Intradiscal pressure for different surgical constructs at 10 Nm with 400N follower load

Table 4.8: Percentage change in intradiscal pressure at L4-L5 for different surgical constructs compared to intact IDP at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>IDP at L4-L5</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Ext</th>
<th>Flex</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObS+ISS</td>
<td>-60.25</td>
<td>-15.25</td>
<td>-15.25</td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>-98.38</td>
<td>-12.63</td>
<td>-12.63</td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>-98.38</td>
<td>-11.54</td>
<td>-11.54</td>
</tr>
<tr>
<td>Injured</td>
<td>-95.56</td>
<td>7.37</td>
<td>7.37</td>
</tr>
</tbody>
</table>

4.2.1.3 Facet Loads

In extension, for the implanted cases, there were no loads acting on the facets for SSL intact, 50% resected and 100% resected. Also, the facet loads in injured case i.e, ISL and SSL transected with no device, were same as that of intact case. In flexion and lateral
bending, there was no effect of instrumentation and resection of SSL, on facet loads. In axial rotation, the facet loads were slightly decreased. Similarly, with the application of follower load (400N), the facets were completely unloaded in extension for all the cases of instrumentation.

Figure 4-9: L4-L5 Facet loads for different surgical constructs at 10 Nm without follower load

Table 4.9: Percentage change in facet loads at L4-L5 for different surgical constructs compared to intact facet loads at 10 Nm without follower load

<table>
<thead>
<tr>
<th>L4-L5</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Left Facets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ObS+ISS</td>
<td>-</td>
<td>-100</td>
<td>-0.47</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>-</td>
<td>-100</td>
<td>-0.95</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>-</td>
<td>-100</td>
<td>-0.98</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>-</td>
<td>-0.02</td>
<td>-1.88</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td><strong>Right Facets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ObS+ISS</td>
<td>-</td>
<td>-100</td>
<td>-5.75</td>
<td>-17.08</td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>-</td>
<td>-100</td>
<td>-13.53</td>
<td>-15.61</td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>-</td>
<td>-100</td>
<td>-14.17</td>
<td>-17.85</td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>-</td>
<td>-0.02</td>
<td>11.12</td>
<td>-2.47</td>
<td></td>
</tr>
</tbody>
</table>
4.2.2 Comparison of Range of Motion for *In vitro* and FE Studies

Figure 4-10 and Figure 4-11 show the comparison of range of motion for the six loading modes in flexion, extension, left and right lateral bending, left and right axial rotation for cases of without and with preload (400N) respectively. It can be observed that the motion results of the FE study are in the range of standard deviation of *in vitro* results for most of the cases. However, for some cases, the FE results were near the lower limit of the standard deviation of *in vitro* results. In case of extension, the FE results for the instrumented cases were significantly lower than that of *in vitro* results. This may be attributed to the stiffness of the FE model of the implant.

![Motion at L4-L5 (10 Nm Bending Moment)](image)

Figure 4-10: Comparison of motion for *in vitro* and FE studies at 10 Nm without follower load
4.2.3 Finite Element Analysis using L3-S1 Model

L3-S1 model was used to conduct the same study as discussed above (using L4-L5 model). This was performed in order to evaluate the effect of ISS with and without SSL on adjacent segments. The ranges of motion, IDP and facet loads are reported for implanted and adjacent segment levels.

4.2.3.1 Range of Motion

The range of motion at the implanted level L4-L5 was found to be significantly reduced in extension when compared to intact by \(\approx 86\%\) for all the cases with SSL intact, 50\% resected and 100\% resected. Flexion increased slightly with the degree of resection of SSL for implanted cases. The range of motion in lateral bending and axial rotation were not affected. The adjacent segment L3-L4 was not affected in all the loading modes.
However, for L5-S1 segment, a slight decrease in motion was observed in case of extension for all the instrumented test cases while the other loading modes were not affected.

Figure 4-12: L3-L4 motion for different surgical constructs at 10 Nm with 400N follower load

Table 4.10: Percentage change in range of motion at adjacent level L3-L4 for different surgical constructs compared to intact motion at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>L3-L4 Motion</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObS+ISS</td>
<td>0.25</td>
<td>9.93</td>
<td>0.62</td>
<td>1.06</td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>0.14</td>
<td>9.93</td>
<td>0.62</td>
<td>1.06</td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>-0.05</td>
<td>9.93</td>
<td>0.62</td>
<td>1.06</td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>-0.50</td>
<td>-0.10</td>
<td>0.04</td>
<td>0.00</td>
<td></td>
</tr>
</tbody>
</table>
Figure 4-13: L4-L5 motion for different surgical constructs at 10 Nm with 400N follower load

Table 4.11: Percentage change in range of motion at L4-L5 for different surgical constructs compared to intact motion at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>L4-L5 Motion</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObS+ISS</td>
<td>19.67</td>
<td>-72.72</td>
<td>-3.45</td>
<td>-6.02</td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>27.98</td>
<td>-72.72</td>
<td>-3.46</td>
<td>-1.53</td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>39.37</td>
<td>-72.72</td>
<td>-3.45</td>
<td>7.43</td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>39.72</td>
<td>-0.02</td>
<td>0.05</td>
<td>0.33</td>
<td></td>
</tr>
</tbody>
</table>
Figure 4-14: L5-S1 motion for different surgical constructs at 10 Nm with 400N follower load

Table 4.12: Percentage change in range of motion at adjacent level L5-S1 for different surgical constructs compared to intact motion at 10 Nm with 400N follower load.

<table>
<thead>
<tr>
<th>L5-S1 Motion</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObS+ISS</td>
<td>-3.50</td>
<td>-25.14</td>
<td>4.26</td>
<td>-6.18</td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>-1.44</td>
<td>-25.14</td>
<td>7.19</td>
<td>-6.95</td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>1.79</td>
<td>-25.14</td>
<td>8.38</td>
<td>-1.23</td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>7.59</td>
<td>-0.01</td>
<td>-0.03</td>
<td>-0.37</td>
<td></td>
</tr>
</tbody>
</table>

4.2.3.2 Intradiscal Pressure

There was a considerable decrease in intradiscal pressure in extension at L4-L5 level in comparison to intact by ~63% for all the instrumented cases i.e. with SSL intact and with partial and complete transection of SSL. IDP in flexion increased with progressive...
transection of SSL. The IDP at the adjacent segments L3-L4 and L5-S1 were not affected in any of the loading modes.

Figure 4-15: Intradiscal pressure at L3-L4 for different surgical constructs at 10Nm with 400N follower load

Table 4.13: Percentage change in IDP at adjacent level L3-L4 for different surgical constructs compared to intact IDP at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>IDP at L3-L4</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObS+ISS</td>
<td>0.92</td>
<td>4.25</td>
<td>-0.56</td>
<td>-0.23</td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>1.33</td>
<td>4.25</td>
<td>-0.63</td>
<td>-0.23</td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>1.96</td>
<td>4.25</td>
<td>-0.56</td>
<td>-0.23</td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>1.99</td>
<td>-0.58</td>
<td>-0.31</td>
<td>0.05</td>
<td></td>
</tr>
</tbody>
</table>
Figure 4-16: Intradiscal pressure at L4-L5 for different surgical constructs at 10Nm with 400N follower load

Table 4.14: Percentage change in IDP at index level L4-L5 for different surgical constructs compared to intact IDP at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>IDP at L4-L5</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObS+ISS</td>
<td>15.92</td>
<td></td>
<td>-62.61</td>
<td>-3.25</td>
<td>-2.13</td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>22.80</td>
<td></td>
<td>-62.61</td>
<td>-3.27</td>
<td>-2.13</td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>32.42</td>
<td></td>
<td>-62.61</td>
<td>-3.24</td>
<td>-2.13</td>
</tr>
<tr>
<td>Injured</td>
<td>32.63</td>
<td></td>
<td>-0.49</td>
<td>0.07</td>
<td>0.30</td>
</tr>
</tbody>
</table>
4.2.3.3 Facet Loads

The facet loads were not affected for the adjacent segment L3-L4 in all loading modes. At the implanted level, loads on the facets reduced significantly in extension when compared to the intact. There was a decrease in facet loads in axial rotation while there
was a slight decrease in lateral bending as well. At L5-S1, there was a slight increase in facet loads in extension while there was no change in other loading modes.

Figure 4-18: Facet loads at L3-L4 for different surgical constructs at 10Nm with 400N follower load

Table 4.16: Percentage change in facet loads at adjacent level L3-L4 for different surgical constructs compared to intact facet loads at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>L3-L4</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left</td>
<td>ObS+ISS</td>
<td>-</td>
<td>-1.74</td>
<td>2.20</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>50%S+ISS</td>
<td>-</td>
<td>-1.74</td>
<td>2.17</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>100%S+ISS</td>
<td>-</td>
<td>-1.74</td>
<td>2.20</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Injured</td>
<td>-</td>
<td>0.07</td>
<td>-0.02</td>
<td>-</td>
</tr>
<tr>
<td>Right</td>
<td>ObS+ISS</td>
<td>-</td>
<td>-1.74</td>
<td>12.67</td>
<td>0.22</td>
</tr>
<tr>
<td></td>
<td>50%S+ISS</td>
<td>-</td>
<td>-1.74</td>
<td>12.78</td>
<td>0.22</td>
</tr>
<tr>
<td></td>
<td>100%S+ISS</td>
<td>-</td>
<td>-1.74</td>
<td>12.66</td>
<td>0.22</td>
</tr>
<tr>
<td></td>
<td>Injured</td>
<td>-</td>
<td>0.07</td>
<td>0.14</td>
<td>0.03</td>
</tr>
</tbody>
</table>
Figure 4-19: Facet loads at L4-L5 for different surgical constructs at 10Nm with 400N follower load

Table 4.17: Percentage change in facet loads at index level L4-L5 for different surgical constructs compared to intact facet loads at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>L4-L5</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left Facets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ObS+ISS</td>
<td>-</td>
<td>-90.28</td>
<td>-46.36</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>-</td>
<td>-90.27</td>
<td>-46.45</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>-</td>
<td>-90.28</td>
<td>-46.43</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>-</td>
<td>0.19</td>
<td>-0.10</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Right Facets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ObS+ISS</td>
<td>-</td>
<td>-89.53</td>
<td>47.72</td>
<td>-55.39</td>
<td></td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>-</td>
<td>-89.53</td>
<td>46.63</td>
<td>-55.40</td>
<td></td>
</tr>
<tr>
<td>100%S+ISS</td>
<td>-</td>
<td>-89.53</td>
<td>47.43</td>
<td>-55.40</td>
<td></td>
</tr>
<tr>
<td>Injured</td>
<td>-</td>
<td>0.19</td>
<td>-0.16</td>
<td>-0.32</td>
<td></td>
</tr>
</tbody>
</table>
Figure 4-20: Facet loads at L5-S1 for different surgical constructs at 10Nm with 400N follower load

Table 4.18: Percentage change in facet loads at adjacent level L5-S1 for different surgical constructs compared to intact facet loads at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>L5-S1</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left</td>
<td>ObS+ISS</td>
<td>-</td>
<td>20.08</td>
<td>2.34</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>50%S+ISS</td>
<td>-</td>
<td>20.08</td>
<td>2.32</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>100%S+ISS</td>
<td>-</td>
<td>20.08</td>
<td>2.34</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Injured</td>
<td>-</td>
<td>0.06</td>
<td>-0.01</td>
<td>-</td>
</tr>
<tr>
<td>Right</td>
<td>ObS+ISS</td>
<td>-</td>
<td>21.04</td>
<td>-</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>50%S+ISS</td>
<td>-</td>
<td>21.04</td>
<td>-</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>100%S+ISS</td>
<td>-</td>
<td>21.04</td>
<td>-</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>Injured</td>
<td>-</td>
<td>0.06</td>
<td>-</td>
<td>0.08</td>
</tr>
</tbody>
</table>
4.2.3.4 Von Mises Stresses in SSL

The Von Mises Stress in SSL was found to be greater in flexion for the implanted case with SSL intact, when compared to intact case. This is because of increased flexion in implanted case due to transection of interspinous ligaments. As a result of which SSL is subjected to additional stress to limit flexion. The implanted case with 50% SSL transected experienced overall low stress as 50% of the SSL was resected.

![Figure 4-21: Von Mises Stress in SSL at L4-L5 level for different surgical constructs at 10Nm with 400N follower load](image)

Table 4.19: Percentage change in Von Mises Stress in SSL at index level L4-L5 for different surgical constructs compared to intact SSL stresses at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>Von Mises Stress in SSL (MPa)</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>L4-L5</td>
<td>ObS+ISS</td>
<td>7.75</td>
<td>-97.61</td>
<td>-25.69</td>
<td>-99.83</td>
</tr>
<tr>
<td>50%S+ISS</td>
<td>-31.49</td>
<td>-98.82</td>
<td>-65.71</td>
<td>-99.91</td>
<td></td>
</tr>
</tbody>
</table>
4.2.3.5 Von Mises Stresses in ISS

The peak Von Mises stresses in the implant were same for all the test cases i.e. with SSL intact, 50% resected and 100% resected in extension, lateral bending and axial rotation. However, a gradual decrease was observed in flexion with the degree of resection of SSL.

![Figure 4-22: Peak Von Mises Stress in ISS implanted at L4-L5 segment for different surgical constructs at 10Nm with 400N follower load](image)

Table 4.20: Peak Von Mises Stress in ISS for different surgical constructs at 10Nm with 400N follower load

<table>
<thead>
<tr>
<th>Peak Von Mises Stress in ISS (MPa)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObS + ISS</td>
<td>2.23E+03</td>
<td>2.45E+03</td>
<td>3.97E+03</td>
<td>4.11E+03</td>
</tr>
<tr>
<td>50%S + ISS</td>
<td>2.16E+03</td>
<td>2.45E+03</td>
<td>3.97E+03</td>
<td>4.11E+03</td>
</tr>
<tr>
<td>100%S + ISS</td>
<td>2.05E+03</td>
<td>2.45E+03</td>
<td>3.97E+03</td>
<td>4.11E+03</td>
</tr>
</tbody>
</table>
4.2.3.6 Stress Distribution Plots of ISS

The stress distribution plots of ISS are presented below for different test cases i.e. with SSL intact, 50% resected and 100% resected, in extension, flexion, lateral bending and axial rotation.

Figure 4-23: Stress plots of ISS placed in the lumbar spine at L4-L5, with SSL intact (ObS+ISS) (a) Extension (b) Flexion (c) Left Bending (d) Left Rotation
Figure 4-24: Stress plots of ISS placed in the lumbar spine at L4-L5, with 50% transection of SSL (50% +ISS). (a) Extension (b) Flexion (c) Left Bending (d) Left Rotation
Figure 4-25: Stress plots of ISS placed in the lumbar spine at L4-L5, with 100% transection of SSL (100%S +ISS). (a) Extension (b) Flexion (c) Left Bending (d) Left Rotation

The stress distribution plots demonstrate that in case of extension, the peak Von Mises Stress are seen at the interface of inferior border of L4 spinous process and the middle portion of the superior cam lobe of the implant. In flexion, maximum stresses were observed at the interface between implant and the superior border of L5 spinous process. In lateral bending and axial rotation, maximum stresses were observed at the superior
cam lobes of the implant as they intend to limit the rotation in frontal plane and transverse plane.

4.2.4 Finite Element Analysis using L3-S1 Model to Study the Effect of Graded Facetectomies on the Lumbar Spine Implanted with ISS

The range of motion, intradiscal pressure and facet loads are presented for different grades of facetectomy at the implanted level. These parameters are presented for adjacent levels as well. The different grades of facetectomy include 50%, 75%, and 100% with unilateral and bilateral comparison.

4.2.4.1 Range of Motion

Following the placement of ISS, extension significantly reduced for all cases with different grades of facetectomy for both unilateral and bilateral cases in comparison to intact motion. Flexion increased with the progressive graded facetectomies and the maximum increase was observed for 100% unilateral and bilateral facetectomies. Also, the total facetectomy showed a relative increase over the unilateral facetectomy which is obvious due to the increased instability. A slight increase in lateral bending and a slight decrease in axial rotation were observed for all the cases. However, these changes were insignificant. For the adjacent segment L3-L4, a very slight increase was observed in all six loading modes i.e. flexion, extension, lateral bending and axial rotation for different grades of facetectomies. Also, there was no difference between different cases of graded facetectomies. For L5-S1 adjacent segment, a slight decrease in extension was observed.
for all the cases when compared to intact while range of motion in other loading modes was same as that of intact.

Figure 4-26: Motion at the adjacent level L3-L4 for instrumented cases with different grades of facetectomies at 10 Nm and 400N Preload

Table 4.21: Percentage change in range of motion at adjacent level L3-L4 for different grades of facetectomies compared to intact motion at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>L3-L4 Motion</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>RB</th>
<th>LR</th>
<th>RR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>50% Unilateral Facetectomy+ISS</strong></td>
<td>3.90</td>
<td>11.38</td>
<td>12.71</td>
<td>12.77</td>
<td>21.42</td>
<td>22.26</td>
<td></td>
</tr>
<tr>
<td><strong>50% Bilateral Facetectomy+ISS</strong></td>
<td>4.03</td>
<td>8.42</td>
<td>12.75</td>
<td>12.75</td>
<td>22.80</td>
<td>22.80</td>
<td></td>
</tr>
<tr>
<td><strong>75% Unilateral Facetectomy+ISS</strong></td>
<td>3.91</td>
<td>11.46</td>
<td>12.69</td>
<td>12.76</td>
<td>21.42</td>
<td>22.26</td>
<td></td>
</tr>
<tr>
<td><strong>75% Bilateral Facetectomy+ISS</strong></td>
<td>4.04</td>
<td>11.65</td>
<td>12.75</td>
<td>12.75</td>
<td>22.85</td>
<td>22.85</td>
<td></td>
</tr>
<tr>
<td><strong>Total Unilateral Facetectomy+ISS</strong></td>
<td>9.56</td>
<td>11.66</td>
<td>12.68</td>
<td>12.75</td>
<td>21.73</td>
<td>22.95</td>
<td></td>
</tr>
<tr>
<td><strong>Total Bilateral Facetectomy+ISS</strong></td>
<td>11.63</td>
<td>12.06</td>
<td>12.78</td>
<td>12.78</td>
<td>22.99</td>
<td>22.99</td>
<td></td>
</tr>
</tbody>
</table>
Figure 4-27: Motion at instrumented level L4-L5 for different grades of facetectomies compared to intact motion at 10 Nm with 400N follower load

Table 4.22: Percentage change in range of motion at implanted level L4-L5 for different grades of facetectomies compared to intact motion at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>L4-L5 Motion</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>RB</th>
<th>LR</th>
<th>RR</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% Unilateral Facetectomy+ISS</td>
<td>29.08 / -73.91</td>
<td>14.09</td>
<td>-17.42</td>
<td>-16.97</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50% Bilateral Facetectomy+ISS</td>
<td>32.03 / -63.26</td>
<td>13.70</td>
<td>13.70</td>
<td>-16.32</td>
<td>-16.32</td>
<td></td>
<td></td>
</tr>
<tr>
<td>75% Unilateral Facetectomy+ISS</td>
<td>29.85 / -73.89</td>
<td>14.76</td>
<td>12.46</td>
<td>-16.97</td>
<td>-16.21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Unilateral Facetectomy+ISS</td>
<td>47.17 / -73.82</td>
<td>16.42</td>
<td>12.69</td>
<td>-16.87</td>
<td>-10.59</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Bilateral Facetectomy+ISS</td>
<td>51.27 / -73.59</td>
<td>16.02</td>
<td>16.02</td>
<td>-10.58</td>
<td>-10.58</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 4-28: Motion at the adjacent level L5-S1 for instrumented cases with different grades of facetectomies at 10 Nm and 400N Preload

Table 4.23: Percentage change in range of motion at adjacent level L5-S1 for different grades of facetectomies compared to intact motion at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>L5-S1 Motion</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>RB</th>
<th>LR</th>
<th>RR</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% Unilateral Facetectomy+ISS</td>
<td>1.27</td>
<td>-22.32</td>
<td>-6.30</td>
<td>-6.12</td>
<td>9.11</td>
<td>9.11</td>
<td></td>
</tr>
<tr>
<td>50% Bilateral Facetectomy+ISS</td>
<td>0.97</td>
<td>-13.26</td>
<td>-6.05</td>
<td>-6.05</td>
<td>5.63</td>
<td>5.63</td>
<td></td>
</tr>
<tr>
<td>75% Unilateral Facetectomy+ISS</td>
<td>1.22</td>
<td>-22.38</td>
<td>-6.71</td>
<td>-6.13</td>
<td>9.11</td>
<td>9.11</td>
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</tr>
<tr>
<td>75% Bilateral Facetectomy+ISS</td>
<td>0.85</td>
<td>-22.58</td>
<td>-6.65</td>
<td>-6.65</td>
<td>5.54</td>
<td>5.54</td>
<td></td>
</tr>
<tr>
<td>Total Unilateral Facetectomy+ISS</td>
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<td>-22.71</td>
<td>-6.84</td>
<td>-6.16</td>
<td>4.63</td>
<td>5.51</td>
<td></td>
</tr>
<tr>
<td>Total Bilateral Facetectomy+ISS</td>
<td>8.08</td>
<td>-23.31</td>
<td>-6.88</td>
<td>-6.88</td>
<td>3.83</td>
<td>3.83</td>
<td></td>
</tr>
</tbody>
</table>
4.2.4.2 Intradiscal Pressure

Figure 4-30 shows that at instrumented level, IDP values in flexion increased with progressive grades of facetectomy with the maximum value for 100% unilateral and bilateral facetectomy. In extension, it reduced significantly for all the cases, with no significant difference found between different grades of facetectomy. In lateral bending and axial rotation, there was a slight increase at the implanted level for all the cases and again there was no difference between different grades of facetectomy. At the adjacent segment L3-L4, there was an increase in IDP in all loading modes. However, in flexion the increase was seen to be maximum for 100% unilateral and bilateral facetectomies while there was no significant difference for other loading modes comparing different grades of facetectomy. At the adjacent segment L5-S1, same observations were made with one exception that there was no change in the IDP in extension for all the cases.

Figure 4-29: IDP at the adjacent level L3-L4 for instrumented cases with different grades of facetectomies at 10 Nm and 400N Preload
Table 4.24: Percentage change in IDP at adjacent level L3-L4 for different grades of facetectomies compared to intact IDP at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>IDP at L3-L4</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>RB</th>
<th>LR</th>
<th>RR</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% Unilateral Facetectomy+ISS</td>
<td>16.73</td>
<td>10.25</td>
<td>30.07</td>
<td>30.08</td>
<td>27.50</td>
<td>27.50</td>
<td></td>
</tr>
<tr>
<td>50% Bilateral Facetectomy+ISS</td>
<td>16.98</td>
<td>10.25</td>
<td>30.15</td>
<td>30.15</td>
<td>27.50</td>
<td>27.50</td>
<td></td>
</tr>
<tr>
<td>75% Unilateral Facetectomy+ISS</td>
<td>16.79</td>
<td>10.33</td>
<td>30.16</td>
<td>30.10</td>
<td>27.50</td>
<td>27.50</td>
<td></td>
</tr>
<tr>
<td>75% Bilateral Facetectomy+ISS</td>
<td>17.08</td>
<td>10.37</td>
<td>30.19</td>
<td>30.19</td>
<td>27.55</td>
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<tr>
<td>Total Unilateral Facetectomy+ISS</td>
<td>45.50</td>
<td>10.45</td>
<td>30.25</td>
<td>30.10</td>
<td>26.74</td>
<td>27.43</td>
<td></td>
</tr>
<tr>
<td>Total Bilateral Facetectomy+ISS</td>
<td>45.50</td>
<td>10.57</td>
<td>30.26</td>
<td>30.26</td>
<td>27.45</td>
<td>27.45</td>
<td></td>
</tr>
</tbody>
</table>

Figure 4-30: IDP at the instrumented level L4-L5 with different grades of facetectomies at 10 Nm and 400N Preload
Table 4.25: Percentage change in IDP at implanted level L4-L5 for different grades of facetectomies compared to intact IDP at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>IDP at L4-L5</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>RB</th>
<th>LR</th>
<th>RR</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% Unilateral Facetectomy+ISS</td>
<td>35.30 / -57.75</td>
<td>33.42</td>
<td>31.63</td>
<td>19.20</td>
<td>19.20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50% Bilateral Facetectomy+ISS</td>
<td>37.31 / -41.73</td>
<td>33.41</td>
<td>33.41</td>
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<tr>
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<td>35.88 / -56.93</td>
<td>34.02</td>
<td>31.73</td>
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<td>38.51 / -55.68</td>
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<tr>
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Figure 4-31: IDP at the adjacent level L5-S1 for instrumented cases with different grades of facetectomies at 10 Nm and 400N Preload
Table 4.26: Percentage change in IDP at adjacent level L5-S1 for different grades of facetectomies compared to intact IDP at 10 Nm with 400N follower load

<table>
<thead>
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<th>IDP at L5-S1</th>
<th>Percentage increase (+) / decrease (-)</th>
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<th>Ext</th>
<th>LB</th>
<th>RB</th>
<th>LR</th>
<th>RR</th>
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<tbody>
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<td>-0.09</td>
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<td>21.72</td>
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<tr>
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<td>-0.05</td>
<td>11.10</td>
<td>11.57</td>
<td>21.72</td>
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</tr>
<tr>
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<td>-0.10</td>
<td>11.07</td>
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<td>21.65</td>
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<tr>
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<td>11.56</td>
<td>20.88</td>
<td>22.57</td>
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</tr>
<tr>
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<td>10.85</td>
<td>21.86</td>
<td>21.86</td>
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4.2.4.3 Facet Loads

The facet loads at the instrumented level significantly decreased with the progressive facetectomies. These minimal loads in comparison to intact demonstrate that the facets were unloaded to a great extent. Also, a decrease in facet loads was seen in lateral bending and axial rotation. At the adjacent segment L3-L4, there was a slight increase in lateral bending and axial rotation. However, there was no difference for different grades of facetectomy. At L5-S1, there was an increase in extension, lateral bending and axial rotation with no significant differences between different grades of facetectomy.
Figure 4-32: Facet loads at the adjacent level L3-L4 for instrumented cases with different grades of facetectomies at 10 Nm and 400N Preload
Table 4.27: Percentage change in facet loads at adjacent level L3-L4 for different grades of facetectomies compared to intact facet loads at 10 Nm with 400N follower load

<table>
<thead>
<tr>
<th>L3-L4</th>
<th>Percentage increase (+) / decrease (-)</th>
<th>Flex</th>
<th>Ext</th>
<th>LB</th>
<th>RB</th>
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<th>RR</th>
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<tbody>
<tr>
<td></td>
<td>50% Unilateral Facetectomy+ISS</td>
<td>-0.77</td>
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<td>5.31</td>
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<td>8.54</td>
<td>8.08</td>
<td>5.31</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Right</td>
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<td>8.49</td>
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<td>Total Bilateral Facetectomy+ISS</td>
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<td>6.99</td>
<td>5.45</td>
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Figure 4-33: Facet loads at the instrumented level L5-S1 for instrumented cases with different grades of facetectomies at 10 Nm and 400N Preload
Table 4.28: Percentage change in facet loads at implanted level L4-L5 for different grades of facetectomies compared to intact facet loads at 10 Nm with 400N follower load

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<th>Ext</th>
<th>LB</th>
<th>RB</th>
<th>LR</th>
<th>RR</th>
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<td>-60.96</td>
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<td>-55.70</td>
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<tr>
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<td>-91.71</td>
<td>-49.49</td>
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<td>-56.51</td>
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<td>75% Unilateral Facetectomy+ISS</td>
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<td>-</td>
<td>-</td>
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<td>-</td>
</tr>
<tr>
<td></td>
<td>Total Bilateral Facetectomy+ISS</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</tr>
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Figure 4-34: Facet loads at the adjacent level L5-S1 for instrumented cases with different grades of facetectomies at 10 Nm and 400N Preload
Table 4.29: Percentage change in facet loads at adjacent level L5-S1 for different grades of facetectomies compared to intact facet loads at 10 Nm with 400N follower load

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<th>LB</th>
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Chapter 5

Discussion

This chapter will discuss the results of the in vitro and finite element studies presented in the previous chapter compare it with the previous studies in the literature and draw conclusions. Study limitations and scope of future work will also be discussed.

5.1 In vitro Study

Degenerative lumbar spinal stenosis has been treated by various different surgical techniques. Decompressive surgery is the most commonly used therapy. The clinical success of this therapy reported in the literature varies from moderate to excellent results [50-52]. One of the drawbacks associated with decompression surgery is the creation of instability as a consequence of the degeneration of the disc, facets or a combination of both [53]. Therefore different methods of stabilization have been developed one of which is rigid stabilization systems with pedicle screw fixation [54]. However, it has been acknowledged that the rigid systems increase the loads acting on the adjacent segments, which may lead to accelerated degeneration. In order to prevent such overloading, dynamic stabilization systems have been established [35].

Interspinous implants have been used as one of the motion-preserving stabilization systems for the treatment of primarily posterior lumbar spinal pathologies such as spinal
stenosis or facet joint arthritis [55]. The goals of this device are to unload the facet joints, to restore foraminal height and to provide increased stability mainly in extension while the range of motion is unaffected in other loading modes, at the treated segment. The advantages of interspinous decompression technology are as follows: the surgery can be performed much faster, with less blood loss, less risk to the nerve roots and anterior vasculature and without the need for fluoroscopic guidance [56]; there is no need of pedicle instrumentation which involves osseous procedures to insert pedicle screws; less immobilization post surgery and faster recovery period. However, this technology is still in an early stage of development and the indications are not yet clearly defined because scientific evidence is lacking [7, 57].

In the present study, the biomechanical efficacy of an investigational device Superion Interspinous Spacer (ISS) (Vertiflex®, San Clemente, CA) has been evaluated. The results of the study showed that the device as expected provided stability in extension while maintaining normal range of motion in other loading modes. Although the results demonstrated a minimal decrease in flexion, it was not significant. These results are in agreement with the previous biomechanical studies conducted on different lumbar interspinous spacers. Wilke et al. [39] conducted an in vitro study to assess the biomechanical effect of four different interspinous implants namely Coflex, Wallis, Diam and X-Stop, on flexibility of the lumbar spine implanted with these devices. At the index level, all these devices showed a significant reduction of ROM in extension and an increase in flexion with Coflex, Diam and X-Stop, similar to ISS. This was predicted due to the transection of interspinous and supraspinous ligaments in case of Coflex and interspinous ligaments transected in case of Diam and X-Stop. The Wallis implant
restabilized the specimens to the value of intact specimens in flexion as well. However, all these devices intended to reduce ROM in extension while maintaining normal ROM in other loading modes.

While placing the device in the interspinous space, the adjacent spinous processes are distracted to accommodate the device. This may result in producing slightly kyphotic deformation of the specimens. In the present study, the decrease of mean ROM in flexion following the placement of ISS may be attributed to the kyphosis induced post-implantation. In the same study by Wilke et al [39], they observed that the segmental tilt became different between the four implant groups. While implantation of the Diam caused an increasing kyphosis, implantation of the Wallis or X-Stop or Coflex had almost no effect on the kyphosis caused by the defect. In the present study, due to limitations of the facilities at our lab the kyphosis induced in the specimens tested was not evaluated. However, visual observation showed that the device induced kyphosis. The decrease in ROM in flexion can also be due to the firm gripping of the ISS with that of spinous processes, which may prevent it from flexible movement during flexion. The results of ROM in flexion are in agreement with that of an in vitro investigation conducted by Fuchs et al on X-STOP. They showed that X-STOP resulted in significant decrease in ROM both in flexion and extension. As mentioned earlier, for the present study even though there was an overall decrease in the mean ROM in flexion, no statistical significant difference was observed in comparison to intact ROM in flexion (p>0.05). The differences in the results could be attributed to the design specifications of these two devices.
The ROM in extension without and with the application of follower load of 400N showed that there was a significant decrease in ROM in extension (54%) with follower load in comparison to intact while the decrease was only 24% when the follower load was not applied. Similarly, the decrease in ROM in flexion with follower load was 29% and without follower load was 14% when compared to intact ROM with and without preload respectively. This infers that there may be an effect of muscles on the kinematics of the spinal motion segments which suggests the use of follower load in order to simulate the physiological \textit{in vivo} conditions to obtain accurate results. Hartmann et al. [58] conducted an \textit{in vitro} biomechanical evaluation on the change in the range of motion of the affected and adjacent segments following implantation of different interspinous devices: Aperius, In-Space, X-Stop and Coflex. This study focused on evaluating the effect of follower load on range of motion of the lumbar spine implanted with these devices. All interspinous devices caused a significant reduction in extension of the instrumented segment without significantly affecting the other directions of motion with and without application of follower load with the exception that flexion was reduced by all implants only when the follower load was applied. All devices caused a higher ROM of the entire spine during lateral bending and rotation. This infers that there can be an increase in ROM at the adjacent segments in spite of maintaining normal range of motion at the instrumented level. Some authors suggest that the higher mobility of adjacent segments may be associated with an increased risk of adjacent segment degeneration as seen in the adjacent segments of fused segment.

The measured bending moments required to achieve the same range of motion as the intact spine (hybrid moments) significantly increased in case of extension. As expected,
there was a rapid reduction in the moment required for the injured (ISL and SSL transected and without ISS) segment to reach the same range of motion as that of the intact. However, it is to be noted that the significance of applying hybrid moments is to study the effect of implanted device on the adjacent segments as described by Panjabi et al [47]. In the present study, since the specimens used were only single motion segments, the hybrid moments do not add value to the results.

5.1.1 The Effect of Transection of Supraspinous Ligament on the Biomechanical Efficacy of the Superion Interspinous Spacer

The surgical procedure involved in the placement of interspinous spacer requires the transection of interspinous ligaments to create space between the adjacent spinous processes for its proper positioning. For some of the interspinous spacers, the supraspinous ligaments (SSL) may be transected as well. As the SSL is a strong stabilizing structure in flexion, there is a potential for an increased flexion. For the present device, during the surgical procedure, a posterior incision is made to access the interspinous space through dilation of the supraspinous ligaments followed by the transection of the interspinous ligaments. However, there is a potential risk that SSL may be resected accidentally due to its very small size. To accommodate such scenarios and the possible compromise in the stability due to the removal of SSL, the effect of transection of SSL on the lumbar spine implanted with ISS was investigated in the present study.

The ROM obtained for the implanted cases with SSL intact, dilated, 50% resected and 100% resected showed that there was no statistically significant difference in any of the
loading modes. The hybrid moments for the implanted specimens with SSL intact, dilated, partial and complete transection were the highest in extension, than in other loading modes. Overall, the results implied that the motion at the implanted level had decreased in extension, irrespective of the SSL integrity. The data suggests that the SSL plays an insignificant role in segmental stability in all loading modes. Furthermore, partial or complete transection or dilation of the SSL does not affect the stabilizing ability of the ISS.

5.2 Finite Element Studies

The in vitro study provided kinematic results that are comparable to the physiological in vivo conditions. The devices placed in the human cadaver spine, can give a clear understanding of how these devices affect the motion of the spine segment. However, ROM studies themselves may fail to predict the effects of the motion segment on the components of the ISS, such as stresses seen in the implant within a certain range of the segmental motion. Also it is difficult to accurately quantify facet loading and intradiscal pressure using in vitro studies due to measurement errors and lack of repeatable techniques. For these reasons, a validated finite element (FE) model can be a very useful tool in studying not only the motion of the spine, but the effects on the implants and spinal structures-implant junctions.

In the present study, a finite element analysis has been performed using experimentally validated 3D L3-S1 and L4-L5 FE models simulating the test constructs same as that of in vitro study. However, the kyphotic deformation of the specimens observed in in vitro testing scenario has not been simulated in FE analysis. The range of motion results of the
FE analysis are in agreement with that of *in vitro* study in extension, lateral bending and axial rotation except for flexion. Unlike *in vitro* results, there was an increase in ROM in flexion in case of FE results. This may be due to the transection of interspinous ligaments for the placement of the device. There were no significant changes in ROM at adjacent segments in any of the loading modes. In a finite element study performed by Bellini et al, it was shown that ROM decreased at instrumented level by 17% in flexion, 43% in extension following the placement of DIAM interspinous spacer whereas in the present study, it showed a decrease in extension by 64% and an increase in flexion by 13%. Also, there were no significant changes in ROM at the adjacent segments with DIAM as observed with ISS.

The intradiscal pressure measured at the implanted level decreased in extension due to the unloading of the disc while it increased slightly in flexion. In an *in vitro* study by Wilke et al [39], all the four implant groups showed a strong reduction in IDP in extension while in all other loading directions i.e. flexion, lateral bending and axial rotation, none of the implants caused a significant change in the IDP. Swanson et al [59], in an *in vitro* investigation also showed that there was a significant decrease in IDP following the placement of X-STOP interspinous spacer in neutral and extended positions. The facet loads decreased significantly in extension unloading the facets to a great extent. The facet loads in other loading modes were not affected. Both IDP and facet loads at the adjacent segments were not affected in any of the loading modes.

Also, the high implant stresses in extension showed that the device was successful in limiting extension to a great extent. The superior and inferior cam lobes of the device

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were designed in such a way that they conform to the anatomical surface of the spinous processes which helps in resisting lateral bending and axial rotation such that the normal range of motion is preserved in these planes. In flexion, the implant stresses were not significant indicating that the device does not play a major role in providing stability in flexion. Also, it is to be noted that the magnitude of peak stresses in the implant were higher than that of yield point of titanium and this may be attributed to the tie constraints defined in the FE model.

Similar results were observed by Lafage et al, who conducted a combined in vitro and finite element analysis to assess the biomechanical effect of Wallis implant on the lumbar spine. They concluded that the effect of interspinous implant appears only in flexion-extension. In this load case, experimental results showed a reduced ROM while FEM analysis indicated decrease of disc stresses and increase of loads transmitted through the spinous processes [43].

It may thus be concluded from the FE results of this study that this novel ISS device provided increased stability mainly in extension at the treated segment.

5.2.1 The Effect of Transection of Supraspinous Ligament on the Biomechanical Efficacy of the Superion Interspinous Spacer

Using the same validated L3-S1 and L4-L5 FE models, the effect of transection of SSL on the lumbar spine implanted with ISS has been studied. The FE results are in agreement with that of in vitro study in all ranges of motion except for flexion. In the FE analysis, an increase in ROM in flexion was observed with increase in degree of resection of SSL. As
discussed above, transection of SSL decreases the ability to limit flexion as it is one of the strong stabilizing structures during flexion. Thus, FE results showed that there was no significant effect of transection of SSL in extension, lateral bending and axial rotation but there was a slight increase in flexion with progressive transection of SSL. Also, the motion at the adjacent segments was not affected in any of the loading modes.

The intradiscal pressure at the instrumented level increased slightly with the progressive resection of SSL in flexion. With the increase in resection of SSL, the loads on the intervertebral disc increase proportionately leading to increase in IDP in flexion. The IDP did not change in other loading modes with SSL intact, partial or completely resected. Also, IDP was not affected at the adjacent segments in any of the loading modes. The facet loads were not affected for any of the loading modes for SSL intact, 50% resected and 100% resected.

5.2.2 The Effect of Graded Facetectomies on the Lumbar Spine Implanted with Superion Interspinous Spacer

In degenerative lumbar spinal canal stenosis, the nerve roots are compressed mainly in the lateral part of the spinal canal. Medial facetectomy, unroofing of the lateral recess, is commonly performed for decompression of the nerve root. Furthermore, total facetectomy is sometimes performed for the excision of the intraforaminal herniated disc, spinal tumor at the posterior parts, etc. In patients with severe stenosis at multilevel, decompressive surgeries such as different grades of facetectomies in combination with posterior stabilization systems such as Interspinous Spacers may alleviate the symptoms related to LBP and provide increased stability. In this study, this device was evaluated for
different grades of facetectomies including 50%, 75% and 100% for both unilateral and bilateral cases. However, it is to be noted that the use of this device is not indicated with concomitant lumbar surgery according to the developers of the device. It is clinically indicated for mild to moderate cases of spinal stenosis and used as a stand-alone device.

From the FE analysis of L3-S1 model, the kinematic parameters showed that at the instrumented level, there is a significant change in flexion while there was no effect in other loading modes for different grades of facetectomies with both unilateral and bilateral facetectomies. Flexion increased with progressive grades of facetectomies for both unilateral and bilateral cases. Extension ROM reduced for all the implanted cases with different grades of facetectomies but there was no significant change within the implanted groups due to varying degree of facetectomy for both unilateral and bilateral cases. There was also no significant change in lateral bending and axial rotation.

It has been acknowledged in the literature that the intervertebral facet joint has an important role in stabilizing lumbar spinal motion segment especially in axial rotation. In an in vitro study by Abumi et al. it has been shown that ROM in flexion increased following unilateral medial facetectomy and an increased ROM in axial rotation after bilateral total facetectomy. Also, extension and lateral bending were not affected even by bilateral total facetectomies [60]. In a cadaver study conducted by Fuchs et al. on the effect of graded facetectomies on lumbar spine implanted with X-STOP, they found that a bilateral total facetectomy caused a significant increase in range of motion during flexion and axial rotation but not extension and lateral bending. The unilateral medial facetectomy and unilateral total facetectomy did not affect the range of motion during
any of the six loading modes [61]. The results of the present study are not completely in agreement with these results. The range of motion was not affected by 50%, 75% and total facetectomies for both unilateral and bilateral cases in extension, lateral bending, and axial rotation except in flexion. ROM in flexion increased with increasing degree of facetectomies for both unilateral and bilateral cases. It is very interesting to know that axial rotation was not affected even by the total facetectomy. This may be attributed to the design of ISS with the superior cam lobes highly resisting excessive axial rotation that is produced with the bilateral total facetectomies. In spite of this, ISS may not be used in combination with different graded facetectomies for both unilateral and bilateral cases due to an increased ROM in flexion. However, it is worth noting that FE analysis validated with in vitro studies can be best used to draw such conclusions.

5.3 Conclusion

ISS provided increased biomechanical stability in extension while allowing normal range of motion in flexion, lateral bending and axial rotation. Unlike in vitro results, FE results showed that there was a nominal increase in ROM in flexion post-implantation. From these results, it can be concluded that ISS can be used as a viable treatment option in patients with mild to moderate spinal stenosis as it provides a great relief in extension. There was no effect of transection of SSL in extension, flexion, lateral bending and axial rotation. Unlike in vitro results, FE results showed that progressive transection of SSL resulted in increased ROM in flexion to a small extent. Thus partial or complete transection of SSL does not alter the biomechanics of the spine implanted with ISS. This reduces the effort of surgeon to be very cautious to make sure that SSL is intact. With the
increasing grades of facetectomies i.e. 50%, 75% and 100% facetectomies for both unilateral and bilateral cases, there was progressive increase in ROM in flexion. Thus, ISS may not be used in combination with different graded facetectomies (50%, 75% and 100%) for both unilateral and bilateral cases. Also, total facetectomy may expose the nerve such that it may come into direct contact with the device leading to nerve compression/irritation causing pain.

5.4 Study Limitations

For the in vitro testing, L2-L3 and L4-L5 motion segment specimens were used. Traditionally, motion segments are used for evaluating the biomechanics of the spine as it is the smallest unit representing the general mechanical behavior in a given region of the spine. However, the effect of the device and/or surgery on the adjacent segments cannot be studied with the use of single motion segments.

The cadaver spinal segments have been frozen and thawed, possibly disturbing some tissue. Also, they do not have the surrounding musculature as in vivo which may affect the motion characteristics when compared to how the devices would perform in the body. Also, the size and bone mineral density of each specimen vary according to age and may also affect the data presented here. Hence the results of this biomechanical study are not directly applicable to the clinical setting, which is where these devices will ultimately be used. With regards to finite element analysis, the process inherently has limitations since the method is an approximation. While these analyses with proper knowledge, and highly advanced technical methods can produce results close to the in vivo scenario, but still they are approximations.
Since, this device is currently under clinical trials, the clinical relevance of the data presented in this study is warranted and requires further investigation.

5.5 Future Work

The amount of kyphosis induced in the motion segment post-implantation with ISS needs to be evaluated. At present, Superion ISS is being used clinically at bi-level adjacent segments for mild to moderate spinal stenosis. It will be interesting to see the effect of ISS’s on the sandwiched spinous process in terms of shear forces acting on it. This study is important as tremendous forces acting on the spinous process due to both the devices may lead to its fracture.
References


Appendix A

Functional Anatomy of Spine

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

The top seven vertebrae starting from the neck comprises cervical spine and are labeled C1-C7. C1 is called atlas and C2 is called axis. Thoracic spine consists 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.

The bony vertebrae are separated by flexible intervertebral discs in each of these regions of the spine. Any two adjacent vertebrae with the intervertebral disc and the associated ligaments is called a motion segment or a functional spinal unit. It represents general mechanical behavior of the entire spine. 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 extent the shape of the vertebrae.
Figure A-1: Vertebral column (Source: http://www.spine1.com/)

Figure A-2: Functional spinal unit of lumbar spine
(Source: www.spineuniverse.com)
Vertebral body

A vertebra consists of an anterior block of bone, the vertebral body, and a posterior bony ring known as the neural arch, containing articular transverse and spinous processes [62]. The vertebral body consists of cancellous core contained in a thin shell of cortical bone. The superior and inferior surfaces of the cortical bone are called as the endplates. The posterior bony ring also called as the neural arch consists of two pedicles and two laminae from which seven processes arise. The vertebral bodies carry the major share of load in most physiological conditions. This load is transmitted through the endplate of the vertebra to the intervertebral disc.

Intervertebral disc

Intervertebral disc constitutes 20-33% of the entire height of the spinal column. It is soft, gel like structure between the vertebral bodies and 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 fibers oriented in different directions providing flexibility to the spine. These fibers transfer the compression, bending, shear forces and torsion between the vertebrae [62]. It was studied that an intervertebral disc can carry as much as 3 times the weight of the trunk in sitting position. 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 and 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 and inferior endplates and annulus fibrosis which encloses the nucleus. Endplate is made of hyaline cartilage and separates intervertebral
disc from the vertebrae. The biochemical framework and distribution system of these plates helps the diffusion of nutrients between the vertebra and the disc.

**Ligaments**

There are seven major ligaments in the spine: anterior longitudinal, posterior longitudinal, capsular, ligamentum flavum, supraspinous, interspinous and intertransverse ligaments. They allow adequate physiological motion between the vertebrae while limiting the excessive motion [62]. 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 anterior surface of the spinal canal. It plays an important role in limiting flexion. Supraspinous ligament runs along the posterior edge of the spinous process and provides stability in flexion. 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. The intertransverse ligament attaches to neighboring transverse processes and restricts motion in bending and axial rotation. The capsular ligaments surround the facet joint and are oriented perpendicular to the facet surface to provide stability in flexion.
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 the one 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 provides smooth movement. Orientation of the facets varies between cervical, thoracic and lumbar regions. Facet joints play a major role in stabilizing the spine and are also major source of pain. They allow small degrees of flexion and extension and majorly limit axial rotation and thus ultimately protect the intervertebral disc from translational shear stresses. They carry a part of the compressive loads (up to 33%) along with the vertebral body and provide 45% of the torsional strength for the functional spinal unit [62].