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A Thesis

titled

Biomechanical Comparison of Various Posterior Dynamic Stabilization Systems for Different Grades of Facetectomy and Decompression Surgery

by

Rachit Parikh

Submitted to the Graduate Faculty as partial fulfillment of the requirements for the Master of Science Degree in Bioengineering

Dr. Vijay Goel, Committee Chair

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The University of Toledo

December 2010
An Abstract of

Biomechanical Comparison of Various Posterior Dynamic Stabilization Systems for Different Grades of Facetectomy and Decompression Surgery

by

Rachit Parikh

Submitted as partial fulfillment of the requirements for the Master of Science Degree in Engineering

The University of Toledo

December 2010

Spinal stenosis is a degenerative process, caused by progressive narrowing of the lumbar spinal canal and neural foramen, leading to a constriction of the nerve roots of the cauda equina. Currently, facetectomy and laminectomy combined with fusion are the standard methods of decompression for the degenerative lumbar spinal stenosis with resultant alteration in established inter-relationships between various vertebral column components. However due to myriad of degenerative complications at the fused level and adjacent level degeneration, numerous new posterior dynamic stabilization systems have been developed. The objective of this biomechanical study was to investigate the influence of different grades of factectomy, spinal decompression and laminectomy procedures in conjunction with various dynamic stabilization implants viz. Dynesys, In-Space spacer and Stabilimax. A validated, 3-D, nonlinear finite element model of the intact L3-S1 lumbar spine was used to evaluate the biomechanics of these devices. The load control protocol was used to evaluate these devices. Various biomechanically relevant parameters like range of motion, facet loading, disc stresses were evaluated. An
in vitro study was also performed comparing Dynesys with novel PEEK Rod dynamic stabilization system for decompression surgery with discectomy.

The finite element results showed that the Dynesys and Stabilimax systems were capable of stabilizing the decompression surgery in flexion, extension and lateral bending. The In-Space spacer effectively reduced motion in extension and did not interfere with motion in other loading modes at the implanted level. All the systems were capable of loading through the intervertebral disc. Results also showed that after complete facetectomy the systems did not restore stability in axial rotation.

Further a cadaveric study was to done to compare the Dynesys stabilization system with that of a novel PEEK rod pedicle screw stabilization system after simulating decompression surgery. The biomechanical comparison of monosegmental fixation on L4-L5 and bi-segmental fixation of L3-L5 as topping off procedure with fusion were done for this study. The predicted range of motion for the PEEK rod stabilization system was consistent with the Dynesys for monosegmental fixation.
To my parents, and friends, who have been ever supportive of me, guiding and encouraging me through my endeavors.
Acknowledgments

This thesis is an outcome of two years of research, hard work and perseverance. It has been an excellent learning experience that also inculcated a sense of responsibility and discipline in me.

I would like to express my profound gratitude to Dr Vijay K Goel, who has been a wonderful teacher, guide, and philosopher for the last two years. I am deeply indebted to him for his support and I will always consider him a part of the foundation of my future success. I would also like to thank my committee members for offering learning and research assistance throughout this process.

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Chapter 1

Introduction

1.1 Overview

Low back pain and the evolution of surgical techniques for its treatment will be discussed in this chapter. The advantages of non-fusion systems over the conventional fusion will be discussed. Also the need and the scope of the study will be addressed.

1.2 Introduction

The functions of the spine are to provide flexibility, support the upper body weight, and protect the spinal cord and nerve roots. Some idiopathic diseases and severe external loads may cause compression on nerves and make the spine become unstable. Low back pain (LBP) is often described as sudden, sharp, persistent, or dull pain felt in the lower back. LBP is very common and affects the majority of people at some point during their life. It is an impairment that gives rise to functional limitations and disability which also affects the performance of an individual at jobs or daily activities. Mechanical LBP is the most common cause of work-related disability in the United States. It has been found
that mechanical LBP represents the most common cause of disability and is generally associated with a work-related injury for individuals younger than 45 years. For individuals older than 45 years, mechanical LBP is the third most common cause of disability, and a careful history and physical examination are vital to evaluation, treatment, and management [1]. Hence, there is a need to study the origin of pain associated with the lumbar spine and search for simple, cost effective, and safe treatment options for the same.

1.3 Lumbar Spine Anatomy

The spine consists of thirty-three vertebrae spanning five main regions. There are seven vertebrae in the cervical region, twelve in the thoracic, five in the lumbar, five in the sacral, and four in the coccygeal. These vertebrae are separated by intervertebral discs. Two consecutive vertebrae connected by one intervertebral disc, with the attached ligaments, is referred to as a functional spine unit (FSU), or motion segment. In total, the spine supports the torso, upper limbs, and head, as well as protects the spinal cord. The five lumbar vertebrae will be the focus of this study. They are numbered sequentially from the superior to inferior end of the region as L1 to L5. Being at the bottom of the spine, this region bears the bulk of the weight of the upper body, and as a result, most of biomechanical failures and injuries. The vertebral bodies and intervertebral discs make up the anterior column of the spine. The posterior column consists of the laminae, pedicles, and the articular, transverse, and spinous processes. The spinal cord runs the length of the column through the neural arch, protected by the laminae and the vertebral bodies. The articular processes prevent excessive motion and are separated by a small capsule with
synovial fluid. The transverse and spinous processes serve as attachment points for ligaments which also restrict excessive motion. The main structural features of the spine can be seen in Figure 1-1.

![Figure 1-1 Lateral and posterior view of vertebrae with intervertebral discs](image)

The intervertebral disc has two sections: the annulus and the nucleus pulposus. The annulus consists of concentric fibrous bands radiating out from the nucleus. It is most strongly attached to the vertebral body at the periphery. The nucleus pulposus is the softer region which is able to absorb much of the pressure of the spine. There are seven ligaments which are present in a motion segment. These are the anterior longitudinal, posterior longitudinal, ligamentum flavum, articular capsular, interspinous, supraspinous, and intertransverse ligaments. Together these ligaments are able to provide resistance in all directions to help the joints prevent excessive motion and damage to the spinal cord.
and other key elements. A more detailed explanation of the anatomy is provided in Appendix A.

1.4 Evolution of Surgical Techniques for the Treatment of LBP

Various surgical techniques have emerged over the years for the treatment of spinal disorders. However, no definite treatment modality exists for any disorder and treatment choices are highly specific to the surgeon involved. Continuous advancements are being made to understand the spine and its function in order to arrive at an optimal solution for the treatment of various spinal disorders. The present day aim is to find procedures, which are minimally invasive, tissue sparing, more physiological and cost effective.

Chronic low back pain due to degeneration of the lumbar spine, commonly referred to as mechanical back pain, is thought to be due to instability of the lumbar motion segment that is secondary to disc degeneration and facet arthrosis [3]. As defined by Panjabi [4], spinal stability is the degree of motion that prevents pain, neurological deficit, and abnormal angulation. Instability leads to a non-specific mechanical failure of the spine causing abnormal movement at the joints and altered load transmission which results in pain. Instability of lumbar spine from degenerative causes is a common problem involving mainly the L4-5 and L5-S1 levels. This instability comes from the degeneration of facets and discs resulting in laxity and causes abnormal motion under the physiological load of daily activity. Other possible complications of spinal instability are trauma, disorders like scoliosis, lesions, infections and tumors [5].
Low back pain is highly patient specific and variable depending upon the different disease states. The common disabling spinal disease is disc degeneration disease (DDD) [6]. Since degenerated disc loses height and hydration, it possibly pinches exiting nerve root to result in pain. Injury or damage to the lower back or aging leads to the degeneration of the skeletal and muscular structures of the lumbar area of the spine. This degenerative process creates instability in the spine and narrowing of the spinal canal also known as spinal stenosis.

Lumbar stenosis is an abnormality that may be present alone or with some other disorder such as the disc bulge or herniation, degenerative spondylolisthesis or scoliosis. The stenosis is caused by hypertrophy of the ligament flavum and facet joints which result in the nerve compression in one or more motion segments [7,8,9,10]. There are about 1.4 million individuals in the United States with a primary or secondary diagnosis of LSS [9,10]. Facet joints may also be the cause of the low back pain. Facet arthritis may cause nerve root irritation due to the projection of the facet into the spinal canal resulting in nerve pinching [11].

Undercutting decompression is a standard procedure in the therapy of lumbar spinal stenosis [12,13]. The decompression surgery involves facetectomy and laminectomy procedures to decompress the nerve and provide relief from pain. In a laminectomy procedure, the spinous process and the lamina are removed at the level of stenosis along with associated ligaments. The facet joints may be partially or completely removed in a facetectomy procedure [12,14,15]. Accompanying segmental instability may occur, which is caused either by degenerative segmental disease involving the intervertebral
disc, the zygapophysial joints and ligaments, or as a consequence of the surgical
decompression itself [14,15,16]. It is thus reasonable to assume that decompressive
technique thus influences the remaining stability of the involved section.

Fusion is the gold standard to address segmental instability caused due to the
decompression surgery [17,18,19]. The term fusion literally means fusing one or more of
the vertebrae of the spine so that motion no longer occurs between them. The general
goal of any rigid stabilization device is to immobilize or fuse one or more segments and
bridge the dysfunction or instability between vertebral segments. There are numerous
clinical studies that report accelerated disc degeneration at adjacent segment after fusion
screw misplacements, pedicle fractures or screw breakages [20,21,22,23,24,25]. Among
other aspects, there is biomechanical alteration of stress distribution on the adjacent
segment. It is also still not proven but hypothesized that fusion is responsible for this
adjacent level syndrome because the stiff region in the spine leads to overloading of the
segments above and below [15,26]. Therefore, a paradigm shift from stiff implants to
motion preserving implants is seen in the last few years.

Various devices have emerged in recent years aiming at replicating the function of the
disc, facets and ligaments which are the main load bearing and motion governing
components of the spine. Dynamic stabilization systems are a class of motion
preservation devices meant to replicate the function of joints and ligaments that have
been compromised due to decompression surgery. They allow some micro motion at the
implanted level as compared to fusion which immobilizes the fused segment. In addition
to motion sparing, another goal of dynamic stabilization devices is to share load so as to
allow anatomically similar loads through the disc. It is hypothesized that these motion
preservation implants will prevent all the complications associated with fusion and provide better clinical outcomes.

1.5 Scope of the Present Study

The purpose of this study is to evaluate the biomechanics of the lumbar spine with dynamic stabilization systems by means of finite element study and an invitro study. The systems studied in this work are: (i) Stabilimax NZ (Applied Spine Technologies, New Haven, CT) (ii) Dynesys (Zimmer Spine, Warsaw, IN) (iii) Viper Semi Constrained (S.C.) Pedicle screw system (Depuy Spine, Raynham, MA) and (iv) In-Space spacer (Synthes Spine, West Chester, PA).

The first part is a finite element analysis comparing the various posterior dynamic systems viz. Stabilimax, Dynesys and In-Space spacer for varying grades of facetectomy and decompression surgery. Parameters such as range of motion (ROM), disc pressure and facet forces will be compared for the various devices.

The second part of the study will consist of an invitro study of 8 human cadaver L1-S1 lumbar spines in which the Dynesys implant will be compared to Viper S.C. PEEK rod system after performing a decompression surgery. Each spine will be tested intact, stabilized with Dynesys and Viper S.C. PEEK rod system after decompression surgery and finally fused at the index level with an intervertebral body cage and posterior instrumentation and dynamic stabilization at the adjacent level as an adjunct to the fusion.
CHAPTER 2

Literature Review

2.1 Overview

This chapter discusses about the causes of intervertebral disc disease and spinal canal stenosis that lead to low back pain. The concept of posterior dynamic stabilization for treatment of intervertebral disc degeneration and spinal canal stenosis is discussed. Finally, the details of each posterior stabilization system that were used in this particular study along with their concerning literature is presented.

2.2 Introduction

Low back pain is a broad term describing many different disorders associated with lower back and leg pain. Symptoms of the back pain may also vary with the cause. In fact, there are numerous possible pain producers including muscles, soft connective tissue, ligaments, joint capsules, cartilage, discs and nerves. Doctors are not always able to pinpoint the exact source of back pain. Decades of investigations have helped delineate some causes and few possible treatment methodologies. However, there is still no
consensus regarding the effective treatment for LBP. The goals of the treatment for LPB are to reduce pain and improve the quality of life.

2.3 Spinal Disorders

The human spine accommodates extensive range of motion and considerable load carrying capacity owing to specific tissues and anatomical structures. Mechanical property changes resulting from degeneration are likely contributors to lumbar spine instability that may lead to other pathologies. This instability may further be accelerated by injuries or deformities. Back pain arising from the degenerative disease could be discogenic or may be directly due to diseased facet joints. Various causes for the low back pain include the following:

2.3.1 Lumbar Strain

Lumbar strain is a stretch injury to the ligaments, tendons, and/or muscles of the low back. The stretching incident results in microscopic tears of varying degrees in the tissues. The injury can occur because of overuse, improper use, or trauma. Soft-tissue injury is commonly classified as acute if it has been present for days to weeks. Chronic strain occurs if the pain lasts longer than three months.

2.3.2 Lumbar radiculopathy

Lumbar radiculopathy is the nerve irritation that is caused by damage to the discs between the vertebrae. Damage to the disc occurs because of degeneration of the outer ring of the disc, traumatic injury, or both. As a result, the central softer portion of the disc
can rupture causing disc herniation through the outer ring of the disc and abut the spinal cord or its nerves as they exit the bony spinal column. This causes compression of the nerves and causes pain that passes down the leg known as sciatic pain.

### 2.3.3 Bony Encroachment

This is caused due to movement or growth of the vertebra of the spine which limits the space for the adjacent spinal cord and nerves. Causes of bony encroachment of the spinal nerves include:

1) Spondylolisthesis which is primarily the slippage of one vertebra relative to the other
2) Spinal canal stenosis caused due to compression of the nerve roots or spinal cord caused by bony spurs or osteophytes. Osteophytes can be found at the margins of diarthrodial joints, apophyseal joints and vertebral bodies and may be responsible for nerve root compression with severe pain, requiring surgical removal.
3) Foraminal narrowing caused due to the narrowing of the area through which the spinal nerves pass from the spinal column, out of the spinal canal to the body resulting in impingement of the nerves.

### 2.3.4 Intervertebral Disc Degeneration

The intervertebral discs lie between the vertebral bodies, linking them together. They are the main joints of the spinal column and occupy one-third of its height. Their major role is mechanical, as they constantly transmit loads arising from body weight and muscle activity through the spinal column. The intervertebral discs are complex structures that
consist of a thick outer ring of fibrous cartilage termed the annulus fibrosis, which surrounds a more gelatinous core known as the nucleus pulposus. The nucleus pulposus is sandwiched inferiorly and superiorly by cartilage end-plates. The pressure is transmitted from the nucleus as a circumferential tension to the annulus and thus makes the intervertebral disc a load bearing structure.

In a healthy spine, about 70% of the load passes through the intervertebral disc and the cortical shell and about 30% passes through the facets [27]. With degeneration, however the biomechanical properties of the disc are altered and more loads pass through the facet joints. Several factors like aging, mechanical factors due to occupational exposure [28], abnormal loading conditions and the loss of nutrition to the disc are responsible for degenerative disc disease [29]. Abnormal motion, ligamentous hypertrophy and osteophyte formation lead to various clinical symptoms including pain and/or neurological deficits.

As discs degenerate, the nucleus becomes more consolidated and fibrous and is less clearly demarcated from the annulus fibrosis. The nucleus loses its water content and leads to a change in the mechanical and structural properties of the tissue. Thus the nucleus pulposus undergoes a transition from fluid-like to solid-like behavior with aging and degeneration [30]. Focal defects appear in the cartilage endplate, and there is a decrease in the number of layers of the annulus with an increase in the thickness and spacing of the collagen fibers [29,31]. This also leads to an increase in the interlaminar shear stress in the annulus. The degenerated annulus begins to tear radially, separates from end plate as well as shows macroscopic mechanical degradation. As a result of the reduced radial tensile strength of annulus, the disc bulges out leading to disc herniation.
The loss of water content, results in reduced disc height or disc thinning. Loss of disc height along with the gradual ossification of end plate and protrusion of disc tissue causes stenosis that eventually leads to back pain. Damage to a vertebral body endplate also has a dramatic effect on the adjacent disc; the nucleus is immediately decompressed, and this can often be an initiating event in disc degeneration. So, structural changes in either the vertebral body or disc can lead to subsequent changes in the adjacent levels also. The altered stress distribution in the disc may also lead to overloading of the spinal ligaments, muscles, and facet joints, possibly damaging these structures [32].

Thus, once degeneration sets in, the intervertebral disc goes through a cascade of degenerative changes resulting in the biomechanical alteration of the load transfer through the disc causing changes in the mechanical properties and composition of the tissue as well as alters the kinematics of the spine. Spondylosis, spondylolisthesis, disc herniation, and spinal stenosis may follow these degenerative changes in the segment [29, 30].

2.3.5 Posterior Element Degeneration

Posterior element degeneration mainly occurs at the facet joints. Facet Syndrome can be defined as the degeneration of facet joints due to mechanical factors like wear and increased facet loading. Facet joints mainly prevent extension, rotation and shear [25]. Very high facet loads and stresses in extension, shear and rotation may cause facet hypertrophy or facet osteoarthritis eventually leading to spinal stenosis [15,33].
When disc degeneration and height loss become severe, there is a radical shift in compressive load-bearing from the vertebral body on to the neural arch. In lordotic postures, such as erect standing, more than 50% of the compressive force on the spine can be resisted by the neural arch, with high stress concentrations arising in the apophyseal joints, especially where the inferior articular processes impinge on the lamina below [34,35]. Willis and colleagues used the concept of the 3-joint complex of the spine (the intervertebral disc and the 2 posterior facet joints) to help illustrate how degeneration might lead to some of the clinical sequelae seen by clinicians [36]. The function of the disc and the facet joints are intimately related; changes in one will inevitably lead to changes in the other, leading to degeneration of the whole complex. The first change usually seen in the facets is a synovial reaction. Articular destruction usually follows, producing some degree of capsular laxity. This laxity, in addition to the disc space narrowing produced as a result of disc degeneration, allows the superior vertebral body to sublux forward relative to the lower vertebra, reducing the size of the foramen and possibly causing entrapment of the nerve root. Aforementioned changes in the facet joint may affect the stress distribution, load sharing as well as segmental motion throughout the spinal column. Eventually, osteophytes form around the articular processes and the vertebral body, and the lamina undergo a reactive thickening that can result in a spinal stenosis. It is also seen that increased sagittal orientation of the facets lead to spondylolisthesis [37]. Partial and complete factectomy are done to relieve pain due to spinal canal stenosis and spondylolisthesis caused due to posterior element degeneration. However factectomy leads to increase instability in various loading modes as well as increased loading of the adjacent disc thus accelerating adjacent disc degeneration. It is
proposed by various studies that factectomy should be supplemented with instrumentation to prevent further instability [38,39,3,27,40].

2.4 Spinal Canal Stenosis

Lumbar spinal stenosis (LSS) is a developmental or acquired condition that results in the narrowing of either the spinal canal or the neural foramina. Degenerative lumbar stenosis is a disabling syndrome of low-back pain that results from chronic compression of the cauda equina by degenerative hypertrophic lesions of the facet joints and ligament flavum as well as due to herniation and degeneration of the intervertebral discs [41]. The patients may complain of low back pain, buttock pain, or trochanteric and posterior thigh pain that may radiate to the knee and occasionally to the feet. This pain aggravates during walking, standing and exercising and other normal activities [42]. Pain is generally relieved during sitting, leaning forward and squatting. It has been seen that some patients may not be able to walk for long period of time. Treatment of patients suffering from LSS depends on the severity of the diseases. In the early stages of the diseases conservative non operative therapies may be suggested. However, if the pain persists for a longer duration and the symptoms continue to exacerbate the pain, surgical options may be considered.

2.5 Surgical Decompression Surgery

Surgical decompression may be suggested in case of DDD where there is disc height reduction and disc herniation as well as due to lumbar stenosis which may be due to narrowing of the spinal canal primarily due to osteophytes, facet hypertrophy and
thickening of the ligamentum flavum. The surgeon decompresses the affected level by removing the osteophytes by laminectomy associated with partial or complete facetectomy depending upon the level of facet arthritis and osteophyte formation. Degrees of laminectomy vary from a small portion to a wide laminectomy in which the entire lamina along with all ligaments and spinous process is removed retaining the facets [43].

Facetectomy removes facet joint and results into severe destabilization of spinal motion segment [38,39,40]. From different methods of decompression, unilateral laminectomy, unilateral laminectomy with unilateral facetectomy, unilateral laminectomy with bilateral facetectomy, bilateral facetectomy and total bilateral laminectomy would result into large segmental instability [40]. Thus additional instrumentation may be suggested to prevent further complications at the treated level as well as to prevent adjacent level degeneration

2.6 Fusion

Generally fusion has been the traditional mainstay for treatment after surgical decompression to prevent DDD and spinal canal stenosis. The goal of the lumbar fusion is to have the two vertebrae fuse so that there is no longer any motion between them. Removing the intervertebral disc or bone spurs can reduce some of the pressure on the nerves, helping to reduce pain. Additionally, by fusing the two vertebrae together this will stop the formation of bone spurs at that location, further reducing pain and potential nerve injury. However, postoperative complications were higher with fusion compared to without fusion [40,44,45]. Also, operating costs, discharge time were more for fusion.
Traditional interbody fusion surgeries have utilized either autograft or fibular allograft. Many complications related to graft expulsion and migration, donor site morbidity; pseudarthrosis have been reported in the literature [11,14,15,16,19]. Fusion may also lead to the adjacent level degeneration and immobility at the treated level and it may be not a good option in early stages of degenerative disc disease where the symptoms can be reversed, preventing adjacent level morbidity.

To overcome the problems mentioned above (adjacent segments degeneration, lower success rates, operating costs, postoperative complication) new alternative treatments are investigated by the researchers. Also, since the age group of the patients is shifting to the younger population, often times fusion is an over-treatment for many patients since it leads to limited activities at a very young age and also further possibility of complications since the high rate of daily activities performed by younger age group. Surgeons are looking for alternative procedures to avoid or at least delay fusion especially, for young patients whose indications are considered promising for such alternative procedures [46].

2.7 Non Fusion Systems

Non fusion systems represent a new paradigm in the surgical management of spinal pathology. As an alternative to conventional methods of spinal arthrodesis, dynamic stabilization restores the functional biomechanical properties of the motion segment, prevent adjacent level degeneration and protects the neurovascular structures especially in spinal canal stenosis where there is neurogenic intermittent claudication of the nerves.
2.7.1 Artificial Discs

The artificial disc falls in the category of dynamic stabilization systems where they replace the function of the degenerative disc by mimicking physiologic motion. The various artificial discs that have evolved for the lumbar spine are Charite, Prodisc, and Maverick. A total disc replacement surgery involves surgical removal of the pain causing disc and replacement with a mechanical device, which would mimic the normal spine kinematics. However a large number of complications like subsidence of the implant, facet joint arthrosis at the same and adjacent level as well as hypertrophy of the facets have been reported with artificial disc arthroplasty [47,48]. Also the long term wear debris might be an issue if implanted in younger population and hence the focus has been shifted to posterior dynamic stabilization systems.

2.7.2 Posterior Dynamic Stabilization of the Lumbar Spine

The posterior systems are of interest because in a spinal segment, not only the disc but also the facet joints may degenerate independently from each other. From a biomechanical point of view, as well as due to the above mentioned complications of the artificial disc arthroplasty and arthrodesis, it is not desirable to sacrifice a moderately degenerated disc, therefore, surgeons prefer to maintain the disc. This is true especially in younger patients where there is still a lot of activity present in their day to day life and fusing a segment may lead to limited motion and further degeneration of the adjacent segments. Moreover, in elderly patients where spinal stenosis is the most prevalent, a longer surgery time may lead to a psychological effect on these patients. The attempt to preserve the disc by using only an internal fixator may lead to fatigue failure of the
implant system, as seen in unsuccessful bony fusions stabilized with an internal fixator. Hence the concept of posterior dynamic fixators to reconstruct and maintain the posterior elements.

The goal of any dynamic stabilization system is to favorably alter the load transmission and movement through the spinal segment. These systems are implemented for younger population with multi-segmental disc degeneration, stabilization of decompression surgeries and in addition to fusion to avoid adjacent level degeneration [49]. Dynamic stabilization, also known as soft stabilization or flexible stabilization leaves the spinal segment mobile, and its intention is to alter the load bearing pattern of the motion segment, as well as to control any abnormal motion at the segment. The main two functions of any dynamic stabilization system are: (i) It has to permit motion across different segments, (ii) Share load with the disc and the facets. A remote expectation is that, once normal motion and load transmission is achieved, the damaged disc may repair itself, unless of course the degeneration is too advanced.

2.8 Classification of Posterior Dynamic Stabilization Devices

A large number of posterior dynamic stabilization devices have emerged in the market since 1990’s. Particularly in the last 10 years, a lot of interest has developed in the concept of dynamic stabilization. There dynamic stabilizations systems can be classified into three categories:-

1) Pedicle based dynamic rod devices systems
2) Posterior Interspinous based systems
3) Total facet replacement systems

Following section describes some implants related to pedicle based dynamic rods and interspinous based systems.

2.9 Posterior Interspinous Based Systems

A number of interspinous process (ISP) devices have recently been introduced to the lumbar spine implant market. Designs vary from static spacers to dynamic spring like devices and they are composed of an array of different materials including bone allograft, titanium, polyetheretherketone (PEEK), and elastomeric compounds. The common link between them is the mechanical goal of distracting the spinous processes and blocking extension to affect the intervertebral relationship. Therefore, the amount of distraction is maintained above a threshold. What is more variable are the purported clinical goals, which range from treatment of degenerative spinal stenosis, discogenic low back pain, facet syndrome, disc herniation, and instability. These devices are used as standalone implants to augment open decompression by preventing instability. The main principle for these implants is to limit the dynamic extension of the concerned segment. Early clinical trials are promising and long-term studies are still pending. However this technology is still in an early stage of development and the indications are not yet clearly defined because scientific evidence is lacking [50,51].

The advantages of using an ISS is it exposes the patient to very little additional risk or operative morbidity compared with procedures such as discectomy or decompression. They also do away with the need for pedicle screw fixation, reducing both the risk and seriousness of other complications. Different ISS devices place the stenotic segment in
slight flexion without affecting adjacent levels, decrease facet loads at the implanted segment, diminish intradiscal pressure, enlarge the spinal canal and foramen, and increase the anterior and posterior disc heights [50]. There are several interspinous-based devices, currently available viz. X-Stop (Medtronic Spine LLC, Memphis, TN), DIAM, Wallis (Zimmer, Inc., Warsaw, IN) and the newly designed PEEK interspinous spacer In-Space. A brief description of X-stop, Wallis as well as the In-Space spacer used in this study has been described below.

2.9.1 In-Space

The In-Space interspinous spacer (ISS) is a percutaneous, minimally invasive device that is introduced through a small incision on the lateral aspect of the lumbar spine, under fluoroscopic view, with the patient in the prone position. The In-Space device is not attached to the bony structures or soft tissue of the spine. It is restricted from migrating posteriorly by the supraspinous ligament, anteriorly by the laminae, cranially and caudally by the spinous processes, and laterally by the metallic wires (Figure 2-1). The implant provides a minimally invasive procedure to indirectly decompress the spine, thus taking pressure of the posterior annulus, maintaining the foraminal height, and opening the spinal canal. The implant is placed between two adjacent spinous processes at the stenotic vertebral segment. The In-Space will presumably limit extension of the spine, while preserving flexion, axial, rotational, and lateral bending. The ISS consists of a body having 2 cylindrical pieces made of polyetheretherketone (PEEK) and held together by titanium alloy connector screw. The advantages of using PEEK is that it has an elastic modulus closer to that of the bone and hence it provides better stress shielding and
avoiding fractures of the spinous process [53]. After the device is positioned in the appropriate location, a central mechanism is turned to compress the body together. This maneuver releases 2 superior and 2 inferior titanium alloy retainers that engage the spinous processes and limit lateral displacement. The inclusion/exclusion criteria for the In Space are discussed below:

**Inclusion Criteria:**

- ≥ 50 years in age
- Leg/buttock/groin pain, with or without back pain, that can be completely relieved by flexion such as when sitting in a chair.
- Zurich Claudication Questionnaire Score ≥ 2.0
- Neurogenic intermittent claudication secondary to moderate lumbar spinal stenosis
- Has completed at least 6 months conservative therapy

**Exclusion Criteria:**

- Axial back pain only without leg/buttock/groin pain
- Has had any prior lumbar spine surgery at any level
- Significant scoliosis, defined as Cobb angle > 10°
- Spondylolisthesis > Grade 1 or isthmic spondylolisthesis at affected level
- Osteoporosis
- Morbid obesity, defined as BMI > 40 kg/m²
2.9.2 X-Stop

The X-stop interspinous spacer was the first interspinous process decompression device approved by the FDA for general use. The X-stop was developed to provide a safer, less invasive treatment option for those who fail conservative management and those needing the riskier decompression surgery. The implant is designed to be placed without removing any bony or soft tissues. The technique is minimally invasive and is usually performed with the patient under local anesthesia. The X-Stop consists of an Oval spacer, 2 lateral wings and the tissue expander. The tapered tissue expander allows for easier insertion between the spinous processes. The universal and the fixed wings limit anterior and lateral migration (Figure 2-2).
Various biomechanical as well as clinical results have shown promising results for the X-Stop spacer. In an in vitro cadaveric study by Lindsey [54] extension at the implanted level decreased by 62% following implantation of the X-Stop spacer although range of motion in other modes was not affected. A study on cadaveric disc pressure following implantation of interspinous spacer showed that the intradiscal pressure dramatically reduced in extension [55]. These studies concluded that the implant does not significantly change the intradiscal pressures at the adjacent levels, yet it significantly unloads the intervertebral disc at the instrumented level in the neutral and extended positions. Another study by Wiseman [33] showed that the mean facet force decreased by 68% in extension with the X-stop. Thus the biomechanical studies for X-Stop showed that the spacer restricts extension and produces significant unloading of the disc and the facets. Clinical outcomes of the X-stop done at 1 year and 2 year follow up showed a significantly greater percentage of patients with an improvement in ZCQ scores (Zurich claudication rates) as compared to the control group [56,57]. Thus outcomes of the X-
stop have been shown to be vastly superior to non-operative therapy in LSS patients with mild-to-moderate symptoms.

2.9.3 Wallis Dynamic Stabilization

The Wallis implant is a floating system, consisting of a PEEK block. It is augmented by two woven dacron ribbons, which are wrapped around the spinous processes and fixed under tension. The implant shape fits securely between the spinous processes. The flat bands are woven polyester and are anchored at opposing corners of the implant, from which they can be passed around the corresponding spinous process. To secure and tension the bands, each is looped through a PEEK strap fastener, which snap-fixes to the implant. The Wallis implant consists of a PEEK block as compared to the titanium spacer in most of the other interspinous implant. (Figure 2-3).

An invitro and finite element study done by Lafage [58] showed that the effect of the implant mainly appeared in flexion/extension. The experimental results showed reduced range of motion of the instrumented spine as compared to injured segment. The stiffness was restored, neutral zone was reduced and the excessive translation was abolished. Furthermore, pressure transducer studies showed off-loading of the motion segment with the Wallis stabilization system. Also, facet joints loads were relieved with a 39% reduction in mean loads and a 55% reduction in peak loads [33].

The clinical results over the first 2 years showed a statistical improvement at 3 months to 2 year in the Visual Analog Scale (VAS), the Japanese Orthopaedic Association Score (JOA), the Oswestry Disability Index (ODI) of patients and the SF-36 scores [59,60].
Better clinical outcomes were seen for the Wallis stabilization system primarily due to less invasive nature of the surgery, the preservation of the posterior musculature and, most particularly, the maintenance of the motion at the instrumented level.

![Wallis interspinous device](image)

Figure 2-3 Wallis interspinous device (Zimmer, Inc., Warsaw, IN) [61]

### 2.10 Pedicle Screw Based Systems

Pedicle screw based dynamic stabilization systems have been derived from traditional pedicular-based instrumented spinal fusions. In these devices, the rigid rod and pedicle screws are replaced with flexible constructs to provide load sharing and reduce stiffness of the instrumentation to allow for more physiologic load transmission at the instrumented levels. Compared to interspinous spacers, these devices are intended for use in cases where tissue resection is necessary in the form of laminectomy, factectomy and discectomy. Currently these devices have been approved by FDA only as an adjunct to fusion. This is based on the argument that they may improve fusion by allowing micro movements across the end plates. Following is a discussion about some of the pedicle screw based posterior dynamic stabilization systems.
2.10.1 Dynesys

The Dynesys (Dynamic Neutralization System) spinal system is a pedicle screw-based system developed by Dr. Gilles Dubois. The Dynesys stabilization system is generally indicated to treat conditions of the lumbar spine characterized by mild to moderate segmental instability. The Dynesys system was introduced in the market in 1994. It is the only pedicle screw based dynamic stabilization system approved by FDA. Five indications have been reported for Dynesys viz.

1. Spinal stenosis with moderated instability,
2. Grade 1 spondylolisthesis
3. Disc herniation
4. Adjacent segment degeneration
5. Degenerative disc disease

Dynesys system consists of three components:

1. Polycarbonate Urethane Spacers (PCU)
2. Polyethylene Terephthalate cord
3. Pedicle screws

The Dynesys restabilizes and realigns the segments in a physiological position and neutralizes the excessive forces. Once the devices are attached bilaterally to the affected segments, the dynamic push-pull relationship between the spacer and the polyester cord stabilizes the joints and keeps the vertebra in neutral position. This theoretically reduces segmental motion to a physiological level, neutralizing bending, torsional, and shear forces. The stabilizing cords resist flexion movements, and the spacers resist compressive
forces. Tensile forces, which act during flexion movements, are stabilized by the pre-tensioned PET cords, which run through the hollow core of the PCU spacers (Figure 2-4). A standardized preload of 300 N is applied to the cord during implantation. However, the length of the spacer, which has to be adjusted to match each patient, directly influences lordosis, the intersegmental motion and loading. The overall effect of this stabilization is designed to limit the loading of the disc.

Several biomechanical and FEM studies have been conducted to study the efficacy of this system. A study done by Schmoelz [62] has showed that Dynesys is in general flexible than conventional pedicle fixation but stiffer then intact spine hence giving stability as well as preventing adjacent level degeneration. An in-vitro study undertaken by Aylott [63] investigated the intervertebral disc stresses at the instrumented and adjacent levels, under compressive loading. It was seen that Dynesys eliminated the peak stress values for flexion-extension and minimal change in stress distribution at adjacent level. Various other in vivo and in vitro studies measuring the effect of Dynesys have showed that the measured stabilization is in the range of 20-40% of the intact motion [64,65,66]. A clinical study of 83 patients investigated by Stoll et al [67] concluded that dynamic neutralization system proved to be a safe and effective alternative in the treatment of unstable lumbar conditions. A prospective study done by Bothmann et al [68] on 40 patients showed that the postoperative pain scores improved by 73% for these patients as compared to conventional rigid fusion systems.
The clinical studies as well as the biomechanical studies thus indicate that patients receiving dynamic stabilization following decompressive laminectomies showed statistically significant improvements in VAS for back and leg pain, morbidity rates and screw loosening as compared to traditional rigid fixation.

2.10.2 Stabilimax NZ

The Stabilimax NZ device was designed to complement Panjabi’s principles of spinal biomechanics [70]. This device, a posterior pedicle screw–based dynamic stabilization system, features dual concentric springs combined with a ball and socket joint, all to enhance spinal stability around neutral posture. The Stabilimax NZ is designed to increase the resistance of the passive spinal system around neutral posture, while maintaining the maximum ROM. It includes the pedicle screws, a single-level or
multilevel dynamic connector, and an end connector. The system is designed to be used from L1-S1 in either single level or multilevel configurations (Figure 2-5).

Figure 2-5 Stabilimax Implant (Applied Spine Technologies, New Haven, CT) [71]

Various studies have been conducted by Panjabi, Goel and Patwardhan to verify the effect of the device following progressive destabilization procedures [72, 70]. Panjabi established the spring stiffness of 90 N/mm as the optimal stiffness when the device was capable of consistently reducing the neutral zone to the pre-destabilized levels regardless of specimen condition while maintaining the maximum possible range of spinal motion. Patwardhan investigated the effect of Stabilimax on six L2-L5 cadaveric spines following destabilization which consisted of L3 laminectomy, bilateral L3-L4 foraminotomy, and L3-L4 nucleotomy [69]. It was found out that with the application of Stabilimax NZ, the range of motion and neutral zone of the instrumented level were reduced, stabilizing the motion of the spine. Another cadaveric study by Panjabi showed the comparison of Stabilimax with fusion constructs at the implanted and adjacent level. The average adjacent-level effect in the form of increased motion for Stabilimax NZ was
approximately half that for fusion [71]. Goel performed a verification study using a validated finite element model of the ligamentous lumbar spine, levels L3-S1, instrumented with the Stabilimax NZ. The finite element model analysis demonstrated that the Stabilimax NZ device provided approximately twice the motion compared with a typical fusion system in response to moments placed on the superior vertebra [70]. Thus the Stabilimax NZ provides a new alternative for the treatment of spinal degeneration by stabilizing the neutral zone.

### 2.10.3 Viper S.C. PEEK Rod System

It has been shown by many studies that supraphysiological stresses created by rigid metallic fixation is the central cause of adjacent segment disease in the lumbar spine [73,74,75]. Although pedicle screw/rod constructs optimizes fusion, such a rigid system may become more of a liability than an asset in the long term after a bony fusion is achieved. Also, the exact origin of adjacent-segment disease remains uncertain. Biomechanical studies have established that fusion shifts the center of rotation posteriorly, which in turn increases the stress on facets and discs at adjacent, unfused segments [21].

The Viper S.C. PEEK rod system (Depuy Spine, Raynham, MA) is made of semi-crystalline thermoplastic polymer PEEK (Figure 2-6). The PEEK rods are semi-rigid constrained devices which bridge the gap between fully dynamic constructs such as disc arthroplasty, constrained dynamic constructs such as Dynesys, and rigid fixation systems such as titanium pedicle screw/rod constructs. The use of PEEK rods for fusion in the lumbar spine addresses the causative factors of adjacent-segment disease, but this
theoretical benefit remains to be proven. Studies have shown that PEEK rods have
improved load sharing patterns between the anterior and posterior elements in a manner
that closely replicates the normal load distributions in the human spine [76,77]. It has
been hypothesized that PEEK will lead to reduced loads on the bone screw interface thus
reducing stress shielding that occurs with titanium constructs and would allow more
physiological loads to pass though the adjacent levels and assist in load sharing thus
bridging the gap between fusion and dynamic stabilization systems.

Figure 2-6 PEEK Rods with Viper S.C. pedicle screws [76]

2.11 Summary

Fusion has been the gold standard treatment for number of years to treat low back
pain. There have been several complications reported in the literature regarding adjacent
segment degeneration, lower success rates and higher re-operation rates. Fusion surgeries
utilizing bone graft have many problems related to graft expulsion, migration and donor
site morbidity. Non-fusion systems have been developed to avoid problems mentioned
above. The concept of dynamic stabilization has come up with the ideal goal of motion
preservation with pain alleviation. Several biomechanical parameters have been defined
in order to evaluate the effectiveness of dynamic stabilization devices such as range of
motion, load sharing between disc and facets and adjacent level loading. Most of the
dynamic stabilization in the market till now are in the class of semi-rigid devices. However, more flexible spring based devices have also emerged recently and a biomechanical evaluation of these devices is important to give complete understanding of these devices. Many of these parameters are difficult to measure experimentally and finite element analysis serves as a useful tool to evaluate those parameters. This study tries to accomplish that by comparing various posterior dynamic stabilization systems.
CHAPTER 3

Materials and Methods

3.1 Introduction

In this chapter, first, the finite element method and its application to model the lumbar spine have been explained. Description of the intact lumbar spine model, the boundary conditions and the loads applied will be explained. Simulations of the various posterior stabilization systems viz. Dynesys, Stabilimax and the In-Space in the lumbar spine model are described in detail. The details of the surgical procedures simulated for each of the posterior devices are given. The chapter concludes with the methodology applied for conducting an in vitro investigation, comparing Viper S.C. screws and Dynesys after decompression surgery. The experimental set up along with the material and methodology used for the cadaveric study is explained.

3.2 Finite Element Analysis

FEA is a computational tool that is used to solve physical problems in engineering analysis as well as design systems. In finite element method, a complex region defining a
continuum is divided into simple geometric shapes called finite elements. Various biomechanical parameters can be calculated for different implant geometries, materials. FE simulations give full information about stresses, strains that are very difficult to obtain through experimental analysis. FEA has become a tool for predicting the failure due to unknown stresses by showing problem causing areas in a material and allowing designers to see all of the theoretical stresses within. Thus, FE analysis has become a valuable tool for the design and analysis of orthopedic implants to analyze the load sharing characteristics and failure modes for the implant.

3.3 Intact L3-S1 Finite Element Model

This portion of the study was to perform finite element analysis (FEA) choosing parameters to replicate in vitro conditions most accurately. The model used was an L3-S1 model adapted from a previously validated L3-S1 model used in published studies [78, 79, 80, 81, 82]. The original model was created from 1.5 mm thick transverse slices from computed tomography scans of a healthy cadaver spine. 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 film. An example of this is shown in Figure 3-7. Due to the symmetry of the transverse cross-sectional shape across the mid-sagittal plane, only one-half of the model was digitized. Using Abaqus, this half of the model is then reected to create the full spine. The element layers at different cross sections were then assembled to generate three-dimensional mesh of the spine segment. The mid-transverse plane of the L3-L4 disc was horizontal.
3.3.1 Vertebral body and Posterior Bone Modeling

The vertebral body and posterior bony regions were defined using three-dimensional hexagonal elements. The vertebral bodies have been modeled as a cancellous (porous) bone core surrounded by a 0.5 mm thick cortical (dense) bone shell. The appropriate isotropic material (refer Table 3.1) properties were defined for the respective regions. The vertebral body and posterior elements were made with three-dimensional solid continuum elements with eight nodes, with each node possessing six degrees of freedom.

3.3.2 Intervertebral Disc

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

3.3.3 Ligaments

Interspinous, supraspinous, intertransverse, capsular, posterior longitudinal and anterior longitudinal ligaments are the seven major spinal ligaments that were simulated in the model. Spinal ligaments were constructed using three dimensional and two node (T3D2) truss elements. The non-linear material properties and the cross sectional areas
were selected on the basis of those documented in the literature. Assigning these truss elements with the hypoelastic material properties helped the simulation of naturally changing ligament stiffness (initially low stiffness at low strains followed by increasing stiffness at higher strains) and also allowed the definition of axial stiffness as the function of axial strain. The hypoelastic material property was attributed by specifying the Young’s modulus and Poisson’s ratio along with the strain invariants at the specified strain rate. Although the longitudinal ligaments and the ligamentum flavum experience pre stress at rest, all the spinal ligaments were assumed to be unstressed initially. The magnitude of the pre stress is in direct relation with the geometric configuration of the region; due to the large inter specimen variability, precise values are difficult to achieve. The defining elements were aligned along the respective ligament fiber orientation. The behavior of the ligaments was non linear.

3.3.4 Apophyseal (Facet) Joint

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

### 3.3.5 Assignment of the Material Properties

The material properties assigned in the model were assumed to be homogeneous and isotropic. These material properties were selected in agreement with the literature. The material properties are condensed in the table 3.1 [81,82].

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

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<th># Elements</th>
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<th>Poisson's Ratio</th>
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<td>T3D2</td>
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<td>10.0(&lt;11%), 20.0(&lt;11%)</td>
<td>0.3</td>
<td>2.4</td>
</tr>
<tr>
<td>Anterior Longitudinal</td>
<td>T3D2</td>
<td>240</td>
<td>7.8(&lt;12%), 20.0(&lt;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%), 19.6(&lt;6.2%)</td>
<td>0.3</td>
<td>5</td>
</tr>
<tr>
<td>Capsular Ligaments</td>
<td>T3D2</td>
<td>64</td>
<td>7.5(&lt;25%), 32.9(&lt;25%)</td>
<td>0.3</td>
<td>3.27</td>
</tr>
<tr>
<td>Intervertebrose</td>
<td>T3D2</td>
<td>30</td>
<td>10.0(&lt;18%), 56.7(&lt;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(&lt;14%)</td>
<td>0.3</td>
<td>2.857</td>
</tr>
<tr>
<td>Supraspinous</td>
<td>T3D2</td>
<td>12</td>
<td>8.0(&lt;20%), 15.0(&lt;20%)</td>
<td>0.3</td>
<td>7.5</td>
</tr>
</tbody>
</table>
3.3.6 Boundary and Loading Conditions

Boundary conditions are an important part of the finite element modeling. The inferior surface of S1 vertebral body and posterior elements were constrained in all the six degrees of freedom. To simulate the physiologic spinal loading conditions, a novel technique was used to apply 400N follower load such that its application did not induce any rotation in the vertebrae. Springs were bilaterally positioned across each motion segment and iteratively placed in such a way that load in the spring did not induce any relative rotational motion across the motion segment. The springs were assigned zero stiffness and a pre tension of 200N was given to springs on each side. The zero spring constant assured that deflection in the spring did not affect the pre tension and, thus it acted as a rope with constant tension of 200N on either side. Since individual nodes had no rotational degrees of freedom, moment loading was applied to the stiff crossed beams rigidly attached to the superior most nodes of the L3 vertebral body. A bending moment was applied in the various degrees of freedom, which are flexion, extension, lateral bending and axial rotation. The lumbar FE model is symmetric about the mid sagittal plane hence results were computed for left rotation and right bending only. For all practical purposes, results calculated in left bending and rotation, are equal and reversed for right rotation and left bending.

3.4 Application of Follower Preload

In a healthy human body, the spine is stabilized by all the surrounding muscles and upper body weight. To simulate the upper body weight, the follower preload concept
developed by Patwardhan was used [83]. To mimic the in vivo scenario, a follower preload of 400N was applied using two springs one on either side of the spine. The characteristics of these springs were given by:

1. Zero stiffness
2. Pre Tension of 200N each and
3. Non linear curve was defined for the springs.

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

![Application of follower preload for the L3-S1 finite element model](image-url)
3.5 Injury

3.5.1 Creating Facetectomy in the FE Model

The intact L3-S1 FE model was modified to study the effects of laminectomy and different grades of facetectomy with posterior instrumentation. The intact L3-S1 model was modified to simulate 50% graded factectomy by removing 50% of the elements from the facet and the capsular ligaments. 100% or total factectomy was simulated by removing all of the facets and the capsular ligaments.

![Image of original facets and 50% bilateral medial facetectomy]

Figure 3-2 50% Bilateral Medial Facetectomy at L4-L5 level
3.5.2 Simulation of Decompression Surgery using Laminectomy Procedure

For the purpose of decompression, bilateral laminectomy with 25% factectomy was performed. Disectomy was simulated by removing all the elements of the nucleus pulposes by performing bilateral annulotomy (6mm x 5mm) as performed during real time surgery.
3.6 Finite Element Model of the Intact Model with Instrumentation

The three dimensional drawings of the various fixation devices were imported in the ABAQUS/STANDARD version 6.5. The intact L3-S1 model was modified such that the posterior fixation devices were placed at the L4-L5 level. The in depth simulation of each device is explained in this section.

3.6.1 Dynesys System

Dynesys was simulated for the biomechanical comparison with the other fixation devices. Dyneys system consists of a polycarbonate urethane (PCU) spacer and a polyethylene-terephthalate (PET) cord such that the spacer acts in extension whereas the
cord acts in flexion. The spacer and the cord mechanism were approximated using two non-linear springs attached between the superior and the inferior screws bilaterally. These springs were modeled such that one of the two springs would act in extension and the other would act in flexion. SPRING option in the ABAQUS/STANDARD was used to generate the springs and define the load-displacement curve that would determine the behavior of these springs at the body temperature. A recommended preload of 150 N was applied to the cord in each implanted case. A friction less contact interaction was defined between the contact surfaces of the spacer and pedicle screws. The stiffness of the spacer and the cord were taken as 63 N/mm and 414 N/mm respectively. For the pedicle rods, cylindrical rods of uniform cross sections were tied to the superior and inferior pedicle screws, bilaterally. The pedicle screws were meshed with hexagonal elements and positioned up to two thirds of the vertebral body at the L4-L5 segment. The rods and the screw were simulated with elastic properties and were assigned material properties of titanium (Young’s Modulus, $E= 115$ GPa; Poisson’s Ratio, $\nu= 0.3$). Surfaces were created in the model in order to define interaction between the bone and the screw shaft, screw head and the rod using the ‘tie’ constraint in the ABAQUS/STANDARD. The ‘tie’ constraint applies constraints on the nodes such that there is no relative motion between them simulating perfect bone in growth. The approximation made in this model was that the threads in the screw were ignored.
3.6.2 Stabilimax Implant Formulation

The Stabilimax system consists of dual springs and spherical joints. The dual spring mechanism has been designed so as to be rigid enough to provide stability to the injured motion and flexible enough at the same time to allow motion in the motion segment and also allow some load to pass through the disc. The spherical joints in the system transfers minimum bending moment to the pedicle screws. There are two springs in the Stabilimax system. Around the neutral zone, both the springs are engaged and therefore the effectiveness of the system is the sum of the stiffness of the two springs. However beyond the neutral zone, only one of the springs is active and therefore the system behaves less stiff.

The solid model of the Stabilimax system was imported in ABAQUS and meshed using tetrahedral elements. A frictionless contact was simulated at all the ball and socket joints. The rod and the connector were tied to each other and a spring of stiffness
100N/mm was defined between rod cap and the end. The implant formulation details are as shown in Figure 3-6. All the parts of the implant were assigned the properties of Co-Cr-Mo with Young’s Modulus of 241316 MPa and poisson’s ratio of 0.3. A tie was defined between the screw and the pedicle hole. Material propeties of Ti-6Al4-V were assigned to the pedicle screws with young’s modulus of 115000 MPa and poisson ratio of 0.32.

Figure 3-6 Stabilimax implant interactions between interconnections

3.6.3 In Space Model Formulation

The nominal sized In-Space spacer is comprised of three main functional elements – a body, a screw, and four wires. The body is made of PEEK and is the main load bearing
element of the device. The body consists of two cores and two caps. The two caps mate by turning the central screw. Initially the wires are in the non-deployed position, but as the end caps mate the wires are deployed. Both the screw and the four metallic wires are fabricated from Ti-6Al-4V (TAV) alloy. The material properties for the In-Space are as shown in Table 3-2. To accommodate the spacer, the intact L3-S1 model was modified by removing some fibers of the interspinous ligaments (Figure 3-7) at the L4-L5 level. The spacer was modeled with three-dimensional tetrahedral elements (C3D4). The In-Space was placed approximately in the middle of the interspinous space. The inferior surface of the In-Space was tied with the L5 spinous process and a sliding friction interaction with a coefficient of friction as 0.1 was defined between the superior of the spacer and the L4 spinous process. Sliding friction interaction was also defined between the wings of the spacer and the sides of the spinous process. Tie was achieved using the ‘tie’ option in interaction module of ABAQUS.

Table 3.2 Material Properties for various In-Space components

<table>
<thead>
<tr>
<th>Material Properties for various components of In-Space</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part</td>
</tr>
<tr>
<td>CORE</td>
</tr>
<tr>
<td>Screw and Wires</td>
</tr>
</tbody>
</table>
3.7 Data Analysis

The output databases were analyzed for relative rotational motion across adjacent vertebral bodies and the resultant von Mises stress distribution in various anatomical structures.

3.7.1 Rotational Motion across Functional Spinal Unit

Segmental stability can be characterized by computing the rotational motion at any segment. In order to measure the rotational angles of the motion segment the deformations of a constant set of nodes present mid-way on the vertebral bodies were used. The absolute positions of co-ordinates of two points on opposite sides of the vertebral body parallel to the plane of deflection were recorded. These measurements are
taken in the sagittal plane for flexion/extension, transverse plane for axial rotation and frontal plane for lateral bending.

### 3.7.2 Facet Loads

In the finite element model, the facets are modeled using uniaxial gap elements. The gap elements have a unit cross sectional area. Hence stress in these gap elements directly indicates the force transmitted through the facets. The facet force is along the axis of the gap elements that are inclined with respect to the horizontal.

### 3.7.3 von Mises Stresses for the Intervertebral Disc

ABAQUS/STANDARD have an option to plot von Mises stress contours for the output file being analyzed. The stress contours in the intervertebral disc were observed and the maximum von Mises stress was reported. The peak von Mises stresses for the nucleus pulposus at L3-L4, L4-L5 and L5-S1 disc were computed for all the models. These peak stress values indicate the loading patterns for the intervertebral disc for the intact and the instrumented model.

### 3.8 Human Cadaveric Testing

The invitro study consisted of investigation of the Dynesys system with Viper S.C. PEEK rod system after decompression procedure and adjacent level stabilization.

The study used eight fresh, ligamentous L1-S1 human cadaveric spine specimens. Radiographs and DEXA scans were taken for each specimen to ensure usability in the study, eliminating those that were severely osteoporotic or that had fused levels. The
specimens were potted in hardened resin superiorly at the L1 level and inferiorly at the S1 level, as shown in Figure 3-7. The specimens were fixed to the frame at the caudal end and free to move in any plane at the proximal end. The top frame of the potted specimens contained threaded rods on each of the four sides. Weights were hung on these rods using a system of pulleys to apply pure moments to the specimen in extension (Ext), flexion (Flex), lateral bending (LB), and axial rotation (AR). The injury consisted of transection of the intraspinous and surpaspinos ligaments and complete laminectomy and 25% medial facetectomy. For the topping of procedure, bilateral discetomy was performed and PLIF cages were inserted at L4-5 with topping off procedure which consisted of Dynesys/Viper S.C. screws at the adjacent level L3-4. The following conditions were evaluated:

1. Intact
2. L4 Laminectomy with 25% medial facetectomy
3. Dynesys @ L4-L5
4. Viper S.C. @ L4-L5 (randomized with above)
5. PLIF cages at L4-L5 with instrumentation from previous step extended to L3-L5
6. PLIF cages at L4-L5 with Dynesys, from L3-L5
Figure 3-7 Experiment setup showing the L1-S1 spine with Infrared LEDs

Figure 3-8 Experiment setup showing the Dynesys system implanted at L4-5

Figure 3-9 Experiment setup showing the Viper S.C. PEEK rod system implanted at L4-5
Figure 3-10 Experiment setup showing the Viper S.C. PEEK rod system implanted from L3-5 with Bilateral cages at L4-5

Figure 3-11 Experiment setup showing the Dynesys system implanted from L3-5 with Bilateral cages at L4-5

3.8.1 Motion Measurement

Range of motion data was collected during all loading sequences for each instrumented case. An Optotrak® (NDI, Waterloo, ON, CAN) motion tracking system was used to record ROM data for each loading step. This system uses infrared emitting diode (IRED)
markers to record X, Y, and Z-coordinates. The positions of the markers were recorded at 0, 1.5, 3, 4.5, and 6 Nm for extension, lateral bending, and axial rotation. A step at 8 Nm was added during flexion only. The data collected from the Optotrak system was used to calculate the euler angles of these local coordinate systems and subsequently to calculate the relative angular motion between the vertebra by means of specially developed software and MS excel macros. From this data, the percentage change in relative angular motions of various test conditions was calculated at different load levels. The p-values were then compiled for the L3-S1 motion to determine any significant differences between the cases for a given loading condition. The student’s paired T-test was performed using Minitab statistical software (Minitab Inc., State College, PA). The hypothesis was that for injured case the motion will be greater than that of intact and instrumented cases and hence one tailed paired student’s t-test performed at the significance level of 0.05 (p <0.05). Another hypothesis made was that the there will be no difference between the intact and the instrumented cases and for this we performed two tailed paired student’s t-test performed at the significance level of 0.05 (p <0.05).
CHAPTER 4

Results

This chapter discusses the results for the various finite element surgical procedures explained in Chapter III comparing various posterior dynamic stabilization systems. Angular motion, intradiscal pressure and facet loads for various loading conditions have been reported. In each case the results were compared with the intact. Results for the ROM have been reported for the in vitro cadaveric testing comparing the Dynesys with the Viper S.C. PEEK rod system after bilateral decompression procedure.

4.1 Results for Different Grades of Factectomy

4.1.1 Range of motion after Partial Factectomy

The resultant motion is evaluated for intact, Dynesys, Stabilimax and In-Space spacer after 50% factectomy and total factectomy. Loading condition simulated was 400N follower load with a pure moment of 10N-m. Extension, flexion, lateral bending and axial
rotation were simulated. The angular displacement of the (L3-S1) segment and that of each motion segment (L3-L4, L4-L5 and L5-S1) was computed.

The motion in the instrumented model was then compared to the intact case to check the implant stability. Figures 4-1 to 4-4 shows the comparison of the angular motion at different levels for the various loading modes. The percentage change in motion to the intact level for various conditions is shown in Table 4-1. The motion required to achieve the motion similar to intact was achieved using the hybrid protocol approach and is presented in Figure 4-5.

4.1.1.1 Extension

In extension, the range of motion increased by 11% after partial factectomy. However, with implantation of all the devices there was a considerable decrease in the ROM at the index level. The Stabilimax NZ implant led to a decrease in ROM by 52.45%, Dynesys by 66.53%, whereas the In-space spacer led to a decrease by 68.23%. The change in the adjacent level motion was within 10% of the intact ROM, except at L5-S1 level for the In-space spacer where it increased by 15.04%. To achieve the same amount of motion as that of intact, using the hybrid protocol, it was found that Stabilimax required 2.0° of more motion, Dynesys required 1.6° of more motion and In-space required 4.8° of more motion.

4.1.1.2 Flexion

In flexion, the range of motion was similar to that of the intact with 50% factectomy. However, with implantation of the Stabilimax NZ implant and Dynesys there was a
considerable decrease in the ROM at the index level. There was no change in motion in flexion after implantation of the In-space spacer. The Stabilimax NZ implant led to a decrease in ROM by 52.61% and Dynesys by 63.93%. The change in the adjacent level motion was within 10% of the intact ROM. To achieve the same amount of motion as that of intact, using the hybrid protocol, it was found that Stabilimax required 4.0° of more motion, Dynesys required 6° of more motion and In-space required 0.4° of motion less than that of intact.

4.1.1.3 Lateral Bending

In lateral bending, the range of motion was similar to that of the intact with 50% factectomy. However, with implantation of the Stabilimax NZ implant and Dynesys the ROM decreased at the index level. There was no change in motion in LB after implantation of the In-space spacer. The Stabilimax NZ implant led to a decrease in ROM by 46.43% and Dynesys by 54.84%. There were very minor changes at the adjacent level after implantation of the various devices. To achieve the same amount of motion as that of intact, using the hybrid protocol, it was found that Stabilimax required 2.0° of more motion, Dynesys required 2.8° of more motion and In-space required 1.6° of motion compared to that of intact.

4.1.1.4 Axial Rotation

In Axial rotation, there was no significant change in the ROM to that of the intact with 50% factectomy. However, with implantation of the Stabilimax NZ implant and Dynesys the ROM decreased at the index level. There was no change in motion in AR after
implantation of the In-space spacer. The Stabilimax NZ implant led to a decrease in ROM by 8.43% and Dynesys by 21.22%. There were very minor changes at the adjacent level after implantation of the various devices. To achieve the same amount of motion as that of intact, using the hybrid protocol, it was found that Stabilimax required 0.5° of more motion, Dynesys required 1.6° of more motion and In-space required 0.2° of motion less as compared to that of intact.

**4.1.2 Range of Motion after Total Factectomy**

**4.1.2.1 Extension**

Total Factectomy led to a significant increase in the ROM of the spine. The ROM at the index level increased by 226.42%, at the adjacent level the ROM increased by 39.02% at L3-L4 and by 41.02% at L5-S1 level. However, with implantation of all the devices there was a considerable decrease in the ROM at the index level. The Stabilimax NZ implant led to a decrease in ROM by 44.25%, Dynesys by 67.54%, whereas the In-space spacer led to a decrease by 69.54%. The change in the adjacent level motion was within 10% of the intact ROM, except at L5-S1 level for the In-space spacer where it increased by 15.04%. To achieve the same amount of motion as that of intact, using the hybrid protocol, it was found that Stabilimax required 1.5° of more motion, Dynesys required 0.4° of more motion and In-space required 5.2° of more motion.
4.1.2.2 Flexion

In flexion, the range of motion was similar to that of the intact after total factectomy. However, implantation of the Stabilimax NZ implant and Dynesys led to a decrease in the ROM at the index level. There was in slight increase in motion (12.81%) in flexion after implantation of the In-space spacer. The Stabilimax NZ implant led to a decrease in ROM by 52.69% and Dynesys by 54.51%. The change in the adjacent level motion was within 8% of the intact ROM. To achieve the same amount of motion as that of intact, using the hybrid protocol, it was found that Stabilimax required 4.0° of more motion, Dynesys required 6.8° of more motion and In-space required 0.4° of motion less than that of intact.

4.1.2.3 Lateral Bending

Similar to flexion, the range of motion was almost same as that of the intact with total factectomy in lateral bending. However, with implantation of the Stabilimax NZ implant and Dynesys the ROM decreased at the index level. There was no change in motion in LB after implantation of the In-space spacer. The Stabilimax NZ implant led to a decrease in ROM by 43.88% and Dynesys by 55.24%. There were very minor changes (less than 5%) at the adjacent level after implantation of the various devices. To achieve the same amount of motion as that of intact, using the hybrid protocol, it was found that Stabilimax required 1.6° of more motion, Dynesys required 2.4° of more motion and In-space required 0.2° of motion compared to that of intact.
4.1.2.4 Axial Rotation

Similar to that of extension, there was a significant increase in the ROM to that of the intact after total factectomy. The removal of facets led to increase by ROM by 130% at the index level and 9.31% at the L5-S1 level. Implantation of the Stabilimax NZ implant further increased the ROM by 135% and with Inspace it by 127.81%. Dynesys also led to an increase in the ROM by 15.91% at the index level. The moment required to achieve the same motion as that of intact was relatively less for all the conditions.

Figure 4-1 Relative motion in extension for different grades of factectomy
Figure 4-2 Relative motion in flexion for different grades of facetectomy.

Figure 4-3 Relative motion in lateral bending for different grades of facetectomy.
Figure 4-4 Relative motion in axial rotation for different grades of facetectomy.

Figure 4-5 Hybrid moments required at L4-5 after different grades of facetectomy.
Table 4.1 Percent change in relative motion for all the loading modes after partial and total facetectomy. A positive percent change indicates an increase in relative motion whereas a negative percent change indicates a decrease in relative motion.

### EXTENSION

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<th>%Change</th>
<th>L4-L5</th>
<th>%Change</th>
<th>L5-S1</th>
<th>%Change</th>
</tr>
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<td>---</td>
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<td>---</td>
<td>3.0</td>
<td>---</td>
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<td>-0.1%</td>
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<td>16.7%</td>
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<td>-57.3%</td>
<td>3.3</td>
<td>11.7%</td>
</tr>
<tr>
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<td>2.66</td>
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<td>2.2</td>
<td>-25.7%</td>
<td>3.6</td>
<td>21.0%</td>
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<td>3.0</td>
<td>-0.9%</td>
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### FLEXION

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### LATERAL BENDING

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<tr>
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<td>4.70</td>
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<td>-11.6%</td>
</tr>
<tr>
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<td>4.7</td>
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<tr>
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<td>-43.9%</td>
<td>3.6</td>
<td>2.7%</td>
</tr>
<tr>
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<td>5.91</td>
<td>25.9%</td>
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<td>-55.2%</td>
<td>4.5</td>
<td>29.7%</td>
</tr>
<tr>
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<td>4.8</td>
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<td>-12.3%</td>
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</table>

### AXIAL ROTATION

<table>
<thead>
<tr>
<th></th>
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<th>L4-L5</th>
<th>%Change</th>
<th>L5-S1</th>
<th>%Change</th>
</tr>
</thead>
<tbody>
<tr>
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<td>2.58</td>
<td>---</td>
<td>2.6</td>
<td>---</td>
<td>2.2</td>
<td>---</td>
</tr>
<tr>
<td>50% Facetectomy</td>
<td>2.58</td>
<td>0.1%</td>
<td>2.6</td>
<td>0.1%</td>
<td>2.2</td>
<td>0.1%</td>
</tr>
<tr>
<td>50% Facetectomy+Stabilimax</td>
<td>2.74</td>
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<td>-11.4%</td>
<td>2.2</td>
<td>1.7%</td>
</tr>
<tr>
<td>50% Facetectomy+Dynesys</td>
<td>3.10</td>
<td>11.2%</td>
<td>1.5</td>
<td>-24.1%</td>
<td>2.7</td>
<td>13.5%</td>
</tr>
<tr>
<td>50% Facetectomy+Spacer</td>
<td>2.58</td>
<td>0.0%</td>
<td>2.6</td>
<td>1.4%</td>
<td>2.0</td>
<td>-4.9%</td>
</tr>
<tr>
<td>100% Facetectomy</td>
<td>1.50</td>
<td>-23.1%</td>
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<td>43.2%</td>
<td>1.2</td>
<td>-27.4%</td>
</tr>
<tr>
<td>100% Facetectomy+Stabilimax</td>
<td>2.65</td>
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<td>0.7%</td>
</tr>
<tr>
<td>100% Facetectomy+Dynesys</td>
<td>2.27</td>
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<td>3.2</td>
<td>13.0%</td>
<td>2.0</td>
<td>-6.6%</td>
</tr>
<tr>
<td>100% Facetectomy+Spacer</td>
<td>2.52</td>
<td>-1.3%</td>
<td>8.3</td>
<td>124.9%</td>
<td>2.2</td>
<td>-1.2%</td>
</tr>
</tbody>
</table>
4.2 Stresses in the Nucleus Pulposus for Different Grades of Factectomy

The von Mises stresses in the intervertebral disc was computed for each posterior stabilization system after performing factectomy and was compared with the nucleus pulposus stresses from the intact model. Figures 4-5 to 4-8 presents the von Mises stress comparison for the nucleus pulposus for all the fixation systems in all the loading modes. Table 4-2 presents the peak von Mises stress values in the nucleus pulposus and their percentage changes with respect to the intact values. The intervertebral disc stress at the implanted level helps determine how much load is shared by the instrumentation.

4.2.1 Stresses in the Nucleus Pulposus after 50% Factectomy

4.2.1.1 Extension

In extension, it was seen that with 50% factectomy the IDP increased at the implanted level in extension by 11.4%. Stabilization with Stabilimax led to decrease in IDP by 36% whereas Dynesys led to a decrease in IDP by 18.5%. The implantation of the In-space led to the greatest decrease in IDP by 54.5%. The IDP at the adjacent level increased with the implantation of Stabilimax. The IDP increased by 15.56% at L3-L4 and 19.1% at L5-S1 after implantation of Stabilimax.

4.2.1.2 Flexion

In flexion, factectomy did not lead to any change in IDP at the implanted level. Stabilimax led to decrease in IDP by 18.2% whereas Dynesys led to a decrease in IDP by 21.1%. The implantation of the In-space did not cause any change in the IDP. The IDP at
the adjacent did not increase with the implantation of the Stabilimax and In-space spacer. However, IDP increased by 45.33% at L3-L4 and 32.7% at L5-S1 after implantation of Dynesys.

### 4.2.1.3 Lateral Bending

In lateral bending, 50% factectomy did not lead to any change in IDP at the implanted level. Stabilimax led to decrease in IDP by 43.4% whereas Dynesys led to a decrease in IDP by 38.1%. The implantation of the In-space did not cause any change in the IDP. The IDP at the adjacent did not increase with the implantation of the Stabilimax and In-space spacer. However, IDP increased by 26.91% at L3-L4 and 27.4% at L5-S1 after implantation of Dynesys.

### 4.2.1.4 Axial Rotation

Similar to lateral bending and flexion, 50% factectomy did not lead to any change in IDP at the implanted level. The IDP increased by not more than 10% for all the cases at the index level. Similarly, the IDP did not increase at the adjacent level with Dynesys and In-Space but the IDP increased at L3-L4 level by 15.37% and by 10.5% at the L5-S1 level after implantation with Stabilimax.
4.2.2 Stresses in the Nucleus Pulposus after Total Factectomy

4.2.2.1 Extension

In extension, with total factectomy the IDP increased significantly at the implanted level in extension by 153.7%. Stabilization with Stabilimax led to decrease in IDP by 36% whereas Dynesys led to a decrease in IDP by 7.2%. The implantation of the In-space led to the greatest decrease in IDP by 54.8%. The IDP at the adjacent level increased with the implantation of Stabilimax. The IDP increased by 16.12% at L3-L4 and 18.1% at L5-S1 after implantation of Stabilimax.

4.2.2.2 Flexion

In flexion, factectomy did not lead to any change in IDP at the implanted level. Stabilimax led to decrease in IDP by 19.1% whereas Dynesys led to a decrease in IDP by 15.2%. The implantation of the In-space led to a slight increase in IDP at the index level. The IDP at the adjacent did not increase with the implantation of the Stabilimax and In-space spacer. However, IDP increased by 49.18% at L3-L4 and 37.3% at L5-S1 after implantation of Dynesys.

4.2.2.3 Lateral Bending

In lateral bending, total factectomy did not lead to any change in IDP at the implanted level. Stabilimax led to decrease in IDP by 43.8% whereas Dynesys led to a decrease in IDP by 30.2%. The implantation of the In-space did not cause any change in the IDP at the index level. The IDP at the adjacent did not increase with the implantation of the
Stabilimax. However, IDP increased by 23.05% at L3-L4 and 30.2% at L5-S1 after implantation of Dynesys and decreased by 11.8% at L5-S1 with In Space spacer.

4.2.2.4 Axial Rotation

Total factectomy led to an increase in IDP at the index level by 10.2%. All the devices led to an increase in IDP at the implanted level. There was no significant change in IDP at the index level with Dynesys and Inspace. However, the IDP increased by 19.9% with the implantation of Stabilimax. At the adjacent level, there was not any substantial change in IDP with any of the implant.

Figure 4-6 von Mises stress in extension for different grades of factectomy
Figure 4-7 von Mises stress in flexion for different grades of factectomy

Figure 4-8 von Mises stress in lateral bending for different grades of factectomy
Figure 4-9 von Mises stress in axial rotation for different grades of facetectomy
Table 4.2 von Mises stress and percentage change in the nucleus pulposus for different grades of factectomy. A positive percent change indicates an increase in relative motion whereas a negative percent change indicates a decrease in relative motion.

<table>
<thead>
<tr>
<th></th>
<th>Extension</th>
<th>Flexion</th>
<th>Lateral Bending</th>
<th>Axial Rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>L3-L4 %Change</td>
<td>L4-L5 %Change</td>
<td>L5-S1 %Change</td>
<td>L3-L4 %Change</td>
</tr>
<tr>
<td>Intact</td>
<td>0.127</td>
<td>0.119</td>
<td>0.151</td>
<td>0.191</td>
</tr>
<tr>
<td>50% Facetectomy</td>
<td>0.12</td>
<td>-1.4%</td>
<td>0.13</td>
<td>11.4%</td>
</tr>
<tr>
<td>50% Facetectomy+Stabilimax</td>
<td>0.15</td>
<td>15.6%</td>
<td>0.08</td>
<td>-36.0%</td>
</tr>
<tr>
<td>50% Facetectomy+Dynsys</td>
<td>0.14</td>
<td>10.3%</td>
<td>0.10</td>
<td>-18.4%</td>
</tr>
<tr>
<td>50% Facetectomy+Spacer</td>
<td>0.13</td>
<td>2.8%</td>
<td>0.05</td>
<td>-54.8%</td>
</tr>
<tr>
<td>100%Facet</td>
<td>0.12</td>
<td>-6.3%</td>
<td>0.30</td>
<td>153.7%</td>
</tr>
<tr>
<td>100%Facet+Stabilimax</td>
<td>0.15</td>
<td>16.1%</td>
<td>0.07</td>
<td>-36.9%</td>
</tr>
<tr>
<td>100%Facet+Dynsys</td>
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<td>0.11</td>
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</tr>
<tr>
<td>100%Facet+Spacer</td>
<td>0.13</td>
<td>2.8%</td>
<td>0.05</td>
<td>-54.6%</td>
</tr>
</tbody>
</table>

Note: The table continues with similar data for other grades of factectomy and motion types.
4.3 Facet forces for Different Grades of Facetectomy

Total facet loads were computed for each fixation at 400N follower preload and pure moment of 10Nm and were compared to intact. The facets are not functional in flexion mode. Therefore the loads on the facet in flexion are nearly zero. Hence the facet loads in flexion are not reported. The facet forces at the index level were calculated for 50% factectomy only since in total factectomy both the facets were completely removed. The facet forces at the adjacent levels were evaluated for both 50% and 100% factectomy. The percentage change in facet load with respect to the intact is reported in table 4-5.

4.3.1 Extension

It was found that the facet forces decreased significantly in extension for the Stabilimax and Inspace spacer. Facet forces decreased by almost 100% for the Inspace spacer in extension at the index level whereas it decreased by 64.3% with implantation of Stabilimax. The decrease in facet forces for the Dynesys was relatively low and was approximately 21.4% at L4-L5. At the adjacent level, L5-S1, the facet forces increased for all the constructs with both 50% and 100% factectomy.

4.3.2 Lateral Bending

With lateral bending, it was found out that the facet forces increased with 50% factectomy by 86% with Dynesys whereas, it decreased by 23.4% for the In-space spacer and by 6.7% for Stabilimax. At the adjacent level L3-L4, there was an increase in facet force with factectomy for Stabilimax by 63.5%. The facet forces were similar to intact for Dynesys and Inspace spacer at the adjacent level.
**4.3.3 Axial Rotation**

Facetectomy led to an increase in facet forces for the Dynesys and Stabilimax constructs by 14.8% and 39.0% respectively whereas it was similar to Intact for In-space at the index level after 50% factectomy. With total factectomy adjacent level forces increased by approximately 25% at the adjacent level with Inspace spacer and by 10.8% at L5-S1 level with Stabilimax. There were not any significant changes at L3-L4 with Dynesys and Stabilimax.

![Facet Forces in Extension](image)

Figure 4-10 Total facet loads in extension for different grades of factectomy
Figure 4-11 Total facet loads in lateral bending for different grades of facetectomy

Figure 4-12 Total facet loads in axial rotation for different grades of facetectomy
Table 4.3 Total facet loads and percentage changes for all the loading modes for different grades of factectomy. A positive percent change indicates an increase in relative motion whereas a negative percent change indicates a decrease in relative motion.

**EXTENSION**

<table>
<thead>
<tr>
<th></th>
<th>L3-L4 %Change</th>
<th>L4-L5 %Change</th>
<th>L5-S1 %Change</th>
</tr>
</thead>
<tbody>
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<td><strong>Intact</strong></td>
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<td>---</td>
<td>267.43</td>
</tr>
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<td>264.59</td>
</tr>
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<td>374.17</td>
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<td>324.00</td>
</tr>
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</tr>
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<td>341.68</td>
<td>-1.9%</td>
<td>335.17</td>
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<td>100% Facetectomy</td>
<td>363.81</td>
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<td>261.95</td>
</tr>
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<td>748.92</td>
<td>115.1%</td>
<td>650.74</td>
</tr>
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<td>100% Facetectomy+Dynesys</td>
<td>372.99</td>
<td>7.1%</td>
<td>289.10</td>
</tr>
<tr>
<td>100% Facetectomy+Spacer</td>
<td>341.67</td>
<td>-1.9%</td>
<td>335.17</td>
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</table>

**LATERAL BENDING**

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<th></th>
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<th>L4-L5 %Change</th>
<th>L5-S1 %Change</th>
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<td><strong>Intact</strong></td>
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<td>141.82</td>
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<td>141.20</td>
</tr>
<tr>
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<td>63.5%</td>
<td>175.22</td>
</tr>
<tr>
<td>50% Facetectomy+Dynesys</td>
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<td>174.99</td>
</tr>
<tr>
<td>50% Facetectomy+Spacer</td>
<td>110.12</td>
<td>0.5%</td>
<td>135.70</td>
</tr>
<tr>
<td>100% Facetectomy</td>
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<td>100% Facetectomy+Stabilimax</td>
<td>179.34</td>
<td>63.7%</td>
<td>176.22</td>
</tr>
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<td>100% Facetectomy+Dynesys</td>
<td>123.62</td>
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<td>171.21</td>
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<tr>
<td>100% Facetectomy+Spacer</td>
<td>112.89</td>
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**AXIAL ROTATION**

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<th>L4-L5 %Change</th>
<th>L5-S1 %Change</th>
</tr>
</thead>
<tbody>
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<td>322.64</td>
<td>---</td>
<td>300.59</td>
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<tr>
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<td>322.79</td>
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<td>299.71</td>
</tr>
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<td>327.56</td>
<td>4.5%</td>
<td>315.65</td>
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</tr>
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<tr>
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<td>324.20</td>
<td>1.4%</td>
<td>300.00</td>
</tr>
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</table>

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4.4 Range of Motion after Decompression Surgery

4.4.1 Extension

In extension, the range of motion increased by 22% after decompression surgery. However, with implantation of all the devices there was a considerable decrease in the ROM at the index level. The Stabilimax NZ implant led to a decrease in ROM by 61.2%, Dynesys by 20.9%, whereas the In-space spacer led to a decrease by 77%. The change in the adjacent level motion was within 15% of the intact ROM for all the constructs. To achieve the same amount of motion as that of intact, using the hybrid protocol, it was found that Stabilimax and Dynesys required 1.6° of more motion, and In-space required 2.4° of more motion.

4.4.2 Flexion

In flexion, the range of motion increased by 11.7% after decompression surgery as compared to intact. However, implantation of the Stabilimax NZ implant and Dynesys led to a decrease in the ROM at the index level by 35.5% and 70.4% respectively. There was an increase in motion (21.1%) in flexion after implantation of the In-space spacer. Adjacent level motion increased by 42.1% at L3-L4 level and 30.6% at L5-S1 level. To achieve the same amount of motion as that of intact, using the hybrid protocol, it was found that Stabilimax required 4.8° of more motion, Dynesys required 1.6° of more motion and In-space required 0.8° of motion less than that of intact.
4.4.3 Lateral Bending

In lateral bending, the range of motion was 15.5% greater than that of intact with decompression surgery. However, with implantation of the Stabilimax NZ implant and Dynesys the ROM decreased at the index level. There was an increase in motion by 16.9% in LB after implantation of the In-space spacer. The Stabilimax NZ implant led to a decrease in ROM by 37.8% and Dynesys by 52.7%. The adjacent level motion increased for lateral bending with the Dynesys construct. However, no significant changes were found with the Stabilimax and Dynesys implant. To achieve the same amount of motion as that of intact, using the hybrid protocol, it was found that Stabilimax required 1.6° of more motion, Dynesys required 2.4° of more motion and In-space required 0.1° of less motion as compared to that of intact.

4.4.4 Axial Rotation

In axial rotation, the ROM increased by 11.4% with decompression as compared to intact. There was no significant change in motion in AR after implantation of any of the constructs. There were very minor changes at the adjacent level after implantation of the various devices. To achieve the same amount of motion as that of intact, using the hybrid protocol, it was found that Stabilimax and In-space required 0.8° and 0.4° of more motion, and Dynesys required 0.4° of more motion as compared to that of intact.
Figure 4-13 Relative motion at all levels in extension after decompression surgery

Figure 4-14 Relative motion at all levels in flexion after decompression surgery
Figure 4-15 Relative motion at all levels in lateral bending after decompression surgery

Figure 4-16 Relative motion at all levels in axial rotation after decompression surgery
Figure 4-17 Hybrid moments at L4-5 after decompression surgery
Table 4.4 Percent change in relative motion in response for all the loading modes after decompression surgery. A positive percent change indicates an increase in relative motion where as a negative percent change indicates a decrease in relative motion.

<table>
<thead>
<tr>
<th>Extens</th>
<th>L3-L4</th>
<th>%Change</th>
<th>L4-L5</th>
<th>%Change</th>
<th>L5-S1</th>
<th>%Change</th>
</tr>
</thead>
<tbody>
<tr>
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<td>---</td>
<td>2.95</td>
<td>---</td>
<td>3.50</td>
<td>---</td>
</tr>
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<td>2.08</td>
<td>-9.9%</td>
<td>3.60</td>
<td>22.0%</td>
<td>3.49</td>
<td>-0.3%</td>
</tr>
<tr>
<td>Decomp Surgery+S</td>
<td>2.59</td>
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<tr>
<td>Decomp Surgery+Dynsys</td>
<td>2.66</td>
<td>15.0%</td>
<td>2.33</td>
<td>-20.9%</td>
<td>3.56</td>
<td>1.9%</td>
</tr>
<tr>
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<td>2.51</td>
<td>8.8%</td>
<td>0.68</td>
<td>-76.9%</td>
<td>2.95</td>
<td>-15.8%</td>
</tr>
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<table>
<thead>
<tr>
<th>Flexion</th>
<th>L3-L4</th>
<th>%Change</th>
<th>L4-L5</th>
<th>%Change</th>
<th>L5-S1</th>
<th>%Change</th>
</tr>
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<td>5.22</td>
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</tr>
<tr>
<td>Decomp Surgery</td>
<td>4.87</td>
<td>-1.3%</td>
<td>5.69</td>
<td>11.7%</td>
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<td>1.8%</td>
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<td>Decomp Surgery+S</td>
<td>5.04</td>
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<td>-35.5%</td>
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<td>0.8%</td>
</tr>
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<td>Decomp Surgery+Dynsys</td>
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<td>1.51</td>
<td>-70.4%</td>
<td>6.80</td>
<td>30.3%</td>
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<tr>
<td>Decomp Surgery+Spacer</td>
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<td>21.1%</td>
<td>5.21</td>
<td>-0.2%</td>
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<table>
<thead>
<tr>
<th>Lateral Bending</th>
<th>L3-L4</th>
<th>%Change</th>
<th>L4-L5</th>
<th>%Change</th>
<th>L5-S1</th>
<th>%Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>4.69</td>
<td>---</td>
<td>4.54</td>
<td>---</td>
<td>3.46</td>
<td>---</td>
</tr>
<tr>
<td>Decomp Surgery</td>
<td>4.63</td>
<td>-1.2%</td>
<td>5.24</td>
<td>15.5%</td>
<td>3.46</td>
<td>0.1%</td>
</tr>
<tr>
<td>Decomp Surgery+S</td>
<td>4.74</td>
<td>1.0%</td>
<td>2.82</td>
<td>-37.8%</td>
<td>3.54</td>
<td>2.4%</td>
</tr>
<tr>
<td>Decomp Surgery+Dynsys</td>
<td>5.88</td>
<td>25.4%</td>
<td>2.15</td>
<td>-52.7%</td>
<td>4.52</td>
<td>30.6%</td>
</tr>
<tr>
<td>Decomp Surgery+Spacer</td>
<td>4.67</td>
<td>-0.4%</td>
<td>5.31</td>
<td>16.9%</td>
<td>3.07</td>
<td>-11.4%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Axial Rotation</th>
<th>L3-L4</th>
<th>%Change</th>
<th>L4-L5</th>
<th>%Change</th>
<th>L5-S1</th>
<th>%Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>2.58</td>
<td>---</td>
<td>2.58</td>
<td>---</td>
<td>2.19</td>
<td>---</td>
</tr>
<tr>
<td>Decomp Surgery</td>
<td>2.48</td>
<td>-2.1%</td>
<td>3.10</td>
<td>11.4%</td>
<td>2.15</td>
<td>-1.1%</td>
</tr>
<tr>
<td>Decomp Surgery+S</td>
<td>2.72</td>
<td>3.0%</td>
<td>2.88</td>
<td>6.7%</td>
<td>2.28</td>
<td>2.7%</td>
</tr>
<tr>
<td>Decomp Surgery+Dynsys</td>
<td>2.79</td>
<td>4.5%</td>
<td>2.08</td>
<td>-10.9%</td>
<td>2.41</td>
<td>6.4%</td>
</tr>
<tr>
<td>Decomp Surgery+Spacer</td>
<td>2.58</td>
<td>0.0%</td>
<td>3.18</td>
<td>13.3%</td>
<td>2.03</td>
<td>-4.6%</td>
</tr>
</tbody>
</table>
4.5 IDP for Various Loading Conditions after Decompression Surgery

Since complete disectomy was performed at the operated level, there was no IDP pressure recorded at the L4-L5 level. The changes in the IDP at the adjacent level for various loading modes have been discussed. It was seen that the IDP increased in extension for Stabilimax where it was 15.6% more than intact at L3-L4 level and 19.1% at L5-S1. With Dynesys, the IDP increased by a significant amount in both flexion and lateral bending. In Flexion, the IDP increased by 38.4% and 27.0% respectively at L3-L4 and L5-S1 levels, whereas in lateral bending it increased by 23.1% and 23.6% respectively. The implantation of In-space did not show any significant changes with decompression surgery at the adjacent levels in any of the loading modes.

Figure 4-18 von Mises stresses in extension after decompression surgery
Figure 4-19 von Mises stresses in flexion after decompression surgery

Figure 4-20 von Mises stresses in lateral bending after decompression surgery
Figure 4-21 von Mises stresses in axial rotation after decompression surgery
Table 4.5 von Mises stresses and percentage change in the nucleus pulposus for all the loading modes after decompression surgery. A positive percent change indicates an increase in relative motion whereas a negative percent change indicates a decrease in relative motion.

<table>
<thead>
<tr>
<th></th>
<th>L3-L4 %Change</th>
<th>L4-L5 %Change</th>
<th>L5-S1 %Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EXTENSION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>0.127</td>
<td>---</td>
<td>0.119</td>
</tr>
<tr>
<td>Decompression Surgery</td>
<td>0.12</td>
<td>-4.1%</td>
<td>0</td>
</tr>
<tr>
<td>Decompression Surgery+Stabilimax</td>
<td>0.15</td>
<td>15.6%</td>
<td>0.00</td>
</tr>
<tr>
<td>Decompression Surgery+Dynesys</td>
<td>0.14</td>
<td>10.3%</td>
<td>0.00</td>
</tr>
<tr>
<td>Decompression Surgery+Spacer</td>
<td>0.13</td>
<td>3.1%</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>FLEXION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>0.19</td>
<td>---</td>
<td>0.168</td>
</tr>
<tr>
<td>Decompression Surgery</td>
<td>0.19</td>
<td>-0.8%</td>
<td>0.00</td>
</tr>
<tr>
<td>Decompression Surgery+Stabilimax</td>
<td>0.18</td>
<td>-5.3%</td>
<td>0.00</td>
</tr>
<tr>
<td>Decompression Surgery+Dynesys</td>
<td>0.26</td>
<td>38.4%</td>
<td>0.00</td>
</tr>
<tr>
<td>Decompression Surgery+Spacer</td>
<td>0.19</td>
<td>0.0%</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>LATERAL BENDING</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>0.270</td>
<td>---</td>
<td>0.219</td>
</tr>
<tr>
<td>Decompression Surgery</td>
<td>0.27</td>
<td>-0.1%</td>
<td>0.00</td>
</tr>
<tr>
<td>Decompression Surgery+Stabilimax</td>
<td>0.26</td>
<td>-3.6%</td>
<td>0.00</td>
</tr>
<tr>
<td>Decompression Surgery+Dynesys</td>
<td>0.33</td>
<td>23.1%</td>
<td>0.00</td>
</tr>
<tr>
<td>Decompression Surgery+Spacer</td>
<td>0.27</td>
<td>0.0%</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>AXIAL ROTATION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>0.125</td>
<td>---</td>
<td>0.108</td>
</tr>
<tr>
<td>Decompression Surgery</td>
<td>0.13</td>
<td>1.1%</td>
<td>0.00</td>
</tr>
<tr>
<td>Decompression Surgery+Stabilimax</td>
<td>0.15</td>
<td>7.7%</td>
<td>0.00</td>
</tr>
<tr>
<td>Decompression Surgery+Dynesys</td>
<td>0.13</td>
<td>1.4%</td>
<td>0.00</td>
</tr>
<tr>
<td>Decompression Surgery+Spacer</td>
<td>0.13</td>
<td>0.1%</td>
<td>0.00</td>
</tr>
</tbody>
</table>
4.6 Facet Forces after Decompression Surgery

Total facet loads were computed for each fixation at 400N follower preload and pure moment of 10Nm and were compared to intact. Similar to the factectomy condition, the facets are not functional in flexion mode. Therefore the loads on the facet in flexion are nearly zero. Hence the facet loads in flexion are not reported. The percentage change in facet load with respect to the intact is reported in table 4-5.

4.6.1 Extension

It was found that the facet forces decreased significantly in extension for the Stabilimax and Inspace spacer. Facet forces decreased by 96.1 % for the Inspace spacer in extension at the index level whereas it decreased by 71.2 % with implantation of Stabilimax. As seen with different 50% factectomy, it was found that the decrease in facet forces for the Dynesys was relatively low and was approximately 31.3% at L4-L5. At the adjacent level, L5-S1, the facet forces increased for all the constructs with the maximum increase shown for the In-space spacer of about 26%.

4.6.2 Lateral Bending

In lateral bending, decompression surgery led to an increase in the facet forces at the index level by 23.7%. Both the Dynesys and the Stabilimax led to a further increase in the instability. Dynesys increased the facet forces by 85.6% whereas the Stabilimax increased it by 11.6% at L4-L5 level. The In-space spacer had facet forces similar to intact. At the adjacent level L3-L4, there was an increase in facet force with factectomy for Stabilimax by 65% and dynesys by 17.3%. At L5-S1 level, the facet forces showed
similar trends with increase by 25% for Stabilimax and 20.1% for dyneys. The facet forces at the adjacent level with In-space were similar to intact.

4.6.3 Axial Rotation

Similar to lateral bending, axial rotation led to a significant amount of instability for dynesys, where the facet forces increased by 77%. With Stabilimax, the facet forces increased by 22.6% whereas it did not lead to any change in force for the In-space spacer. At the adjacent level L3-L4, facet force increased for Dynesys by 14.5%. There was no significant change in facet forces for the other constructs at the adjacent level and they were similar to intact.

![Facet Forces in Extension](image)

Figure 4-22 Total facet loads in response to extension after decompression surgery
Figure 4-23 Total facet loads in lateral bending after decompression surgery

Figure 4-24 Total facet loads in response to axial rotation after decompression surgery
Table 4.6 Total facet loads and percentage changes for all the loading modes after decompression surgery. A positive percent change indicates an increase in relative motion whereas a negative percent change indicates a decrease in relative motion.

<table>
<thead>
<tr>
<th></th>
<th>EXTENSION</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>L3-L4</td>
<td>%Change</td>
<td>L4-L5</td>
<td>%Change</td>
<td>L5-S1</td>
</tr>
<tr>
<td>Intact</td>
<td>174.12</td>
<td>---</td>
<td>163.60</td>
<td>---</td>
<td>133.72</td>
</tr>
<tr>
<td>Decompression Surgery</td>
<td>188.4</td>
<td>8.2%</td>
<td>183.4</td>
<td>12.1%</td>
<td>126.7</td>
</tr>
<tr>
<td>Decompression Surgery+Stabilimax</td>
<td>187.4</td>
<td>7.6%</td>
<td>47.0</td>
<td>-71.2%</td>
<td>152.9</td>
</tr>
<tr>
<td>Decompression Surgery+Dynesys</td>
<td>202.8</td>
<td>16.5%</td>
<td>112.3</td>
<td>-31.3%</td>
<td>156.3</td>
</tr>
<tr>
<td>Decompression Surgery+Spacer</td>
<td>170.5</td>
<td>-2.1%</td>
<td>6.4</td>
<td>-96.1%</td>
<td>168.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>LATERAL BENDING</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>L3-L4</td>
<td>%Change</td>
<td>L4-L5</td>
<td>%Change</td>
</tr>
<tr>
<td>Intact</td>
<td>54.76</td>
<td>---</td>
<td>58.85</td>
<td>---</td>
</tr>
<tr>
<td>Decompression Surgery</td>
<td>69.4</td>
<td>26.7%</td>
<td>72.8</td>
<td>23.7%</td>
</tr>
<tr>
<td>Decompression Surgery+Stabilimax</td>
<td>90.4</td>
<td>65.0%</td>
<td>65.7</td>
<td>11.6%</td>
</tr>
<tr>
<td>Decompression Surgery+Dynesys</td>
<td>64.2</td>
<td>17.3%</td>
<td>109.2</td>
<td>85.6%</td>
</tr>
<tr>
<td>Decompression Surgery+Spacer</td>
<td>55.6</td>
<td>1.5%</td>
<td>55.5</td>
<td>-5.8%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>AXIAL ROTATION</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>L3-L4</td>
<td>%Change</td>
<td>L4-L5</td>
<td>%Change</td>
</tr>
<tr>
<td>Intact</td>
<td>161.32</td>
<td>---</td>
<td>160.00</td>
<td>---</td>
</tr>
<tr>
<td>Decompression Surgery</td>
<td>169.7</td>
<td>15.3%</td>
<td>166.7</td>
<td>11.4%</td>
</tr>
<tr>
<td>Decompression Surgery+Stabilimax</td>
<td>164.5</td>
<td>5.8%</td>
<td>173.3</td>
<td>22.6%</td>
</tr>
<tr>
<td>Decompression Surgery+Dynesys</td>
<td>169.6</td>
<td>15.2%</td>
<td>205.3</td>
<td>77.0%</td>
</tr>
<tr>
<td>Decompression Surgery+Spacer</td>
<td>161.9</td>
<td>1.0%</td>
<td>162.0</td>
<td>3.4%</td>
</tr>
</tbody>
</table>
4.7 Invitro Comparison of ROM for Dynesys and Viper S.C. screws

The average ROM normalized to intact for all the loading modes is as shown in Figs 4.1- 4.6. It was found that the ROM increased with destabilization of the spine at L4-L5 in all the loading modes. In extension, the motion of the injured level (L4-L5) is much higher than intact, as shown in figure 4.1. Both the Dynesys and PEEK rod systems reduce motion at the injured level in flexion-extension and lateral bending (p<0.05). When these systems are instrumented from L3-L5 with the bilateral cages at L4-L5, the motion of the L3-L4 and L4-L5 segments is reduced by at least half. In flexion, the results were similar for each segment. When the two systems were placed from L3-L5 with the bilateral cages at L4-L5, the reduction in motion at L3-L4 and L4-L5 was even more significant. This trend was also observed in right and left bending. In axial rotation, the reduction of motion is less pronounced, and especially in right rotation, it is difficult given the standard deviation bars to say there is a difference between the modes with any certainty. P-values for the comparison of motion between intact and the various test conditions and injured versus various test conditions at L4-L5 motion segment is as given in Table 4-7 & Table 4-8.
Figure 4-25 In vitro ROM normalized to intact in extension at 6 Nm

Figure 4-26 In vitro ROM normalized to intact in flexion at 8 Nm
Figure 4-27 In vitro ROM normalized to intact in left bending at 6 Nm

Figure 4-28 In vitro ROM normalized to intact in right bending for 6 Nm
Figure 4-29 In vitro ROM normalized to intact in left rotation at 6 Nm

Figure 4-30 In vitro ROM normalized to intact in right rotation at 6 Nm
Table 4.7 P-values of student's one tailed student's paired t-test of L3-S1 motion as compared to intact for eight specimens without follower load. Highlighted values indicate statistical significance between the conditions ($p < 0.05$)

<table>
<thead>
<tr>
<th>Loading Modes</th>
<th>Intact vs. Injury</th>
<th>Injury vs. Dynesys</th>
<th>Injury vs. Dynesys + Cages</th>
<th>Injury vs Viper S.C.</th>
<th>Injury vs Viper S.C + Cages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ext</td>
<td>0.0595</td>
<td>0.297</td>
<td>0.282</td>
<td>0.191</td>
<td>0.135</td>
</tr>
<tr>
<td>Flex</td>
<td>0.143</td>
<td>0.068</td>
<td>0.116</td>
<td>0.061</td>
<td>0.045</td>
</tr>
<tr>
<td>LB</td>
<td><strong>0.036</strong></td>
<td><strong>0.029</strong></td>
<td><strong>0.041</strong></td>
<td><strong>0.023</strong></td>
<td><strong>0.002</strong></td>
</tr>
<tr>
<td>RB</td>
<td>0.453</td>
<td>0.104</td>
<td>0.193</td>
<td>0.059</td>
<td>0.045</td>
</tr>
<tr>
<td>LR</td>
<td>0.172</td>
<td>0.109</td>
<td><strong>0.761</strong></td>
<td><strong>0.006</strong></td>
<td><strong>0.035</strong></td>
</tr>
<tr>
<td>RR</td>
<td>0.105</td>
<td>0.446</td>
<td>0.664</td>
<td>0.288</td>
<td>0.634</td>
</tr>
</tbody>
</table>

Table 4.8 P-values of two tailed student’s paired t-test of L3-S1 motion as compared to injured for eight specimens without follower load. Highlighted values indicate statistical significance between the conditions ($p < 0.05$)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ext</td>
<td>0.887</td>
<td>0.883</td>
<td>0.297</td>
<td>0.282</td>
<td>0.191</td>
<td>0.135</td>
</tr>
<tr>
<td>Flex</td>
<td>0.721</td>
<td>0.952</td>
<td>0.068</td>
<td>0.116</td>
<td>0.061</td>
<td>0.045</td>
</tr>
<tr>
<td>LB</td>
<td>0.811</td>
<td>0.664</td>
<td>0.029</td>
<td>0.041</td>
<td>0.023</td>
<td>0.002</td>
</tr>
<tr>
<td>RB</td>
<td>0.453</td>
<td>0.642</td>
<td>0.104</td>
<td>0.193</td>
<td>0.059</td>
<td>0.045</td>
</tr>
<tr>
<td>LR</td>
<td>0.096</td>
<td>0.521</td>
<td>0.109</td>
<td>0.761</td>
<td>0.006</td>
<td>0.035</td>
</tr>
<tr>
<td>RR</td>
<td>0.176</td>
<td>0.601</td>
<td><strong>0.444</strong></td>
<td>0.664</td>
<td><strong>0.288</strong></td>
<td><strong>0.634</strong></td>
</tr>
</tbody>
</table>
CHAPTER 5

Discussion

This chapter will attempt to explain the results of both the in vitro and finite element studies and draw conclusions. It will also highlight results from previous studies to compare those achieved here. It will end with conclusions and present some limitations for the study and opportunities for future work.

5.1 Comparison of Dynamic Stabilization Systems over Fusion Systems

The goal of dynamic spinal stabilization is to restore normal segmental kinematics of the spine. Motion preservation technologies have been progressively introduced to address the major shortcomings of spinal fusion: stiffness, pseudarthrosis, mechanical failure, and/or adjacent degenerative disease [73,78,79]. Pedicle screw-based PDS systems are based on techniques familiar to surgeons who have experience with traditional pedicular-based instrumented spinal fusions. The basic concept of PDS is to reduce the stiffness of the instrumentation to allow for more physiologic load transmission at the instrumented levels. PDS devices theoretically are flexible enough to allow increased anterior column load sharing which may favor osteogenesis and enhance
interbody fusion in accordance with Wolff’s Law [80]. Dynamic systems like Dynesys and Viper S.C. system, thus can be used with interbody fusion devices and provide anterior load sharing preventing adjacent level degeneration. The Stabilimax and In-space interspinous spacer on the other hand are only indicated for mild to moderate disc degeneration or spinal canal stenosis and have not been cleared by FDA for use in adjunct with fusion. They are mainly indicated for mild to moderate spinal canal stenosis and prevent further degeneration of the disc.

5.2 Finite Element Study and Validation with Invitro Studies

The finite element study in this work consisted of comparing Dynesys, Stabilimax and Interspinous spacer for different grades of factectomy and decompression surgery which consisted of partial factectomy (25% removal of facets), partial laminectomy and 100% nucleotomy. The aim of the study was to find out if the dynamic devices were able to stabilize the index level as well as adjacent level after performing varying degrees of destabilization.

Various degrees of facetectomy are often recommended for nerve decompression to alleviate radicular and arthritic pain. The excision of the facet joints however affects the kinematics of the index level, possibly leading to additional stresses in the remaining structures. The Dynesys surgical technique recommends performing a decompression that preserves at least 50% of the facet joints. The objective of this finite element study was to evaluate the biomechanical performance of the Dynesys dynamic stabilization system as a function of graded facetectomies and ascertain with our hypothesis that the performance
of the device is altered at 50% facetectomy as well as compare Dynesys with other PDS devices.

Our results showed that the In-space spacer was not suitable in reducing the motion and hence the facet loads with total bilateral factectomy in lateral bending and axial rotation. However, with decompression surgery and 25% factectomy, the In-Space was able to stabilize the motion segment in extension. The ROM, IDP and facet loads in other loading modes at the index and adjacent level were not significantly affected, hence indicating that the In-Space may be a possible solution for treating patients who have undergone decompression surgery due to impingement of the nerves possibly due to facet arthritis or narrowing of the spinal canal. A study undertaken by Park et al. [84] showed that In-space spacer reduced the motion in extension by approximately 70% at L3-4 level after discetomy procedure. Although our study performed a more aggressive surgery in the form bilateral laminectomy, partial facetectomy + discectomy at L4-5 level (Decompression surgery), it was still seen that the Inspace reduced the motion by 76.9% in extension and was not affective in other loading modes similar to findings of the invitro study. Similar findings were also found by Lazaro et al. [85] where they implanted the In-Space spacer in a function spinal unit at L1-L2 where they found a reduction in motion by approximately 44.5% at L1-2 segments and reduction in facet forces by approximately 69% at the implanted levels only in extension with no significant effects in other loading modes. Although, our spine model consisted of an L3-S1 model with spacer implanted at L4-5 level, the trend for the motion and facet forces in various loading modes was similar after performing various surgical procedures.
For Dynesys and Stabilimax it was found that with varying grades of facetectomy and decompression surgery, there was a reduction in motion and IDP in all the loading modes at the index level except for axial rotation mode with total facetectomy, where the ROM and IDP increased for both the implants due to complete removal of the facets. The motion and IDP at the adjacent level increased with Dynesys in flexion and lateral bending modes with partial and total facetectomy as shown in Table 4-2. The facet loads increased with partial facetectomy for Dynesys in lateral bending and axial rotation at the index level and at the adjacent level for Stabilimax with 100% facetectomy. Thus it can be assumed that with partial facetectomy, Stabilimax might be better fixation option as compared to Dynesys because of increased adjacent level motion in lateral bending and axial rotation. However with total facetectomy, both the implants were unable to restrict axial ROM at the index level and hence rigid fixation or artificial facet replacement systems might be a viable option. An in vitro study undertaken by Niosi et al. [86] comparing various lengths of Dynesys spacer after performing decompression surgery with nucleotomy showed that in general that with a follower load of 600N and a moment of 7.5 Nm, there was a significant decrease in ROM for all the constructs in flexion/extension, and lateral bending by approximately 80, 90 and 91% respectively whereas the decrease in ROM was not significant in axial rotation. The FEM study which we had undertaken consisted of follower load with 400N and a moment of 10Nm. Our results showed a decrease in motion by approximately 55% in extension, 70.4% in and 55% in lateral bending with findings similar to the cadaveric study showing that a significantly less decrease in axial rotation by only 10%. The differences in decrease in ROM in Flex/Ext, lateral bending between the in vitro and FEM study probably might be
due to different loading conditions, the compression applied to the spacer and the
moments applied although, the trends for both the studies looked similar. An in vitro
study undertaken by Panjabi et.al [70] showed that implantation of Stabilimax at L4-5
level after decompression surgery lead to a decrease in ROM after flexion/extension and
lateral bending similar to our results. The Stabilimax NZ was not effective in reducing
ROM in axial rotation. The study undertaken by Panjabi comparing the Stabilmax and a
fusion system showed that as compared to fusion system the Stabilimax reduced the
motion by only 22% of the intact condition similar to our study which showed an
approximate decrease of 30%.

5.3 Invitro Study

The current invitro study analyzed and compared the ROM for the Dynesys and the
Viper S.C. PEEK rod system. The ROM was compared after destabilization as well as
compared to topping off procedure where a PLIF cage was inserted at the index level and
fused whereas the adjacent level was supported with a PDS device to prevent adjacent
level degeneration.

It was found out from the invitro investigation that both the systems significantly
reduced ROM in flexion-extension at the index level as compared to the injured case.
Insertion of PLIF cages and topping off with a PDS device led to a further decrease in the
ROM as compared to the injured case. Our study found similar sagittal plane ROM and
behavior, more lateral bending (possibly due to more aggressive defect), and similar axial
plane ROM for the Dynesys system as compared to the study done by Schomelz et. al
[57]. They performed an in vitro investigation comparing Dynesys and fusion constructs
on six lumbar cadaveric spines after dissection of posterior ligaments, ligament flavum, transection of facet joint capsules and posterolateral nucleotomy. It was seen that compared to the intact spine, the Dynesys implanted specimen showed decreased flexion and lateral bending, equivalent extension, and more motion in axial rotation. On average, the combination of PEEK rod flexibility and screw head mobility allowed approximately 63% of the intact spine’s sagittal plane motion while the Dynesys allowed approximately 40% of the intact’s ROM.

It is assumed that PDS topping off a fusion will relieve adjacent level intradiscal pressure and facet loads since the motion at adjacent level is decreased. Assuming that the stresses contribute to adjacent-level disc disease, these data indicates that PDS topping off a fusion may provide some protection against fusion-induced adjacent-level degeneration. A cadaveric study by Cheng et al. [87] showed that the dynesys was more rigid than the natural motion segment at the adjacent level but less rigid than pedicle screw fixation when used in hybrid constructs consisting of cirumferential fusion. Thus it is seen that dynamic systems may be advantageous in situations where excessive rigidity at the adjacent segment is neither desirable nor necessary.

5.4 Summary

The current study examined the intersegmental motion of the instrumented and adjacent segments due to factectomy and decompression surgery on different dynamic stabilization systems.

Based on the FEM results we can conclude that after partial facetectomy, PDS provides the expected range of motion and unloads the facets in extension. With complete
facetectomy, however, the PDS may not provide the necessary stability since the segment becomes highly unstable in axial rotation and extension. This may result in unexpected loads on PDS, leading to fixation overload, and ultimately implant loosening. Therefore, in cases requiring complete facetectomy, alternative approaches, such as fusion or facet replacement systems, may be a better option.

The results for the decompression surgery indicate that the dynamic stabilization systems are more flexible than rigid systems but not flexible enough to say that they preserve motion. It was seen that Stabilimax may be a better option for treating patients with decompression surgery since it did not increase the motion in lateral bending and axial rotation at the adjacent level as compared to that of the Dynesys stabilization system. Also in early stages of spinal canal stenosis and degeneration implantation of the In-space spacer will be beneficial since it requires a minimal invasive percutaneous procedure and prevents iatrogenic destabilization and complications.

The in vitro study leads to the conclusion that PEEK rods provide ROM similar to that of Dynesys stabilization system and can be advantageous as compared to fusion systems since they can reduce stresses on the screw bone anchor points and potentially reduce pedicle fractures and construct failure. It is assumed that the use of PEEK rods for fusion in the lumbar spine addresses the causative factors of adjacent-segment disease, but this theoretical benefit remains to be proven.

5.5 Limitations of the Study and Future Work

The current study consisted of invitro study comparing the Dynesys stabilization system with the PEEK rod system. However there were no finite element studies to
investigate the load sharing behavior of these implants in the topping off procedure as well as the stress analysis at the implant bone interface. The studies in this direction would possible help us to investigate the loading patterns as well as the high stress points in the implant and the spine. There are also limitations to performing in vitro studies. First, the cadaver spines 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. This biomechanical study is 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, definition of parameters, and a fine mesh can produce results close to the real scenario, they are still approximations. Two types of injury were performed in the FEM study viz. different grades of facetectomy and laminectomy with partial facetectomy and nucleotomy for decompression procedure. These are extreme cases of injury. Even with this type of extreme injuries, the devices studied show a need of more flexibility. However on the other hand, surgeons might not agree with performing a complete nucleotomy and then leaving the motion segment with only a posterior dynamic system. They would fill the gap with some other instrumentation to provide more stability to the segment anteriorly since the posterior stabilization alone might not be sufficient. Also, further in vitro studies could be undertaken to validate the finite element studies. Hence posterior dynamic stabilization along with total disc replacement might be a better choice in such extreme cases of injuries. Hence, it would be interesting to study the load sharing
characteristics of the dynamic stabilization systems with an artificial disc replacement system. Also, long term clinical outcome data are needed to determine the true performance of these dynamic stabilization systems.
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Appendices

Appendix A

Functional Anatomy of the Spine

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

The spine as a whole serves as protection for the spinal cord and the nerve roots. Since each rib connects to a thoracic vertebra to form the rib cage, it also serves to protect many internal organs as well. It also provides the strength necessary to support the head, shoulders, and chest. In this way, it forms the connection between the lower and upper body. It also provides the necessary mobility and exibility of the upper body. The articulation between vertebrae can perform complex motion such as forward bending (extension), backward bending (flexion), lateral bending (left and right), axial rotation (left and right), and combinations of these. The cervical and lumbar regions are lordotic, and the thoracic is kyphotic.
**A.1 Vertebral Body**

Each vertebra has anterior and posterior arch which form a hole called foramen through which spinal cord passes. Anterior arch is called the vertebral body. Vertebral body is made of cancellous bone which is surrounded by a thin layer of cortical bone. 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.

**A.2 Facet Joints**

Each vertebra has two pairs of facet joints. One pair facing upwards is the superior articular facet, and the other pair facing downwards is the inferior articulating facet. The facet joint is a synovial type of a joint with a lubricating joint capsule. They are primarily designed to allow vertebral bodies to rotate with respect to each other. Orientation of the facet changes along length of spine. The facet joints play a major role in stabilizing the spine. These facet joints allow small degrees of flexion and extension and limit the rotation and ultimately protect the intervertebral disc from translational shear stresses.

**A.3 Ligaments**

There seven major ligaments in the in the spine: anterior longitudinal (ALL), posterior longitudinal (PLL), supraspinous, facet capsular ligaments, interspinous, ligamentum flavum and intertransverse ligaments, the anterior and posterior longitudinal ligaments run the length of the spine along the anterior and posterior surfaces. The anterior longitudinal ligament is a strong band of fibers which is broader and thicker in the lumbar region. The posterior longitudinal ligament is situated within the vertebral canal. Anterior
longitudinal ligaments play an important role in limiting the motion in extension. 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 lamina. The capsular ligaments encase the periphery of each facet joint and are perpendicular to the joint line.

A.4 Intervertebral Discs

The intervertebral discs make up approximately 20-33% of the entire length of the spinal column. These discs are avascular structures located in between adjacent vertebral bodies and allow flexion, extension, and lateral bending motions. It is made of outer annulus fibrosis and inner jelly like nucleus pulposus and the cartilaginous end-plate.

Annulus fibrosis is composed of collagen, protein and water which make it almost incompressible. Annulus fibrosis consists of many annulus fibers oriented in different directions provides flexibility to the spine and anchor to the vertebral bodies. It helps in transferring the compression, bending, shear forces and torsion between the vertebrae.

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. Under loading the nucleus pulposus acts like a fluid filled bag and swells under pressure, thus transmitting a circumferential tension to the annulus converting it to a load bearing structure. This whole setting acts as a shock absorber for the spine such that there is no high spot loading at any point and complex motion occurs.
The cartilaginous end plate that is located between the vertebral body and disc, functions as a growth plate and transfers nutrients from the vertebral body to the disc.

Figure A-1 Sagittal view of spine [88]

Figure A-2 Axial and lateral view of lumbar spine [88]
Figure A-3 Ligaments of the lumbar spine [88]