A Thesis Entitled

A Biomechanical Evaluation of Dynamic Stabilization Systems

By

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Submitted as partial fulfillment of the requirements for
the Master of Science in Bioengineering

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Graduate School

The University of Toledo

August 2005
The University of Toledo

College of Engineering

I HEREBY RECOMMEND THAT THE THESIS PREPARED UNDER MY
SUPERVISION BY Srilakshmi Vishnubhotla

ENTITLED A Biomechanical Evaluation of Dynamic Stabilization Systems

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

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Dynamic stabilization may provide a more physiologic alternative to fusion for patients suffering from low back pain. A validated 3-D nonlinear finite element model of the intact L3-S1 lumbar spine was used to evaluate the biomechanics of various dynamic stabilization systems in comparison with rigid screw rod system that is used in conventional fusion. The intact model was modified at L4-L5 to simulate stabilization with, rigid screw-rod system, rigid screw flexible rod system, Dynesys system, Cosmic system, and Wallis system. These devices were also simulated in decompression surgery to evaluate the stability. The load control and hybrid protocols were used to evaluate these devices. Various biomechanically relevant parameters like range of motion, facet loading, disc stresses, implant stresses, instantaneous axis of rotation and load sharing were evaluated. Results show that the flexible rod system does not vary much in terms of stiffness and load sharing capabilities from the rigid screw rod system. Dynesys, Cosmic and Wallis systems are more flexible than rigid systems but not flexible enough to say that they preserve motion. However, they have the ability to allow for loading through the intervertebral disc. All the flexible stabilization systems were capable of stabilizing the
decompression surgery in flexion and extension and lateral bending. Dynesys and Cosmic systems do not restore stability in axial rotation.
Acknowledgment

This thesis is a result of two years of work, which was possible only with the support and encouragement of many people. I take this opportunity to express my appreciation to all of them.

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. Without his support, encouragement, and guidance this work would have never been possible. I would like to thank Dr Koichi Sairyo for sharing with me his boundless enthusiasm for research, and for his ever-friendly smile when it mattered the most.

I would like to thank Miranda Shaw, for being a constant support for me through all the hard times, and for all the great fun, we have had. I also extend my thanks to people in the Spine Research Center and the bioengineering department for giving me the feeling of being at home at work. A special thanks to Ashutosh Khandha and Sasidhar Vadapalli for helping me in my initial days of research. I would like to thank Spine Wave, Inc. for partially funding this project. Lastly, I would like to thank my family for being so wonderfully supportive of me at all times.
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Chapter I

Introduction

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

Introduction
Low back pain (LBP) is one of the major reasons for disability for people under the age of 45 years in the US. More than 80% of North Americans suffer LBP at some point of their life. According to an estimate over $90 billion dollars were spent in treating back pain through medical care in the year 1998 alone. This represents roughly 1% of the US gross domestic product (GDP) [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.

Evolution of surgical techniques for the treatment of LBP
In the initial stages of LBP, majority of the physicians advise conservative therapies like heat therapy, traction, exercise, osteopathic manipulation, and/or mobilization of the
spine. Orthoses or corsets, also provide relief from pain. In acute low back pain, rest is necessary and adjunct to the abovementioned therapies. A patient for whom low back pain limits his/her daily activities for a prolonged period of time is an ideal candidate for surgery.

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, and more physiological.

The generation of low back pain has been traditionally attributed to the abnormal motion at the degenerative joint. Eliminating the motion with joint arthrodesis (fusion) was deemed an effective treatment option. Fusion has had a success in providing temporary pain relief, but restoring the natural disc function with a fusion procedure has been impossible due to the destruction of the anatomy and loss of mobility at the segments involved. Measuring the success of a fusion procedure with the amount of fusion achieved might not be clinically relevant since the outcomes of fusion by itself have been good but do not correlate well with the clinical success. The drawbacks of fusion surgery include pain at the bone harvesting site, adjacent level degeneration, and variability in the success of fusion surgeries [1]. In the long term, follow up of fusion, adjacent level degeneration has been the major concern. Many clinical and biomechanical studies have shown that fusion at one segment affects the adjacent segments. It is not clear, if the adjacent segment degeneration is due to the iatrogenic production of a rigid motion
segment or if it is the progression of the natural history of the underlying degenerative
disease [2, 3, 4, 5].

Various non fusion technologies have emerged in recent times to replace the conventional
fusion techniques. They aim at providing a more physiological solution to the problem.
The various non fusion techniques include spinal arthroplasty (artificial discs), facet
replacement devices, nucleus replacements, annulus repair, and dynamic stabilization
systems.

The intervertebral disc and facet joints are the main load bearing structures in the spine
and hence are most susceptible to mechanical wear and tear. Back pain arising from the
degenerative disease could be discogenic or may be directly due to diseased facet joints.

Advanced stage of disc degeneration or facet degeneration might call for a replacement
surgery. Disc arthroplasty and facet joint replacement technologies aim at restoring the
normal kinematics of the spine by acting as load bearing devices [6]. The surgery for
these devices is highly invasive. Replacing either the disc or the facet joint would be
considered a partial joint replacement. Being load bearing structures there is also a
possibility of wear of the device finally leading to osteolysis. There is also a lack of
literature on the kinematic effect of these replacement technologies on remaining
structures of the motion segments [6].

Nucleus replacement restores the disc height and maintains the normal biomechanical
behavior and the range of motion. The indications for use of a nucleus replacement
device are loss of disc height and voluminous disc herniation for patients who have a
relatively healthy disc. The advantage of using these devices is the ease of surgery when
compared to fusion or total disc replacement.
Annulus repair is a mechanical solution to reinforce the annulus. Current technology uses autograft tissue or polymers to create a sealing mechanism. This technology can be used along with the nucleus replacement surgery to avoid recurrent herniation. There have been very little biomechanical studies on the nucleus replacement and annular repair technologies, and the possible complications of using these devices especially with nucleus replacement might be device migration or/and instability.

*Dynamic stabilization* technology is indicated for younger patients with disc degeneration in more than one segment and for whom adjacent level disc degeneration is a possibility in long term follow up. It is hypothesized that adjacent level degeneration occurs due to the abnormal loading conditions caused by immobilization of the joint with fusion. The aim of using a dynamic stabilization system is to modify the kinematic behavior/remodeling of the involved segment to achieve the “normal” spinal unit. This would probably cause a physiological amount of load to pass through the intervertebral disc thus initiating and aiding the regeneration of the disc. The major difference between dynamic stabilization and arthroplasty is that dynamic stabilization aims at load sharing with the disc [6]. The advantage of using dynamic stabilization systems is that they involve minimum surgical procedure, thus preserving articular structures. Furthermore, revision surgery is easier than that for an arthroplasty or fusion procedure.

**Purpose of the study**

A number of dynamic stabilization devices are available clinically. Unfortunately, there is no sound biomechanical basis for their usage or clinically proven efficacy of their performance. Their popularity is based more on lack of satisfaction with conventional
spinal fusion rather than their proven superiority [6]. The purpose of this study is to evaluate the biomechanics of the lower lumbar spine with rigid stabilization system as well as with dynamic stabilization system using finite element modeling and analysis. The various dynamic stabilization systems included in this study are: (i) Rigid screw with a flexible rod (Nitinol, superelastic metal), (ii) Dynesys (Zimmer holdings) a pedicle screw based dynamic stabilization system, (iii) Cosmic (Ulrich, Ulm Germany) a pedicle screw based dynamic stabilization system, and (iv) Wallis (Spinetech, Inc) an interspinous based dynamic stabilization system.

The hypothesis is that dynamic stabilization systems restore kinematics and relative motion of the lumbar spine closer to that of the intact spinal segment as compared to the rigid stabilization system. Another hypothesis is that dynamic stabilization systems allow for near physiologic biomechanical parameters like stresses and loads.

A validated 3-D nonlinear finite element model of the intact L3-S1 lumbar spine will be modified to simulate rigid screw-rod, rigid screw flexible rod, and Dynesys, Cosmic, and Wallis systems at L4-L5 level. These devices will be simulated in decompression surgery to evaluate the stability. Physiologic loads will be applied to the intact L3-S1 model and the instrumented models. Stress distribution, loads, and motion characteristics will be evaluated in each case.

The layout for the study will be as follows: Chapter II describes disorders causing LBP, treatment options, various surgical procedures, and designs of various dynamic stabilization systems and their history. Chapter III describes the finite element model of the lumbar spine, the methods used to simulate various devices and explain the data
analysis. Chapter IV presents the biomechanical data obtained from the study. Chapter V provides a discussion of the results from the study and concludes the study.

Appendices A and B describe the spine anatomy and normal spine biomechanics to provide a basic understanding of the fundamentals. Appendix C provides a detailed validation study for the lumbar spine FE model. Appendix D provides details about the validation of Dynesys model with the results published by Schomelz et al. Appendix E describes modeling of the super-elastic metal Nitinol employing a user subroutine in ABAQUS. Appendix F has the list of publications by the author.
Chapter II

Literature Review

Overview
This chapter discusses low back pain caused due to various spinal disorders. The diagnosis of back pain, conservative treatment, and surgical treatment options will be explained along with the biomechanical considerations. Finally, the chapter introduces the concept of dynamic stabilization. Details regarding various dynamic stabilization systems clinically available will be provided.

Introduction
Low back pain is a broad term describing many different disorders associated with any pain in the lower back region. Decades of research on the causes of back pain have helped to explain some of the causes and effective treatments; however, questions remain. Nutrition, occupation, genetic factors, level of daily activity etc. can contribute to the low back pain, or the pain could just be idiopathic. Symptoms of the back pain may also vary with the cause. With such varying causes and end results it is a challenge for the physician to find optimal solutions for the patients.
**Low Back Pain Disorders**

The human spine is composed of highly specific tissues and structures, which together provide an extensive range of motion and considerable load carrying capacity [7]. Alteration of the form of these structures with increasing age, injury or any other reason can have a profound influence on the quality of the life. Low back pain is generally associated with degenerative changes occurring in the spine. 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 [8]. Vertebral body degeneration and ligament degeneration are degenerative diseases, which can occur with age [9]. The intervertebral disc and two facet joints form a three-joint complex, and share majority of the load on the spine, Figure 2.1 [10]. Due to this, degenerative changes of the spine can be initiated as disc degeneration or facet joint osteoarthritis [6].

![Three joint complex between the intervertebral disc and facet joints](http://www.brispine.com.au)

**Figure 2.1:** Three joint complex between the intervertebral disc and facet joints [11]
Vertebral body degeneration:

The vertebral body is made up of cancellous bone surrounded by a dense and solid cortical shell. The cancellous bone has individual trabeculae, which are oriented around the paths of principal forces and play a crucial role in the transfer of the compressive forces along the spine [10]. Osteoporosis and several morphological changes such as trabecular thinning, increased intratrabecular spacing and loss of connectivity between trabeculae are the various age related degenerative changes associated with the vertebral bodies. In osteoporosis, the bone becomes porous and there is a loss in the bone mineral density. As a result, bones become brittle, and hence are prone to fractures. Osteoporosis of the vertebrae may lead to, vertebral compression fractures, collapse of the vertebrae, and a decrease in the vertebral height, Figure 2.2. This results in severe back pain, nerve pain, or dysfunction, loss of height, or spinal deformities such as Kyphosis (severely stooped posture).

The vertebral endplates serve the main purpose of evenly distributing the loads from the intervertebral disc to the underlying cancellous bone. With age, thinning of the endplates may occur, thus leading to vertebral fracture. On the other hand, extreme ossification of the endplates may hamper the nutritive supply to the intervertebral disc [7].

Figure 2.2: Vertebral fracture and loss of disc height caused due to osteoporosis [12] (http://www.spineuniverse.com)
**Posterior Element degeneration:**

Posterior element degeneration is generally seen at the facet joints. The facet joints are clinically important since they are found to be a direct source of pain [10]. Facet blocks with anesthetic and cortisone, and even facet denervation procedures, have been recommended as treatment for patients with low back pain.

Biomechanically, the facet joints are important stabilizing structures, and carry about 18% of the total compressive load borne by a lumbar spine segment [10]. Facets also are mainly responsible for preventing large extension rotation and shear [13]. Higher facet loads and stresses are seen in extension rotation and shear, which might lead to facet osteoarthritis or hypertrophy leading to spinal stenosis. Degeneration of facet joints due mechanical factors like increased facet loading and wear, is called “the facet syndrome.”

**Intervertebral disc degeneration:**

The intervertebral discs play a very important role in mobility and load transfer through the spinal column. Any load through the spinal column is transmitted to the intervertebral disc from the vertebral body. The normal intervertebral disc is an isotropic structure, the jelly like nucleus pulposus acts like a fluid filled bag and swells under pressure. This pressure transmits as 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 allows for complex motion to occur.

With degeneration, however the biomechanical properties of the disc are altered. 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. A structural disorganization is seen due to which the hydrostatic mechanism might fail.

Even though, the exact pathogenesis of the degenerative process is still unknown [14], several factors that might cause degeneration are: aging, mechanical factors due to occupational exposure [15, 16], abnormal loading conditions [17], and the loss of nutrition to the disc. Ala kokko, 2001, has found that disc degeneration might also be predetermined genetically [17].

There are different ways a degenerated disc can lead to low back pain, depending on if the degeneration occurs in the nucleus pulposus or the annulus (Figure 2.3). A degenerated annulus can have fissures, microscopic fragmentation of individual fibers. Annular tears at the corners of the vertebral body separating the annulus from the endplates (due to age, wear and tear), concentric cracks cavities, and radiating ruptures are seen [19, 20]. Disc bulging may occur due to decrease in the radial tensile strength of the annulus. The degeneration of the nucleus occurs due to loss of water content, collagenation of the nucleus. Nucleus degeneration combined with the annular degeneration may cause disc herniation into the spinal canal causing low back pain due to nerve pinching. Thinning of the disc and a loss of disc also can occur in a degenerated disc. This loss of disc height combined with gradual ossification of the endplate and protrusion of the disc tissue causes stenosis, which again leads to back pain.

Biomechanically the degeneration in the disc causes the depressurization of the nucleus, and an increase in the load transmitted through the annulus. Loading the annulus, unprotected by the supporting pressure of the nucleus, may cause an increase in the interlaminar shear stresses of the annulus [6, 20]. Due to this, the principal areas of load
transmission across the disc depend on the posture: in flexion, the anterior annulus, in extension, the posterior annulus. This abnormally high transmission of load through the different areas of annulus with change in posture may cause posture and activity related mechanical back pain [6]. This altered stress distribution in the disc may also lead to overloading of the spinal ligaments, muscles, and facet joints, possibly damaging these structures [22].

At a macromolecular level, it has been seen that the activity of the cells can be regulated by growth factors, cytokines (proteins), and physical factors like mechanical stress. It has been suggested that under normal conditions, applied stress affects cellular activity and the disc remodels to build a matrix, which minimizes the stress [23]. In response to prolonged heavy mechanical stress, cells of the intervertebral disc may degenerate. Hence, we can hypothesize that a degenerated disc can be repaired by reversing the mechanically damaging load environment.

Figure 2.3: Degenerative diseases of the intervertebral disc [21]

(http://www.augustaortho.com)
**Other degenerative conditions:**

Initial degenerative changes in the lumbar spine most commonly occur within the intervertebral disc. Disc degeneration and facet joint osteoarthritis are usually related, but usually disc degeneration precedes facet joint osteoarthritis [24, 25, 20]. Spondylosis, spondylolisthesis, disc herniation, and spinal stenosis may follow these degenerative changes in the segment. Spinal stenosis is defined as a pathological narrowing of the spinal canal or foramen and may occur simultaneously in multiple locations. This may occur with aging due to the thickening of ligaments (ligamentum flavum), disc degeneration, posterior osteophyte projection into the spinal canal and facet hypertrophy. The other diseases of the lumbar spine can be congenital (e.g., spinal bifida), tumors or can be caused due to a traumatic injury.

**Diagnosis**

It is of importance to diagnose the origin of low back pain to prescribe the most suitable treatment applicable. Imaging the spine has been a standard technique for diagnosis of various spinal disorders. Before the advent of the recent imaging techniques, plain radiographs or invasive techniques like discography were used to determine the patients eligible for surgery. Plain radiographs (usually the initial imaging because they are inexpensive) when taken in flexion/extension and oblique direction show the disc space height and changes in the endplates.

Magnetic resonance Imaging and CT being non-invasive are now the popular tools to evaluate the disc degeneration disease. Magnetic resonance imaging is a better option since it does not involve radiation effects. In an MRI image the anatomical features like
disc height, tears in the annulus and fissures in the nucleus, level of hydration in the nucleus can be represented. Vjevtic, 2001 described the MR depiction of different discovertebral lesions [26]. N. Tanaka et al., 2001 have shown correlation between the extent of intervertebral disc degeneration and MRI images [27].

Instability can be interpreted as abnormal motion under normal physiological load. [6] The exact relationship between mobility of the segment and disc degeneration, facet arthrosis has not been clearly established yet [28]. However Tanaka et al, 2001 have found from MRI studies that disc degeneration in early stages causes instability and in the later stages, the mobility decreases [27]. In spite of abnormal translation being seen radiologically in the cases of disc degeneration with spondylolisthesis, it is not always present in symptomatic disc degeneration. It is therefore very difficult to find any basis for the concept of abnormal movement or instability as a cause of back pain.

**Conservative treatment of the low back pain**

Conservative treatment of the low back pain involves using non-invasive techniques to restore the patient to a normal daily routine. These conservative techniques generally involve medications, exercises, muscle manipulation, and toning amongst other techniques. In many cases of acute back pain, prescription of rest generally reduces the magnitude of the pain and decreases the recovery time.
**Surgical treatment**

When conservative therapies fail to reduce the pain, invasive surgical techniques are used. The aim of such invasive surgeries is to remove the pain causing structures, to stabilize the segment, and to correct the bone failure due to trauma or disease.

**Decompression surgery**

Low back pain or radiating leg pain is often caused due to neural impingement. Neural impingement can be caused due to spinal stenosis, disc herniation, facet hypertrophy, isthmic spondylolisthesis, degenerative spondylolisthesis, or (rarely) a spinal tumor. Decompression is a surgical procedure that is performed to alleviate pain caused by pinched nerves (neural impingement). These procedures generally involve removal of a part of the lamina (laminectomy), spinous process, facets (facetectomy), ligaments, and/or sometimes removing the part of the intervertebral disc (microdiscectomy) [29]. Clinical studies have shown that decompression surgery enhances neurological recovery, pain relief, and mobility [30, 31]. However, significant destabilization of the spinal motion segment is seen after decompression, especially if the facet joint is removed [32, 33, 34, 35]. Out of various methods of decompression (unilateral laminectomy, unilateral laminectomy with unilateral facetectomy, unilateral laminectomy with bilateral facetectomy, total bilateral laminectomy) total bilateral laminectomy, would lead to the largest segmental instability [33, 29]. In a finite element study done by Lee & Teo, 2004, this was found to be true under most of physiological loadings, along with an increase in the von Mises stresses in the annulus [33]. Hence, this case will be analyzed in this study.
Zander 2003 also found that the laminectomy does not affect the facet loads at the adjacent segments [35].

Success of a decompression surgery, in relieving back pain is about 64% on an average, with results deteriorating over time due to the instability [36]. To restore strength and stability of the lumbar spine after a decompression surgery, fixation or fusion surgery maybe required [33, 34, 37, 38].

**Fusion**

Fusion surgery is the current state of art of surgical treatment of most kinds of acquired or iatrogenic lumbar spine instabilities. The term “fusion” literally means fusing one or more of the vertebrae of the spine so that motion no longer occurs between them. Instability was thought to be the main cause of the pain in the low back; hence, fusion was indicated to be an appropriate solution.

The first fusion surgery was performed with bone arthrodesis in 1911 by Albee and Hibbs. [39]. Albee used tibial grafts between spinal processes to stabilize the spine. Hibb’s "feathered" the lamina and decorticated the facet joints and then added morsalized bone derived from the local dorsal spinous processes. Hibb's technique represented the very first documented example of *flexible stabilization* utilizing autologous local bone for reconstructive purposes. Burns in 1933 (Anterior Lumber Interbody) and Briggs and Milligan, Cloward and Jaslow (Posterior Lumbar Interbody Arthrodesis) added the interbody approach and in the 1930s metallic implants were first introduced [40]. Over the years, various fusion techniques adopted by surgeons are, posterior lumbar interbody fusion (PLIF), transforaminal posterior lumbar interbody fusion (TLIF), anterior lumbar
interbody fusion (ALIF), posterior lateral fusion (PLAT). PLIF and TLIF are known to be
the more rigid constructs and more popular for active age groups than the ALIF. In
addition, majority of the surgeons are more comfortable with the posterior or lateral
approaches than the anterior approaches [41].
Fusion has been a successful technique in decreasing intervertebral motion and for
increasing the spinal stiffness in various spinal disorders including degenerative stenosis,
instability due to decompression, and iatrogenic lumbar spondylolisthesis [42, 43, 44, 45,
46]. With the recent fusion techniques, successful fusion rates have approached 100%,
but this has failed to reflect a comparable increase in the successful clinical outcome [47].
The clinical outcomes after fusion appear to be quite inconsistent: a systematic review of
mainly retrospective case series reported that satisfactory clinical outcomes ranged from
just 16% to as high as 95%, with an average of around 68% [48]. In addition, a
significant apprehension of adjacent segment disease in the long-term follow-up has
always been a concern for the surgeons [6].
Chen et al, 2001 conducted a finite element study to understand the stress distribution of
the adjacent disc to fusion in flexion, extension, lateral bending, and torsion. They found
that the von Mises stress increase was larger in the upper adjacent segment to fusion than
the lower adjacent segment [49]. However, Rohlmann A et al., 2001 conducted a similar
finite element study and found only a minor change in the adjacent segment stresses [5].
Chow et al, 1996, measured segmental mobility and intradiscal pressure in six cadaveric
lumbar spine specimens before and after, single level L4-5 and double level L4-5-S1
anterior interbody fusions. They found that there was an increase in the motion at the
adjacent levels. However, they found no evidence that the loads at the adjacent segments increased [50].

Cunningham BW et al., 1997, in an in vitro biomechanical testing in human lumbar spines analyzed the effects of spinal destabilization and instrumentation on lumbar intradiscal pressure [51]. They quantified the intradiscal pressures using pressure needle transducers, in axial compression (0-600N), flexion, and extension. They found that in response to destabilization and instrumentation, adjacent disc pressures increased as much as 45%, and operative pressure levels decreased by about 41-55%.

A review of literature on lumbar fusion reported the abnormal processes observed radiologically at the adjacent segment after spinal fusion to be: (i) disc degeneration (Loss of Disc Height, Disc Space Narrowing), (ii) spondylolisthesis (iii) instability, (iv) herniated nucleus pulposus, (v) stenosis, (vi) hypertrophic facet arthritis, (vii) osteophyte formation, (viii) scoliosis, (ix) vertebral compression fracture [52].

Lai PL et al., 2004, conducted a retrospective study of 101 patients who had undergone posterolateral lumbar fusion, to analyze the association between adjacent instability and the extent of laminectomy before fusion. They found that 74% of patients with laminectomy and, 6.5% of patients without laminectomy developed instability. They concluded that the extent of laminectomy was directly related to adjacent segment instability [53].

Okuda S et al., 2004 conducted a study using radiology and found that there was no correlation between the degeneration of the adjacent segment and clinical results [54]. They concluded that, development of adjacent segment degeneration maybe a part of the normal aging and degenerative process and not direct consequence of altered stresses that
arises due to lumbar fusion. It is still unclear whether the radiographic and clinical findings of adjacent segment instability and degeneration are a direct outcome of iatrogenic production of a rigid motion segment with spinal fusion, or these represent the progression of the natural history of the underlying degenerative disease [4, 5, 52, 45]. From a biomechanical point of view, rigid spinal fusion is inherently a non-physiologic procedure. It represents a less-than-optimal solution to the management of spine disorders for many patients, particularly those afflicted with multi-level degenerative and genomic disorders. Many patients with rigid fusion develop incapacitating "transitional" degenerative changes at adjacent spinal segments and often need additional spine surgery. It is now well accepted that degeneration of the spine is often, but not invariably associated with pain. It has been noted that back pain is primarily related to position or posture, rather than movement of the lumbar spine. It has thus been hypothesized that, rather than the abnormal movement itself, it is the abnormal pattern of loading that is associated with degeneration [6]. The fact that, in a given patient, the precise position that provokes an abnormal loading pattern is rarely known may explain why the results of fusing the spine in one position appear to be somewhat “random” as regards clinical success [40, 55]. 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 [6].

**Non fusion systems**

With the age group of the patients shifting to the younger population, often times fusion is an over-treatment for many patients [1]. Hence non fusion technologies are evolving to
provide a more physiological solution to the problem at hand. The ideas of non-fusion systems range from replacing the disc with complete excision of the disc, replacing the disc while maintaining the annulus, or maintaining the disc with a controlled motion of the segment. Joint replacement systems (total disc replacement, facet joint replacement) and dynamic stabilization systems will be discussed in detail.

**Total disc replacement and facet replacement technologies (spinal arthrosis)**

The main goal of spinal arthrosis is to restore normal mobility to the degenerated spinal segment and restore the disc height. Spinal arthrosis has gained interest over the recent years due to the obvious disadvantages in the fusion surgeries, which include adjacent level degeneration and restriction of mobility of the patient.

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. Indications for a total disc replacement are, advanced stage of disc disease, multiple level discectomy, or as a secondary procedure after a failed fusion surgery [1]. The contraindications include posterior facet joint disease (i.e. facet joint osteoarthritis), prior spinal fusion, osteoporosis, spinal stenosis, and spondylolisthesis. The various artificial discs that have evolved for the lumbar spine are Charite, Prodisc II, and Maverick.

Cunningham et al., 2003, conducted an in *vitro* biomechanical study using 8 cadaveric lumbar spine specimens to quantify the multidirectional intervertebral kinematics following total disc replacement arthroplasty (Charite disc) compared to conventional stabilization techniques (fusion). They used, range of motion (ROM) and centers of intervertebral rotation as the parameters to quantify the kinematics of the spinal segment.
When compared to the intact at the instrumented level, Charite increases the ROM by 44% in axial rotation, 3% in flexion and extension, and 16% in lateral bending. The fusion case reduced the motion by 80% in axial rotation, 93% in flexion and extension, and 83% in axial rotation. No significant changes were found at the adjacent levels [56].

Based on flexion-extension radiographs, the intervertebral centers of rotation were calculated and it was found that disc replacement with Charite preserves the normal mapping of segmental motion [56]. Dmitriev AE et al., 2005, conducted an in vitro investigation of cervical adjacent level intradiscal pressures (IDP’s) following a total disc replacement arthroplasty. They concluded that artificial disc replacement does not affect the adjacent segment IDP’s [57]. The early randomized clinical trials for comparison of fusion with disc replacement showed that disc replacement patients reported significantly less pain and disability [58].

McAfee et al. published a report of 60 prospective randomized cases in the US for a one level discogenic pain with a one third of the cases undergoing fusion surgeries and the other two-thirds Charite disc replacements. They looked for functional outcome measurements and found that the results were comparable to fusion surgeries [59].

Another group concentrated on the complications after implantation up to 127 months after implantation of Charite artificial disc and reported the complications involved degeneration of other lumbar discs, facet joint arthrosis at the same or other levels, and subsidence of the prosthesis [60].

The exact surgical implantation of the device is of primary concern because it might cause abnormal load distribution through the segment [61]. The subsidence of the artificial disc is also an issue [61]. The long term effect of wear debris in these designs is
also a concern if implanted in a younger age group of patients. Hallab et al., 2003, did a study that highlighted the association between spinal implants particulate wear debris and increased potential for osteolysis.

A facet joint replacement or arthroplasty is to replace the degenerative facets with an articulating prosthesis that would imitate the motion of the natural facet joint, thus preserving motion. Facet joint replacement technology is of interest especially with more number of the total disc replacement surgeries taking place. Preliminary designs for the facet joint replacement are being developed. Since this concept is in the early stages, studies have to be taken up to understand the biomechanical issues involved in the design of facet joints [1].

**Dynamic stabilization**

Spinal fusion surgeries aim at limiting the motion of the segment and restoring the stability. Spinal arthroplasty (artificial disc and facets) devices restore motion by sharing the kinematics of the remaining joints of the spinal motion segment. Dynamic stabilization systems aim at altering favorably the movement and load transmission through the spinal motion segment [6]. The advantages of using dynamic stabilization systems over fusion and arthroplasty techniques are:

(i) Ability to be performed posteriorly: Familiarity of surgeons with the posterior approach is advantageous for accuracy purposes.

(ii) Tissue sparing
(iii) Load sharing: This is an advantage over the total disc replacement and prosthetic
disc replacement, which cannot be used for patients with significant posterior
pathology.
(iv) Can be used adjunctly with other non fusion technologies: Dynamic
stabilization/motion preservation technologies can be utilized with total disc
replacements and disc nucleus replacements.

The present day indications for the use of dynamic stabilization systems are for, younger
patients with multisegment disc degeneration, stabilization of decompression surgeries,
and adjacent to fusion to avoid adjacent level degeneration [1]. However, they cannot be
used as stand alones in cases where the disc is completely degenerated.

The hypothesis behind dynamic stabilization system is that control of abnormal motion
and more physiologic load transmission would relieve pain and prevent adjacent segment
degeneration. A remote expectation is that, once normal motion and load transmission is
achieved, the damaged disc may repair itself, unless the degeneration is too advanced.
This is supported by the fact that, many clinical studies suggest that cells of the
intervertebral disc respond favorably to reduced but not eliminated mechanical loading
through deposition of extracellular matrix proteins into the disc space [63,64,65]. In initial
clinical trials with one such system (Wallis, Spine next, Inc) it was seen that the
degenerated disc became hydrated over time [1].

The biomechanical action of a dynamic stabilization system is two fold; (i) it has to
permit motion, (ii) it has to share load with the disc and the facets. The load sharing
should be more or less uniform during the entire range of motion. This implies that the
kinematics of the dynamic stabilization system should be similar to that of the intact spine. This is said to be achieved when the location of the optimum instantaneous axis of rotation of the system lies close to that of the intact segment [6]. Implant fatigue failure is seen in rigid systems due to pseudoarthrosis, since the rigidity of the implant does not permit any motion. Flexible stabilization may accommodate this movement and may avoid a fatigue failure. A closer look however needs to be taken at the kinematics of the dynamic stabilization before the fatigue life may be determined. [6]. The pertinent biomechanical questions in dynamic stabilization at present are: (1) how much control of motion is desirable?, (2) how much load should be shared by the system to unload the damaged disc?, and (3) long term implant failure implications.

There are two types of dynamic stabilizations systems, which are currently available; 1) pedicle screw based systems, 2) interspinous based. These systems will be discussed in detail.

**Interspinous ligament devices**

Wires and tension bands have been used for many years in orthopedic surgery. Posterior spinal ligament complex stability has known to be reestablished by the use of sublaminar wires and cables. From this concept, inter-spinous ligament devices have emerged. These devices bind the two adjacent spinous processes using only a ligament, without any metal anchorage. These devices may be used as a stand alone or along with fusion to stabilize adjacent segments. Caserta et al, 2002 have used these inter spinous ligament devices as stand alone and as adjacent to fusion and have found that these devices are effective as a stand alone for recurrent disc herniation cases [66]. Mochida J et al, 1997 [67] have
described two surgical procedures for treatment of unstable lumbar spine using the Leeds-Keio ligament, which has been earlier used for reconstruction of ACL in the knee [68]. They conducted a clinical study on 21 patients with a two year follow up and concluded that treatment with Leed-Keio artificial ligament might be advantageous over rigid stabilization for patients suffering from degenerative spondylolisthesis or degenerative disc lesions, herniated disc with instability during flexion. Suzuki K et al, 1999 conducted a biomechanical study with the porcine vertebral model to assess the stability offered by Leed-Keio ligament in degenerative lumbar spondylolisthesis [69]. Five porcine motion segments (L4-L5) were tested in the intact, destabilized, and Leeds-Keio-instrumented conditions. Specimens were loaded in flexion and extension, and construct stiffness was measured during the initial loading cycle and at 250 cycle intervals for 1500 cycles. They found that the system was effective in initially stabilizing an unstable degenerative lumbar spondylolisthesis model; it further maintains its stabilizing effect during cyclic loading. Garner et al, 2002 have described the loop cable (Spineology, Inc, MN) system, which is made up of braided polyethylene, Figure 2.4. They state that the loop system has higher fatigue strength than metal cables and has strength similar to that of a titanium cable system [70].

![The loop system](image)

**Figure 2.4:** The loop system [6]
The surgery required for Interspinous ligament devices is very simple and they also are known to be effective in restoring stability in flexion. However, they do not unload the disc in extension at all, hence the evolution of interspinous spacer devices [6].

**Interspinous distraction devices**

The interspinous distraction devices are floating devices, which are not rigidly connected to the vertebrae. The interspinous spacers are designed to off load the posterior disc and the facet joint, by distracting the spinous processes [6]. Their usage is meant to be for the treatment of early stage intervertebral disc degeneration, or to increase the foraminal space in patients with stenosis [1]. There are several interspinous-based distraction devices, the descriptions and the indications for their use are described below.

*Weiss springs:* The Weiss springs consist of springs anchored to the lamina; the indication for the usage of this system is for fracture and deformity applications [71]. This system was modified further by Dr. Larson to consist of a rod portion attached to spinous process by using bands; these rods were meant to control rotation. A comparison a study with the Harrington distraction rods concluded that modified Weiss springs often maintain better spinal stability [72].

*St Francis medical technologies X-Stop IPD:* The X stop is intended to provide a minimally invasive, non-fusion, alternative to current treatments for degenerative lumbar spinal stenosis from L2-L5 levels, which include medical management, epidural steroid injections and decompressive laminectomy with or without fusion. The X stop is made of high strength titanium alloy, and consists of two parts (Figure 2.5). The device is introduced between the spinous processes of adjacent level vertebral bodies and is held in
place by the Supraspinous ligament keeping the segment in a slightly flexed position. Due to the slightly flexed position, the nerves get decompressed thus providing relief from pain.

Lindsey DP et al., 2003, conducted an In vitro biomechanical test using seven lumbar spines to quantify the kinematics of the lumbar spine with the X-stop. The spines were tested in flexion-extension, axial rotation, and lateral bending. Images were taken during each test to determine the kinematics of each motion segment. They found that flexion-extension range of motion was significantly reduced at the instrumented level, axial rotation and lateral bending ranges of motion were not affected at the instrumented level. They also found that the range of motion at the adjacent segments was not significantly affected by the implant [73].

Fuchs et al., 2005 conducted an in vitro biomechanical testing with the X stop spacer in conjunction with graded factectomy procedure and found that in bilateral total factectomy the Interspinous implant significantly decreased the range of motion in flexion and extension; had no effect on axial rotation; significantly increased the ROM for lateral bending [74].

Swanson KE et al, 2003 conducted a biomechanical investigation using eight cadaver lumbar specimens (L2-L5). The specimens were loaded in flexion, neutral, and extension. A pressure transducer was used to measure the intradiscal pressure and annular stresses during each of the three positions at each of the three disc levels. An appropriately sized interspinous implant (X-stop) was placed at L3-L4, and the pressure measurements were repeated. They found that the implant does not significantly change the intradiscal
pressures at the adjacent levels, yet it significantly unloads the intervertebral disc at the instrumented level in the neutral and extended positions [75].

Wiseman C, et al, 2003, measured the facet loading parameters of lumbar cadaver spines during extension; before and after the placement of the X stop interspinous spacer in seven cadaver lumbar spines. The specimens were loaded to 15 Nm of extension and 700 N compression with and without X STOP placed between the L3-L4 spinous processes. Pressure-sensitive film was placed in the facet joints of the implanted and adjacent levels. After loading, the film was digitally analyzed for peak pressure, average pressure, contact area, and force. These values were compared between the intact and implanted specimens at the adjacent and implanted levels using a paired t test. They found that the implant significantly reduced the mean peak pressure, average pressure, contact area, and force at the implanted level, no significant change was seen at the adjacent levels. They concluded that stabilization with interspinous implant may not cause adjacent level facet pain or accelerated facet joint degeneration. Furthermore, pain induced from pressure originating in the facets and/or posterior annulus of the lumbar spine may be relieved by surgery with X stop [76].

Figure 2.5: The X stop spacer [6]
**DIAM (Medtronic Sofamor Danek):** French orthopedic surgeon Jean Taylor developed this device. The device for intervertebral assisted motion (DIAM) system consists of a polymeric inter-spinous spacer, with extended wings to act as a posterior shock-absorbing device. It consists of a flexible spacer and dual independent ligaments, which attach the spacer to the spinous process above and below the spinous process transfer some of the axial load to the posterior elements in flexion and extension (Figure 2.6). The flexible spacer is made with an inert medical-grade silicone core material, and the ligament is made from the Graf/ Senegas ligament. The surgical procedure involved for the DIAM device is to distract the spinous process to place the spacer and then to insert each ligament into the adjacent interspinal space. There is minimal wear debris seen in the DIAM since there are no articulating surfaces.

Minns et al., 1997, measured the intradiscal pressure and sagittal plane stiffness in compression at four angles of flexion with loads up to 700 N in a cadaveric study using the DIAM interspinous system. They concluded that the DIAM system stabilizes the spinal segment with a reduction in intradiscal pressure [77].

Mariottini A et al, 2005 have used DIAM for 43 patients suffering from back pain and sciatica and have found that in 97% of the cases had satisfying results [78].

*Figure 2.6: DIAM system*
**Wallis system:** - In the early 1980’s Sénégas proposed a metallic or polymeric spacer installed with a polyester ligament between the spinous processes to normalize and stabilize discectomy patients to prevent recurrent herniation [80]. The present day Wallis system (Abbott laboratories, Inc) is an extension of this concept. The first generation device was a titanium spacer stabilized within the interspinous space by two ligaments attached to the spinous processes of the adjacent segments. The limitations of the first generation implant were, ligament loosening and spinous process fracture due to the titanium spacer. The second generation spacer was made of PEEK composite with two attached polyester ligaments (Figure 2.7). The elastic stiffness of PEEK lies between that of the cortical bone and the cancellous; thus reduces the stress that might be caused at the bone implant interface. The surgical technique involves a minimally invasive posterior approach it is generally associated with unilateral decompression and discectomy procedures (Figure 2.8). The device can be used at one level or multiple levels including S1. The current indications for using the Wallis are: (i) discectomy for massive herniated disc leading to substantial loss of disc material, (ii) secondary discectomy for the recurrence of herniated disc, (iii) discectomy for herniation of a transitional disc with sacralization of L5, (iv) degenerative disc disease at a level adjacent to a previous fusion, and (v) additional stabilization for anterior surgeries like nucleus replacement or total disc replacement [1, 6, 80].

Test information from Abbott laboratories, has shown that the Wallis system increases the segment stiffness, and reduces the segment displacement [1]. However, there has been no published test data available on the Wallis system until now. The international clinical study for patient follow up with MRI, after implantation with Wallis showed a
distinct change in the hydration of the level treated with the Wallis system (Figure 2.9). The study claims that the increase in hydration has been observed in almost 50% of the patients [1].

In January 2002, Spine Next began an eight center clinical study to assess the safety and efficacy of the Wallis system [1]. However, there is a lack of biomechanical studies evaluating the effect of the Wallis system on various clinically relevant parameters like stability, disc stresses, and facet loads. In the present study, an attempt will be made to quantify the various biomechanical parameters for the instrumentation with the Wallis system.
Figure 2.7: The Wallis interspinous spacer system

Figure 2.8: The Implantation of Wallis system

Figure 2.9: Pre-operative and post-operative MRI’s distinctly showing a change in the hydration of the level treated with Wallis [1]
**Pedicle screw based systems**

Some flexible stabilization systems have relied upon fixation to the pedicle of the vertebrae. Such systems consist of pedicle screws threaded into adjacent segments and a member spanning between the heads of the pedicle screws to limit the movements of the spinal segment.

**Graf Ligament:** In 1994 Henri Graf, (Lyon, France), pointed out that: "a fused" spine is not a physiologic state. He subsequently introduced the Graf ligament, designed to provide less stressful load sharing [40]. It consists of a non elastic band as a ligament to connect the pedicle screws across the segment to be stabilized to lock the segment in full lordosis (Figure 2.10). The concept was that abnormal rotatory movement causes instability and locking the facets would control the rotation movement. The system would allow for limited flexion and no rotatory motion. The ligaments get lax in extension hence there is no restriction in the motion [81].

Markwalder & Wenger, 2003, conducted a clinical study with an average follow up of 7.4 years for 39 patients implanted with Graf ligament. The indications for the use of the Graf ligament in this study were young patients with mild or no facet joint degeneration, and minor disc degeneration. 66.6% of the patients participating in the study reported complete disappearance of back pain and 92.5% patients reported a complete disappearance of leg pain. They concluded that soft stabilization of lumbar motion segments yields favorable long term results only in a highly selected patient population [82].
D. BrechbuÈhler et al, 1998, conducted a clinical and radiological study of surgical outcomes of the Graf system and stated that it had good surgical outcomes in degenerative disc disease with decompression of the lumbar segment. They observed that, regional as well as global lumbar lordosis was maintained. Although statistically not significant, an increase of intervertebral distance was observed in adjacent segments in flexion of the lumbar spine. They concluded that these phenomena might represent pressurization of instrumented as well as adjacent discs after the insertion of ligament prostheses [83]. Graf ligamentoplasty procedure also produces a significant increase in lateral canal stenosis especially if there is any preexisting degenerative change in the facet joints or in the ligamentum flavum, causing early clinical failure of the Graf ligament [81].

**Figure 2.10:** Graf Ligament system. [81]

(Mulholland and Sengupta, 2002)

*FASS system:* The Fulcrum Assisted Soft Stabilization system (FASS system) was developed to address the disadvantages of the Graf ligament. In this system, a fulcrum is
placed between the pedicle screws in front of the ligament (Figure 2.11). The fulcrum distracts the posterior annulus. When the elastic ligament is placed posterior to the fulcrum, to compress the pedicle screw heads, the fulcrum transforms this posterior compression force into an anterior distraction force, which distracts the anterior annulus. The lordosis is not dependent on the patient’s ability but is created by the tension in the ligament. Experimental studies have shown that the implant unloads the disc, but the flexibility of the segment is lost as greater unloading of the disc occurs by the adjustment of the tension in the ligament and the fulcrum. [81]

![Fulcrum Assisted Soft Stabilization system](image)

**Figure 2.11:** Fulcrum Assisted Soft Stabilization system [81]

(Mulholland & Sengupta, 2002)

*Dynesys*: The Dynesys system was (DYnamic NEutralization SYStem) was developed by Gilles & Müller [40]. Dynesys system comprises of three components, (i) pedicle screws, (ii) polyethylene-terephthalate (PET) ligaments, and (iii) polycarbonate urethane (PCU) spacers (Figure 2.12). The spacers are bilaterally placed between the pedicle screw heads to withstand compressive loads. The ligaments are run through the hollow core of the
spacers. A tensile preload of about 300N is used to stabilize the construct [81]. The plastic cylinder between the screw heads limits the degree of lordosis that can be created. As the ligament is not elastic, flexion compresses the disc, and the axis of flexion is the posterior ligament, which is well posterior to the normal axis of flexion [81]. Active extension will open up the anterior annulus without compression of the posterior annulus. Theoretically, lordosis can be achieved by the action of the spinal extensor muscles and in extension; the cylinder will take increasing load [81]. Thus, the principle of the system is its ability to create load sharing and restoration of disc height, not necessarily motion preservation because the system is rigid [1].

The present indications for use of Dynesys system are: (i) central spinal stenosis, (ii) spondylolisthesis, (iii) primary discopathy, (iv) hyper mobile, functional instability, and (v) mono or multisegmental stenosis. The contraindications for the usage of Dynesys are osteoporosis, degenerative and rotational scoliosis. Dynesys also cannot be used when the spinal disc is completely degenerated.

Freudiger et al, 1999, tested the Dynesys system on four cadaveric spine specimens on a lumbar spine simulator, which allowed the simultaneous application of bending moments, compressive and shear loads. They concluded that the Dynesys reduces flexion and extension angles significantly [84].

Aylott et al., 2004, investigated the stresses of the intervertebral discs at the instrumented and the adjacent segments under compressive loading (1kN) in flexion (6°) and extension (4°), in an in vitro study. The effects of spacer height on the intradiscal pressure distribution were also evaluated. They observed that Dynesys eliminated the peak stresses in the anterior annulus in flexion, and in extension. The peak annulus stresses increased
with decrease in the spacer height. However, there was no change in the stresses in the adjacent segment discs [85].

Niosi et al., 2004, conducted an *in vitro* biomechanical study to investigate the effect of spacer length of Dynesys on the range of motion. The test conditions included intact, injury at L3-L4, Dynesys at L3-L4 (standard spacer, long spacer, and short spacer).

They quantified range of motion and facet contact loads for a pure moment of ±7.5Nm with and without a preload of 600N. The trends in motion were similar with and without preload, long spacer reduced the motion more than the other two cases, the contact loads of the long and short spacer were 150% and 64% that of the standard spacer respectively [86].

Wilson et al., 2004, investigated 10 cadaveric lumbar spine specimens, subjected to pure moments of ±7.5Nm (axial rotation, flexion, and extension) to compare range of motion and facet loads of intact specimens with those of injured specimens stabilized with Dynesys. The facet loads were measured using thin film electroresistive pressure sensors. They found that the facet loads decreased in axial rotation after implantation of Dynesys, in extension they were similar to the intact spine, extension facet load values showed no significant difference compared to the intact case. They however found that the facet loads were significantly higher in flexion with the Dynesys due to device compression.

It was found that the Dynesys system reduced spinal motion from intact and decreased peak facet loading [87].

Schmoelz et al., 2003, studied the effect of dynamic stabilization on adjacent segments, in *vitro*. Six lumbar spine specimens were tested with pure moments of ± 10Nm in the six degrees of motion. The four situations studied were: (i) intact spine, (ii) destabilized spine
(dissection of ligamenta supraspinous, ligamenta interspinous, ligamenta flavum, tenotomy of facet joint capsules and nucletomy), (iii) stabilization of the defect in L3–L4 with the Dynesys system. (iv) stabilization of the defect in L3–4 with an internal fixator.

The range of motion was quantified by using a motion analyzer system [88]. At the instrumented segment, it was seen that in flexion, there was no difference in the stiffness of Dynesys when compared to the internal fixator. In extension, lateral bending, and axial rotation both the Dynesys and internal fixator stabilized the segment, however the internal fixator was stiffer than Dynesys. They found that in terms of stability there was no difference at the adjacent levels when compared to the intact. They concluded that Dynesys provides substantial stability in case of degenerative pathologies and can replace conventional fusion surgery in these indications while the motion segment is preserved.

A clinical study of 83 patients investigated by Stoll TM, 2002, concluded that dynamic neutralization proved to be a safe and effective alternative in the treatment of unstable lumbar conditions [89]. However, screw loosening was observed in seven cases, early surgical intervention was needed in four cases, and late surgery was needed in five cases in the same segment and in seven cases for the adjacent segments. Grob et al, 2005, did a surgical and patient oriented outcome study in 50 cases after an average of 2 years with the Dynesys system. Their primary indication for the implantation of Dynesys was degenerative disc and stenosis with associated instability. The surgeries were done at multilevels. They found that both back pain and leg pain on an average were moderately high 2 years after instrumentation with the Dynesys [90].

Many clinical studies have been undertaken by Zimmer Holdings to evaluate the long-term effects of implantation with the Dynesys. Surgeons in Europe think that Dynesys is
a good system for avoiding fusion. They see it working later in the degenerative process than the artificial disc, and it has been used in conjunction with other non fusion technologies as ancillary posterior support. The main advantage of using Dynesys is the ease of the surgical procedure [1].

In this study, the kinematics and various other clinically relevant parameters will be evaluated for the Dynesys system.

**Figure 2.12:** (a) polyethylene-terephthalate (PET) ligaments, (b) polycarbonate urethane (PCU) spacers, (c) Dynesys system, applied to two motion segments in a spine model. [81]

*Cosmic system:* The Cosmic system is a pedicle screw based dynamic instrumentation system (Ulrich, Ulm, Germany). Equipped with a hinge between the screw head and
threaded portion Cosmic is a load sharing system reducing mechanical stress on the implants (Figure 2.13). Thus, protection against implant failure and loosening is achieved. The hinged screw allows only for axial load, due to this, it is important to have a largely intact anterior column for implantation of this system. While Dynesys stabilizes by neutralizing motion, Cosmic corrects the sagittal plane and maintains motion in flexion/extension.

![Cosmic system](http://www.ulrich-ulm.de/eng/wirbelsaeule/cosmic-intro.html)

**Figure 2.13:** Cosmic system [91]

Scifert et al., 1999, conducted *in vitro* load-displacement tests using ten fresh calf spine lumbar segments to compare biomechanical stabilization of a rigid versus a hinged posterior fixation device. Specimens were potted at L5 and a loading frame was secured to T12. They evaluated the specimens in the intact, destabilized and stabilization with the hinge screw system. The destabilization involved bilateral facetectomy, total laminectomy, discectomy, and dissection of supraspinous and interspinous ligaments. The load displacement data showed both the rigid and hinged dynamic devices stabilized the destabilized spine and reduced the motion by 65% in flexion and extension and by 90% in lateral bending when compared to the intact specimen. In axial rotation, the
devices only could restore stability to levels similar to those in an intact spine [92]. Goel et al., 2001 conducted a finite element study with a similar hinged screw construct to compare load sharing ability of a rigid versus a hinged pedicle screw-rod system in the presence of a bone graft. The stiffness of the bone graft was changed and the load sharing for the rigid screws and the hinged screw was quantified for 800N compression. For the cancellous bone, they found that the rigid system bore 10.95%; hinge system bore 4% of the total compressive load. They found that the load transferred through the nucleus was greater for the hinged device, while it imparted rotational stability similar to the rigid device [93].

In this study the various biomechanical parameters including, range of motion, facet loads, intervertebral disc stresses, instantaneous axis of rotation and load sharing will be evaluated for the instrumentation with the Cosmic system.

**Conclusions**

In an instrumented spine several biomechanical parameters like, range of motion, loading patterns and instantaneous axis of rotation etc., change [94]. Many cadaveric and experimental studies have been formulated to study these parameters. Disc pressure measurements have been made and facet loads have been quantified. However, there are many factors, which come into play like the specimen variability and errors involved in experimental testing. In addition, prototyping of many implants at once is not physically easy. Mathematical models in recent times are being widely used to quantify forces and moments acting on the lumbar spine during various activities in life. They can be used to quantify stresses at any area thus pointing towards the area where a fracture might occur.
Almost all the results seen in experimental testing can be quantified by using mathematical modeling. Hence, the use of a mathematical method like the finite element method is justified for the study of lumbar spine.

Lack of satisfaction with the conventional fusion techniques has lead to the development of non fusion devices. The idea is to evolve towards more physiologic and "patient-friendly" methods. There is a need for a system that converts to and from a soft stabilization to a more rigid or completely rigid system. During the last decade, several dynamic stabilization systems have been used clinically in Europe and the East [6]. Unfortunately, none of these systems has a proven biomechanical efficacy. Hence, a study quantifying the various biomechanical parameters for the dynamic stabilization is very much needed to give us a complete understanding of the biomechanics of the instrumented spine and predict the implant success.
Chapter III

Materials and Methods

Overview:
This chapter describes the finite element method and the advantages of applying this method to model the lumbar spine. This is followed by a description of the intact lumbar spine model, the boundary conditions and the loads applied. Simulations of the various posterior stabilization systems in the lumbar spine model are described in detail. The details of the surgical procedures simulated for each of the posterior devices are given. Details regarding validation of the finite element model will be given. The load and the displacement control protocols are explained in detail. Lastly, the methods used to analyze the data are described.

Introduction to finite element methods
The basic idea for the finite element method originated from advances made in aircraft structural analysis in the 1940’s. The finite element method has become a powerful tool for the numerical solution to a wide range of engineering problems. In this method of analysis, a complex region defining a continuum is broken into simple geometric shapes called finite elements. The material properties and the governing relationships are considered over these elements and expressed in terms of unknown values of element corners. With the advances in computational power and the CAD, systems complex problems can now be solved with relative ease. Specialized FEM software’s like
ABAQUS, ANSYS are providing linear, nonlinear, static, and dynamic solutions to many industrial problems.

The FE modeling plays a special role in simulating human tissue, which is non-linear in nature. It is challenging to simulate biological conditions in FEM, as this requires deep understanding of the nature of the system that needs to be modeled. It is however advantageous as it provides quantitative full stress-strain field analysis, for a system, which is difficult or impossible to obtain in experimental models. Prototype designs of implants can be tested with minor modifications in the design to study the outcomes and the right design can be formulated based upon the FE results. Thus, FE analysis has become a valuable tool for the design and analysis of orthopedic implants to analyze mechanical reaction of tissues to instrumentation as well as the load characteristics of the instrument itself.

**Intact Finite Element Model**

**Geometric modeling**

*L3-L5 Model development:* The intact FE model of ligamentous lumbar spine model first developed in our lab consisted of two motion segments (L3-L5) [98]. The geometric data for the L3-L4 motion segment were acquired from 1.5 mm thick CT scans (transverse slices) of a cadaveric ligamentous spine specimen. Each region was then divided into several quadrilateral shaped elements. The four nodes characterizing a particular element were digitized to obtain their X and Z coordinates with respect to the global axes system. The Y coordinate equaled the depth of the corresponding transverse slice on the CT film. The transverse cross sectional shape of an intact normal specimen is symmetric about the mid sagittal plane. Hence, only one-half of the model was digitized and the other half was
simulated as a reflection of the first half automatically by the finite element software. The coordinate data of elements from different cross sections were then assembled to generate three-dimensional meshes. The model consisted of 13,339 elements and 16,240 nodes (Figure 3a). The mid transverse plane of the L3-L4 disc was horizontal. A lordotic curve of approximately 9° was simulated at the L4-L5 level of the FE model, based on the anthropometric data. The model validation study was undertaken by Kong [95].

*Development of the L3-S1 model:* To the existing L3-L5 model, the L5-S1 disc and the S1 vertebral body were added. The intact refined L3-S1 model is shown in Figure 3b. A total lordotic curve of approximately 27° was simulated across the L3-S1 level with the mid L3-L4 disc kept horizontal. The L3-S1 model has a total of 27,540 elements and 32,946 nodes. Table 3.1 shows the number of elements and the material properties of the intact L3-S1 model.

*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.

*Intervertebral disc*

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

Apophyseal (Facet) joint

Simulation of the facet joints is crucial for the spine model since it drastically affects the outcome of the analysis. In the present FE model, the facet joint was simulated using 20 three-dimensional gap elements (GAPUNI). The facets were oriented at an inclination of 72° from the horizontal plane. An initial gap of 0.5 mm was specified between these elements. Force is transmitted by using the ABAQUS “softened contact” which exponentially adjusts the force transfer as the gap is closed. At full closure, the joint assumes the same stiffness as the posterior bone.

Ligaments

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

<table>
<thead>
<tr>
<th>Element Set</th>
<th># Elements</th>
<th>Element Type</th>
<th>Young’s Modulus (MPa)</th>
<th>Poisson’s Ratio</th>
<th>Cross-Sectional Area (mm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bony Regions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vertebral Cortical Bone</td>
<td>3312</td>
<td>C3D8</td>
<td>12000</td>
<td>0.30</td>
<td></td>
</tr>
<tr>
<td>Vertebral Cancellous</td>
<td>10608</td>
<td>C3D8</td>
<td>100</td>
<td>0.20</td>
<td></td>
</tr>
<tr>
<td>Posterior Cortical Bone</td>
<td>3632</td>
<td>C3D8</td>
<td>12000</td>
<td>0.30</td>
<td></td>
</tr>
<tr>
<td>Posterior Cancellous</td>
<td>1834</td>
<td>C3D8</td>
<td>100</td>
<td>0.20</td>
<td></td>
</tr>
<tr>
<td>Intervertebral Disc</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annulus (Ground)</td>
<td>5376</td>
<td>C3D8</td>
<td>1.2</td>
<td>0.45</td>
<td></td>
</tr>
<tr>
<td>Annulus Fibers</td>
<td>2685</td>
<td>REBAR</td>
<td>357.5 - 550</td>
<td>0.30</td>
<td>0.00601 – 0.00884</td>
</tr>
<tr>
<td>Nucleus Pulposus</td>
<td>1920</td>
<td>C3D8</td>
<td>1.0</td>
<td>0.4999</td>
<td></td>
</tr>
<tr>
<td>Joints</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apophyseal Joints</td>
<td>216</td>
<td>GAPUNI</td>
<td>Softened, 12000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ligaments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior Longitudinal</td>
<td>216</td>
<td>T3D2</td>
<td>7.8(&lt;12%),20.0(&gt;12%)</td>
<td>0.30</td>
<td>74</td>
</tr>
<tr>
<td>Posterior Longitudinal</td>
<td>144</td>
<td>T3D2</td>
<td>10.0(&lt;11%), 20.0(&gt;11%)</td>
<td>0.30</td>
<td>14.4</td>
</tr>
<tr>
<td>Intervertransverse</td>
<td>30</td>
<td>T3D2</td>
<td>10.0(&lt;18%), 58.7(&gt;18%)</td>
<td>0.30</td>
<td>1.8</td>
</tr>
<tr>
<td>Ligamentum Flavum</td>
<td>21</td>
<td>T3D2</td>
<td>15.0(&lt;8.2%),19.5(&gt;6.2%)</td>
<td>0.30</td>
<td>40</td>
</tr>
<tr>
<td>Interspinous</td>
<td>21</td>
<td>T3D2</td>
<td>9.8(&lt;14%),12.0(&gt;14%)</td>
<td>0.30</td>
<td>40</td>
</tr>
<tr>
<td>Supraspinous</td>
<td>9</td>
<td>T3D2</td>
<td>8.8(&lt;20%),15.0(&gt;20%)</td>
<td>0.30</td>
<td>30</td>
</tr>
<tr>
<td>Capsular</td>
<td>84</td>
<td>T3D2</td>
<td>8.48(&lt;25%), 32.9(&gt;25%)</td>
<td>0.30</td>
<td>34</td>
</tr>
</tbody>
</table>

**Table 3.1**: Element types and material properties for the intact L3-S1 finite element spine model [96].
Figure 3.1a: Finite element mesh of L3-L5 lumbar spine model [97]

Figure 3.1b: Finite element mesh of L3-S1 lumbar spine model
Figure 3.2: Mid-sagittal section of the lumbar spine model (L3-S1) showing various anatomical features
Finite element formulation of the intact spine with instrumentation

The 3D solid drawings of the various devices were created in PRO/ Engineering, and exported in the IGS format. These drawings were imported and meshed in ABAQUS/Standard™ version 6.4 (HKS, Pawtucket, Rhode Island). The intact L3-S1 model was modified to simulate the various posterior devices at L4-L5 level. The details of simulation of each of the devices are given below:

Rigid screw and rod system

Rigid pedicle screws of 6.5mm diameter and 55mm in length were placed through the pedicle and up to two-thirds of the vertebral body at the L4-L5 segment. Rigid rods of 6.5mm diameter and 50mm length were placed between the screw heads, Figure 3.3. The implantation was bilateral. Surfaces were created at each interface. The interaction between the screw shaft and bone, screw head and rod were simulated using the ‘tie’ constraint. The ‘tie’ constraint imposes constraints on the nodes such that there is no relative motion between them. The approximation made in this model was that the threads in the screw were ignored. The screw and the rod were simulated as elastic materials and were assigned the material property of titanium (Table 3.3).

Rigid screw flexible rod system

For the above-mentioned rigid screw system, the rod was simulated by using superelastic material property of a flexible metal like Nitinol. The superelastic material was simulated using the UMAT subroutine custom-written for Nitinol. Appendix E describes the simulation of Nitinol in detail.
**Dynesys system**

The Dynesys system has a spacer and a ligament and it is built such that the spacer acts in extension, and the ligament acts in flexion. In the FEM model, however simulating this kind of an interaction is very difficult. Initially the solid models were created and the ‘no compression’ option was specified for the ligament and the ‘no tension’ option was specified for the spacer. However, this model encountered convergence difficulties. Thus, this model had to be simplified and the combined action of the spacer and the ligament had to be decoupled. This was done by using the truss approximation. The ligament and the spacer were approximated to be three dimensional truss elements with the cross sectional areas specified. The ‘no compression’ option was specified for the ligament, and the ‘no tension’ option was given for the spacer. Screws were modeled similar to that as in the rigid screw system. Figure 3.4, shows the Dynesys system modeled in the FE model of the lumbar spine. The spacer was defined as polycarbonate urethane (PCU) and the ligament was defined as polyethylene-terephthalate (PET). Table 3.3, shows the material properties for the various components of the Dynesys system.

**Cosmic system**

The cosmic system is a pedicle screw rod system based system. It has a hinge joint simulated between the screw head and the threaded portion of the screw. It consists of 6mm screws and a hinge portion. The hinge part of the screw was modeled as a revolute joint between the screws and the hinges. A ± 15 degree constraint was defined by the contact elements between the nodes of the stoppers of the hinge and the surface of the screws in the model. In the model, the hinge axis was oriented perpendicular to the pedicular axis and was in the transverse plane. The initial hinge position was presumed to
be zero degrees. Figure 3.5 illustrates the cosmic system at L4-L5. The material properties used for the screws are shown in Table 3.3.

**Wallis system**

The Wallis spacer placed between the L4-L5 interspinous processes was modeled using solid 3D hexahedral elements, Figure 3.6. The surgical technique involved removing the interspinous ligament with the supraspinous ligament left intact [1]. The implant bone interfaces were simplified by defining a “tied” contact for the inferior surface of the Wallis and the L5 spinous process. Hard sliding contact formulation was used for the superior surface of the Wallis system and the L4 spinous process. The ligament-cables in Wallis system that tie the spacer to the spinous processes were modeled using 3D truss elements with the “no compression” option. The spacer was given the property of PEEK (polyethereetherketone) and the ligament was given the property of polyester, Table 3.3.

**Decompression with instrumentation models**

Indications for the use of dynamic stabilization systems often times involve decompression surgery (partial laminectomy and partial facetectomy, with an intact disc). The stability offered by the different posterior stabilization systems in such cases was evaluated. The surgery was simulated by modifying the intact model, and it involved partial laminectomy, partial facetectomy (removal of the inferior facet), removal of the facet capsule, removal of supra spinous and interspinous ligaments. The surgical procedure is illustrated in Figure 3.7.
<table>
<thead>
<tr>
<th>Material</th>
<th>Young's Modulus (MPa)</th>
<th>Poisson’s Ratio</th>
<th>Cross sectional Area (mmsq)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rigid Screw Rod</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screw (Titanium)</td>
<td>105,000</td>
<td>0.3</td>
<td>X</td>
</tr>
<tr>
<td>Rod (Titanium)</td>
<td>105,000</td>
<td>0.3</td>
<td>X</td>
</tr>
<tr>
<td><strong>Rigid Screw Flexible Rod</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screw (Titanium)</td>
<td>105,000</td>
<td>0.3</td>
<td>X</td>
</tr>
<tr>
<td>Rod (Nitinol)</td>
<td>Super elastic</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>Dynesys</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screw (Titanium)</td>
<td>105,000</td>
<td>0.3</td>
<td>X</td>
</tr>
<tr>
<td>Spacer (Polycarbonate urethane)</td>
<td>85</td>
<td>0.4</td>
<td>101.13</td>
</tr>
<tr>
<td>Ligament (Polyethylene terephthalate)</td>
<td>1,000</td>
<td>0.4</td>
<td>15.2</td>
</tr>
<tr>
<td><strong>Cosmic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screw system (Stainless steel alloy)</td>
<td>200,000</td>
<td>0.3</td>
<td>X</td>
</tr>
<tr>
<td><strong>Wallis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spacer (Polyetheretherketone)</td>
<td>3,100</td>
<td>0.4</td>
<td>X</td>
</tr>
<tr>
<td>Ligament (Polyester)</td>
<td>1,000</td>
<td>0.4</td>
<td>3.14</td>
</tr>
</tbody>
</table>

Table 3.3: Material properties used for the different posterior stabilization systems
Figure 3.3: Simulation of the rigid screw rod system at L4-5 in the L3-S1 lumbar spine model
Figure 3.4: Simulation of the Dynesys system at L4-5 in the L3-S1 lumbar spine model
Figure 3.5: Simulation of the cosmic system at L4-5 in the L3-S1 lumbar spine model
Figure 3.6: Simulation of the Wallis system at L4-5 in the L3-S1 lumbar spine model
Figure 3.7: Simulation of the decompression surgery at L4-5 in the L3-S1 lumbar spine model
Finite Element Model Validation

Formulating an FE model for a biological system often involves making justifiable assumptions. Validation of a finite element model is very essential to indicate whether the model predictions are similar to the experimental predictions. Previous biomechanical studies using the intact two-segment FE model were validated with experimental *in vitro* studies [99, 19, 100].

Axial compressive preload acts as the major component of the in vivo preload. The exact degree and magnitude of the net preload relies on the degree of lumbar lordosis and the posture of the individual during physiologic loading. Axial compressive preload affects the load displacement characteristics of the joint [10]. The model was subjected to an axial preload of 400N as a follower load since it is physiological. In addition to the axial preload, motion was predicted for all the six degrees of freedom with a moment of 10.6 Nm. Schultz et al., have reported the load-displacement properties in all principal directions with a compressive preload of 400 N. The compressive preload of 400 N was maintained while moments (4.7 Nm and 10.6 Nm) about the three principal axes were applied individually [100]. Table 3.2 provides a comparison of the model predictions in response to bending and torsional moments compared to those reported by Schultz et al. The predicted facet loads were compared with Yang and King, Shirazi-Adl and Drouin, and Kim [99]. Radial disc bulge predictions at L4-L5, measured at the disc mid-height, were compared to previous experimental and analytical results. In response to the compressive preload, the mean lateral disc bulge was 0.12 mm for a 400 N load, these values although somewhat low, the values were in the range reported by Reuber et a [96]. Ligament strains were predicted in response to an axial compressive load of 400 N,
coupled with bending moments of 5 and 10 Nm about the three principal axes, the trends seen were close to the in vitro work reported by Panjabi et al. [102]

The finite element solutions are dependent on the mesh refinement. Using a large number of elements is known to reduce error and the mesh should be refined until a stage is reached when the results from the current refinement iteration are similar to the results obtained by the previous refinement iterations. Such a mesh would be an optimized mesh and this enables the model to predict correct results. Further refinement beyond this point can theoretically induce more errors. Thus the mesh of the L3-L5 finite element model was further refined and the L5-S1 segment was added. The results between the L3-L5 model and L5-S1 model exhibited a strong correlation (Table 3.2).
Table 3.2: Comparison of intact L3-L5 and L3-S1 finite element predictions and results from Schultz et al. [100]. FE model predictions fall within one standard deviation of in-vitro results.
The model was also validated with posterior instrumentation by comparing it with data obtained from a cadaver study using strain sensors. Pertinent information is included in Appendix C.

To further validate the L3-S1 model, more recently a cadaveric study was undertaken. The study involved comparing experimentally predicted load-displacement behavior using the Optotrak with FE model predictions [104]. Five fresh ligamentous lumbar L1-S1 spine specimens were used for the experimental tests. Specimens were potted in a rigid base secured to the sacrum and a loading frame likewise was secured to the L1 vertebral body. To determine the load-displacement behavior of the specimen, a set of three LEDs was attached to each vertebral body (Figure 3.8A). Opto-Trak® motion measuring system (Northern Digital Inc, Waterloo, Ontario, Canada) was used to track the spatial location of the LED-markers secured rigidly to the vertebral bodies, including the base, during the load-displacement evaluation. The specimen was loaded to a maximum of 9 Nm in all the six degrees of freedom. The intact FE model was also subjected to similar loading of 9 Nm as the cadaveric testing. The angular displacement data for the experimental testing and the FE model were compared across L3-S1 L3-L4, L4-L5, and L5-S1 segments. It was found that the finite element model predicted angular displacements across the segments fall within one standard deviation of the experimental data (Figures 3.8b, c and d).
**Figure 3.8a:** The ligamentous L1-S1 segment with LEDs, used to predict angular displacements

**CADAVERIC AND FEM COMPARISON**

**Figure 3.8b:** Comparison of the experimental and FE results for flexion and extension in response to 9Nm pure moment.
**Figure 3.8c:** Experimental and FE results are compared in left and right bending in response to 9Nm pure moment.

**Figure 3.8d:** Experimental and FE results are compared in left and right rotation in response to 9Nm pure moment.
Boundary and loading conditions

The inferior surface of S1 vertebral body and posterior elements were constrained in all the six degrees of freedom. A preload of 400N was applied on the L3 top vertebra to simulate body weight. The compressive load was applied on the top of nodes of the L3 vertebra as an evenly distributed load. A bending moment was applied in the various degrees of freedom, which are flexion, extension, lateral bending, and axial rotation. Since the FE model is symmetric about the mid sagittal plane only the right rotation and right bending were computed. For all practical purposes, results calculated in right bending and rotation, are equal and reversed for left bending and rotation. The load application is simulated as the follower load, which means that the direction of the load rotates along with the rotation at the node. Since the nodes of the solid continuum elements do not have rotational degrees of freedom by themselves moment load application, required construction of high stiffness beams at the top of the L3, which allowed for the application of loads to the spinal segment.

Load control protocol

Load control protocol investigates physiologic loads, which include an axial compressive force of 400 N combined with moments up to 10.6 Nm, in steps of 1.06Nm. The load control protocol was employed for all the models i.e., intact, instrumented model and models with decompression surgery.

Hybrid control protocol

The hybrid control protocol involves varying the applied pure moment for the instrumented models until the angular motion of the L3-S1 equaled the values of intact load control case, Figure 3.9. This protocol was employed for the instrumented
models in flexion and extension in the intact with instrumentation models only due to the complexity involved in calculating the exact moment required for the instrumented model motion to equal the intact motion. This is justified by the fact that flexion and extension modes are more clinically relevant, especially for dynamic stabilization systems. This protocol was also not employed to the decompression models with instrumentation due to the same constraint.

In flexion/extension, rigid screw rod system required 14.36Nm/15.8Nm, rigid screw flexible rod system required 14.3Nm/15.75Nm, cosmic system required , 14.1Nm/15.8Nm, Dynesys system required 14.1Nm/15.25Nm, and the Wallis system required 14.77Nm/15.36Nm respectively to equal the L3-S1 motion of the intact spine.

*Instantaneous axis of rotation*

The instantaneous axis of rotation was calculated at the instrumented level (L4-L5). An axial compression load of 400N with 10.6 N-m flexion/extension moment was applied at the superior most surface of L4. All models were constrained at the inferior end of the L5 vertebral body.

*Load sharing*

The amount of load shared by the intervertebral disc and the various posterior stabilization systems was computed. An axial compressive load of 400N was simulated, which would be distributed between the disc and the posterior stabilization system. Load sharing will be quantified for both the intact with instrumentation and decompression with instrumentation models.
Figure 3.9: Schematic showing the hybrid protocol: an increasing load is applied to the instrumented spine until the intact displacement is reached. (a) Intact 10.6 Nm, (b) Instrumented 15 Nm
Data analysis

The various instrumented models were simulated with a combination of loads and moments. The output files were analyzed for relative rotational motion across adjacent vertebral bodies and resultant von Mises stress distributions in the disc and the implants.

Rotational motion across functional spinal unit

Rotational motion measured at any segment characterizes the segmental stability. The rotational angles were calculated using the nodal deformations of a constant set of nodes, which were present mid-way on the vertebral bodies. This was accomplished by recording the absolute position of co-ordinates of two points on opposite sides of the vertebral body parallel to the plane of deflection, Figure 3.10. The deflection of each of the co-ordinates was measured and an angle was determined. This measurement was taken in the frontal plane for lateral bending, the transverse plane for axial rotation, and the sagittal plane for flexion and extension. Although finite element analysis produces many different types of output, deflection is the characterizing variable because of its ease of measurement *in-vitro*.

Figure 3.10: Schematic showing the locations and numbers of the nodes and the equations used to determine the rotation of the vertebrae in the finite element model
**Facet loads**

In the FE model, facets are represented using uniaxial gap elements. Stresses along this axis, S11, are reported by the FE software. The gap elements have a unit cross sectional area (1mm$^2$). Hence, the force transmitted through the facets is directly indicated by S11. The total facet loads, which are perpendicular to the direction of the contact, will be calculated at all the segments in this study.

**Von Mises stresses**

The peak von Mises stresses at L3-L4, L4-L5, and L5-S1 discs (nucleus pulposus and annulus fibrosus) were calculated for all the models. These stress contours and the peak stress values would demonstrate the loading patterns through the intervertebral disc for the intact and the instrumented model. Implant peak von Mises stresses were also calculated for all the models.

**Instantaneous axis of rotation**

The instantaneous axis of rotation was calculated using the methodology reported in Panjabi et al [104]. As shown in Figure 3.11, two points on the vertebral body were selected. The instantaneous displacements of the two points at every load step were traced to the final position of interest. Perpendicular bisectors were drawn from the displacement tracings. The point of intersection of the bisectors was the instantaneous axis of rotation for that load step. The path of IAR was plotted on the spine.
Figure 3.11: Methodology to calculate the instantaneous axis of rotation for a vertebral body

Load Sharing
A free-body diagram approach was used to quantify the load sharing between the disc and the posterior systems. This method requires that an imaginary section or "cut" be made through the region where internal loads are to be determined. In this case, the cut was made through the center of the intervertebral disc as shown in Figure 3.12. The total load through the disc was computed using the “SOF” option in “section print” command in ABAQUS. For the intact with instrumentation models, the load through the instrument was calculated as the difference between the total load applied and the load through the disc, vertical component of the facet load. For the decompression with instrumentation models, the load through the instrument was calculated as the difference between the total load applied and the load through the disc.
Figure 3.12: Lateral view of the L3-L5 finite element model showing the section used for the free-body diagram approach
Chapter IV

Results

Overview

This chapter includes the various results obtained from this study. Relative rotational motion, facet loads, intervertebral disc stresses, and implant peak stresses will be provided for the intact with instrumentation models in all the loading modes in the load control approach, and for flexion/extension in the hybrid control approach. The above mentioned results will again be evaluated for the decompression with instrumentation models. The instantaneous axis of rotation data will be presented in the load control approach in flexion and extension modes for all the different systems. Finally, the results pertaining to the load sharing of the different systems with the disc in response to 400N compression will be presented.

Results for intact with instrumentation models in load control protocol

Range of motion for intact with instrumentation models in load control protocol

The range of motion with respect to the intact from the simulations of the rigid screw rod system, rigid screw system with flexible rod, Dynesys, Cosmic and the Wallis systems placed at L4-L5 segment using the load control approach in flexion, extension, lateral bending and axial rotation were evaluated. Figures 4-1a, b, c and d show the angular
displacements for each of the instrumentations. The angular displacements and the percentage changes compared to the intact case are given in Table 4.1.

**Rigid screw rod system**

The rigid screw and rod system placed at L4-L5 greatly reduced the motion at the instrumented level. The overall motion (L3-S1) decreased in all the loading modes. In flexion, the reduction in motion at L4-5 level was 70% with a corresponding increase of 12% and 4% at L3-4 and L5-S1 respectively. In extension at L4-5, the motion was reduced by 85.4% with a decrease of 15% at L5-S1 and no change at L3-4 level. In lateral bending and axial rotation the reduction at L4-5 was 81% and 77% respectively with a minor change at the other levels.

**Rigid screw and flexible rod system**

The angular motion predictions for the rigid screw and flexible rod system were very close to that of the rigid screw rod system. The decrease in motion at the L4-5 segment in flexion was 69% with a corresponding increase of 11.6% at L3-L4 and an increase of 3.7% at L5-S1. In extension, the reduction in motion at L4-L5 was 85% with no change at L3-L4 and a 15% decrease at L5-S1. In lateral bending and axial rotation, the reduction in motion at L4-L5 was 78.8% and 75.5% respectively with a minor change at the other levels.
Dynesys system

In all the loading modes, the angular motion for the Dynesys system was greater than the rigid screw rod system. In flexion, the reduction in motion at L4-5 segment was 65.4%, with a corresponding increase of 12% and 4.13% at L3-L4 and L5-S1 respectively. In extension, the reduction at L4-L5 was 79.5% with a decrease of 15% at L5-S1 and no change at L3-L4. In lateral bending and axial rotation, the reductions in motion at L4-5 were 63% and 26% with a minor change at the adjacent segments.

Cosmic system

The cosmic system shows angular motion closer to the rigid system in flexion and is stiffer than the rigid system in extension. In flexion, the reduction in motion at L4-L5 was 67% with a 4% increase at L3-L4 and a 15% decrease at L5-S1. In extension, the decrease in motion at L4-L5 was 88.5% with a corresponding decrease of 15% at L5-S1 and no change at L3-L4. In lateral bending and axial rotation, the reductions in motion were 70% and 25% respectively, with a minor change at the adjacent levels.

Wallis system

The Wallis system was more flexible than Dynesys and rigid screw rod systems especially in lateral bending and axial rotation. In flexion, the reduction in motion at L4-5 when compared to the intact was 55%. In extension, the reduction at L4-5 was 74% with a corresponding decrease of 27% at L5-S1. In lateral bending, when compared to the intact the reduction of motion at L4-5 was 11.4% and the global decrease in motion (L3-
S1) was 4%. In axial rotation, at L4-5, the decrease in motion when compared to intact was 21% and at L3-S1, the decrease was 7.5%.
**Figure 4.1a:** Relative motions (degrees) at all the levels of the lumbar spine for intact with instrumentation models systems in 400N compression and 10.6Nm flexion.

**Figure 4.1b:** Relative motions (degrees) at all the levels of the lumbar spine for intact with instrumentation models in 400N compression and 10.6Nm in extension.
**Figure 4.1c:** Relative motions (degrees) at all the levels of the lumbar spine for intact with instrumentation models in 400N compression and 10.6Nm in lateral bending.

**Figure 4.1d:** Relative motions (degrees) at all the levels of the lumbar spine for intact with instrumentation models in 400N compression and 10.6Nm in axial rotation.
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**Extension**

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**Lateral Bending**

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**Axial Rotation**

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**Table 4.1:** The angular displacements (degrees) and the percentage changes compared to the intact case for intact with instrumentation models in 400N compression and 10.6Nm moment. (Negative % change indicates a reduction in the motion)
Facet Loads for intact with instrumentation models in load control protocol

The total facet loads were determined for each model at 400N compression and 10.6Nm moment and were compared to the intact case. Figures 4-2a, b and c, show facet loads for the intact and different posterior stabilization systems. The facet loads in flexion were negligible and hence not reported. Table 4-2, shows the total facet loads and the percentage changes compared to the intact case for the different posterior stabilization systems in 400N compression and 10.6Nm moment.

Rigid screw rod system

The facet loads for the rigid screw rod system decreased in all the loading modes. In extension, at L4-L5 the decrease was 91% with a corresponding increase of 2.5% and 10.9% at L3-L4 and L5-S1. In lateral bending and axial rotation, the decrease in facet loads at L4-5 was around 54%. The increases at the adjacent segments were 7.5%/6.4% and 5.1/0.4% at L3-L4/L5-S1 in lateral bending and axial rotation respectively.

Rigid screw flexible rod system

The trends in the facet loads for the rigid screw flexible rod system were similar to the rigid screw rod system in all the loading modes. In extension, at L4-L5 the decrease was 88% with a corresponding increase of 2.6% and 10.9% at L3-L4 and L5-S1 respectively. In lateral bending, the decrease at L4-L5 was 49% with an increase of 7.5%/7% at L3-L4/L5-S1 respectively. In axial rotation, the decrease at L4-L5 was 54% with an increase of 4.8% at L3-L4 and no change at L5-S1.
**Dynesys system**

The facet load reduction at L4-5 with the Dynesys system was comparable to that of the rigid screw system in extension with the corresponding reduction being 89%. At L3-L4/L5-S1, the corresponding increases were 2.6%/10.3%. In lateral bending, the facet loads decreased by 21.4% at L4-L5 and increased by 6.9%/9.2% at L3-L4/ L5-S1 respectively. In axial rotation, an increase in the facet loads was seen at L4-L5 (21%) with minor changes in the adjacent segment.

**Cosmic system**

With the cosmic system, facet loads at L4-5 in extension decrease by 96% with increases of 2.7%/ 9.4% at L3-L4/L5-S1 segments. In lateral bending, the decrease in facet load at L4-L5 was 40% with 6.6%/12.4% increase at L3-L4/L5-S1 segments. In axial rotation, the decrease was 90% at L4-L5 with a minor change in the adjacent segments.

**Wallis system**

In extension, the facet load reduction at L4-5 was highest in Wallis (99%) when compared to the other devices. The corresponding increase in facet loads at L5-S1 was 30% with no change at L3-4. In lateral bending, there was an increase of 50% at L4-L5 with a corresponding decrease of 9% at L5-S1 and no change at L3-4. In axial rotation, at L4-L5 a reduction of 26% was seen with no changes at the adjacent levels.
**Figure 4.2a:** Total facet loads (N) in response to 400N compression and 10.6Nm moment in extension for intact with instrumentation models.

**Figure 4.2b:** Total facet loads (N) in response to 400N compression and 10.6Nm moment in lateral bending for intact with instrumentation models.
Figure 4.2c: Total facet loads (N) in response to 400N compression and 10.6Nm moment in axial rotation for intact with instrumentation models.
Table 4.2: Total facet loads and the percentage changes compared to the intact case for intact with instrumentation models systems in 400N compression and 10.6Nm moment.

(Negative % change indicate a reduction in the load)
Stresses in the annulus fibrosus and nucleus pulposus for intact with instrumentation models in load control protocol

The von Mises disc stresses with the posterior stabilization systems were compared to that of the intact. Figures 4-3, 4-4, 4-5 and 4-6, illustrate the von Mises stress plots for the nucleus pulposus and the annulus fibrosus for all the loading modes. Tables 4.2 and 4.3, report the peak von Mises stress values in the nucleus pulposus and annulus fibrosus and their percentage changes with respect to the intact values, respectively.

Rigid screw rod system

From stress contours for the rigid system, it can be seen that in flexion the anterior and posterior regions of the annulus at all levels indicate increased stresses when compared to the intact case, Figure 4-3b. It can be seen that the rigid system provides the most unloading of the disc in all the loading modes. In flexion, the reduction in peak von Mises stress in the annulus/ nucleus was 32.7% / 37.2% at L4-L5. Extension has the highest reduction of 71.7% / 74.47% in the annulus/nucleus respectively. In lateral bending and axial rotation, reductions were 60% / 69% and 31% / 45% in the annulus/nucleus at L4-L5, respectively. The adjacent segment peaks stresses had only minor changes.

Rigid screw flexible rod system

The rigid screw flexible rod system provides unloading of the disc similar to that of the rigid screw rod system. The stress distribution patterns for both the cases are similar. The reduction in the peak von Mises stress in extension was the highest 68.6% / 71.22% in
annulus/nucleus. In lateral bending and axial rotation, the reduction in peak annulus/nucleus stresses were 58.6%/67.4% and 29.3%/43.4% respectively.

**Dynesys system**

From the stress contours, it can be seen that the Dynesys system has higher stresses at L4-L5 than the rigid screw rod system but less than the intact. The stress contours in axial rotation show that the Dynesys causes high stresses at the instrumented level, Figure 4-6b. In flexion and extension, the reductions in peak von Mises stresses at L4-L5 in annulus/nucleus were 27.6%/42.32% and 66.2%/65.37% respectively. In lateral bending, the corresponding reductions were 47.9%/51.7%. In axial rotation, there was an increase of 27.6% in the annulus and a 12.9% decrease in the nucleus.

**Cosmic system**

The cosmic system performs similar to the rigid screw rod system in flexion and extension in terms of reduction of stresses. However, in axial rotation the stresses in the disc increase when compared to the intact case, Figure 4-6a. The reduction in peak stresses in flexion, extension, and lateral bending in annulus/ nucleus are 23.2%/39.02%, 73.7%/76.28%, and 54%/58.6% respectively. The increase in the peak annulus stress in axial rotation was 28.7% and the decrease in nucleus stress was 13%.

**Wallis system**

The Wallis system allows for more loading than the rigid screw rod system in all the loading modes. In lateral bending, the stress plots for the Wallis system are similar to that
of the intact (Figure 4-5 a & b). In comparison to Dynesys, it allows for more loading in lateral bending but allows for less loading in axial rotation. The reductions in stresses in flexion, extension, lateral bending, and axial rotation in annulus/nucleus was 34.1%/30.98%, 65.3%/58.79%, 54%/58.6%, and 13.7%/10% respectively.
Figure 4.3a: von Mises stress plots in the nucleus pulposus for intact with instrumentation models in 400N compression and 10.6Nm in flexion

Figure 4.3b: von Mises stress plots in the annulus fibrosus for intact with instrumentation models in 400N compression and 10.6Nm in flexion
**Figure 4.4a:** von Mises stress plots in the nucleus pulposus for intact with instrumentation models in 400N compression and 10.6Nm extension.

**Figure 4.4b:** von Mises stress plots in the annulus fibrosus for intact with instrumentation models 400N compression and 10.6Nm extension.
Figure 4.5a: von Mises stress plots in the nucleus pulposus for intact with instrumentation models in 400N compression and 10.6Nm lateral bending

Figure 4.5b: von Mises stress plots in the annulus fibrosus for intact with instrumentation models in 400N compression and 10.6Nm lateral bending
Figure 4.6a: von Mises stress plots in the nucleus pulposus for intact with instrumentation models in 400N compression and 10.6Nm axial rotation

Figure 4.6b: von Mises stress plots in the annulus fibrosus for intact with instrumentation models in 400N compression and 10.6Nm axial rotation
### Table 4.3: Peak von Mises stresses in nucleus pulposus (MPa) and percentage changes with respect to intact for 400N compression and 10.6Nm moment for intact with instrumentation models. (Negative % indicates a decrease in the stress)
### Table 4.4

Peak von Mises stresses in the annulus fibrosus (MPa) and % changes with respect to intact for 400N compression and 10.6Nm moment for different posterior stabilization systems. (Negative % indicates a decrease in the stress)
Peak Implant stresses for intact with instrumentation models

Peak von Mises stresses were determined for all the instrumentations. Stress plots of all the implants are shown with the tables of the peak von Mises stress occurring in each component of the system are also included. The stresses and loads are shown for the left and right sides of the spine in bending and rotation. Since the FE model is symmetric about the mid sagittal plane, only the right rotation and right bending were computed. For all practical purposes, the results calculated in right bending and rotation will be true for left bending and rotation.

Rigid screw rod system

Figure 4-7, illustrates the stress plots of the rigid screw rod system in all the loading modes. Table 4-5, reports the peak von Mises stresses occurring at the various components in the rigid screw rod system. The highest peak von Mises stress of 120MPa is seen at the rod in lateral bending. The peak von Mises stresses for the other loading conditions were 117MPa in flexion and extension, 113 MPa in axial rotation.

Rigid screw flexible rod system

Figure 4-8, shows the stress plots of the rigid screw flexible rod system in all the loading modes. Table 4-6, reports the peak stress values for the different components of the system. For the flexible rod system, the peak von Mises stress decreased to 93MPa in extension when compared to the 111MPa of the rigid screw rod system. The highest stress of 132 MPa was seen in axial rotation in the L5 Screw and the flexible rod.
**Dynesys system**

Figure 4-9, shows the stress plots of the rigid screw flexible rod system in all the loading modes. Table 4-7, reports the peak stress values for the different components of the system. The stresses occurring through the spacer and the ligament are axial (S11). Hence the loads through these components have been reported in Table 4-8. The peak stresses seen in the screw of the Dynesys system are comparable to the rigid screw rod system in flexion. However, in extension, lateral bending, and axial rotation the peak stresses seen are much lower in the screws of the Dynesys system. In flexion, the ligament of the Dynesys system carries a total load of 173.74N. In extension, the spacer carries a load of 98.55N. In right bending, the spacer on the right side of the spine carries a load of 98N and the ligament on the left side carries a load of 110N. In axial rotation, the spacer does not carry any load, the ligament on the left side of the spine carries a load of 25N, and the ligament on the right side of the spine carries a load of 28N.

**Cosmic system**

The stress plots of the cosmic system are shown in Figure 4-10, the peak von Mises stresses are shown in Table 4-9. The peak von Mises stresses were constant for all the loading modes in the cosmic system and were higher than the stresses seen in the rigid system. Peak stress of 146 MPa was seen at both the L4 and L5 screws. The peak stress seen at the rod of the system was 147 MPa.
**Wallis system**

The Stress plots for the Wallis system in various loading modes are given in Figure 4-11. Tables 4-10 and 4-11, show the peak von Mises stress values for the spacer and the loads through the ligament in the various loading modes. In flexion, the peak stress value for the spacer was 141 MPa. In extension, lateral bending and axial rotation the peak stress values were 146MPa for all the cases. In flexion, the load carried by the ligament in the Wallis system was 105.73N. In lateral bending (right), the ligament on the left side carried a load of 83.62N. In axial rotation (right), the ligament on the right side carried a load of 47.76N.
Figure 4.7: von Mises stress plots for the rigid screw rod system in all the loading modes for intact with instrumentation case in 400N compression and 10.6Nm moment

Table 4.5: Peak von Mises stress values (MPa) for the rigid screw rod system in all the loading modes for intact with instrumentation case in 400N compression and 10.6Nm moment. (Lateral bending and axial rotation correspond to right bending and right rotation)
**Figure 4.8:** von Mises stress plots for the rigid screw flexible rod system in all the loading modes for intact with instrumentation case in 400N compression and 10.6Nm moment.

<table>
<thead>
<tr>
<th></th>
<th>Flexion</th>
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<th>Lateral Bending</th>
<th>Axial Rotation</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Right</td>
<td></td>
</tr>
<tr>
<td>L4 Screw</td>
<td>95</td>
<td>116</td>
<td>106</td>
<td>73</td>
</tr>
<tr>
<td>L5 Screw</td>
<td>112</td>
<td>110</td>
<td>110</td>
<td>112</td>
</tr>
<tr>
<td>Rod</td>
<td>130</td>
<td>93</td>
<td>103</td>
<td>103</td>
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<td></td>
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</table>

**Table 4.6:** Peak von Mises stress values (MPa) for the rigid screw flexible rod system in all the loading modes for intact with instrumentation case in 400N compression and 10.6Nm moment. (Lateral bending and axial rotation correspond to right bending and right rotation)
Figure 4.9: von Mises stress plots for the Dynesys system in all the loading modes for intact with instrumentation case in 400N compression and 10.6Nm moment.

Table 4.7: Peak von Mises stress values (MPa) for the Dynesys system in all the loading modes for intact with instrumentation case in 400N compression and 10.6Nm moment. (Lateral bending and axial rotation correspond to right bending and right rotation)

<table>
<thead>
<tr>
<th></th>
<th>Flexion</th>
<th>Extension</th>
<th>Lateral Bending</th>
<th>Axial Rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Right</td>
<td>Left</td>
<td>Right</td>
</tr>
<tr>
<td>L4 Screw</td>
<td>114</td>
<td>80</td>
<td>78</td>
<td>77</td>
</tr>
<tr>
<td>L5 Screw</td>
<td>129</td>
<td>78</td>
<td>74</td>
<td>73</td>
</tr>
</tbody>
</table>

Table 4.8: Loads (N) through the spacer and the ligament of the Dynesys system in all the loading modes for intact with instrumentation case in 400N compression and 10.6Nm moment. (Load= S11*Cross-sectional area) (Lateral bending and axial rotation correspond to right bending and right rotation)
Figure 4.10: von Mises stress plots for the Cosmic system in all the loading modes for intact with instrumentation case in 400N compression and 10.6Nm moment.

<table>
<thead>
<tr>
<th></th>
<th>Flexion</th>
<th>Extension</th>
<th>Lateral Bending</th>
<th>Axial Rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>L4 Screw</td>
<td>146</td>
<td>146</td>
<td>146</td>
<td>146</td>
</tr>
<tr>
<td>L5 Screw</td>
<td>146</td>
<td>146</td>
<td>146</td>
<td>146</td>
</tr>
<tr>
<td>Rod</td>
<td>147</td>
<td>147</td>
<td>147</td>
<td>147</td>
</tr>
</tbody>
</table>

Table 4.9: Peak von Mises stress values (MPa) for the Cosmic system in all the loading modes for intact with instrumentation case in 400N compression and 10.6Nm moment. (Lateral bending and axial rotation correspond to right bending and right rotation)
Figure 4.11: von Mises stress plots for the Wallis system in all the loading modes for intact with instrumentation case in 400N compression and 10.6Nm moment.

<table>
<thead>
<tr>
<th>Spacer</th>
<th>Flexion</th>
<th>Extension</th>
<th>Lateral Bending</th>
<th>Axial Rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>141</td>
<td>146</td>
<td>146</td>
<td>146</td>
</tr>
</tbody>
</table>

Table 4.10: Peak von Mises stress values (MPa) for the Wallis system spacer in all the loading modes for intact with instrumentation case in 400N compression and 10.6Nm moment. (Lateral bending and axial rotation correspond to right bending and right rotation)

<table>
<thead>
<tr>
<th>Ligament</th>
<th>Flexion</th>
<th>Extension</th>
<th>Lateral Bending</th>
<th>Axial Rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>105.73</td>
<td>0.00</td>
<td>7.34</td>
<td>83.62</td>
</tr>
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<td></td>
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<td></td>
<td>47.76</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>17.60</td>
</tr>
</tbody>
</table>

Table 4.11: Loads (N) through the ligament of Wallis system in all the loading modes for 400N compression and 10.6Nm moment. (Load= S11*Cross-sectional area) (Lateral bending and axial rotation correspond to right bending and right rotation)
Results for intact with instrumentation models in the hybrid test protocol

The hybrid test protocol was used to evaluate the effects of the instrumentation at the adjacent levels in flexion and extension. The moments were applied for all the instrumented models until the motion equaled that of the L3-S1 of the intact model.

The angular motions, facet loads, and disc stresses were then evaluated at that moment for all the models and compared to that of the intact. Figures 4-12a & b show the range of motion using the hybrid protocol in flexion and extension respectively. The range of motion and the % changes with respect to intact are presented in Table 4-12.

Figure 4-13, shows the facet loads. Table 4-13 shows the total facet loads and % changes with respect to the intact in extension at various levels. The von Mises stress plots of the nucleus pulposus and annulus fibrosus are shown in Figures 4-14 and 4-15. The peak von Mises stress values and % changes with respect to the intact in the nucleus pulposus and annulus fibrosus are shown in Tables 4-14 and 4-15. Implant stress plots are shown in Figures 4-16, 4-17, 4-18, and 4-19. The implant peak stresses are shown in Tables 4-16 through 4-22. The stresses and loads in the tables are shown for the left and right sides of the spine in bending and rotation. Since the FE model is symmetric about the mid sagittal plane only the right rotation and right bending were computed. For all practical purposes the results calculated in right bending and rotation will be true for left bending and rotation.
**Rigid screw rod system**

The rigid screw rod system required 14.36Nm/15.82Nm in flexion/extension to equal the motion of intact L3-S1 segment. In flexion and extension, the reductions in motion at the instrumented segment were 64% and 76% respectively using the hybrid protocol. The adjacent level L3-4/L5-S1 increases were 37%/21% and 39%/38% in flexion and extension respectively. The facet loads in extension increased at the adjacent segments by 48%/62% at L3-4/L5-S1 and decreased by 89% at the instrumented level. The adjacent level disc stresses increased when compared to the intact case, Figures 4-14 & 4-15.

The peak von Mises stress in the nucleus pulposus in flexion/extension decreased by 28.7%/77.8% at L4-L5. The corresponding increases at L3-L4 and L5-S1 were 32.3%/22.3% and 19%/24%. The peak von Mises stress in the annulus decreased by 25.62% in flexion at L4-L5 with corresponding increases of 27.72%/17.65% at L3-L4/L5-S1. In extension the peak von Mises stress in annulus decreased by 80.05% at L4-L5 with increases of 64.79%/35.15% at L3-L4/L5-S1 respectively. The peak stresses of the rigid system in the hybrid protocol increased when compared to load control. The highest stress of 179MPa was seen in the rod in flexion. Table 4-16 gives the peak von Mises stresses in the various components of the rigid screw rod system in the hybrid protocol in flexion and extension.

**Rigid screw flexible rod system**

The rigid screw flexible screw system required 14.3Nm/15.75Nm in flexion/extension to equal the motion of intact L3-S1 segment. In flexion and extension, the reduction in motion at the instrumented segment was 63% and 74% respectively. The motion at the
adjacent levels increased and was comparable to the increases in the rigid screw rod system. The facet loads in extension increased at the adjacent segments by 48%/61% at L3-4/L5-S1 and decreased by 85% at the instrumented level.

The peak von Mises stress in the nucleus pulposus in flexion/extension decreased by 27.8%/ 73.7% at L4-L5. The corresponding increases at L3-L4 and L5-S1 were 31.2%/21.9% and 19%/23.8%. The peak von Mises stress in the annulus decreased by 25.64% in flexion at L4-L5 with corresponding increases of 26.88%/ 17.42% at L3-L4/L5-S1. In extension, the peak von Mises stress in annulus decreased by 76.28% at L4-L5 with increases of 63.75%/ 34.51% at L3-L4/L5-S1 respectively. The peak implant stresses for the rigid screw flexible rod system in hybrid protocol are given in Table 4-17.

The highest peak stress of 167MPa was seen in the L5 screw in flexion. The peak stresses in the flexible rods were 164MPa and 146MPa in flexion and extension respectively.

**Dynesys system**

The Dynesys system required 14.1Nm/15.25Nm in flexion/extension to equal the motion of intact L3-S1 segment. The reduction in motion at the instrumented segment was 61% and 66% in flexion and extension respectively using the hybrid protocol. The motion at the adjacent levels had a corresponding increase in both flexion and extension modes. The facet loads in extension increased at the adjacent segments by 44%/55% at L3-4/L5-S1 and decreased by 88% at the instrumented level. The stress in the nucleus was more than the rigid screw system in extension, Figure 4-15a. The reductions in the peak stresses at L4-L5 in flexion for nucleus/annulus were 28.5%/20.33% and in extension, the corresponding reductions were 65.8%/68.75%. The increases at L3-L4 for nucleus/
annulus in flexion and extension were 31.2%/25.88% and 20.1%/ 57.36. At L5-S1, the corresponding increases were 18.4%/16.41 and 20.8%/30.81%. The peak stresses in the screws of the Dynesys system are given in Table 4-18. The increases in peak implant stresses in hybrid control when compared to load control were higher in extension. Table 4-19 shows the loads carried by the spacer and the ligament of the Dynesys system. In flexion, the ligament carried a load of 126.84N and in extension, the spacer carried load of 141.24N.

Cosmic system

The cosmic system required 14.1Nm/15.8Nm in flexion/extension to equal the motion of intact L3-S1 segment. The reductions in motion at L4-L5 segment were 61.68% and 76.82% in flexion and extension respectively. In flexion/extension, the increases in motion at L3-L4 and L5-S1 were 34.95%/39.16% and 20.17%/38.28 respectively. In extension, L4-L5 facet load reduced by 97%, corresponding increases of 48.6% and 59.8% were seen at L3-L4 and L5-S1. The peak von Mises stresses in the nucleus/annulus reduced by 23.9%/14.88 and 81.2%/83.44% in flexion and extension at L4-L5. At L3-L4, the increases in nucleus/annulus stresses were 30.5%/26.73% and 23%/66.33% in flexion and extension. The peak von Mises stresses in the cosmic system did not change from the load control, Table 4-20.

Wallis system:

The Wallis system required 14.77Nm/15.36Nm in flexion/extension to equal the motion of intact L3-S1 segment. The reduction in motion at the instrumented segment was 44%
and 56% in flexion and extension respectively using the hybrid protocol. The motion at
the adjacent levels had a corresponding increase in both flexion and extension modes.
The highest increase was at L3-L4 of 38% in extension. The facet loads in extension
increased at the adjacent segments by 40%/8% at L3-4/L5-S1 and at the instrumented
level there was no facet loading seen (100% reduction). The peak von Mises stress in the
nucleus decreased by 10.5% in flexion at L4-L5 with corresponding increases of 27.3%/11.9%
at L3-L4/L5-S1. In extension, the peak von Mises stress in nucleus decreased by
58.4% at L4-L5 with increases of 19.1%/22.2% at L3-L4/L5-S1 respectively. The peak
von Mises stress in the annulus in flexion/extension decreased by 22.3%/64.71% at L4-
L5. The corresponding increases at L3-L4 and L5-S1 were 24.05%/58.30% and
14.01%/36.85%. The peak implant stresses for the Spacer of the Wallis system in hybrid
protocol are 160MPa and 113MPa in flexion and extension respectively, Table 4-21. The
load carried by the ligament of the Wallis system in flexion was 152N, Table 4-22.
Figure 4-12a: Relative motions (degrees) at all the levels of the lumbar spine for intact with instrumentation models in response to hybrid approach in flexion.

Figure 4-12b: Relative motions (degrees) at all the levels of the lumbar spine for intact with instrumentation models in response to hybrid approach in extension.
Table 4.12: The angular displacements (degrees) and the percentage changes compared to the intact case for intact with instrumentation models in 400N compression and hybrid approach. (Negative % change indicates a reduction in the motion)
Table 4.13: Total facet loads (N) and the percentage changes compared to the intact case for intact with instrumentation models in 400N compression and hybrid control protocol in extension. (Negative % change indicate a reduction in the load)
Figure 4-14a: von Mises stress plots in the nucleus pulposus for intact with instrumentation models in 400N compression and hybrid protocol in flexion.

Figure 4-14b: von Mises stress plots in the annulus fibrosus for intact with instrumentation models in 400N compression and hybrid protocol in flexion.
Figure 4-15a: von Mises stress plots in the nucleus pulposus for intact with instrumentation models in 400N compression and hybrid protocol in extension.

Figure 4-15b: von Mises stress plots in the annulus fibrosus for intact with instrumentation models in 400N compression and hybrid protocol in extension.
### Table 4.14: Peak von Mises stresses in the nucleus pulposus (MPa) and percentage changes with respect to intact for intact with instrumentation models in 400N compression and hybrid protocol. (Negative % indicates a decrease in the stress)

<table>
<thead>
<tr>
<th></th>
<th>L3-L4 % Change</th>
<th>L4-L5 % Change</th>
<th>L5-S1 % Change</th>
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<tbody>
<tr>
<td><strong>Flexion</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>0.188</td>
<td>---</td>
<td>0.168</td>
</tr>
<tr>
<td>Rigid Screw Rod (14.36Nm)</td>
<td>0.248</td>
<td>32.3</td>
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</tr>
<tr>
<td>Rigid Screw Flexible Rod (14.3Nm)</td>
<td>0.246</td>
<td>31.2</td>
<td>0.121</td>
</tr>
<tr>
<td>Dynesys (14.1Nm)</td>
<td>0.245</td>
<td>30.6</td>
<td>0.120</td>
</tr>
<tr>
<td>Cosmic (14.1Nm)</td>
<td>0.245</td>
<td>30.5</td>
<td>0.128</td>
</tr>
<tr>
<td>Wallis (14.77Nm)</td>
<td>0.239</td>
<td>27.3</td>
<td>0.151</td>
</tr>
<tr>
<td><strong>Extension</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>0.162</td>
<td>---</td>
<td>0.139</td>
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<tr>
<td>Rigid Screw Rod (15.82Nm)</td>
<td>0.198</td>
<td>22.3</td>
<td>0.031</td>
</tr>
<tr>
<td>Rigid Screw Flexible Rod (15.75Nm)</td>
<td>0.197</td>
<td>21.9</td>
<td>0.036</td>
</tr>
<tr>
<td>Dynesys (15.25Nm)</td>
<td>0.194</td>
<td>20.1</td>
<td>0.047</td>
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<tr>
<td>Cosmic (15.8Nm)</td>
<td>0.199</td>
<td>23.0</td>
<td>0.026</td>
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<tr>
<td>Wallis (15.36Nm)</td>
<td>0.192</td>
<td>19.1</td>
<td>0.058</td>
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</table>
Table 4.15: Peak pressures in the annulus fibrosus (MPa) and percentage changes with respect to intact for intact with instrumentation models in 400N compression and hybrid protocol. (Negative % indicates a decrease in the stress)
Figure 4-16: Rigid screw rod system von Mises stress plots for intact with instrumentation models in flexion and extension for 400N compression and hybrid protocol.

Table 4.16: Rigid screw rod system peak von Mises stress values (MPa) for intact with instrumentation models in flexion and extension for 400N compression and hybrid protocol.
Figure 4-17: Rigid screw flexible rod system von Mises stress plots for intact with instrumentation models in flexion and extension for 400N compression and hybrid protocol.

<table>
<thead>
<tr>
<th></th>
<th>Flexion (14.3Nm)</th>
<th>Extension (15.75Nm)</th>
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</thead>
<tbody>
<tr>
<td>L4 Screw</td>
<td>109</td>
<td>128</td>
</tr>
<tr>
<td>L5 Screw</td>
<td>167</td>
<td>152</td>
</tr>
<tr>
<td>Rod</td>
<td>164</td>
<td>146</td>
</tr>
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</table>

Table 4.17: Rigid screw flexible rod system peak von Mises stress values (MPa) for intact with instrumentation models in flexion and extension for 400N compression and hybrid protocol.
Figure 4-18: Dynesys system von Mises stress plots for intact with instrumentation models in flexion and extension for 400N compression and hybrid protocol.

<table>
<thead>
<tr>
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<th>Flexion (14.1Nm)</th>
<th>Extension (15.25Nm)</th>
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<tr>
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<td>128</td>
</tr>
<tr>
<td>L5 Screw</td>
<td>167</td>
<td>152</td>
</tr>
</tbody>
</table>

Table 4.18: Dynesys system peak von Mises stress values (MPa) for intact with instrumentation models in 400N compression and hybrid protocol.

<table>
<thead>
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<th>Flexion (14.1Nm)</th>
<th>Extension (15.25Nm)</th>
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</thead>
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<tr>
<td>spacer</td>
<td>0.00</td>
<td>141.24</td>
</tr>
<tr>
<td>ligament</td>
<td>126.84</td>
<td>0.00</td>
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</table>

Table 4.19: Loads (N) through the spacer and the ligament of the Dynesys system for intact with instrumentation model in 400N compression and hybrid protocol. (Load= S11*Cross-sectional area)
Figure 4-19: von Mises stress plots for the cosmic system for intact with instrumentation model in 400N compression and hybrid protocol.

Table 4.20: Peak von Mises stress values (MPa) for the Cosmic system for intact with instrumentation model in 400N compression and hybrid protocol.
Figure 4.20: von Mises stress plots for the Wallis system for intact with instrumentation model in 400N compression and hybrid protocol.

<table>
<thead>
<tr>
<th>Spacer</th>
<th>Flexion (14.77Nm)</th>
<th>Extension (15.36Nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>146</td>
<td>146</td>
</tr>
</tbody>
</table>

Table 4.22: Peak von Mises stress values (MPa) for the Wallis spacer for intact with instrumentation model in 400N compression and hybrid protocol.

<table>
<thead>
<tr>
<th>Ligament</th>
<th>Flexion (14.77Nm)</th>
<th>Extension (15.36Nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>152</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 4.23: Loads (N) through the ligament of Wallis system for intact with instrumentation model in 400N compression and hybrid protocol. (Load = S11*Cross-sectional area)
Instantaneous axis of rotation for intact with instrumentation models in load control protocol

The instantaneous axis of rotation (IAR) at L4-5 segment was calculated in flexion and extension to assess the behavior of the functional spinal unit with and without instrumentation. Figures 4-21 through 4-26 show the paths of IARs for the different models. The description of the IAR path for each of the posterior instrumentation systems is given below.

**Intact spine**

The instantaneous axis of rotation for the intact spine is shown in Figure 4-21. The initial location of the IAR is at the junction of the anterior two thirds and posterior one third of the endplate forming the lower margin of the disc space. In flexion the IAR starts out at the near the posterior L5 endplate-intervertebral disc junction (F1) and moves superior and anterior towards the mid disc region (F2). In extension the starting point is E1 which is very close to the starting point of flexion (F1) and moves further posterior and superior (E2).

**Rigid screw rod system**

The instantaneous axis of rotation for the rigid screw rod system lies in supero-posterior region of the L4 vertebrae. The IAR region is highly localized in both flexion (F) and extension (E). The flexion is slightly anterior to extension, Figure 4-22.
**Rigid screw flexible rod system**

The IAR’s of the rigid screw flexible rod system lie in the L4 vertebral body and are localized to the supero-posterior region. They are inferior to the IAR’s of the rigid screw rod system, Figure 4-23.

**Dynesys system**

The region of the IAR’s of the Dynesys system is closer to that of the intact spine however, the paths vary figure 4-24. In flexion, the IAR starts from infero-posterior disc region (F1) and moves towards mid-intervertebral (F2) at extreme flexion. In extension, the IAR starts out from infero-posterior part of the intervertebral disc (E1) and moves towards the L5 endplate-disc junction (E2).

**Cosmic system**

The Cosmic system IAR’s are shown in figure 4-25. In flexion, the IAR is concentrated at posterior one third of the L4 endplate and intervertebral disc junction (F). In extension, the IAR is in the infero-posterior part of L4 vertebra (E).

**Wallis system**

The Wallis system IAR’s are shown in figure 4-26. In flexion, the IAR is concentrated at posterior part of the L4 endplate and intervertebral disc junction (F). In extension, the IAR’s lie mostly in the L4 vertebra. The start point (E1) of the IAR in extension is infero-posterior part of L4 vertebra and moves further posterior towards the mid vertebra.
Figure 4-21: Instantaneous axis of rotation path for the intact spine in 400N compression and 10.6Nm in flexion and extension

Figure 4-22: Instantaneous axis of rotation path for the rigid screw rod system in 400N compression and 10.6Nm in flexion and extension
Figure 4-23: Instantaneous axis of rotation path for the rigid screw flexible rod system in 400N compression and 10.6Nm in flexion and extension.

Figure 4-24: Instantaneous axis of rotation path for the Dynesys system in 400N compression and 10.6Nm in flexion and extension.
Figure 4-25: Instantaneous axis of rotation path for the Cosmic system in 400N compression and 10.6Nm in flexion and extension

Figure 4-26: Instantaneous axis of rotation path for the Wallis system in 400N compression and 10.6Nm in flexion and extension
Load sharing for intact with instrumentation models

The load sharing between the intervertebral disc and the posterior instrumentation in decompression surgery were predicted for a total compressive load of 400N. It was seen that the rigid systems carried more load than the flexible systems in pure compression. The 400N compression load was distributed between the intervertebral disc, facet joint, and the posterior instrumentation. For rigid screw rod system the facet joint and instrumentation bore 3.33%, 3.86% of the total compressive load, respectively. For the rigid screw flexible rod, system the load borne by the facet was 3.55% and for instrumentation, it was 3.67%. For the Dynesys, Cosmic, Wallis systems the total load was borne by the disc and the facet joints. The dynamic stabilization systems allowed for higher axial displacements, and flexion angles.

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Table 4.24: Axial displacement, flexion angle, Loads (N) through the intervertebral disc, facet joints, and the various posterior stabilization systems in 400N compression.
Results for decompression with instrumentation models in load control protocol

Range of motion for decompression with instrumentation models in load control protocol

The range of motion with a decompression surgery was evaluated. The angular motion was calculated for the various destabilized models with instrumentation in flexion, extension, lateral bending, and axial rotation. Figures 4-27a, b, c and d show the motion of intact, destabilized and stabilization with different posterior systems. The angular displacements for the destabilized spine and stabilization with posterior instrumentation along with their percentage changes with respect to the intact are given in Table 4-25

Destabilized spine

Destabilization with decompression surgery at L4-5 caused a large increase in motion at that segment. In flexion, the increase was 143% at L4-5 with a corresponding increase of 10% and 15% at L3-4 and L5-S1 respectively. In extension, the increase was 160% at L4-5 and the corresponding increase was 5% at L3-4 and L5-S1 levels. In lateral bending, there was a 7% at L4-L5 and in the destabilized spine when compared to the intact with no change at the adjacent levels. The increase in motion was the greatest in axial rotation (222%) with minor changes at the adjacent levels.

Stabilization with rigid screw rod system

Stabilization with rigid screw rod system reduced the motion in all the loading modes. In flexion, the reduction was 70% with a corresponding increase in adjacent levels of 15%
(L3-4) and 4% (L5-S1). In extension, the reduction in motion was 87% with no change at L3-4 and a 15% reduction at L5-S1. In lateral bending and axial rotation, the decreases in motion at L4-5 were 80% and 73% respectively, with minor changes at the adjacent segments.

*Stabilization with rigid screw flexible rod system*

The motion after stabilization with rigid screw flexible rod system was very similar to the stabilization with rigid screw rod system. In flexion/extension, the reduction in motion at L4-5 was 68% / 85% respectively with a corresponding increase of 15.7% / 4.8% at L3-L4/L5-S1 in flexion and a decrease of 15.5% at L5-S1 in extension. In lateral bending and axial rotation, the decreases in motion at L4-5 were 78% and 72% respectively, with minor changes at the adjacent segments.

*Stabilization with Dynesys system*

Stabilization of decompression with Dynesys system reduced the motion at L4-5 levels in flexion extension and lateral bending, in axial rotation however, Dynesys does not stabilize the segment. In flexion, extension, and lateral bending the decreases in the motion at L4-L5 were 67%, 79%, and 62% respectively. In axial rotation, the increase in motion when compared to the intact was 193%. The changes in the adjacent segment motion were minor except for a 15% increase at L3-L4 in flexion.
**Stabilization with Cosmic system**

The cosmic system restricts motion similar to the rigid screw rod system in flexion and extension. In lateral bending and axial rotation, it restricts motion similar to the Dynesys system. In flexion, the reduction in motion with the cosmic system is 66.4% at the instrumented segment, with corresponding increases of 1.66%/4.6% at L3-L4/L5-S1.

In extension, the reduction in motion was 88.5% at L4-L5 and 15.1% at L5-S1 with no change at L3-L4. In lateral bending, the reduction in motion at L4-L5 was 68.1%. There was an increase of 197.1% at L4-L5 in axial rotation with minor changes at the adjacent levels.

**Stabilization with Wallis system**

Stabilization of the decompression surgery with Wallis reduced motion in flexion and extension by 54% and 65% respectively at L4-L5. A decrease of 26% was seen at L5-S1 segment in extension. In lateral bending and axial rotation, stabilizing the segment with the Wallis system restored motion almost equaling to that of the intact spine at all the levels.
Figure 4-27a: Relative motions (degrees) at all the levels of the lumbar spine in response to 400N compression and 10.6Nm in flexion for intact, destabilized spine and stabilization with the instrumentation.

Figure 4-27b: Relative motions (degrees) at all the levels of the lumbar spine in response to 400N compression and 10.6Nm in extension for intact, destabilized spine and stabilization with the instrumentation.
Figure 4-27c: Relative motions (degrees) at all the levels of the lumbar spine in response to 400N compression and 10.6Nm in lateral bending for intact, destabilized spine and stabilization with the instrumentation.

Figure 4-27d: Relative motions (degrees) at all the levels of the lumbar spine in response to 400N compression and 10.6Nm in axial rotation for intact, destabilized spine and stabilization with the instrumentation.
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**Table 4.25:** The angular displacements (degrees) and the percentage changes compared to the intact case for the destabilized, destabilized spine and stabilization with the instrumentation in 400N compression and 10.6Nm moment. (Negative % change indicates a reduction in the motion).
Facet Loads for decompression with instrumentation models in load control protocol

The total facet loads were determined and compared to the intact case, at L3-L4 and L5-S1 levels for intact, destabilized spine and stabilization with the instrumentation each model at 400N compression and 10.6Nm moment, Table 4-26. Figures 4-28a, b, and c show total facet loads for L3-L4 and L5-S1 levels.

Destabilized spine

The facet loads in the destabilized spine (at L3-L4 and L5-S1) in extension, lateral bending, and axial rotation did not change much when compared to the intact. The highest reduction of 6.9% was seen at L5-S1 in extension.

Stabilization with rigid screw rod system

With the rigid screw rod system the L3-L4 facet load increased by 2.6%, 8%, and 6.3% in extension, lateral bending, and axial rotation respectively. At L5-S1 the corresponding increase in facet loads were 10.7%, 6.7%, and 0.5%.

Stabilization with rigid screw flexible rod system

The facet loads with the rigid screw flexible rod system increased by 2.8%/11%, 8.1%/7.5%, and 6.2%/0.6% at L3-L4/L5-S1 in extension, lateral bending, and axial rotation respectively.
**Stabilization with Dynesys system**

The facet loads at L3-L4 with the Dynesys system increased by 2.7%, 7.6%, and 5% in extension, lateral bending, and axial rotation respectively. At L5-S1, the corresponding increases in facet loads were 10.6%, 10.7%, and 0%.

**Stabilization with Cosmic system**

The facet loads in the destabilized spine with the cosmic system increased by 2.8%/9.3%, 7.2%/14.2% and at L3-L4/L5-S1 in extension and lateral bending. In axial rotation, the facet loads had an increase of 3.3% at L3-L4 and a decrease of 0.5% at L5-S1.

**Stabilization with Wallis system**

The facet loads in the destabilized spine with the Wallis system decreased by 0.5% at L3-L4, and increased by 31% at L5-S1 in extension. In lateral bending and axial rotation, minor changes were seen in the facet loads.
**Figure 4-28a:** Total facet loads (N) in response to 400N compression and 10.6Nm moment in extension for intact, destabilized spine and stabilization with the instrumentation.

**Figure 4-28b:** Total facet loads (N) in response to 400N compression and 10.6Nm moment in lateral bending for intact, destabilized spine and stabilization with the instrumentation.
Figure 4-28c: Total facet loads (N) in response to 400N compression and 10.6Nm moment in axial rotation for intact, destabilized spine and stabilization with the instrumentation.
### Table 4.26: Total facet loads (N) and the percentage changes compared to the intact case for intact, destabilized spine and stabilization with the instrumentation in 400N compression and 10.6Nm moment. (Negative % change indicate a reduction in the load)

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</table>
Stresses in the annulus fibrosus and nucleus pulposus for decompression with instrumentation models in load control protocol

The peak von Mises stresses in the nucleus pulposus and the annulus fibrosus of the destabilized spine and stabilization with instrumentation were compared to that of the intact. Figures 4-29 to 4-32, illustrate the von Mises stress plots for the nucleus pulposus and the annulus fibrosus for all the loading modes. Tables 4.27 and 4.28, report the peak von Mises stress values in the nucleus pulposus and annulus fibrosus and their % change with respect to the intact values, respectively.

Destabilized spine

In the destabilized spine, an increase in the stresses in the nucleus and annulus was seen at L4-L5 in all the loading modes, Figures 4-29 to 4-30. The highest increase of 140%/115.4% was seen in nucleus/annulus in extension at L4-L5. In flexion, the increase in nucleus/annulus peak stresses were 98.9%/83.6% at L4-L5 respectively. In lateral bending, there was an increase of 15% in the annulus peak stress and minor change was seen in the nucleus. In axial rotation, the increase in the peak nucleus/annulus stresses were 34%/107% at L4-L5. The adjacent level peak stresses did not see a major increase in all the loading modes.

Stabilization with rigid screw rod system

In flexion, the reduction in peak von Mises stress in the annulus/ nucleus was 32.9%/36.7% at L4-L5. The highest reduction of 70.5%/ 73.5% in the annulus/nucleus peak stresses was seen in extension. In lateral bending and axial rotation, reductions were
59.7%/70% and 28.6%/45.6% respectively in the annulus/nucleus at L4-L5. The adjacent segment peaks stresses had only minor changes except for in lateral bending where a reduction of 41.7% was seen at L5-S1 segment.

**Stabilization with rigid screw flexible rod system**

The reductions in the peak von Mises stresses in flexion and extension were 32.6%/35.7% and 66.8%/69.7% in annulus/nucleus. In lateral bending and axial rotation the reduction in peak annulus/nucleus stresses were 57.2%/66.8% and 26.3%/44% respectively. There was no major change in disc stresses at the adjacent levels in all the loading modes, except for an increase of 8.3%/10.5% in the annulus/nucleus at L3-L4 in flexion.

**Stabilization with Dynesys system**

Stabilization with the Dynesys system reduced the peak stresses in the disc in all the loading modes except axial rotation. In flexion, the peak von Mises stress reduction for annulus/nucleus at L4-L5 was 64.9%/70.3% with a reduction of 8.3%/10.5% at L3-L4 and 32.8%/40% at L5-S1. In extension and lateral bending, the reduction in the peak annulus/nucleus stresses were 62.5%/63.9% and 51.9%/57.5% at L4-L5. In axial rotation, at L4-L5 there was an increase of 201.5% in the peak stress in the annulus with an increase of 40.7% in the nucleus.
Stabilization with Cosmic system

The cosmic system performs similar to the rigid screw rod system in flexion and extension in terms of reduction of stresses, however in axial rotation the stresses in the disc increase like the Dynesys system Figure 4-32. The reduction in stresses in flexion, extension, and lateral bending in annulus/ nucleus were 19.9%/28.7%, 72.2%/74.9%, and 57.5%/51.9%. The increases in the annulus/nucleus stresses in axial rotation were 203.3%/ 44.7%.

Stabilization with Wallis system

The peak annulus stresses in the Wallis system decrease for all the loading modes except for in lateral bending. In lateral bending, the stress plots of the annulus and the nucleus for the Wallis system are similar to intact, Figures 4-31 a, b. The reductions of the peak stresses for flexion, extension, and axial rotation in annulus / nucleus were 31.6%/24.2%, 59.5%/51.2% and 15%/21.9% respectively. In lateral bending the increase in the peak, stress of the annulus was 8.3% and the decrease in the nucleus was 1%.
**Figure 4-29a:** von Mises stress plots in the nucleus pulposus for intact, destabilized spine and stabilization with the instrumentation in 400N compression and 10.6Nm in flexion

**Figure 4-29b:** von Mises stress plots in the annulus fibrosus for intact, destabilized spine and stabilization with the instrumentation in 400N compression and 10.6Nm in flexion
**Figure 4-30a:** von Mises stress plots in the nucleus pulposus for intact, destabilized spine and stabilization with the instrumentation in 400N compression and 10.6Nm in extension

**Figure 4-30b:** von Mises stress plots in the annulus fibrosus for intact, destabilized spine and stabilization with the instrumentation in 400N compression and 10.6Nm in extension
Figure 4-31a: von Mises stress plots in the nucleus pulposus for intact, destabilized spine and stabilization with the instrumentation in 400N compression and 10.6Nm in lateral bending

Figure 4-31b: von Mises stress plots in the annulus fibrosus for intact, destabilized spine and stabilization with the instrumentation in 400N compression and 10.6Nm in lateral bending
Figure 4-32a: von Mises stress plots in the nucleus pulposus for intact, destabilized spine and stabilization with the instrumentation in 400N compression and 10.6Nm in axial rotation

Figure 4-32b: von Mises stress plots in the annulus fibrosus for intact, destabilized spine and stabilization with the instrumentation in 400N compression and 10.6Nm in axial rotation
Table 4.27: Peak von Mises stresses in nucleus pulposus (MPa) and % changes with respect to intact for intact, destabilized spine and stabilization with the instrumentation in 400N compression and 10.6Nm moment (Negative % indicates a decrease in the stress)

<table>
<thead>
<tr>
<th></th>
<th>L3-L4 % Change</th>
<th>L4-L5 % Change</th>
<th>L5-S1 % Change</th>
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<tbody>
<tr>
<td><strong>Flexion</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>0.188</td>
<td>0.168</td>
<td>0.225</td>
</tr>
<tr>
<td>Destabilized</td>
<td>0.279 (-48.6)</td>
<td>0.335 (98.9)</td>
<td>0.250 (10.8)</td>
</tr>
<tr>
<td>Rigid Screw Rod</td>
<td>0.206 (10.0)</td>
<td>0.106 (-36.7)</td>
<td>0.232 (3.2)</td>
</tr>
<tr>
<td>Rigid Screw Flexible Rod</td>
<td>0.207 (10.5)</td>
<td>0.108 (-35.7)</td>
<td>0.233 (3.3)</td>
</tr>
<tr>
<td>Dynesys</td>
<td>0.164 (-12.7)</td>
<td>0.050 (-70.3)</td>
<td>0.135 (-40.0)</td>
</tr>
<tr>
<td>Cosmic</td>
<td>0.206 (10.0)</td>
<td>0.120 (-28.7)</td>
<td>0.233 (3.6)</td>
</tr>
<tr>
<td>Wallis</td>
<td>0.188 (0.2)</td>
<td>0.128 (-24.2)</td>
<td>0.217 (-3.5)</td>
</tr>
<tr>
<td><strong>Extension</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Intact</td>
<td>0.162</td>
<td>0.139</td>
<td>0.148</td>
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<tr>
<td>Destabilized</td>
<td>0.171 (5.8)</td>
<td>0.322 (140.1)</td>
<td>0.153 (3.1)</td>
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<tr>
<td>Rigid Screw Rod</td>
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<td>0.037 (-73.5)</td>
<td>0.135 (-8.9)</td>
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<tr>
<td>Rigid Screw Flexible Rod</td>
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<td>0.042 (-69.7)</td>
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</tr>
<tr>
<td>Cosmic</td>
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<td>0.035 (-74.9)</td>
<td>0.135 (-8.9)</td>
</tr>
<tr>
<td>Wallis</td>
<td>0.163 (0.7)</td>
<td>0.068 (-51.2)</td>
<td>0.131 (-11.3)</td>
</tr>
<tr>
<td><strong>Lateral Bending</strong></td>
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<tr>
<td>Intact</td>
<td>0.278</td>
<td>0.226</td>
<td>0.226</td>
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<tr>
<td>Destabilized</td>
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<td>0.235 (4.1)</td>
<td>0.226 (0.0)</td>
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<tr>
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<td>0.132 (-41.7)</td>
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<td>0.075 (-66.8)</td>
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</tr>
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<td>0.112 (-50.3)</td>
<td>0.223 (-1.4)</td>
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<tr>
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<td>0.221 (-1.9)</td>
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<tr>
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<td>0.224 (-1.0)</td>
<td>0.225 (-0.1)</td>
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<td><strong>Axial Rotation</strong></td>
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<tr>
<td>Intact</td>
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<td>0.118</td>
<td>0.141</td>
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<tr>
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<td>0.141 (0.0)</td>
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</tr>
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<td>0.166 (40.7)</td>
<td>0.142 (0.8)</td>
</tr>
<tr>
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<td>0.171 (44.7)</td>
<td>0.142 (0.3)</td>
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<td>0.092 (-21.9)</td>
<td>0.141 (-0.4)</td>
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<td></td>
<td>L3-L4 % Change</td>
<td>L4-L5 % Change</td>
<td>L5-S1 % Change</td>
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<td>----------------</td>
<td>----------------</td>
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</tr>
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<td>0.797</td>
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<td><strong>Extension</strong></td>
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<tr>
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<td>1.211</td>
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<td>1.115</td>
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<td>Rigid Screw Rod</td>
<td>0.838</td>
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<tr>
<td>Rigid Screw Flexible Rod</td>
<td>1.387</td>
<td>0.6</td>
<td>0.510</td>
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<tr>
<td>Dynesys</td>
<td>1.385</td>
<td>0.5</td>
<td>0.631</td>
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<tr>
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<td>1.383</td>
<td>0.4</td>
<td>0.573</td>
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<tr>
<td>Wallis</td>
<td>1.380</td>
<td>0.1</td>
<td>1.289</td>
</tr>
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<td><strong>Right Rotation</strong></td>
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<td>1.357</td>
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<td>Rigid Screw Rod</td>
<td>0.903</td>
<td>1.0</td>
<td>0.468</td>
</tr>
<tr>
<td>Rigid Screw Flexible Rod</td>
<td>0.903</td>
<td>1.0</td>
<td>0.483</td>
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<tr>
<td>Dynesys</td>
<td>0.911</td>
<td>1.8</td>
<td>1.975</td>
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<tr>
<td>Cosmic</td>
<td>0.911</td>
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<tr>
<td>Wallis</td>
<td>0.895</td>
<td>0.0</td>
<td>0.557</td>
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**Table 4.28:** Peak von Mises stresses in annulus fibrosus (MPa) and % changes with respect to intact for intact, destabilized spine and stabilization with the instrumentation in 400N compression and 10.6Nm moment (Negative % indicates a decrease in the stress)
Implant peak stresses for decompression with instrumentation models in load control protocol

Peak von Mises stresses in the implants were determined for the stabilization of the decompression surgery with instrumentation. Stress plots of all the implants are shown in Figures 4-33 to 4-37. The stresses and loads in the tables are shown for the left and right sides of the spine in bending and rotation. Since the FE model is symmetric about the mid sagittal plane only the right rotation and right bending were computed. For all practical purposes, the results calculated in right bending and rotation will be true for left bending and rotation.

Rigid screw rod system

Figure 4-33, illustrates the stress plots of the rigid screw rod system in the destabilized spine all the loading modes. Table 4-29, reports the peak von Mises stresses occurring at the various components in the rigid screw rod system. The peak stresses in the destabilized model increased when compared to that in the intact model. The highest peak von Mises stress of 173 MPa occurs in the rod, in axial rotation. The peak von Mises stresses in the rod for the other loading conditions are, 143MPa in flexion, 147MPa in extension, and 149 MPa in lateral bending.

Rigid screw flexible rod system

The stress plots of the rigid screw flexible rod system in all the loading modes are shown in Figure 4-34. Table 4-30, reports the peak stress values for the different components of the system. For the flexible rod system, the highest peak von Mises stress of 132MPa was
seen in flexion at the L5 screw. When compared to the rigid rod the stresses in the flexible rod were much lesser with the highest peak stress of 120MPa seen in lateral bending.

Dynesys system

Figure 4-35, shows the stress plots of the rigid screw flexible rod system in all the loading modes. Table 4-31, reports the peak stress values for the different components of the system. The stresses occurring through the spacer and the ligament are axial (S11). Hence, the loads through these components have been reported in Table 4-32. The peak stresses seen in the screws of the Dynesys system were much lesser when compared to the rigid screw rod system. In flexion, a total load of 100N was seen in the ligament, and a load of 104.22N was seen by the spacer. In lateral bending (right), the spacer on the right side of the spine carries a compressive load of 109.23N and the ligament on the left side carries a load of tensile load of 103.04 N. In axial rotation (right), the ligament on the right side carries a load of 22.66N and a load of 28.68N is seen in the spacer on the left side.

Cosmic system

The stress plots of the cosmic system are shown in Figure 4-36, the peak von Mises stress values are reported in Table 4-33. The peak von Mises stresses do not change for all the loading modes in the hinge system with values being 146MPa for the screws and 147MPa for the rods. The stresses in the screw are higher than that seen in the rigid screw rod system.
**Wallis system**

The Stress plots for the Wallis system in various loading modes are given in Figure 4-37. Tables 4-34 and 4-35, show the peak von Mises stress values for the spacer and the loads through the ligament in the various loading modes. In flexion, the peak stress value for the spacer was 142 MPa. The peak stress values for the spacer were; 146MPa in extension, lateral bending and 144MPa for axial rotation. In flexion, a load of 104.42N was seen in the ligament. In lateral bending (right), the left side ligament experienced a load of 68.18N and in axial rotation (right), the ligament on the left side experienced a load of 50.35N.
**Figure 4-33:** von Mises stress plots for the rigid screw rod system in the destabilized spine for all the loading modes in 400N compression and 10.6Nm moment.

**Table 4.29:** Peak von Mises stress values (MPa) for the rigid screw rod system, in the destabilized spine for all the loading modes in 400N compression and 10.6Nm moment. (Lateral bending and axial rotation correspond to right bending and right rotation)

<table>
<thead>
<tr>
<th></th>
<th>Flexion</th>
<th>Extension</th>
<th>Lateral Bending</th>
<th>Axial Rotation</th>
</tr>
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<tbody>
<tr>
<td></td>
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<td>Right</td>
<td>Left</td>
<td>Right</td>
</tr>
<tr>
<td>L4 Screw</td>
<td>124</td>
<td>123</td>
<td>109</td>
<td>74</td>
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<tr>
<td>L5 Screw</td>
<td>119</td>
<td>116</td>
<td>112</td>
<td>120</td>
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<tr>
<td>Rod</td>
<td>143</td>
<td>147</td>
<td>149</td>
<td>147</td>
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</tbody>
</table>
**Figure 4-34:** von Mises stress plots for the rigid screw flexible rod system, in the destabilized spine for all the loading modes in 400N compression and 10.6Nm moment

<table>
<thead>
<tr>
<th></th>
<th>Flexion</th>
<th>Extension</th>
<th>Lateral Bending</th>
<th>Axial Rotation</th>
</tr>
</thead>
<tbody>
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<td></td>
<td>Right</td>
<td>Left</td>
<td>Right</td>
<td>Left</td>
</tr>
<tr>
<td>L4 Screw</td>
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<tr>
<td>Rod</td>
<td>118</td>
<td>100</td>
<td>119</td>
<td>120</td>
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</table>

**Table 4.30:** Peak von Mises stress values (MPa) for the rigid screw flexible rod system, in the destabilized spine for all the loading modes for 400N compression and 10.6Nm moment. (Lateral bending and axial rotation correspond to right bending and right rotation)
400N + 10.6 Nm Flexion
400N + 10.6 Nm Extension
400N + 10.6 Nm Lateral bending
400N + 10.6 Nm Axial Rotation

Figure 4-35: von Mises stress plots for the Dynesys system, in the destabilized spine for all the loading modes in 400N compression and 10.6Nm moment

<table>
<thead>
<tr>
<th></th>
<th>Flexion</th>
<th>Extension</th>
<th>Lateral Bending</th>
<th>Axial Rotation</th>
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</tr>
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<tr>
<td>L5 Screw</td>
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<td>76</td>
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Table 4.31: Peak von Mises stress values (MPa) for the Dynesys system, in the destabilized spine for all the loading modes in 400N compression and 10.6Nm moment.
(Lateral bending and axial rotation correspond to right bending and right rotation)

<table>
<thead>
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<th>Flexion</th>
<th>Extension</th>
<th>Lateral Bending</th>
<th>Axial Rotation</th>
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<td>Left</td>
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<td>0.00</td>
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<td>103.04</td>
<td>0.00</td>
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Table 4.32: Loads (N) through the spacer and the ligament of the Dynesys system in the destabilized spine for all the loading modes in 400N compression and 10.6Nm moment.
(Load= S11*Cross-sectional area) (Lateral bending and axial rotation correspond to right bending and right rotation)
Figure 4.36: von Mises stress plots for the Cosmic system in the destabilized spine for all the loading modes in 400N compression and 10.6Nm moment

<table>
<thead>
<tr>
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<th>Lateral Bending</th>
<th>Axial Rotation</th>
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<td>Right</td>
<td>146</td>
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<tr>
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<td>147</td>
<td>Right</td>
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</tbody>
</table>

Table 4.33: Peak von Mises stress values (MPa) for the Cosmic system in the destabilized spine for all the loading modes in 400N compression and 10.6Nm moment. (Lateral bending and axial rotation correspond to right bending and right rotation)
Figure 4.37: von Mises stress plots for the Wallis system, in the destabilized spine for all the loading modes in 400N compression and 10.6Nm moment

<table>
<thead>
<tr>
<th></th>
<th>Flexion</th>
<th>Extension</th>
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<th>Axial Rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spacer</td>
<td>142</td>
<td>146</td>
<td>146</td>
<td>144</td>
</tr>
</tbody>
</table>

Table 4.34: Peak von Mises stress values (MPa) for the spacer of the Wallis system in the destabilized spine for all the loading modes in 400N compression and 10.6Nm moment. (Lateral bending and axial rotation correspond to right bending and right rotation)

<table>
<thead>
<tr>
<th></th>
<th>Flexion</th>
<th>Extension</th>
<th>Lateral Bending</th>
<th>Axial Rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ligament</td>
<td>104.42</td>
<td>0.00</td>
<td>6.04</td>
<td>68.18</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50.35</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4.10</td>
</tr>
</tbody>
</table>

Table 4.35: Loads (N) through the ligament of Wallis system in the destabilized spine for all the loading modes in 400N compression and 10.6Nm moment. (Load= S11*Cross-sectional area) (Lateral bending and axial rotation correspond to right bending and right rotation)
Load sharing for Decompression with instrumentation models

The rigid screw rod system saw 8.95% (35.8N) of the total compressive load, whereas the system with the flexible rod saw 6% (24N) of the total load. The Dynesys system bore 1.5% (6N) of the total load. The Cosmic system and the Wallis system bore 2.45% (9.8), 1.9% (7.6) of the total compressive load (400N) respectively. The flexion angles and the axial displacements were larger for the flexible stabilization systems (Table 4.36).

<table>
<thead>
<tr>
<th>Instrumentation</th>
<th>Axial displacement</th>
<th>Flexion angle</th>
<th>Load Sharing (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigid Screw Rod</td>
<td>-0.44</td>
<td>0.4899</td>
<td>364.2</td>
</tr>
<tr>
<td>Rigid Screw Flexible Rod</td>
<td>-0.45</td>
<td>0.4757</td>
<td>376</td>
</tr>
<tr>
<td>Dynesys</td>
<td>-0.71</td>
<td>0.4928</td>
<td>394</td>
</tr>
<tr>
<td>Cosmic</td>
<td>-0.71</td>
<td>0.5896</td>
<td>390.2</td>
</tr>
<tr>
<td>Wallis</td>
<td>-0.78</td>
<td>0.5350</td>
<td>392.4</td>
</tr>
</tbody>
</table>

Table 4.36: Axial displacements, flexion angles, Loads (N) through the intervertebral disc and instrumentation in decompression models in response to 400N compression.
Chapter V

Discussion

Overview
The following sections discuss the protocols used in the present study. A general overview of the various parameters reported in the study will be given. Lastly, the limitations and the scope of future work will be included.

Conclusions
The studies of lumbar spine biomechanics using in vitro cadaveric testing and finite element protocols have been conducted previously. Cadaveric studies provide clinically relevant kinematic data. However, they cannot predict the stress-strain and host of other relevant parameters. Validated finite element studies hence, are important to supplement the in vitro studies to provide extrapolated information, which might be clinically relevant. The experimentally validated L3-S1 model in this study has been used to address several clinically relevant issues in the past [19, 99, 100]. In this study, it was found that the trend in motion in flexion and extension of the segment stabilized using Dynesys system is in agreement with the findings of Schmoelz et al. [88], thus further supporting the validity of our model. The details of this validation are given in Appendix D.
Load control protocol is the study of response of the intact and instrumented models under the application of a constant load. The physiological load of 400N pre compression and a moment of 10.6Nm were used in this study. The hybrid protocol reveals the effects of the instrumentation at the adjacent levels [103,104]. The hybrid test protocol involves applying pure moments to the intact model to yield physiological motion across the spinal segment. This physiological motion across the intact spinal segment is applied to the instrumented models (e.g., implantation with rigid screw, Dynesys, Cosmic, and Wallis systems). Moment is applied until the motion of the instrumented model becomes equal to that of the intact motion. The moment values required to achieve this motion are different from the intact case values. In this study, the hybrid protocol was employed for all the instrumentations in flexion and extension. It was seen that all the systems required more moment than the intact spine to reach the same global motion.

Decompression surgery causes instability, and often warrants additional stabilization. It is also a primary indication for the use of dynamic stabilization. Hence, it is of importance to quantify the range of motion for the different stabilization systems in such a procedure. Total bilateral laminectomy leads to the largest segmental instability, especially in flexion, extension, and rotation, hence this case was analyzed [33, 29, 35].

Range of motion is the usually the primary kinematic parameter reported in the biomechanical evaluation of fusion and non-fusion devices. Fusion, aims at restricting the
motion at the instrumented segment, based upon the hypothesis that abnormal range of motion is the cause for discogenic back pain. Dynamic stabilization systems, on the other hand aim to preserve or recreate the extent of motion to that of the intact segment [1]. The concept of dynamic stabilization is based upon the hypothesis that discogenic back pain is caused due to abnormal changes in the pattern of loading rather than abnormal motion [105]. In degenerated conditions, postural related abnormal load transfer through the annulus is seen causing an alteration in the disc stresses [6]. This might lead to an increase in interlaminar shear stresses of the annulus [19] and finally lead to disc degeneration.

The biomechanical functions of the facet joints in the lumbar spine are guiding segmental motion and carrying a portion of the global mechanical load applied to the spine. The amount of load the facet joints carry varies with the posture. In axial rotation and extension, the facet loads carry considerable load [13]. Alteration of the facet loads might indicate abnormal loading patterns in the segment. However, there is little information available in literature regarding the load in facet joints during physiologic motion.

The facet joints and the intervertebral disc form a three joint complex and share majority of the load on the spine. Any alteration in the intervertebral disc loading or the facet joint loading might instigate a degenerative cascade. In an instrumented spine the normal load sharing is altered such that the load is distributed between the facet joints, intervertebral disc, and the instrumentation. Intervertebral disc stresses, facet joint loading may give as a suggestion about the loading conditions that occur in the instrumented spinal segment.
This information is especially relevant to the evaluation of dynamic stabilization devices in the spine, since an implicit goal of many of these systems is to restore the natural load sharing of the operated segment. In this regard, it would be of great interest to characterize and compare the disc stresses and facet joint loading before and after implantation of the dynamic stabilization systems [1].

Apart from characterizing the above parameters, quantifying the load sharing between the instrumentation, intervertebral disc with and without the facet joints might be relevant in pure compression. Load sharing in bending and torsion are more related to the stability provided by a fixation device rather than to the load sharing characteristics, and hence have not been evaluated in this study. The axial compressive load of 400N, which is the load on the lumbar spine in a quiet standing posture, is simulated. In the intact with the instrumentation model, it was seen that the rigid screw rod system and rigid screw flexible rod system shared load along with the facet joints, however the other dynamic systems did not bear any load, and in fact showed tensile loads. This could be because when compression was applied the motion segment experiences a slight flexion and this flexion angle is more for dynamic stabilization systems than the rigid system. The load sharing data for the decompression with the instrumentation models show that in the absence of facets, dynamic stabilization systems bear some of the compressive load, but lesser than the rigid system. The load sharing results for the Rigid screw rod system and the Cosmic system were close when compared to the study by Goel et al., 2001 [93]. However, direct comparisons cannot be made since their study involved bone graft and the compressive load applied was 800N. We can conclude that in the presence of the
basic supporting structures of the motion segment like the facet joint and the disc, the
dynamic stabilization systems allow for normal loading. However, in destabilized
segments in the absence of facets the dynamic stabilization systems act as load bearing
along with the disc.

Range of motion may not be a sensitive parameter in documenting the spinal kinematics
since it is one-dimensional. The study of the IAR of the vertebral body, which is two
dimensional, may provide more information on the kinematics of the spinal segment [1].

It is very important for the dynamic stabilization systems to provide uniform load
sharing; this is possible when the location of the optimum instantaneous axis of rotation
lies close to that of the intact segment [6]. The most important practical application of the
study of the IAR is in the non-fusion motion preservation devices like the dynamic
stabilization to predict how closely spinal motion is restored to normal following
instrumentation [1]. From a clinical point of view, IAR is most important in flexion and
extension. IAR’s in lateral bending and axial rotation show minimal translation, and
rotation hence are of less practical importance. In this study, the IAR’s of the segment
with different stabilization devices were hence, predicted in flexion and extension. The
trend in the movement of the IAR of the intact segment in flexion and extension was
similar to that reported by Sengupta et al [106].

Implant loosening following fusion surgery is common in the presence of psuedoarthrosis.
Dynamic stabilization has to provide load sharing throughout its life; hence, implant
failure is an important consideration. In this study all, the implant stresses were well
below the actual yield strength of the material used. Hence, the implants are unlikely to
fail under physiological loading, however testing needs to be done to evaluate the implant fatigue failure in the long term.

Fusion devices like the rigid screw rod system, attempt to limit the motion of the instrumented segment. The results from this study indicate that rigid screw system being the most inflexible showed reductions in motion disc stresses and facet loads in all the models. The reductions in peak disc stresses were highest at the instrumented level and the corresponding increases were seen to be highest at the adjacent levels. The IAR for the rigid screw rod system was localized to the posterior aspect of the L4 vertebral body indicating that the pivot point shifts posterior for the rigid fixation. Such a shift in the IAR indicates abnormal motion and abnormal disc loading in the segment.

The rigid screw flexible rod (Nitinol superelastic rod) showed reductions in motion comparable to the rigid screw rod system in all the loading modes. This can be explained by the fact that both systems had a rigid connection between the pedicle screws and the rod. Hence, having a flexible rod rigidly connected to screws may not be advantageous in terms of achieving normal loading patterns.

The Dynesys system achieves stabilization of the motion segment by connecting the pedicle screws with a non-elastic ligament, with a plastic cylinder surrounding the ligament. The ligament acts as an axis for flexion, which is posterior to the normal axis of flexion. In extension, the cylinder takes an increasing load and restricts the motion. In extension hence, there is an unloading of the anterior annulus, without compression of the
posterior annulus. Dynesys reduces the peak annulus stresses in flexion; this is seen since the axis of flexion is through the ligament of the Dynesys system. These results for the Dynesys system were in agreement with stress profilometry study by Aylott et al, 2004 [85]. The reductions in motion due to Dynesys are dependant upon various factors. Niosi et al., have shown that the spacer length of the Dynesys system affects the range of motion [86]. The Dynesys, reduces motion in all the loading cases, these results are agreement with the various studies done previously [84, 87, 88]. However, it is more flexible than the rigid screw rod system. In the decompression model the increase in the motion for the axial rotation was 193%, this increase can be explained by the fact that the neither the spacer nor the ligament of the Dynesys system offer much resistance to torsion. Wilson et al., found that upon implantation with Dynesys the facet loads decreased in axial rotation, did not change in extension, and increased in flexion when compared to the intact [88]. They claimed that the facet loads increased in flexion due to device compression. In this study, the Dynesys reduced the facet loads in all the loading modes except for axial rotation, which saw an increase of 21.3%. The increase in the facet loads in flexion by Wilson et al. was probably seen due to the pretensioning of the Dynesys ligament thus compressing the facet joints at that segment. The FE model of the Dynesys did not simulate the pretension in the ligament and hence these results may not be comparable. The IAR of the Dynesys system was in the same region as that of the intact spine, thus indicating that the Dynesys system restricts motion and yet also allows for physiological loading through the segment.
A hinge system such as the cosmic system was previously studied for its load sharing capabilities in the presence of a bone graft [93]. They have found that the hinge system (similar to the Cosmic system) immobilizes the segment comparable to the rigid screw rod system and allows for load sharing through the segment. This system can be defined as a semirigid fixation of the spine, which might be advantageous for fusion. In extension, the cosmic system showed motion less than the rigid screw rod system (88.5%), along with a near rigid IAR in extreme extension. This can also be due to the fact that cosmic system is made of stiffer metal, than the rigid screw rod system. Scifert et al., in their in vitro study found that the reduction in the intersegmental motion for the hinge screw system and the rigid system was comparable in all the loading modes. The reduction in flexion of the cosmic system in decompression was 67.3%, which is comparable to the reduction of 65% reported by Scifert et al [92]. The cosmic system in axial rotation does not control motion with the increase being 197% along with an increase in the disc stress and facet load. The IAR of the hinge system is highly localized in both flexion and extension since the pivot point for the motion segment in such a system would lie at the hinge axis of the screw system. In extension, the IAR of the hinge screw system is closer to that of the rigid screw rod system, explaining why the behavior of both the systems in terms of motion, disc stresses, and facet loads is similar in extension.

The Wallis system is an interspinous based spacer system, which is held in place between the spinous processes by a ligament. The spacer of the Wallis acts in preventing motion in extension, whereas in flexion the ligament controls the motion. From the present data, it was seen that Wallis was more flexible than Dynesys in all loading modes. In flexion,
this may happen due to the fact that the interspinous ligaments are removed when implanting the Wallis system. In extension, this may be dependant on the height, stiffness of the spacer. In lateral bending and axial rotation, the ROM of the Wallis system was in the range of the intact spine. Wallis being an interspinous spacer distracts the facet joints, and acts as a fulcrum, thus decreasing the facet joint contact. This explains the fact that for the Wallis system even though the range of motion was more than the other systems the decrease in facet loads was higher in extension. This can be further clarified by looking at the motion occurring at the segment when implanted with the Wallis system. Figure 5.1 shows the deformation curve for the Wallis system; where the black lines indicate the original undeformed shape, blue lines indicate the shape after the application of 400N compression and 10.6Nm moment. From the contours, it can be seen that the Wallis system does not move during the entire range of motion suggesting that it acts as a pivot. The IAR data for the L4 vertebral body for the Wallis in extreme extension is closer to the rigid screw rod system; corresponding reduction in facet loads for extreme extension for the rigid system was 91%, whereas for the Wallis system it was 99%.

![Deformation curves for the Wallis system at no load (black contours) 400N compression and 10.6Nm (blue contours)](image)

**Figure 5.1:** Deformation curves for the Wallis system at no load (black contours) 400N compression and 10.6Nm (blue contours)
Summary

The methodology in this study was adapted from a common consensus reached by experts in the spine in the field of spinal biomechanics for the testing protocol of non-fusion devices [106]. The important parameters that needed to be evaluated to assess the performance of the non-fusion devices as stated by the experts were; range of motion in load and hybrid protocols, facet joint loading, disc stresses, IAR data and load sharing between the intervertebral disc and the non fusion device.

The current study examined the effects of five different spinal stabilization systems with different stiffness properties on the intersegmental motion of the instrumented and adjacent segments. This was achieved by employing load and hybrid protocols for all the systems. The effect of these instrumentations on the range of motion, facet loads, and the disc loading patterns were evaluated. The actual nature of the motion at the instrumented segment was quantified by evaluating the instantaneous axis of rotation.

In this study, we started out with the hypotheses that, (i) dynamic stabilization systems restore kinematics and relative motion of the lumbar spine closer to that of the intact spinal segment as compared to the rigid stabilization system, (ii) They also allow for near physiologic biomechanical parameters like stresses and loads.

The results indicate that the dynamic stabilization systems are more flexible than rigid systems but not flexible enough to say that they preserve motion. However, they have the ability to allow for loading through the intervertebral disc. Since intervertebral disc cells
respond favorably to loading [23], use of dynamic stabilization systems might be advantageous in the repair of the damaged disc.

**Limitations of the study**

The major limitation of this study is the lack of experimental data for the various stabilization systems. The other limitations of this study that need to be noted for proper interpretation of the findings of the study are as follows. The models assume a perfect bone screw interface; variation in surgical procedure for different instruments is not taken into account. Changes in the surgical procedure may cause a variation in the load sharing. Modeling of the Dynesys system using three dimensional continuum elements was subject to the computational limitations of the FE (ABAQUS) software. Hence, the spacer and the ligament of the Dynesys were approximated as three dimensional truss elements. Pretension for the ligament in the Dynesys system was not simulated; this might have changed the range of motion and facet joint loading. However, the results of the model predictions of the Dynesys system were in agreement with the experimental results from Schomelz et al [88]. The material properties used in the FE model were isotropic and homogeneous, which is not seen in most cadaveric specimens. In addition, the FE model does not account for variations in the geometry of the specimen such as facet orientation.
**Future work**

The current study is restricted to being a finite element analysis, undertaking a cadaveric study would give us more confidence in the model predictions, especially for the Wallis system. Load sharing characteristics of the Dynesys system as a function of variation in the placement of the screws will be helpful in assessing the optimal surgical placement of the system. Recently the indications for the use of dynamic stabilization have been extended to stabilize an adjacent segment to fusion, a finite element study with dynamic stabilization adjacent to fusion maybe helpful in understanding various biomechanical parameters. Dynamic stabilization systems can be used adjunctly with other non-fusion technologies like the disc nucleus replacements. Hence, it would be interesting to study the load sharing characteristics of the dynamic stabilization systems with a prosthetic disc nucleus.
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Appendix A

Functional Anatomy of the Spine

The human spine is a complex columnar structure beginning at the occiput and ending at the pelvis (Figure A1). The spine has a three-dimensional structure that exhibits non-linear viscoelastic mechanical behavior [107]. The main functions of the spine are; (i) Protection of the spinal cord and many internal organs, (ii) Base for the attachment of ligaments, tendons and muscles, (iii) Gives a structural support for head shoulders and chest, connects upper and lower body, provides balance and weight distribution. (iv) Provides flexibility and mobility to the trunk. (v) Other functions like vertebral bodies producing red blood cells and mineral storage [108].

There are four major regions of the spine namely the cervical, the thoracic, the lumbar, and the sacrum Table A.1. The natural curves in the spine, kyphotic (thoracic) and lordotic (cervical and lumbar), provide resistance and elasticity in distributing body weight and axial loads sustained during movement. The anatomy of each of these regions is important in understanding the function and the types of ailments that may occur at each level.

*Cervical spine:* This part of the spine has seven vertebral bodies. The neck supports the weight of the head and protects the nerves that come from the brain to the rest of the body. The first two cervical vertebral bodies called the atlas and the axis are attached to each other such that axis acts as a post that the atlas rotates around. The next five vertebral segments have three joints at each segment, including one intervertebral disc in the front...
and paired facet joints in the back. The rotation of the cervical spine is a result of the first two segments; the flexion/extension moment mainly comes from C5-C6 and C6-C7. The cervical vertebral bodies have openings to allow arteries to carry blood to the brain.

*Thoracic spine:* The thoracic spine consists of 12 vertebral bodies. These are characterized by small pedicles, long spinous processes and relatively large intervertebral foramen due to which there is less incidence of nerve compression (Figure A.2). The motion occurring at the thoracic spine is very little considering the fact that all the thoracic vertebrae are attached to the rib cage at each level.

*The lumbar spine:* The lumbar spine consists of 5 vertebral bodies and has a lot more motion that thoracic spine. These vertebral bodies are the largest of the spine and they carry the majority of the body’s weight and related biomechanical stress. The pedicles are longer and wider than those in the thoracic spine. The spinous processes are horizontal and more squared in shape. The facet joints of the lumbar spine are aligned such that they allow more flexion/extension than rotation.

*Sacrum and Coccyx:* The sacral and the coccygeal vertebrae are fused, forming a solid, wedge transmitting the axial load of the spinal column over the paired pelvic bones and hip joints into lower extremities.

After understanding the basic regions of the spine we can conclude that the differences in mobility between regions (cervical, thoracic, and lumbar) is due to the splinting effect of
the rib cage, differences in shape and size of the articular processes, and spinous processes. One can consider spine biomechanics on several anatomic levels. On the largest scale, the spine may be considered as a whole – as a segmented column. Then, because certain regions act in concert, the spine may be considered on a smaller scale including the cervical, thoracic, and lumbar regions. Smaller yet, a single functional spinal unit (FSU, or “motion segment”) may be studied [96].

**Functional Spine Unit:** A functional spine unit consists of two adjacent vertebrae and an intervertebral disc along with the facet joints and adjoining ligaments. The functional spinal unit is generally used to quantify stability of the spine.

**Vertebral body:** A vertebra consists of an anterior block of bone, the vertebral body, and a posterior bony ring known as the neural arch, containing articular transverse and spinous processes [10]. The vertebral body consists of cancellous core contained in a thin shell of cortical bone. The superior and inferior surfaces of the cortical bone are called as the endplates. The posterior bony ring also called as the neural arch consists of two pedicles and two laminae from which seven processes arise. The vertebral bodies carry the major share of load in most physiological conditions. This load is transmitted through the endplate of the vertebra to the intervertebral disc.

**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. The
facet joints play a major role in stabilizing the spine. They carry a part of the compressive loads (up to 33%) along with the vertebral body and provide 45% of the torsional strength for the functional spinal unit [10].

**Intervertebral disc:** The intervertebral disc is an important part of the functional spinal unit. It is made up of outer tough cartilaginous annulus fibrosis, which surrounds jelly like nucleus pulposus (Figure A.5). The intervertebral disc forms the main articulation between vertebral bodies along with the osseous endplates. The annulus fibrosis is composed of 15 to 20 layers of collagenous fibrils obliquely running from one cartilage end plate to the other and crossing at 120-degree angles. Any load through the spinal column is transmitted to the intervertebral disc from the vertebral body. 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 intervertebral disc resists compression, tension, shear, bending, and torsion [10]

**Ligaments:** A Functional Spinal Unit (FSU) includes the following 7 ligaments: the anterior longitudinal ligament, the posterior longitudinal ligament, the ligamentum flavum, the facet capsular ligaments, the interspinous ligament, the supraspinous ligament, and the intertransverse ligament (Figure A.6). The anterior and the posterior longitudinal ligaments are located in the anterior and posterior surfaces of the disc and are attached to both the disc and the vertebral bodies. The anterior longitudinal ligament
was found to be two times stronger than the posterior ligament due to increased cross section even though they have the same material properties [10]. The ligamentum flavum is formed between the lamina of the neural arches. It acts as a protective sheath for the spinal cord and has the highest percentage of elastin (65-70%) of any structure in the human body. The capsular ligaments encase the periphery of each facet joint and are perpendicular to the joint line. The interspinous and supraspinous ligaments are quadrilateral in shape and thickest in the lumbar spine. The interspinous ligament extends from the ligamentum flavum, posteriorly to the lumbosacral fascia. In the thoracic spine, they are thin and filamentous. Intertransverse ligaments in the thoracic spine are stout and are part of the paraspinous musculature. In the lumbar spine, they are poorly developed.

Ligaments are uniaxial structures and carry loads along the direction in which the fibers run. They readily resist tension but buckle in compression. The functional properties of a ligament are a combination of its physical properties, direction of the orientation and location with respect to the moving vertebra. A ligament with a larger lever arm provides greater stability to the spine than the shorter lever arm [10].

![Figure A.1: The human spine](http://www.spineuniverse.com)
Table A.1: The different regions of the human spine
(http://www.spineuniverse.com)

<table>
<thead>
<tr>
<th>Term</th>
<th># of Vertebrae</th>
<th>Body Area</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical</td>
<td>7</td>
<td>Neck</td>
<td>C1 – C7</td>
</tr>
<tr>
<td>Thoracic</td>
<td>12</td>
<td>Chest</td>
<td>T1 – T12</td>
</tr>
<tr>
<td>Lumbar</td>
<td>5 or 6</td>
<td>Low Back</td>
<td>L1 – L5</td>
</tr>
<tr>
<td>Sacrum</td>
<td>5 (fused)</td>
<td>Pelvis</td>
<td>S1 – S5</td>
</tr>
<tr>
<td>Coccyx</td>
<td>3</td>
<td>Tailbone</td>
<td>None</td>
</tr>
</tbody>
</table>

Figure A.2: The thoracic vertebrae
(http://www.spineuniverse.com)
**Figure A.3:** The Lumbar vertebrae
(http://www.spineuniverse.com)

**Figure A.4:** Functional spinal unit
(http://www.backpainforum.com)
Figure A.5: Annular fibers and the fiber orientation in the intervertebral disc [10].

Figure A.6: Ligaments of the Lumbar spine [108]

(http://www.spineuniverse.com)
Spine biomechanics relates how the spine behaves when forces or moments act upon it. To quantify the biomechanics of the spine, various research techniques have been employed. These techniques include optoelectronic tracking, finite element modeling, advanced radiographing, *in vitro* analyses, anatomy from MRI images and EMG studies. Natural loading conditions may include various directional load components acting at once. The five primary loading conditions are compression, flexion, extension, axial rotation (torsion), and lateral bending. These will be explained in detail.

*Axial Compression*

In compression, the spine is loaded along its axis, perpendicular to the intervertebral discs. Forces may naturally reach several times body weight during normal tasks, especially lifting, when it can be as high as 6000 to 9000 N [96]. In the lumbar spine most of the compressive load is resisted by the disc because the facet surfaces are oriented nearly parallel to the axial force, but if a slight extension is induced first and if the discs have been compressed for some time, then the facets may share as much as one sixth of the compressive load. Nachemson concluded through facetectomies that the facets carry as much as 18% of the axial compressive load in the lumbar spine. The factors affecting the
stiffness of the spinal unit in compression are degeneration of the soft tissues, segment level, size, and bone density, many of which are related to age and loading history [96]. Compression will cause an FSU to fail at the endplate and not at the disc. This often occurs via cracks in the central region with disc material protruding through the endplate, producing what is called Schmorl’s nodes [10].

**Axial Rotation**

In axial rotation, flexion, extension, and lateral bending a moment applied to the spine induces a rotation. It is has been seen that the rotatory loads are more likely to produce disc failures [10]. In axial rotation (torsion), a moment causes the spine to rotate about its longitudinal axis. Axial rotation is unique from the others because it produces rotation in the same plane as the intervertebral disc. The facet joints are of particular interest in axial rotation because one of the joints will undergo tension and the other will undergo compression. Farfan found that in torsion the load is equally shared between the facets and the disc. The stiffness of the spinal unit in axial rotation is shared between the ligaments (~10%) and the disc (~45%). The facets limit axial rotation to approximately 5° [110].

**Flexion**

In the lumbar spine, the largest range of motion occurs in the sagittal plane, which includes flexion and extension rotations. In flexion, a moment induces a forward rotation of the spine. The lumbar spine’s rotational stiffness in flexion has been reported to be 1.75 Nm/degree by Tencer et al. and 0.8 Nm/degree by Schultz et al. [101]. Several structures contribute to a lumbar FSU’s flexion stiffness. The disc compresses and wedges such that the anterior portion is under compression while the posterior portion is
under tension. Because the center of rotation resides to the posterior of the disc, all the ligaments are stretched as well, except for the anterior longitudinal. In flexion, due to the location of the center of rotation with respect to the facets and because of the facet orientation, the facet joints are not engaged. However, the capsular ligaments are placed in tension.

Failure loads for a lumbar FSU in flexion may be as high as 50 Nm, but physiologic flexion moments can also be very high; some analyses suggest 100 Nm. Such a difference is balanced by muscular contraction, which converts some of the physiologic moment to axial compression [96].

**Extension**

In extension, a moment applied to the spine produces a backward bending. In the lumbar spine, this motion is primarily limited by the facet joints. Loads are shared between the facets, disc, and ligaments. The proportions can vary considerably depending on anatomic factors, degenerative conditions, size, and measurement technique. Tencer reported stiffness values for extension of approximately 0.74°/Nm with the posterior elements, but 1.1°/Nm without [111]. In contrast, Schultz and Markolf found the lumbar FSU to rotate 1.3°/Nm and 0.5°/Nm, respectively [96].

**Lateral Bending**

In lateral bending an applied moment causes the spine to bend to the left or right side of the body. Several structures in the FSU resist lateral bending loads, including the intertransverse ligaments, facet joint ligaments, and lateral portions of the annulus. This is known as coupled motion and is caused by the orientation of the facet joints. As such, without the facet joints, the spine is less stiff in lateral bending. Tencer found the lumbar
lateral bending rotation stiffness to drop from 2.07 Nm/deg to 1.15 Nm/deg when the posterior elements were removed. Schultz and Markolf found varying rotational stiffnesses for the intact lumbar spine: 1.22 and 2.6 Nm/deg, respectively. Again, because of the motion’s complexity, load application techniques and anatomic differences and degeneration can play a large role in determining these stiffnesses. [96]

Range of Motion

The spine’s range of motion in response to pure moment is determined by several structures, including ligaments, the disc, the facets, and the spinous processes. Ligament tension limits displacements between two separating elements. Facets and spinous processes limit range of motion via contacting surfaces. Strains in the intervertebral disc restrain motion between the endplates. Typical ranges of motion (ROM) for the lumbar spine are also listed in Table B.1. Note the dramatic decrease in lateral bending ROM as one approaches the sacrum. This is due to alterations in the lateral processes and facet joints, which are oriented more obliquely in the upper lumbar region than the lower [96].

<table>
<thead>
<tr>
<th>Spinal Level</th>
<th>Flexion</th>
<th>Range of Motion (degrees)</th>
<th>Extension</th>
<th>Lateral Bending</th>
<th>Axial Rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>L1-L2</td>
<td>8</td>
<td>5</td>
<td>10</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>L2-L3</td>
<td>10</td>
<td>3</td>
<td>11</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>L3-L4</td>
<td>12</td>
<td>1</td>
<td>10</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>L4-L5</td>
<td>13</td>
<td>2</td>
<td>6</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>L5-S1</td>
<td>9</td>
<td>5</td>
<td>3</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

**Table B.1:** Ranges of motion for lumbar segments in all rotation modes [96].
Appendix C

Finite Element Model Validation

Objective
The Finite element model validation was carried out by using experimental data. A fresh cadaveric functional spinal unit with posterior instrumentation was tested in compressive load. Bending moment was calculated with the amount of applied load. The intact FE model was modified to simulate the experimental setup. The FE results were correlated with the cadaveric study.

Methods

Cadaveric study
A fresh cadaveric L2/3 segment was used for this study. The specimen was thawed at room temperature. The L2/3 intervertebral disc was removed and replaced by an instrumented silicone disc. The ligaments, tissue, and L2/3 facet joint were also removed from the FSU. The endplates were leveled with polyester material to provide a flat surface area and the superior endplate of L2 was fitted with a rigid polymer plate to resist indentation. Posterior instrumentation with mounted strain gages, pedicle screws and 5mm rods were used to reassemble the unit (Figure C.1 a). The disc space was sized to allow insertion of discs labeled air gap, silicone, and polyurethane, in order of increasing stiffness. The FSU was placed on the load cell of an MTS 850 Bionix (MTS, Eden Prairie MN) testing machine and a controlled compressive load was applied to the top plate.
using a 5.0 mm diameter pin mounted to the MTS actuator (Figure C.1b). The load was applied two inches anterior to the plane of the rods, first medially and then offset to the right. Output was recorded by a voltmeter upon stabilization. Compression loads were applied from 50N to 300N in steps of 50N with corresponding moments in the sagittal plane of 2.54 to 15.24 N-m. The force, displacement, and time were also recorded during the testing. Instrumentation bending moment was calculated and plotted against the applied moment. Results are shown in Figure C.2 for load applied medially.

**Finite element study**

This study was replicated with the finite element model. The intact L3-L5 FE model was modified such that L5 vertebral body and the L4/5 disc was removed, the L3/4 disc was removed and replaced with the models of the inserts used in the cadaveric study, and all posterior elements were removed leaving only the pedicle intact. Pedicle screws were placed into the pedicles and vertebral bodies with 5mm rods as shown in Figure C.3. Interactions were defined at the surfaces in contact at the bone-pedicle screw interface and between the pedicle screw and rod. The model was constrained in all degrees of motion at the inferior most surface of L4 vertebra. A compressive force normal to the superior surface of L3 was applied to simulate the cadaveric MTS compression. Two different discs were modeled; silicone and polyurethane, and material properties simulated are listed in Table C-1. Resulting bending moments were measured at the center of the pedicle screw rod approximately at the location of the strain sensors in the cadaveric study. Results are shown in Figure C.4.
Conclusions

The FE results are in strong correlation with the cadaveric study further substantiating the validity of the model.

Figure C1: (a) Experimental FSU to determine strains in the posterior instrumentation. (b) Specimen setup using the MTS machine.

Figure C.2: Results of measured moment versus applied moment in a cadaveric study.
Figure C.3: FE model simulation of the strain experiment

Table C.1: Material properties simulated in the FE model for the disc inserts

<table>
<thead>
<tr>
<th>Material</th>
<th>Tensile Modulus (psi)</th>
<th>Poisson’s Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyurethane Insert</td>
<td>600, 1750, 3000</td>
<td>0.31</td>
</tr>
<tr>
<td>Silicone Insert</td>
<td>400</td>
<td>0.31</td>
</tr>
<tr>
<td>PMMA</td>
<td>4.64 x 10^6</td>
<td>0.30</td>
</tr>
<tr>
<td>Posterior Instrumentation</td>
<td>1.5 x 10^7</td>
<td>0.30</td>
</tr>
</tbody>
</table>

Figure C.4: Results of measured moment versus applied moment in a FE study
Rotational moments were also validated for the FE model. Predicted motions were compared in rotation to values reported in the literature. Validation of rotational moment is shown in Figures C.5 through C.8.

**Figure C.5:** FE predicted flexion motion for L3 and L4 vertebrae with 400N compression compared to Schultz [101] and Dooris [96]

**Figure C.6:** FE predicted extension motion for L3 and L4 vertebrae with 400N compression compared to Schultz [101] and Dooris [96]
**Figure C.7:** FE predicted lateral bending motion for L3 and L4 vertebrae with 400N compression compared to Schultz [101] and Dooris [96]

**Figure C.8:** FE predicted axial rotation motion for L3 and L4 vertebrae with 400N compression compared to Schultz [101] and Dooris [96]
Appendix D

Comparison of FEM Motion Prediction for Dynesys System with an In Vitro Study

Objectives: This study was undertaken to validate the FEM model of the Dynesys system with an experimental study performed by Schmoelz et al, 2003 [88].

Summary of the In vitro study: The study by Schmoelz et al. (Lit), investigated Dynesys a dynamic non fusion system that is designed to stabilize the instrumented segment while maintaining the disc and the facet joints. The aim of the study was to determine the magnitude of stabilization and effect of stabilization on the instrumented segment and the adjacent segments. The cadaveric spines used were from L2-L5, L5 was potted and a load application of 10Nm was done at L2. The surgical procedure was done at the L3-L4 segment. The cases studied were (1) Intact, (2) Destabilized spine (Dissection of ligamenta flavum, tenotomy of facet joint, and nucleotomy) (3) Stabilization of the defect with the Dynesys.

Methods: The intact model was modified to simulate the destabilized case at L4-L5 (Figure D1). The destabilized model was stabilized with the Dynesys system. The Dynesys system was simulated at L4-L5 segment in the L3-S1 experimentally validated spine model. The spacer and the cord in the Dynesys system were modeled using 3D truss elements (Figure D2). The spacer was given a no tension option and the ligament was given a no compression option. The screws were modeled using 3D solid continuum
elements. The cases and the loading conditions simulated were similar to the study done by Schmoelz et al.

Figure D.1: The stabilization of the defect with Dynesys in the FE model

Figure D.2: Dynesys system
Results: The trends in the motion as reported by Schmoelz et al, were compared against the finite element model predictions in flexion and extension at the instrumented segment and the adjacent segments figures D3 a, b and c. It was found that the FEM model predictions were close to the predictions by the experimental studies (lit) in flexion/extension.

Figure D.3a: Range of motion at the upper adjacent segment for a pure moment of 10Nm in flexion and extension. The lit values show the median and the bars represent the range.
Figure D.3b: Range of motion at the instrumented segment for a pure moment of 10Nm in flexion and extension. The lit values show the median and the bars represent the range.

Figure D.3c: Range of motion at the lower adjacent segment for a pure moment of 10Nm in flexion and extension. The lit values show the median and the bars represent the range.
Conclusions:

The FE model predictions are very to the predictions by Schomelz et al except for the case of the destabilized spine in flexion where the FE model over predicted the range of motion. This can be explained by the fact that the amount of destabilization performed may have varied, making the cadaveric specimen stiffer than the FE model.
Appendix E

Simulation of the Nitinol

Introduction:

The superelastic and shape memory properties of Nitinol, a nickel-titanium alloy, along with its biocompatibility have made it an ideal material for medical implants. Nitinol is an extremely flexible metal alloy that can undergo very large deformations without losing the ability to recover its original shape upon unloading. At rest, the material presents itself in an austenite phase, which behaves linear elastically. Upon loading, this austenite phase transforms into a martensite phase, which is also linear elastic; however, the elasticity of each phase has different constants. The transformation produces a substantial amount of strain and is triggered by stress over a relatively narrow range. Upon unloading, the transformation is reversible. However, the stress level at which such reversible transformation occurs is smaller than the stresses that were required to produce the original transformation. Because the material recovers its original shape upon unloading, it is described as elastic. In addition, because the transformation strains are large (approximately 6%) compared to elastic strains in typical metals (approximately 0.1%), the material is said to be superelastic. If a reverse, loading is applied (for example, in compression instead of tension), a similar behavior is observed, and with the exception that the stress levels required to produce, the transformations are higher, while the transformation strain is lower [112].
Superelastic formulation:

For Version 6.4 of ABAQUS, a constitutive model to simulate the superelastic behavior of alloys such as Nitinol (a nickel-titanium alloy commonly used in medical devices), at finite strains is provided in the form of a UMAT subroutine for ABAQUS/Standard. The model is based on an additive strain decomposition, in which the total strain is taken as the sum of the elastic strain and the transformation strain. The transformation strain is of the order of 6%, but the elastic strain is much smaller, and should be limited to a maximum of 2%. Since the transformation strains are large compared to typical elastic strains in a metal, the material is said to be superelastic. The material data required by the model are obtained from straightforward observations of uniaxial tests in terms of loading, unloading, reverse loading, and temperature effects (Figure E1). The calibration consists of 13 values, as shown in Figure E2. The data characterize the start, end of the phase transformation during loading, unloading, and reverse loading. The different elastic constants for the austenite and martensite phases are accounted for and user control of volumetric transformation strains is allowed. Temperature effects are included as well.

Supported elements: The elements that are supported for use with the material model are: 3D solids, plane strain, axisymmetric, plane stress, 3D shells, 3D membranes, 3D beams.

User interface:

Sample .env file should look like as described below:

```
pre_memory="800mb"
standard_memory="1046 mb"
explicit_precision=DOUBLE_PRECISION
```
# Specify the path to the installed shared libraries

usub_lib_dir = "c:\users\username\path_to_installed_libraries"

The line “c:\users\username\path_to_installed_libraries” should point to the directory which has the installed libraries required for the subroutine UMAT. The libraries include standardU.dll, standardU_static.Lib.

Using this material model requires the user to specify 15 material constants on the data lines of the *USER MATERIAL option. The formulation uses 24 solution-dependent state variables (SDVs); this number is specified using the *DEPVAR option. The material definition for the superelastic metal should look like as below.

```
* MATERIAL, NAME=name*
* USER MATERIAL, CONSTANTS=15 + N_A
E_A, \nu_A, E_M, \nu_M, \epsilon^T, \frac{\partial \sigma}{\partial \epsilon^T}, \sigma_s^T, \sigma_L^T
T_0, \frac{\partial \sigma}{\partial \epsilon^T}, \sigma_s^C, \sigma_L^C, \sigma_u, N_A, N_S1, ...N_SmA

* DEPVAR
24,
```

Input to UMAT/Superelasticity

- **E_A**: Austenite elasticity
- **\nu_A**: Austenite Poisson’s ratio
- **E_M**: Martensite elasticity
- **\nu_M**: Martensite Poisson’s ratio
- **\epsilon^T**: Transformation strain
- \frac{\partial \sigma}{\partial \epsilon^T}: Stress/strain slope
- **\sigma_s^T**: Start of transformation loading
- **\sigma_L^T**: End of transformation loading
- **T_0**: Reference temperature
- \frac{\partial \sigma}{\partial \epsilon^T}: Stress/strain slope
- **\sigma_s^C**: Start of transformation unloading
- **\sigma_L^C**: End of transformation unloading
- **\sigma_u**: Start of transformation stress during loading in compression, as a positive value
- **\sigma_s**: Volumetric transformation stress. If \sigma_s^T = \sigma_s^C, an associated algorithm is used, with \sigma_s^T computed based on \sigma_s^C and \sigma_L^C
- **N_A**: Number of annealings to be performed during the analysis
- **N_S1 - N_SmA**: Step numbers at which all state-dependent variables are set to zero
**Figure E.1:** The mechanical behavior of Nitinol

**Figure E.2:** The data required to define superelastic behavior in ABAQUS model
Appendix F

Publications by the Author Related to the Work


growth plate following physis stress fracture. Submitted to Scoliosis research Society


