Biomechanical evaluation of facet bone dowels in the lumbar spine

Joel M. Gerber
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A Thesis

entitled

Biomechanical Evaluation of Facet Bone Dowels in the Lumbar Spine

by

Joel M. Gerber

Submitted to the Graduate Faculty as partial fulfillment of the requirements for the

Master of Science Degree in Bioengineering

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August 2015
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An Abstract of
Biomechanical Evaluation of Facet Bone Dowels in the Lumbar Spine

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The lumbar spine is associated with a number degenerative conditions and pathologies: stenosis, spondylolisthesis, spondylolysis, facet joint syndrome, and zygapophyseal joint osteoarthritis. The most effective treatment for these conditions often involves a surgical fusion of the affected spinal segment. One method of fusing the spine is through modification of the zygapophyseal joint using facet bone dowels, however this method has not been fully researched. The current study evaluated the effectiveness of these types of implants, specifically the TruFuse implant, the Z-Lift implant, and a novel morphology-conforming implant. The study was performed in two parts: an in vitro experimental component, and a finite element analysis. The in vitro portion consisted of instrumenting functional spinal units with each of the implants and comparing the intact and instrumented range of motion under multiple loading conditions. The functional spinal units were loaded to 10 N*m under flexion, extension, left and right lateral bending, left and right axial rotation, and flexion / extension with a 400 N preload. The finite element models were used to analyze the range of motion of the instrumented spinal segments, as well as to quantify the reduction in intradiscal pressure after...
instrumentation. The stresses in the facets and the change in foraminal area were also analyzed. The finite element models were validated using load displacement data. The range of motion results of the finite element analysis were consistent with the *in vitro* results. All of the implants reduced range of motion under all loading conditions, with the exception of the Z-Lift model under flexion, both with and without a preload. The novel device performed nearly as well as the other implants in reducing motion, and provided a more consistent reduction in intradiscal pressure. All of the implants showed an increase in the cross sectional area of the foramina after instrumentation. The TruFuse and Z-Lift implants showed areas of high stress concentration in the facets, while the morphology conforming implant showed a more uniform stress distribution. While this may result in faster fusion rates for the novel implant, future work must be done to provide support for this hypothesis.
To my family and friends. Thanks!
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List of Abbreviations

ALL...........................Anterior Longitudinal Ligament
BMD .........................Bone Mineral Density
C1 ...........................First Cervical Vertebra
C7 ...........................Seventh Cervical Vertebra
DEXA ......................Dual Energy X-Ray Absorptiometry
Ext.........................Extension
Ext w/.....................Extension with a 400 N Preload
FE............................Finite Element
FEA ..........................Finite Element Analysis
Flx ...........................Flexion
Flx w/.....................Flexion with a 400 N Preload
FSU ..........................Functional Spinal Unit
Hz ...........................Hertz
IDP ..........................Intradiscal Pressure
L1 ...........................First Lumbar Vertebra
L2 ...........................Second Lumbar Vertebra
L3 ...........................Third Lumbar Vertebra
L4 ...........................Fourth Lumbar Vertebra
L5 ...........................Fifth Lumbar Vertebra
LB ...........................Left Lateral Bending
LED ...........................Light Emitting Diode
LF ...........................Ligamentum Flavum
LR ...........................Left Axial Rotation
mm ..........................Millimeter
MPa ..........................Megapascal
N/A ..........................Not Applicable
N*m..........................Newton Meter
PLL ..........................Posterior Longitudinal Ligament
RB ..........................Right Lateral Bending
ROM ..........................Range of Motion
RR ..........................Right Axial Rotation
S1 ..........................First Vertebra of the Sacrum
T1 ..........................First Thoracic Vertebra
T12 ..........................Twelfth Thoracic Vertebra
List of Symbols

° ............................................ Degree

σ ............................................ Standard deviation
Chapter 1

Introduction

1.1 Overview

This chapter provides a general introduction to the biomechanics of the human spine. It begins with a brief discussion of the gross and skeletal anatomy of the spine and elaborates on how the various geometrical components of the spine relate with respect to motion. This chapter also includes a discussion on the types of movement allowed by the spine and the disorders that can disrupt normal spinal motion. A brief discussion of the current standards of treatment is also presented, followed by the primary purpose for this study.

1.2 Anatomy of the Spine

While a more detailed description of spinal anatomy is provided in Appendix A, this section highlights the most relevant anatomy.

The human spine is composed of multiple vertebra, ligaments, joints, and intervertebral discs. It can be divided into five distinct sections: cervical, thoracic, lumbar, sacral, and the coccyx. Each section has different anatomical features and
biomechanical functions. The vertebra are the bones which make up the spine. With the exception of the first cervical vertebra (C1), they all have the same basic landmarks and structural design. The vertebral bodies, in conjunction with the intervertebral discs, provide the primary structural integrity of the spine, and form the main weight-bearing column of the spine while also serving as the anterior wall of the spinal canal. The intervertebral discs are the shock absorbers of the spine. These discs sit between each set of vertebra, with the exception of the sacral region, and provide enhanced mobility for the spine.

The posterior portion of the spine serves two main purposes: to protect the spinal cord and to stabilize and control motion in the spine. Protection of the spinal cord is provided by the vertebra, which provides a boney enclosure for the spinal cord. Motion of the spine is limited by the ligaments; the majority of which attach to posterior portions of the vertebra, as well as the zygapophyseal joints. The ligaments are made of tightly woven collagen fibers which provide resistance while in tension, similar to a rope. The zygapophyseal joints, commonly referred to as facet joints, are bilateral synovial joints that form between each adjacent vertebra. The morphology of these joints changes throughout the different regions of the spine. The curvature of these joints are responsible for controlling which types of motion are allowed at each spinal segment.
1.3 Kinematics of the Spine

1.3.1 The Functional Spinal Unit

While the spine is capable of highly complex motion, individual segment level motion can be attributed to sections known as functional spinal units (FSU). According to Stephen Ferguson, the FSU is “the smallest spine segment that exhibits the typical mechanical characteristics of the entire spine.” [21] A typical FSU consists of two adjacent vertebrae, the intervertebral disc, the facet joints, and the ligaments that connect the vertebrae. All of the complex motions of the spine can be related to the relative motion between each FSU.

1.3.2 The Six Degrees of Freedom

Each FSU is capable of six degrees of freedom: three rotations and three translations [22]. The rotational components are often referred to as flexion / extension, lateral bending, and axial rotation. Within the sagittal plane, flexion represents an anterior rotation of the superior vertebra, and extension represents a posterior rotation of the superior vertebra relative to the inferior vertebra. Lateral bending consists of rotation in the coronal plane. Axial rotation, on the other hand, represents rotation of the superior vertebra around the primary axis of the spine (in the transverse plane).

The translational components of motion are called axial displacement, anterior shear, and lateral shear. The primary type of translational motion experienced by the spine is axial displacement. When the spine is subjected to body weight, the intervertebral discs compress in response to the load. This compression causes the
vertebral bodies to move closer together. Anterior shear represents the anterior motion of one vertebra relative to the other. In a non-pathogenic spine, such translation is often very small. Likewise, lateral shear - the lateral movement of one vertebra relative to the other, accounts for a relatively small amount of motion.

1.3.3 The Helical Axis of Motion

Each FSU is capable of complex motions that comprise two or more rotations and translations. However, for the purpose of this study, only pure motions were considered. When complex motions are analyzed, it is often easier to quantify them as a three-dimensional displacement vector and a rotation about that vector. This is known as the helical axis of motion [23]. Using this method, any relative motion between two vertebral bodies can be effectively quantified. A complete picture of the kinematics of a single FSU are shown in Figure 1-1.

Figure 1-1: The kinematics of the functional spinal units. The six degrees of freedom are shown in (a), the helical axis of motion representation of motion is shown in (b). This image was obtained from [21].
1.4 Spinal Instability

When the normal motion of the spine becomes imbalanced or destabilized, chronic degenerative conditions can result. Instability of the spine can be caused by, or be the result of, multiple pathologies including: spondylolysis, spondylolisthesis, and facet joint arthritis. Instability can also disrupt the normal load transfer between vertebrae, which can result in too great a load being transferred through the disc or facet joints. When too much load is placed on the intervertebral disc, the pressure within the disc will increase and may result in disc herniation or degradation, which may lead to stenosis or impingement of the spinal canal. Spinal instability often results in pain. Excessive motion is believed to be one of the primary causes of facet syndrome. Due to increased weight bearing requirements of the lumbar spine, many of these conditions are even more prevalent in this region, making treatment of the lumbar spine the focus of this study. More detailed descriptions of each of the aforementioned pathologies are provided in Chapter 2.

1.5 Spinal Fixation

The current standard of treatment for spinal instability is surgical fusion of the effected segment. The literature review in chapter 2 provides an in-depth overview of the types of treatments as well as justification for fusion as standard practice, despite its inherent limitation to normal motion. Fusion is achieved through the use of implanted fixation devices. The most notable of these are the pedicle screw and rod constructs. Screws are surgically inserted into the pedicles of the effected segments and sets of
screws are connected by rods. These rods are usually made of titanium, which is stiffer than bone. The resultant difference in adjacent material stiffness leads to an effect known as stress shielding which can delay fusion. Alternatives to pedicle screws and rods exist and can help minimize or eliminate stress shielding. Such alternatives exist in the form of interbody cages and facet bone dowels. Currently, there is a large gap in the literature with regard to the use of facet bone dowels.

1.6 Purpose of Study

Destabilizing pathologies, particularly in the lumbar region, have necessitated the use of fixation devices. This study aims to fill a gap in the literature as it focuses particularly on modification of the zygapophyseal joint through the use of facet bone dowels. Since these types of devices are used for spinal fixation, it can be hypothesized that, through instrumentation of a spinal segment with facet bone dowels, range of motion at the instrumented segment will decrease. Furthermore, the intradiscal pressure at that region should also decrease, reducing the likelihood of further disc degeneration. It has also been suggested (by Dr. Vijay Goel) that use of an implant that conforms to the shape of the zygapophyseal joints will result in better fixation and reduction in intradiscal pressure. A prototype for such a device was presented in this study and compared to currently marketed bone dowels. A biomechanical evaluation of the hypotheses was conducted using a combination of in vitro cadaveric experimentation and finite element analysis.
Chapter 2

Literature Review

2.1 Overview

This chapter covers facet pathologies and the treatments and surgical approaches used to correct them, as well as a review and description of the implants that were analyzed in this study.

2.2 Pathologies

2.2.1 Stenosis

Stenosis refers to the narrowing of the spinal canal or the foramina where the nerve roots leave the spinal cord. The narrowing can be caused by a number of factors, with the most common being herniated discs and the formation of osteophytes [24 and 25]. Herniated discs occur when the pressure in the nucleus pulposus becomes so high that it causes a tear in the annulus fibrosus. As the tear enlarges, the nucleus pulposus can herniate through the opening [26]. This herniation usually occurs on the posterior side of the spine, causing the narrowing of the spinal canal or foramina. Osteophytes, which are another cause of stenosis, are abnormal growths of bone occurring between the vertebral
bodies or between articular processes. The excess bone can cause result in impingement of the nerves and lead to pain and numbness in the extremities. An illustration of foraminal stenosis due to a herniated disc is depicted in Figure 2-1.

![Figure 2-1](image-url)

Figure 2-1: Axial and sagittal views of a spine with stenosis. This stenosis is due to a herniated intervertebral disc. Image obtained from [27].

### 2.2.2 Spondylolisthesis

Spondylolisthesis is a common pathology of the lumbar spine, characterized by an excessive anterior shift of a vertebra relative to the inferior vertebra [28-30]. This shift causes a change in the biomechanics of the spine with respect to the way body weight is transferred between vertebrae and to the pelvis. Since the superior vertebra is shifted anteriorly, the posterior elements can become destabilized [31]. The facets, which normally play a large role in limiting the range of motion of the spine, can resultantly lose their ability to restrict motion at the effected FSU, causing ineffective load transfer
from segment to segment. Frequently, the anterior shift of the vertebra also causes spinal stenosis.

Spondylolisthesis can be caused by a number of mechanisms which have been categorized by Wiltse et al. as: isthmic, degenerative, traumatic, pathologic, and dysplastic [32 and 33]. The two most common forms of spondylolisthesis are degenerative and isthmic [34]. In younger patients, *isthmic* is the most predominant form. While children and adolescents are growing, it is possible for a mechanical disturbance, such as sudden trauma, to cause slippage at the growth plate [31]. Since the growth plate is the site of new bone formation in the axial direction, it is highly susceptible to damage from shear forces. Older patients are more likely to suffer from *degenerative* spondylolisthesis. This type of spondylolisthesis is caused by arthritis of the facet joints and worsens chronically [32].

### 2.2.3 Spondylolysis

Another condition that can lead to spondylolisthesis is spondylolysis. Spondylolysis can be caused by repetitive trauma, usually due to participation in sports or by genetic anatomical variation [35-37]. In either case, the condition begins with a defect, or small fracture, of the pars interarticularis. The pars interarticularis is the part of the vertebra that connects the pedicle to the lamina, and connects the superior and inferior articular surfaces. If not treated, this condition can worsen and result in a complete fracture of the pars interarticularis. Since this portion of bone plays a large role in the transfer of forces during spinal loading, a fracture occurring here can destabilize the posterior portion of the spine, and the vertebra can become displaced anteriorly, resulting
in spondylolisthesis. Spondylolysis primarily affects the L4 and L5 vertebra, and rarely occurs in other vertebra [37].

2.2.4 Facet Syndrome

Facet syndrome is the term given to pain associated with the zygapophysial joint. According to Steib et al., “clinical symptoms include deep pain that is motion dependent, pressure sensitive, and pseudoradicular” [38]. The pain can be caused by a number of mechanisms, ranging from inflammation and arthritis to simple joint motion [39]. The facets are believed to be highly innervated and irritation of these nerves can cause pain. Facet syndrome is usually a symptom of another underlying pathology. It is usually treated conservatively, at first, with intra-articular injections or physical therapy. However, if this fails, patients often elect to undergo surgical intervention [40].

2.2.5 Facet Joint Arthropathy (Osteoarthritis)

Facet joint arthropathy is also known as zygapophysial joint osteoarthritis. This type of osteoarthritis is comparable to the osteoarthritis that occurs in other joints of the body [41]. It is a normal degenerative condition that, with time, results in the wearing away of the articular cartilage of the facets. According to Kalichman et al.:

“The facet joints are the only synovial joints in the spine, with hyaline cartilage overlying subchondral bone, a synovial membrane, and a joint capsule. Because of their high level of mobility and the large forces influencing the facet joints, especially in the lumbar area, they can develop significant degenerative changes and be a potential source of pain and disability.” [42]
The wear pattern that results in facet joint arthropathy shows that the majority of cartilage damage occurs along the outer edge of the articular surfaces, consistent with the areas that are subjected to the highest stresses [43 and 44].

Degradation of the joints can result in other conditions as well. The damaged cartilage can result in higher stresses in the surrounding bones, ultimately leading to osteophyte formation. Such changes can lead to stenosis of the spinal canal or the foramina [45]. Tischer et al. showed that, while osteophytes do occur as a result of facet joint osteoarthritis, the incidence is rare [43]. Damaged cartilage may also destabilize the spine, resulting in spondylolisthesis or scoliosis [42 and 46].

2.3 Treatments

2.3.1 Conservative Treatments

For the majority of the aforementioned spinal conditions, conservative treatments result in favorable patient outcomes. Physical therapy is usually performed on an outpatient basis and is indicated for conditions such as spondylolysis and facet joint syndrome [40]. Such non-surgical interventions are usually able to correct the abnormalities associated with these conditions. However, for patients who have more severe conditions, or for those who do not improve with physical therapy, pain management is usually the next step.

Pain management approaches are usually delivered in the form of anti-inflammatory and pain-relieving drugs. Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen can be used to decrease inflammation and may help alleviate the pain
associated with stenosis and facet joint osteoarthritis. In more severe cases, corticosteroids are used to decrease inflammation. While this type of treatment may be widely used in clinical settings, Kalichman et al. state that there are very few randomized controlled studies that have properly evaluated the effectiveness of localized steroid injections [42].

Another alternative pain management treatment is a zygapophyseal joint blockage. In this procedure, injections are introduced into the area surrounding the facet joint, in order to numb the nerves that innervate the joint. This type of treatment is highly effective but may require patients to undergo multiple injections if the condition worsens. One study demonstrated that patients who were diagnosed with facet joint osteoarthritis via computed tomography experienced a 96% rate of improvement after treatment [46]. However, the joint blockage approach only masks an underlying condition and does not resolve the structural cause. When conservative treatments fail to or improve the outcome of these conditions, surgery is often the next step.

2.3.2 Posterior Spinal Stabilization / Facet Joint Arthrodesis

Arthrodesis of a joint refers to a surgical intervention that results in preventing movement at a joint with the ultimate goal of fusion. This type of surgical operation may be performed to restore the structural integrity of the spinal column and to prevent further degeneration. These types of surgeries may also provide a means to reduce pressure on the intervertebral disc through distraction, therein locking the spine into a new position. However, in conditions that are accompanied by a degenerative disc, posterior spinal
stabilization is often augmented with interbody fusion. Such operations are highly effective and, in specific patient populations, have been shown to be more effective than conservative treatment [47 and 48].

The current gold standard for posterior spinal stabilization is fusion through the use of pedicle screws and rods [49 and 50]. Specially designed screws are inserted into the pedicles of the superior and inferior vertebra of the affected joint. Surgeons can then apply a distraction that can reduce the loading on the facets and disc. Titanium rods are bent to align with the tulips of the pedicle screws and provide the resistance to motion. The distraction is locked into place and the rods are fixed to the pedicle screws using set-screws tightened with a torque wrench. This technique has been in existence for a long period of time and has a history of positive clinical outcomes.

Devices that specifically target arthrodesis of the facets may provide some advantages over traditional pedicle screw based spinal fixation. One major limitation of pedicle rod and screw fixation is that it results in stress shielding. Stress shielding occurs when an implant removes the normal stresses from a bone, resulting in osteopenia [51]. Stress shielding is also known to decrease the rate of fusion and delay the healing process. Facet joint spacers, such as those used in this study, seek to avoid stress shielding and allow for a more natural load transfer. An additional advantage is the capacity for facet fusion to be performed as a minimally invasive surgery (MIS) procedure. This translates to quicker surgeries, less blood loss, reduced post-surgery pain, and faster recovery for the patient.
2.3.3 Dynamic Stabilization

Dynamic stabilization systems operate on the premise that correction of spinal instabilities will restore normal range of motion to the spine. This approach would allow a return to a normal quality of life. It is also hypothesized that this technique will reduce the occurrence of adjacent segment disease, as the adjacent segments would not have to compensate for the lack of motion of a fused spinal segment. While this theory is relatively new, there are a variety of designs for these types of implants [50 and 52]. Most of these approaches can be grouped into four categories: total disc replacement, interspinus spacers, pedicle screw based dynamic stabilization, and total facet replacement. The majority of these implants are pedicle screw based, as they have a small learning curve for surgeons who are already familiar with pedicle screw fixation. [52].

2.3.4 Current State

While dynamic stabilization systems may offer the advantage of restoring normal range of motion, the current trend in spinal surgery is still arthrodesis. Fusion devices have been in existence for a longer period of time and have less associated risks, thus making them the preferred choice for surgeons. Currently, clinical data on dynamic stabilization and motion preservation systems is scarce and, coupled with the novelty of these types of implants, it may still be many years until their use surpasses fusion. A review of motion preservation implants by Shin, Lee, and Kim in 2007 surmised that:

“Although [dynamic stabilization] implants offer some theoretical advantages over fusion, new potential problems such as mechanical failure, device migration, same level degeneration and implant subsidence are associated with new technologies. Furthermore, the efficacy of non-fusion implants in the prevention
of adjacent level degeneration was not yet proved. The popularity of non-fusion implants is based more on the lack of satisfaction [of patients] with conventional spinal fusion rather than their proved superiority.” [50].

As the current trend is fusion, only fusion implants were selected for inclusion in the study outlined herein.

2.4 Facet Implants

2.4.1 TruFUSE

The TruFUSE implant is a facet fusion device developed by minSURG International, Inc. [53]. The implant consists of a cylindrical bone graft that is designed to sit within the facet joint space. It features a tapered edge on the anterior side of the implant which aids in its surgical instrumentation. The implant is seated tightly into the joint space by surgical impaction and is believed to reduce motion at the instrumented FSU. While there is little published data on the device, it appears to be growing in popularity in certain clinical settings. According to Domangue and Shamieh, in a recent retrospective study of patients implanted with the TruFuse facet dowel, over 98% of the patients in the study had positive outcomes after surgery [54].
2.4.2 Z-Lift

The Z-Lift implant is a next-generation implant currently being developed by minSURG [53]. It expands upon the design of the TruFUSE implant by including winged protrusions from the main cylinder. These protrusions, or wings, sit firmly between the superior and inferior facets to prevent rotation of the implant and eliminate the possibility of the bone-on-bone interaction possible with the TruFUSE design. The hallmark of this facet fusion device comes from its surgical instrumentation technique. During the surgical procedure, an axial displacement of the inferior facet of the superior vertebra occurs and is believed to reduce pressure on the intervertebral disc therein relieving foraminal stenosis. When the implant is inserted into the facet joint, the wings allow the implant to maintain the distraction, even after the surgical instruments are removed.

Figure 2-2: An image of a computer model instrumented with the TruFUSE facet implant. This image was obtained from minSURG International, Inc. [53]
2.4.3 Morphology Conforming Implant

A morphology conforming implant was designed specifically for this study. Design drawings and dimensions are provided in Appendix D. A plate-wedge hybrid implant (Figure 2-3) was also considered for this study. This concept was originally suggested by Dr. Anand Agarwal. However, after preliminary research and consultation with multiple parties, it was determined that the morphology conforming implant would provide better results and have a more practical clinical application.

Figure 2-3: A design concept for a facet wedge-plate hybrid implant.
The implant consists of three components connected by a nitinol wire (Figure 2-4). Each of the components (Figure 2-5) are of a similar design, with the only differences being the relative dimensional scaling. Each component is rectangular in shape and oriented with the long axis parallel to the articular surface. The anterior face of each piece features a unique double bevel which serves a dual purpose. The first purpose is that it aids in the insertion of the implant while providing a distraction of the facets. The second purpose of the double bevel is to control the inter-articulation of the components of the implant. The sides designed to make contact with the facets are formed with ridges intended to anchor the pieces into the articular surfaces of the facets and to prevent backing-out of the implant.

Figure 2-4: Morphology conforming implant conceptual design.
Figure 2-5: Individual spacers that comprise the morphology conforming implant. Dimensions of the spacer are detailed in Appendix D.

The nitinol wire (Figure 2-6) serves multiple purposes. The first is that it holds the individual pieces of the implant together, preventing any portion of the implant from becoming dislodged during insertion. The other benefits of the nitinol wire are based on its shape memory alloy material properties. The wire can be pre-shaped to match the ideal shape of the patient’s facet joint, aiding in the surgical implantation of the device. Perhaps the largest benefit of the wire is that it allows inter-articulation between the components of the implant enabling a better match to the shape of the facet joint by conforming to the morphological changes of the joint that occur during the different modes of movement. The shape memory of the wire also provides resistance to any conformational changes of the implant, thus further restricting motion. It is hypothesized
that this will allow the implant to perform comparably to other facet implants at reducing motion while simultaneously reducing the intradiscal pressure.

Figure 2-6: The nitinol wire used in the morphology conforming facet implant. The wire is approximately 70 mm long. Dimensions are detailed in Appendix D.

Figure 2-7: This image shows the nitinol wire that sits within, and connects, the individual bone dowels.
Chapter 3

Materials & Methods

3.1 Overview

This chapter outlines the experimental methods used to evaluate the different zygapophysial implants. *In vitro* experimentation was done to establish the range of motion of the spinal segments before and after instrumentation. A finite element model was created for each implant and was validated against the load-displacement data obtained from *in vitro* experimentation. These models were used to provide a side-by-side comparison of different implants for range of motion and disc pressure.

3.2 *In vitro*

The purpose of the *in vitro* study component was to evaluate the design aspects of each implant. The stability of two currently marketed designs were determined for comparison to a novel design. The objective measure of ‘ability to stabilize the spine’ was determined by performing range of motion testing on the intact specimen, instrumenting a segment according to the proper surgical technique, and repeating the
range of motion testing. This procedure was completed for each implant in order to evaluate the ability of the implant to restrict (reduce) motion.

### 3.2.1 Specimen Acquisition and Preparation

Multiple spines were acquired and used in this study. Dual energy X-ray absorptiometry (DEXA) scans were completed for each specimen and used to evaluate bone mineral density (BMD). The specimens were then separated into L2-L3 and L4-L5 functional spinal units (FSUs) by carefully dissecting the ligaments between the L1-L2, L3-L4, and the L5-S1 vertebra. Screws were then inserted into the vertebral bodies to anchor the specimen to potting, which was prepared by mixing one part automotive Bondo with one part epoxy resin. The screws were adjusted prior to potting to ensure that the mid plane of each disc was level in both the sagittal and coronal planes. The caudal end of each specimen was then placed into a specially designed mold. Hardener and accelerator were added to help facilitate the solidification of the mixture. The mixture was poured into the mold until approximately half of the vertebra was submerged. After the potting was hardened to the touch, approximately 15 minutes, the mold was removed and the rostral vertebra was potted using the same method.

### 3.2.2 Range of Motion Testing

Each of the potted FSUs was fixed on a testing rig located in the field of view of an Optotrak 3020 (NDI, Waterloo, Canada) motion capture system. The testing setup is shown in Figure 3-1. A loading fixture was attached to the potted cranial end of each specimen
and a torque transducer was attached to that fixture. Each vertebral body was affixed with LED (light emitting diodes) markers for recording the spatial locations in response to applied moments. Three markers were attached to each segment to define a plane that could be used for later analysis. The positions of the markers were captured using the Optottrak motion capture system.

The intact FSUs were tested under various loading conditions. The specimens were loaded in extension (Ext), flexion (Flx), left lateral bending (LB), right lateral bending (RB), left axial rotation (LR), and right axial rotation (RR). The torque transducer was used to apply pure moments in increments of 2.5 N·m up to 10 N·m. The locations of the markers were recorded before loading and after each 2.5 N·m increment. After the load was removed, the locations of the markers were recorded again in order to evaluate whether hysteresis was present. Marker data was collected for 1 second at a sampling rate of 100
Hz. Following these loading conditions, a 400 N preload was applied using a wire placed through the potting. The extension and flexion loading conditions were then repeated with the preload.

After the initial intact range of motion data was collected, specimens were instrumented with either the Z-Lift implant, TruFuse implant, or the morphology conforming implant using the surgical procedures outlined in the next section. The range of motion study was repeated after instrumentation for extension, flexion, left lateral bending, right lateral bending, left axial rotation, right axial rotation, and coupled extension and flexion with preload loading conditions.

Following the data collection, the data was processed using a custom MATLAB script. For each set of samples, position data for each marker was averaged. The rigid body transformation was used to calculate the angular rotations of the two vertebrae relative to the base plate. This was then used to calculate the angular displacement at 10 N*m. Mean and standard deviation values were computed for each group (Z-Lift, TruFuse, morphology conforming implant).

### 3.2.3 Surgical Procedures

#### 3.2.3.1 Z-Lift

The initial step of the surgical procedure involved the use of a C-arm to fluoroscopically confirm the location of the left and right facet joints. Steinman pins were inserted into the joints and the fluoroscope was used to confirm their placement (Figure 3-2: A). The keel / wing guide assembly was then placed over the Steinman pin, with the
keel oriented perpendicular to the facet, and advanced into the joint. The spikes on the end of the keel were impacted into the superior and inferior facets with the aid of a surgical hammer. This process was repeated for both the left and right facets (B).

![Image](image-url)

Figure 3-2: Graphical depiction of the Z-Lift Surgical procedure.

Next, the keel on each side was rotated 35°. The left keel was rotated counterclockwise and the right keel was rotated clockwise, thus creating an axial translation of the superior and inferior facets and therein an approximate gain of 3.73 mm in disc height. The rotation of the keel also released the wing guides allowing for them to be advanced into the facet joints and impacted into the joints in order to maintain the axial
translation throughout the remainder of the procedure (C). The keel and Steinman pins were then removed.

A space was created within the facet joints for the implants to sit through the use of specialized drill bits. The wing guides were used to guide the drill bits to ensure that the holes were drilled at the proper angle and to the correct depth. A larger central hole was drilled on each side to accommodate the round central portion of the implants and two smaller holes were created to make room for the rectangular wings of the implants (D).

After the holes were drilled, the implants were inserted into the wing guide assemblies. A tamp was used to seat the implants into the facet joints (E). If needed, a hammer was used to countersink the implants. Once the implants were in position, the wing guides were removed. The implants were then visually inspected to ensure proper placement (F).

3.2.3.2 TruFuse

The instrumentation procedure for the TruFuse device was very similar to that of the Z-Lift implant. The procedure began just as for the Z-Lift by locating the left and right facets using a C-arm and inserting Steinman pins into the joint capsules. A simple working cannula was inserted into one of the joints using the Steinman pin as a guide, after which the pin was removed. The procedure deviated from that of the Z-Lift here as there was no vertical translation of the inferior and superior facets. Also, only one central hole was drilled, as opposed to the three holes in the Z-Lift surgical procedure since the implant was only a cylindrical dowel and did not have wings.
After a hole was drilled an implant was inserted into the cannula. A reamer was then placed into the working cannula and was used to advance the TruFuse implant into the joint. The implant was impacted into the hole to ensure a tight fit. The working cannula was removed and the facet was visually inspected to confirm the implant was properly seated in the joint. The procedure was then repeated for the other facet.

3.2.3.3 Morphology Conforming Implant

Implantation of the morphology conforming implant was done using instruments that were custom designed. The center of the facet joint was located and a Steinman pin was inserted to mark the location. Fluoroscopy was used to verify that the placement was correct. A hole was drilled into the facet using the pin to centralize the hole through use of a 5.2 mm diameter drill bit. The hole was drilled parallel to the exterior face of the facets at an angle of 15° rostral to the L5 superior endplate (Figure 3-3). The hole was drilled to a depth of 10 mm, allowing access to the articular surface of the facet while preserving as much of the joint capsule as possible.

Figure 3-3: Drill angulation used in placing the access hole for the morphology conforming implant. The trajectory of the hole is shown in blue arrows. (Image adapted from http://www.wollaston-chiropractic-clinic.co.uk/html/spinal_anatomy.html)
After drilling the access hole, the articular cartilage was removed. Next, the implant was seated between the articular surfaces of the facets, aligned with the drill hole, and oriented with the ridges in line with the facets. Since the size of the hole was equal to the size of a circle inscribed within the profile of the implant, it was necessary to impact the implant into the joint space. A reamer was placed against the posterior face of the implant and used to hammer the implant into position. The implant was impacted into the joint space in two separate pieces, as the prototype implants used did not contain the nitinol wire, though the pre-shaped nitinol wire would allow the separate sections of the implant to easily conform to the shape of the articular surface of the joint. Since the implants were slightly larger than the joint space, force was exerted outwards on the facets creating a press-fit that held the implants in place. This process was repeated for both sides.

3.3 Finite Element Analysis

3.3.1 Intact Spine Model

The finite element (FE) models used in this study were developed by modifying a previously validated thoracolumbar spinal model [55-61]. Model geometry was prepared from computed tomography scans of a cadaveric spine which was free of pathology or abnormal anatomical variations. Slices were taken at 1.5 mm intervals. Scans were analyzed slice-by-slice, then a 3D model was created and meshed using hexahedral elements. The material properties were obtained from published literature sources [55-
The material properties of the elements that were used in this model are detailed in Table 3.1. The model was validated by comparing the load displacement data from the finite element analysis (FEA) to the load displacement data obtained from physical testing of the cadaveric spine [55-61].

Table 3.1: Element types and material properties assigned to anatomical structures.

<table>
<thead>
<tr>
<th>Material</th>
<th>Element Type</th>
<th>Behavior</th>
<th>Young’s Modulus</th>
<th>Poisson’s Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortical Bone</td>
<td>Hexahedron</td>
<td>Elastic</td>
<td>12,000 MPa</td>
<td>0.3</td>
</tr>
<tr>
<td>Cancellous Bone</td>
<td>Hexahedron</td>
<td>Elastic</td>
<td>100 MPa</td>
<td>0.2</td>
</tr>
<tr>
<td>Posterior Cancellous Bone</td>
<td>Hexahedron</td>
<td>Elastic</td>
<td>3,500 MPa</td>
<td>0.25</td>
</tr>
<tr>
<td>Nucleus Pulpous</td>
<td>Hexahedron</td>
<td>Elastic (Fluid)</td>
<td>9 MPa</td>
<td>0.4999</td>
</tr>
<tr>
<td>Annulus Fibrosis Grounds</td>
<td>Hexahedron</td>
<td>Hyper-Elastic Neo hookian</td>
<td>C1 = 0.3448</td>
<td>D1 = 0.3</td>
</tr>
<tr>
<td>Annulus Fibrosis Fibers</td>
<td>Rebar</td>
<td>Elastic</td>
<td>357.5 - 550 MPa</td>
<td>0.3</td>
</tr>
<tr>
<td>Facet Cartilage</td>
<td>Gap</td>
<td>Gap</td>
<td>0 - 12,000 MPa</td>
<td>N/A</td>
</tr>
<tr>
<td>Ligaments</td>
<td>Truss</td>
<td>Hypo-Elastic</td>
<td>Various</td>
<td>N/A</td>
</tr>
</tbody>
</table>

The boney elements in the model were assumed to behave isotropically and were therefore created as isotropic hexahedrons with elastic material properties. The cortical bone was given a Young’s modulus of 12,000 MPa and a Poisson’s ratio of 0.3. The spinous process, transverse process, and the exterior surface of the remaining bone, were assigned the properties of cortical bone. In the vertebral bodies, cortical bone extended 0.5 mm below the surface. The remaining bone within the vertebra was assigned the properties of cancellous bone with a Young’s modulus of 100 MPa and a Poisson’s ratio of 0.2. The posterior elements, facets, and pedicles were assigned slightly stiffer material properties for their internal elements, with cancellous bone assigned a Young’s modulus of 3,500 MPa and a Poisson’s ratio of 2.5.
Since the disc consists of two distinct parts, it was necessary to model both (anulus fibrosis and nucleus pulpos). The inner portion, the nucleus pulpos, is essentially a fluid filled sack. In order to simplify the calculations required to solve the model, this was not modeled as fluid elements, but rather as an elastic material with a small Young’s modulus (9 MPa) and a high Poisson’s ratio (0.4999). By using these values, these elements essentially act as an incompressible fluid. The anulus fibrosis was created using two different types of elements, with the ground material modeled as a hyper-elastic neo-hookean solid and material constants set to C1 = 0.3448 and D1 = 0.3. Unlike all of the previous elements, the fibers of the anulus were not modeled as hexahedrons, but as rebar elements. Rebar elements are often used in finite element analysis to model composite fiber structures such as the intervertebral disc [62]. While all of the fibers had a Poisson’s ratio of 0.3, the Young’s moduli of the fibers varied from 357.5 MPa to 550 MPa.

The articular cartilage within the facet joint was modeled using gap elements, used to create a compression gap, and provided no resistance to tension. As over-closure occurred within the space defined by the gap elements, the stiffness of the elements could increase exponentially until it was equal to that of the cortical bone (12,000 MPa). The spinal ligaments were modeled as simple truss elements with hypo-elastic material properties. As such, the value of the ligaments’ stiffness varied widely based on the amount of strain. Appropriate values for each ligament were determined based on literature-derived values [55-61].

This validated model was simplified by limiting the analysis to only the L4-L5 motion segment. All other vertebra, discs, and ligaments were deleted except for those
that were relevant to this motion segment in order to optimize the computational efficiency of the model and to accurately recreate the \textit{in vitro} testing performed. The L4-L5 finite element model that was used in this study is shown in Figure 3-4. This model was instrumented with the various implants and run using the boundary conditions as described in the following sections.

Figure 3-4: The validated L4-L5 finite element model. Counter-clockwise from top-right:

- top view, sagittal view, posterior view, isometric view.
3.3.2 Model Preparation

3.3.2.1 Z-Lift Finite Element Model

The Z-Lift finite element model was prepared from the L4-L5 model as previously described. The model was created in a way that best simulated the *in vivo* surgical procedure. Some boney elements were deleted from the inferior L4 facet and the superior L5 facet and replaced by bushings. The bushings were thin sections of material that, on one surface, matched the shape of the holes drilled for the implant. The other surfaces of the bushing were tied to the surrounding bone. Material properties were assigned to these elements based on the boney elements that were deleted in order to replicate the process of drilling the holes in the facets and provide a surface that could be used to create an interaction between the bone and implant.

The implants were created using a computer aided design software and were imported into the model. A three dimensional model of one of the implants is shown in Figure 3-5. Since the implants are made from bone grafts, they were assigned the material properties of cortical bone. However, unlike the cortical elements used in the spine, the implant was meshed using tetrahedral elements. This was done to better approximate the shape of the implant within the finite element model. Figure 3-6 shows the tetrahedral mesh that was used for the implant.
In order to replicate the Z-Lift surgical procedure, it was not necessary to insert the implant while creating the model, but rather while running the model for analysis. The first step in running the model was creating the vertical translation of the facets which was done by fixing the superior L5 facet and applying a displacement boundary.
condition to the inferior L4 facet. The boundary condition resulted in a translation of 3.73 mm, which matched the theoretical displacement achieved during the surgical operation. During the next step, displacement was maintained and the implant was advanced into the joint space. A surface-to-surface interaction was created between the implants and the bushings. The displacement boundary condition was then removed simulating the removal of the wing guide from the joint.

3.3.2.2 TruFuse Finite Element Model

Just as in the surgical procedure, the TruFuse FE model was created in a manner analogous to the Z-Lift model. Boney elements were deleted from the inferior L4 facet and superior L5 facet and replaced with bushings which simulated the hole that was drilled. The bushings were assigned material properties that were consistent with the elements that were deleted and were then tied to the surrounding bone.

The TruFuse implant was created using a computer aided design software and was imported into the FE software. The implant was meshed using tetrahedral elements and was assigned the material properties of cortical bone. Since no translation was involved in the TruFuse procedure, the implant was placed into the model during the model’s creation. The implant was positioned within the model using a concentric alignment constraint between the hole in the bushings and the outer profile of the implant. After the implant was positioned, the constraint was converted and deleted so that the implant would start in the proper position, but not be subject to the constraint while the model was running. Surface to surface interactions between the implant and the bushing were established.
3.3.2.3 Morphology Conforming Implant Finite Element Model

The creation of the morphology conforming implant model was very similar to the creation of the other models. The first step was the removal of boney elements from the inferior L4 facet and superior L5 facet. Deleted elements were replaced with bushings used to create the surface-to-surface interactions between the implants and the facets. The bushings were tied to the surrounding bone to enable load transfer to and from the facets, simulating the creation of a hole via drilling. To properly simulate the drilling of the hole, it was necessary to remove portions of the capsular ligament. The facet cartilage was also deleted as it is removed during *in vivo* surgical procedures.

To aid in the placement of the morphology conforming implants, a custom program was created using the C++ programing language and OpenGL. The program provided a translucent representation of the intact spine model and allowed for meshed 3D models of implants to be imported, translated, and rotated. Once the implants were properly positioned they were exported. The export process multiplied the mesh nodes of the implant by the 3D manipulation matrix (translation, rotation, and scaling) and saved the values in an ASCII text file. The ASCII file could then be copied to the FE script file allowing for correct placement of the implants within the FE model. Finally the surface-to-surface interaction between the implants and the bushings was created, allowing for the transfer of compressive loads while also allowing for separation in tension, therein accurately representing the *in vitro* conditions.
3.3.3 Loading and Boundary Conditions

All models were run using the same loading and boundary conditions. The nodes on the inferior L5 endplate and the inferior most nodes on the posterior elements were selected and assigned displacement and rotation controlled boundary conditions (Figure 3-7). The nodes were restricted in all three translational degrees of freedom as well as in all three rotational degrees of freedom, thus serving as fixed surfaces within the models.

Figure 3-7: Boundary conditions were applied to the highlighted nodes to prevent translational and rotational displacement.

Loads were applied to a reference node that was located just above the L4 vertebra using pure moments. The reference node was kinematically coupled to all of the nodes on the superior L4 endplate (Figure 3-8), ensuring that the load was evenly distributed to the vertebral body. Each model was run under multiple loading conditions
simulating flexion, extension, left bending, right bending, left rotation, and right rotation, each with a 10 N*m moment.

Figure 3-8: Pure moments were applied to a reference node that was coupled to the nodes of the L4 superior endplate. Moments were applied to simulate flexion, extension, left and right bending, and left and right rotation.

Compression was simulated using follower loads. Symmetrical nodes were selected on the L4 and L5 vertebral bodies. Connector assignment properties were then given to each set of nodes (Figure 3-9). For the loading conditions, were flexion and extension were simulated with a preload these connector assignments were active. During the first step of the model, a 200 N compressive load was applied to each connector resulting in a total of 400 N of compression between the L4 and L5 vertebral bodies. After the compressive load was applied, a 10 N*m flexion / extension moment was applied to the previously described reference node.
3.4 Data Analysis

3.4.1 In vitro Range of Motion

The in vitro study was done as a proof of concept study and to provide a means of validating the finite element models. As such, the sample sizes for each group were relatively small. This made performing the t-test, the appropriate statistical test, impractical. To account for the small sample sizes, effect size analysis was performed instead. Cohen’s d was calculated comparing the ROM before and after instrumentation, therein showing the effectiveness of the implants at reducing motion. The value was calculated as the difference in means divided by the average standard deviation. A large
effect was determined as \( d > 0.5 \). Analysis was carried out using Excel (Microsoft Corporation, WA, USA).

### 3.4.2 Finite Element Analysis Range of Motion

The range of motion between the L4 and L5 vertebral bodies was computed using Excel (Microsoft Corporation, WA, USA). The position coordinates of the select nodes were extracted from the output database of the model and imported into Excel. The points were used to define planes and the angle between the planes was calculated. Only the angles within the plane of interest were recorded. During flexion and extension, only the angle within the sagittal plane was considered. For bending, motion was recorded in the coronal plane and for rotation, motion was recorded within the transverse plane. The range of motion of the instrumented models was then compared to the range of motion of the intact model.

### 3.4.3 Finite Element Analysis Disc Pressure

Within the body the nucleus pulposus is a fluid filled sac, and therefore has a uniform pressure. However, since the fluid properties of the nucleus were approximated using rigid body elements, the model does not output a single pressure, but rather a pressure distribution. A conservative approximation was made by recording the disc pressure as the highest pressure value measured within these elements. This method likely overestimates the pressure within the nucleus pulposus, and therefore provides worst case scenario data.
3.4.4 Finite Element Analysis Foramina Cross sectional Area

The size of the foraminal canal was found within the sagittal plane by using a custom MATLAB script. Image slices were taken of the foramina in the sagittal plane and were used as input into the program. This program used small width finite area rectangles to approximate the area. The images were taken by screen capturing orthogonal projections of the finite element model after instrumentation and applying the various loading conditions. The script then converted the image data into a matrix of numbers. Using this data conversion factors were calculated in the x and y direction to find the pixel to distance ratios. It then proceeded to count the number of pixels in a single row that were located within the foraminal opening. The previously calculated conversion factors were used to convert the number of pixels in the row to the area encompassed by the rectangle. The program continued to the next row and repeated the process until the total area of the foramina was found.

3.4.5 Finite Element Analysis Facet Stress Distribution

The stress distribution plots for each of the models and loading conditions were analyzed. The inferior facets of the L4 vertebrae were intersected with the entire model, providing the stress distribution plots for the articular surfaces. The plots were exported from the finite element program and presented side-by-side for each of the loading conditions. The maximum and minimum Von Mises stresses as well as the contours of stresses were shown on each of the distribution plots.
4.1 Overview

This chapter contains the results of the in vitro and FE experiments beginning with the in vitro ROM data for individual specimen and followed by summarized data for each experimental group. The Finite Element portion starts with the validation results and then continues with a comparison of the different finite element models. The models were compared across range of motion, disc pressure, area of the foramina, and facet stress distributions.

4.2 In vitro Range of Motion Results

The results for ROM testing are detailed in Appendix B. Figure 4-1 shows the analyzed data as obtained from the Optotrak system. Results are shown for flexion (Flx), extension (Ext), left bending (LB), right bending (RB), left rotation (LR) and right rotation (RR), flexion with a 400 N preload (Flx w/) and extension with a 400N preload (Ext w/). The blue bars indicate ROM for the intact FSU and the orange bars show the ROM after implantation. Calculated effect sizes are detailed in Table 4.1.
Figure 4-1: Experimental results for specimen 56770 at the L4-L5 motion segment. The graph compares the intact range of motion to the range of motion present after instrumenting the specimen with the TruFuse implant at a load of 10 N*m.

Table 4.1: Cohen’s d effect size analysis of the in vitro range of motion study. Conditions that had a large effect (d > 0.5) are highlighted.

<table>
<thead>
<tr>
<th>Group</th>
<th>Flx</th>
<th>Ext</th>
<th>LB</th>
<th>RB</th>
<th>LR</th>
<th>RR</th>
<th>Flx w/</th>
<th>Ext w/</th>
</tr>
</thead>
<tbody>
<tr>
<td>TruFuse</td>
<td>0.314</td>
<td>3.256</td>
<td>2.510</td>
<td>0.460</td>
<td>0.501</td>
<td>0.862</td>
<td>1.420</td>
<td>3.431</td>
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<tr>
<td>Z-Lift</td>
<td>1.769</td>
<td>2.578</td>
<td>2.888</td>
<td>0.670</td>
<td>1.301</td>
<td>4.601</td>
<td>4.640</td>
<td>1.216</td>
</tr>
<tr>
<td>Morph Implant</td>
<td>0.253</td>
<td>0.378</td>
<td>0.387</td>
<td>1.019</td>
<td>0.201</td>
<td>0.756</td>
<td>0.133</td>
<td>0.569</td>
</tr>
</tbody>
</table>
ROM results for the group instrumented with the TruFuse implants (n=2) are shown in Figure 4-2. Results for flexion, extension, left bending, right bending, left rotation and right rotation, flexion with a 400 N preload and extension with a 400N preload are depicted (Figure 4-2). The blue bars depict ROM for the intact FSU and the orange bars for the TruFuse facet dowel implanted FSU. The error bars shown represent ± 1 SD. The data support that the mean ROM for the group decreased after instrumentation.

**Figure 4-2:** Experimental results for the group of specimen instrumented with the TruFuse implant. The graph compares the mean intact range of motion at 10 N*m to that after instrumentation with the TruFuse implant.
ROM results for the group instrumented with the Z-Lift implant (n=2) are shown in Figure 4-3. Results for flexion, extension, left bending, right bending, left rotation and right rotation, flexion with a 400 N preload and extension with a 400N preload are shown. Blue bars depict the ROM for the intact FSU and the orange bars show the ROM after performing the Z-Lift surgical procedure. The error bars shown represent ± 1 SD. The data support that the mean ROM for the group decreased after instrumentation.

Figure 4-3: Experimental results for the group of specimen instrumented with the Z-Lift implant. The graph compares the mean intact range of motion at 10 N*m to that after performing the Z-Lift surgical procedure.

ROM results for the group instrumented with the morphology conforming implant (n=3) are depicted in Figure 4-4. Results are shown for flexion, extension, left bending, right bending, left rotation and right rotation, flexion with a 400 N preload and extension
with a 400N preload. Blue bars depict the ROM for the intact FSU while orange bars show the range of motion after performing the Z-Lift surgical procedure. The error bars shown represent ± 1 SD. The cadaveric experiment showed an increase in the mean ROM for right bending, left rotation, and flexion without preload. All other loading conditions resulted in decreased mean ROM.

Figure 4-4: Experimental results for the group of specimen instrumented with the morphology conforming implant. The graph compares the mean ROM of the intact and implanted FSUs at 10 N*m.
4.3 Finite Element Analysis Results

4.3.1 Finite Element Analysis Validation

In order to validate the FE models, range of motion results of the \textit{in vitro} experiments were compared to those derived from the FE models. Figure 4-5 shows the validation results for the TruFuse FE model. The values obtained during the different loading conditions (flexion, extension, left bending, right bending, left rotation, right rotation, flexion with a 400 N preload, and extension with a 400 N preload) from the model are shown in orange. The blue bars show the mean ROM for the instrumented \textit{in vitro} TruFuse group. The error bars shown represent $\pm$ 1 SD. For the TruFuse FE model, the output lies within two standard deviations for extension, both modes of rotation, and extension with preload. The model produced results that were outside of this range on the low side for the bending loading conditions as well as for flexion with and without a preload.
Figure 4-5: Validation results for the TruFuse finite element model at loads of 10 N*m. 

*In vitro* results for the instrumented specimen are depicted in blue with error bars noting the standard deviation. The FE model results are shown in orange.

The validation graph for the Z-Lift FE model is illustrated in Figure 4-6. The values obtained during the different loading conditions (flexion, extension, left bending, right bending, left rotation, right rotation, flexion with a 400 N preload, and extension with a 400 N preload) from the FE model are indicated in orange. Blue bars show the mean ROM for the instrumented specimen from the *in vitro* Z-Lift surgical group. The error bars shown represent ± 1 SD. This model produced results that accurately predicted the behavior of the implant for all loading conditions except for left and right bending, and left and right axial rotation.
Figure 4-6: Validation results for the Z-Lift FE model (orange) loaded at 10 N*m. *In vitro* results for the instrumented specimen are shown in blue with error bars indicating standard deviation.

The morphology conforming implant FE model validation is shown in Figure 4-7. The values obtained during the different loading conditions (flexion, extension, left bending, right bending, left rotation, right rotation, flexion with a 400 N preload, and extension with a 400 N preload) from the model are in orange. The blue bars depict the mean ROM for the instrumented *in vitro* morphology conforming implant group. The error bars shown represent ± 1 SD. The FE model output for flexion and extension with preload are within the first standard deviation of the experimental group. All of the other loading conditions lie within the second standard deviation, with the exception of left and right rotation.
Figure 4-7: Validation results for the morphology conforming implant finite element model loaded at 10 N*m. *In vitro* results for the instrumented group are shown in blue with error bars denoting the standard deviation. The output of the FE model is shown in orange.

To provide insight into the inherent variability of the FE results, a validation graph for the intact model is provided. Since the intact FE model was previously validated to the cadaver it was prepared from, this graph (Figure 4-8) depicts the variability in the cadaveric portion of the experiment compared to the FE method. Blue, gray, and yellow bars represent the intact range of motion at a 10 N*m applied load for the specimen used in the TruFuse, Z-Lift, and morphology conforming *in vitro* experimental groups, respectively. The error bars show the first standard deviation of each group. The orange group again represents the output of the FE model, this time for the intact motion segment. For extension with and without preload, the output of the FE
model is within the first standard deviation for all experimental groups. Under both left and right bending conditions, the FE model results lie below the range for the intact TruFuse group. Similar results were witnessed for axial rotation as compared to the intact groups for the Z-lift and morphology conforming implants. For flexion with and without preload, only the ROM for the group instrumented with the Z-Lift surgical procedure yielded a mean and standard deviation that fall outside of the FE model results. In cases where a discrepancy, between the intact experimental groups and the intact FE model, was observed, the FE model has yielded values lower than the experimental groups.

Figure 4-8: Intact FE model validation at a loading of 10 Nm. This graph compares the intact ROM from the various in vitro experimental groups to the intact range of motion of the FE model.
4.3.2 Range of Motion

ROM for each model at 10 N*m is shown for each of the loading conditions (flexion, extension, left bending, right bending, left axial rotation, right axial rotation, flexion with a 400 N preload, and extension with a 400 N preload) in Figure 4-9. The output of the intact L4-L5 FSU is shown in orange. Blue bars represent the output of the FE model instrumented with the TruFuse implant. The ROM results of the model instrumented with the Z-Lift surgical procedure and the model instrumented with the morphology conforming implant are shown in gray and yellow respectively. In all loading conditions, except for flexion with and without preload, the instrumented FE models reduced the ROM relative to the intact model. Under flexion loading conditions, the Z-Lift model demonstrated an increase in ROM. However, under the bending and axial rotation loading conditions, the Z-Lift model had the least ROM. The TruFuse model yielded the lowest ROM for flexion and extension with and without preload. The model instrumented with the morphology conforming implant did not have the lowest ROM for any of the loading conditions, however, it consistently reduced the ROM as compared with the intact model.
4.3.3 Disc Pressure

Disc pressures obtained from the FE models are shown in Figure 4-10. This graph follows the same color scheme as in the previous FE ROM graph. During flexion, both with and without a preload, the TruFuse model resulted in the lowest disc pressure, followed by the morphology conforming implant model, Z-lift model, and finally, the intact model. For the extension loading conditions, the TruFuse model resulted in the lowest disc pressure. The morphology implant model had the highest disc pressure of the instrumented models, however, this was still less than that of the intact model. The model outputs for the left bending and right bending loading conditions followed the same trend. When the models were subjected to axial rotation, the model instrumented with the

![FEA Range of Motion](image-url)
morphology conforming implant yielded the lowest disc pressure, followed by the Z-Lift model. During rotation, the TruFuse model demonstrated a disc pressure that approximated the intact model. For left rotation, the disc pressure of the model instrumented with the TruFuse implant yielded a disc pressure that was 0.0003 MPa greater than the intact model. For right rotation, the TruFuse models disc pressure resulted in a value 0.0013 MPa less than the intact model.

![Figure 4-10: Disc pressures recorded from the FE models. The maximum pressure for each loading condition is shown in MPa.](image)

<table>
<thead>
<tr>
<th></th>
<th>Flx</th>
<th>Ext</th>
<th>LB</th>
<th>RB</th>
<th>LR</th>
<th>RR</th>
<th>Flx w/</th>
<th>Ext w/</th>
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<tr>
<td><strong>Intact</strong></td>
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<td>1.757</td>
<td>1.757</td>
<td>0.4766</td>
<td>0.4766</td>
<td>1.447</td>
<td>1.117</td>
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<tr>
<td><strong>TruFuse</strong></td>
<td>0.5145</td>
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<td>0.275</td>
<td>0.2748</td>
<td>0.4769</td>
<td>0.4753</td>
<td>0.9719</td>
<td>0.152</td>
</tr>
<tr>
<td><strong>Z-Lift</strong></td>
<td>0.8112</td>
<td>0.06877</td>
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<td>0.2454</td>
<td>0.2575</td>
<td>0.2493</td>
<td>1.332</td>
<td>0.145</td>
</tr>
<tr>
<td><strong>Morph Implant</strong></td>
<td>0.645</td>
<td>0.5519</td>
<td>0.746</td>
<td>0.746</td>
<td>0.2457</td>
<td>0.2457</td>
<td>1.106</td>
<td>0.3101</td>
</tr>
</tbody>
</table>
4.3.4 Foramina Cross Sectional Area

The cross sectional area of the foramina of the models after applying the 400N compression are shown in Figure 4-11. Also shown in this graph, for comparison, is the cross sectional area of the foramina for a previously published finite element model of transfacet screw fixation [71-72]. This graph follows the same color scheme as the previous finite element graphs, with the exception of the transfacet screw, which is shown in green. Each model created an increase in the area of the foramina relative to the intact model. The largest increase in area was created by the Z-Lift implant, 15.13 mm$^2$, followed by the morphology conforming implant, 3.38 mm$^2$, and the TruFuse implant, 2.32 mm$^2$. Transfacet screw fixation shows only a small increase in area relative to the intact model with an increase of only 0.33 mm$^2$.

![Foraminal Cross Sectional Area](image)

**Figure 4-11:** Cross sectional area of the foramina after applying a 400 N compressive load. The areas shown are given in units of mm$^2$. (*Transfacet Screw data was obtained from a previously published model [71-72].)
4.3.5 Facet Stress Distribution

The contour plots for the facet stress distributions during the loading conditions are shown in Figures 4-12 through 4-19. These figures show the stresses present within the L4 inferior articular process on both the left and right sides. A finite element model of pedicle screw and rod stabilization was obtained with permission from Agarwal et al. and the facet stress distributions from this model are presented here for comparison [73]. Each figure contains, from top to bottom, the stress distributions for the models instrumented with the TruFuse, Z-Lift, morphology conforming implant, and finally the model instrumented with pedicle screws and rods.
Figure 4-12: Stress distribution within the L4 inferior articular processes present during a 10 N*m flexion moment. (Pedicle screws and rods obtained with permission from [73]).
Figure 4-13: Stress distribution within the L4 inferior articular processes present during a 10 N*m extension moment. (Pedicle screws and rods obtained with permission from [73]).
Figure 4-14: Stress distribution within the L4 inferior articular processes present during a 10 N*m left bending moment. (Pedicle screws and rods obtained with permission from [73]).
Figure 4-15: Stress distribution within the L4 inferior articular processes present during a 10 N*m right bending moment. (Pedicle screws and rods obtained with permission from [73]).
Figure 4-16: Stress distribution within the L4 inferior articular processes present during a 10 N·m left rotation moment. (Pedicle screws and rods obtained with permission from [73]).
Figure 4-17: Stress distribution within the L4 inferior articular processes present during a 10 N*m right rotation moment. (Pedicle screws and rods obtained with permission from [73]).
Figure 4-18: Stress distribution within the L4 inferior articular processes present during a 10 N\(\cdot\)m flexion moment with a 400 N preload. (Pedicle screws and rods obtained with permission from [73]).
Figure 4-19: Stress distribution within the L4 inferior articular processes present during a 10 N*m extension moment with a 400 N preload. (Pedicle screws and rods obtained with permission from [73]).
Chapter 5

Discussion

5.1 Overview

This chapter contains a thorough discussion of the results of this study, beginning with individual \textit{in vitro} experimental groups and proceeding to validation results for the FE models. ROM and disc pressure results of the FE models are then discussed in detail. The conclusions and limitations of this study are also described herein.

5.2 \textit{In vitro}

5.2.1 TruFuse Range of Motion

The group instrumented with the TruFuse implant showed reduced ROM for all loading conditions though the reduction in motion was small (less than 1°) for flexion without a preload, bending, and axial rotation. This was expected as the TruFuse facet dowel’s primary function is to resist extension. Since the TruFuse implant is not anchored to the bone, it only functions under compression. The only loading conditions where both the left and right implants would be subjected to compression are extension with and
without a preload, and flexion with a preload, which correspond to the loading conditions that yielded the greatest decrease in ROM.

5.2.2  Z-Lift Range of Motion

The Z-Lift implant was able to effectively reduce ROM in all loading conditions and performed the best at decreasing flexion ROM both with and without a preload. This result is likely due to the distraction step of the surgery wherein the axial displacement places an increased strain on the posterior ligaments. The material properties of ligaments facilitate increased strain and result in more resistance to motion, likely causing the observed decrease in the flexion ROM.

5.2.3  Morphology Conforming Implant Range of Motion

The morphology conforming implant group demonstrated mixed results. For example, a decrease in ROM for left bending and an increase in ROM for right bending was witnessed. A similar trend was also shown for axial rotation. Since the surgical procedure for the morphology conforming implant is symmetrical, the results were hypothesized to be symmetrical. This was not the case and may be due to multiple factors. The first is the specimens used in the study group displayed large standard deviations as compared to the other groups. The largest SD was 4.8814° as compared to 2.3849° for the Z-Lift group and 2.7135° for the TruFuse group. Since proper procedures were followed in selecting and preparing the specimen, this likely represents inherent variability of cadaveric experimentation. Another possible explanation may be the design
of the implants. Currently, there is only one size available for the morphology
conforming implant. While the implant is designed to fit in the facet joint space, it is
possible that individuals may have differently sized joint spaces. An implant that is too
large or too small may not properly reduce the motion, or may even result in an increased
ROM. Thus, future work should evaluate the need for producing the implant in different
sizes.

5.3 Finite Element Analysis

5.3.1 Finite Element Model Validations

Before analyzing the FE models, it is important to establish model validity. In this
case, validation was performed based on comparison of the FE model load displacement
behavior to that of the \textit{in vitro} experimental groups. Due to small sample sizes, this
analysis was done qualitatively. Any discrepancies, defined as results outside of two
standard deviations of the mean, were further analyzed. Assuming a normal distribution,
two standard deviations represent approximately 95\% of the values. Therefore, model
outputs that were outside of this range were further examined accordingly.

The validation for the TruFuse finite element model is shown in Figure 4-5. The
model’s range of motion can be seen to be out of range of the \textit{in vitro} data for flexion,
both with and without a preload, and bending. During each of these loading conditions,
the FE model showed high stresses in the bushings surrounding the implant, indicating a
potential fracture condition. In the \textit{in vitro} experiment, this would likely result in implant
loosening, therein causing the implant to rock during the bending loading conditions and
provide little resistance to flexion loading conditions. Looking at the in vitro results, little difference between the intact and instrumented measurements was evident, as the standard deviations for the flexion and bending loading conditions overlapped. Also, in the TruFuse validation, model results lie slightly outside two standard deviations from the mean. This, however, may be due to the small sample size. Since the two specimens had a very similar angle of motion, the standard deviation was very small ($\sigma = 0.0260^\circ$).

The Z-Lift model validation showed that, for left and right bending and left and right axial rotation, the model under predicted the motion that was witnessed in cadaveric testing. This discrepancy is likely due to a two-fold reason: the anatomical variations between the model and the specimen tested in conjunction with the axial displacement of the Z-Lift procedure. In the finite element model, the facets are oriented completely vertical with curvature in the transverse plane. Combining this facet orientation with the distraction step results in a strong resistance to these types of motion. Conversely, if the facets are oriented slightly more horizontal, the distraction step can disengage the facets from one another, causing destabilization of the FSU during bending and axial rotation. This yields an increased ROM relative to the results of the FE model, as was seen in the experimental results. Unfortunately, facet orientation was not controlled in this study, as mentioned in the limitations section that follows. However, since these changes are likely due to anatomical variations, the validity of the Z-Lift FE model should not be discredited.

The results of the morphology conforming implant FE model were within two standard deviations of the mean of the cadaver results for all loading conditions with the exception of axial rotation. This was expected, however, due to the group having a larger
than expected intact ROM for both left and right axial rotation. Thus, it is appropriate to accept the validation for the morphology conforming implant FE model.

As mentioned in the results section, Figure 4-8 is not shown to validate the intact model, but rather allows for an understanding of the inherent variability between different specimens. The intact FE model was originally prepared from CT scans and validated against the cadaver from which it was prepared. Each of the groups deviated from the FE model in at least one of the loading conditions. These deviations may represent factors that were not controlled for in this study, such as age, weight, sex, bone quality, race, lifestyle, anatomical variances, and other factors. These differences do not represent flaws in the study, but rather population variability that must be considered when analyzing the results.

The largest impact of population variability was on the validation for the morphology conforming implant group. For axial rotation, the ROM results for the group instrumented with the morphology conforming implants was large as compared with the intact FE model results. For right axial rotation, the motion for the experimental group was more than double that of the FE model. A similar trend was witnessed for left axial rotation. Thus, the instrumented ROM for the in vitro group yielded values higher than those predicted by the instrumented FE model.

### 5.3.2 Finite Element Analysis Range of Motion

The validated FE models provide insight that cannot be obtained from cadaveric studies, such as the ability to perform a true side-by-side comparisons that eliminate
variability due to anatomy, ligament stiffness, and bone quality. Therefore, a sensitivity analysis can be performed on the design of the implants.

For flexion, both with and without a preload, the TruFuse implant best reduced motion, followed closely by the morphology conforming implant. The dowel-like shape of the TruFuse implant allowed it to sit into the superior and inferior facets, likely allowing it to provide better resistance to flexion. Likewise, the morphology conforming implant was able to seat itself into both facets to resist motion. On the other hand, the Z-Lift resulted in increased ROM. This is likely due to the axial displacement that takes place during surgery. As aforementioned, this displacement disengages the facets and destabilizes the spine, while the distraction puts the spine in a slightly flexed position, making it ideal for patients with hyper-lordosis. In a normal spine, such as the FE model of this study, a large degree of flexion results from loading applied to the segment.

It is not surprising that the facet implants performed better during extension than during flexion. When the spinal segments are subjected to extension, the bodies of the implants lie within the facet joint space. Since these implants are made of bone, they yield very little and are able to resist motion, especially as compared to the cartilage present in the joint space of an intact segment. The morphology conforming implant performed slightly worse, likely due to small movements of the individual parts of the implant which had to conform to the change in the shape of the joint space. These small adjustments may have occurred in all of the different loading conditions. Locking the morphology conforming implant to a specific conformation after implantation may help to prevent this. A nitinol wire based approach, such as that which was neglected from the
prototype design for this study, or the use of a small amount of bioactive bone cement, may represent such solutions.

The Z-Lift performed better than all other implants during bending and rotation. This is likely due to the vertical orientation of the facets in the model, combined with the distraction discussed earlier. In addition, the wings of the implant prevent it from rotating and sliding in the joint space. When subjected to a bending moment, the TruFuse implant is able to restrict motion almost as well as the Z-Lift, since it is inserted into both the superior and inferior facets. Since the morphology conforming implant sits in the joint space, it is not anchored to both facets and is able to rotate / roll, which results in slightly more motion than the other two implants.

Under axial rotation loading conditions, the TruFuse implant provided only slight resistance to motion. One possible explanation for this is the cylindrical shape of the implant. This implant, although inserted into both facets, has no anchorage. As the superior vertebra rotates, it is free to slide along with it. The slight resistance most likely results from the friction between the implant and the bone in the articular process. The morphology conforming implant, which sits within the joint space, also likely moved but was able to restrict the motion better due to the ridges on the implant. Unlike the smooth TruFuse implant, the morphology conforming implant was able to anchor itself into the facets, and provide more resistance to the sliding motion. Given ample time for fusion to occur, sliding of the TruFuse and morphology conforming implants would not occur and they would likely restrict motion just as well as the Z-Lift implant.
5.3.3 Finite Element Analysis Disc Pressure

Instrumenting the FE model with various implants resulted in similar or decreased disc pressure under all loading conditions, which is desired, as high intradiscal pressure is associated with pain and an increased risk for herniated discs. The loading condition that resulted in the highest disc pressure for all the instrumented models was flexion with a preload. In the intact model, bending produced the highest disc pressure. However, in the instrumented models, the implants are present between the superior and inferior facets, and as a result more of the load is transferred along this route compared to the intact model. Since these implants are not screwed into place, they cannot actively prevent the separation of the facets during flexion, causing the model to behave almost as if the implants are not present, thus yielding pressures close to intact values. Preload, by itself, will cause an increase in disc pressure, making the flexion with preload loading condition the worst case scenario for these types of implants. The fact that the implants are able to reduce the disc pressure even under the worst-case scenario, is a testament to their applicability.

During flexion, both with and without a preload, the Z-Lift implant resulted in the highest pressure of all implanted FE models. This high pressure is likely due to the large ROM. As previously discussed, the Z-Lift implant resulted in an increase in ROM, while the other implants decreased the ROM. However, when the Z-Lift model was subjected to extension, both with and without a preload, it resulted in the lowest recorded pressures of all models and loading conditions. This large change in pressure may be catastrophic to patients instrumented with the Z-Lift implant. Further testing should be done to
evaluate the effects of cyclic loading of an instrumented specimen in flexion and extension to determine if accelerated disc degeneration results from the large pressure differential.

The TruFuse implant successfully reduced disc pressure in all loading conditions, with the exception of left and right axial rotation. Under left axial rotation, the instrumented model resulted in increased pressure as compared to the intact model. This is likely due to the same factors that resulted in only a slight decrease to the range of motion for this loading condition. The cylindrical shape of the TruFuse implant prevented it from restricting the rotation motion. The facets were free to slide over the implant and the model behaved as if the implant was not present. This is evidenced not only by the range of motion study, but also by the minuscule change in the intradiscal pressure. As fusion occurs, and ROM is reduced, the disc pressure will likely be reduced.

Unlike the Z-Lift implant, the morphology conforming implant yielded similar pressures for both flexion and extension (0.0931 MPa versus 0.7424 MPa). Maintaining a uniform low intradiscal pressure between these two loading conditions may result in a lower risk for degenerative disc disease [63]. The morphology conforming implant performed best at reducing the disc pressure under left and right axial rotation. The ridges on the implant resist rotation of the vertebra and cause more load to be transferred through the facets, resulting in lower disc pressure. The morphology conforming implant performed adequately at reducing the disc pressure under all loading conditions.
5.3.4 Finite Element Analysis Foraminal Cross Sectional Area

The transfacet screw provided only a marginal increase in the cross sectional area of the foramina, while the facet bone dowels each increase the area by $2.3 \text{ mm}^2$ or greater. The largest increase in the cross sectional area of the foramina was obtained by the Z-Lift model. The distraction that occurs during the Z-Lift surgical procedure is able to be maintained through the design of the implant, allowing for the increase in the size of the foramina. The beveled designs of both the morphology conforming implant and the TruFuse implant create a slight distraction as they are inserted into the facets, which in turn also create an increase in the cross sectional area of the foramina. Unlike the facet bone dowels, the transfacet screws when inserted do not create a distraction. The slight decrease in the foraminal area may be due to the increase in stiffness of the facets, which in turn could decrease the IDP and reduce disc bulging, however future work is needed to determine if this is the case.

5.3.5 Finite Element Analysis Facet Stresses

In looking at the stress distribution plots two things are apparent. The first is that the morphology conforming implant has more evenly distributed stresses compared to the other facet implants. The TruFuse and Z-Lift models have concentrated areas of high and low stresses, while the morphology conforming implant model has a more consistent stress distribution within the facets during all loading conditions. This difference in stress distribution is likely due to the implants ability to match the curvature of the articular surfaces, allowing for more contact between the implant and the surfaces. The single
piece implants are not able to bend and therefore are not able to be fully in contact with the articular surfaces. This leads to stress concentrations at the points of contact.

The second phenomena that is observed, is that the model fixed with pedicle screws and rods shows much lower stresses in the facets than the models instrumented with the facet spacers. This confirms the idea that pedicle screw and rod fixation results in stress shielding, while the tested facet implants allow for stresses to be passed directly through the facets.

5.4 Limitations

One of the largest limitations of cadaveric experimentation is anatomical variations between specimens. Depending on the age, sex, height and weight of the individual, the anatomy can vary considerably. The biggest differences effecting spine biomechanics are the size of the vertebral bodies, the size of the disc space, the orientation of the facets, and the presence of osteophytes. The size and shape of the vertebral bodies, as well as the disc space, can result in an increased or decreased lordosis that can effect the ratio of flexion to extension and can result in imbalances that disrupt the symmetry of left and right bending, and left and right axial rotation. The variation in the orientation of the facets can change the way the implants interact with the facets and result in reduced or increased motion, as was witnessed with the Z-Lift FE model. Osteophytes can impact biomechanics by shifting the center of rotation and causing reduced ROM for otherwise intact specimens. These factors are often difficult to control and, due to the nature of using cadavers, can be impractical to control. Additionally, it is
noteworthy to mention that these variations more accurately represent implantation scenarios that occur in living subjects, all of whom have slightly different anatomy.

To overcome the limitations associated with anatomical variations, it is often necessary to secure a sample size of six or greater. However, due to the availability of cadavers at the time of this study, the *in vitro* experimental groups were limited to sample sizes of only two or three specimens. For this reason, statistical comparison between the different groups was not possible. Statistical comparison between the intact and instrumented specimens from the same group should be done using the two-sampled paired student’s t-test, however, this test has \( n/2 – 1 \) degrees of freedom also requiring larger sample sizes. This means that, for both groups with only two specimens and the group with one sample, there is less than one degree of freedom, thus preventing the use of this statistical test. Analysis of the *in vitro* experiments provided herein were therefore qualitative instead of quantitative.

Another limitation in this study was that bone density was not controlled across the testing groups. For the TruFuse and Z-Lift groups, specimens with normal bone density were used. For morphology conforming implant group, on the other hand, specimens with osteopenia and osteoporotic bone quality were included. This difference may have resulted in the morphology conforming implant group experiencing increased ROM as compared to the other groups. However, since *in vitro* groups were not compared to each other, this effect is negligible. However, as the FE model was prepared simulating normal bone density, this difference did affect validation for the model, as the experimental group has an increased range of motion compared to the model. If normal
bone density was present in these specimens, the instrumented \textit{in vitro} results would be even closer to the output predicted by the model.

The largest limitation of the FE technique, in general, is that it only represented a single case. Since the intact FE model was initially prepared from a single cadaver, it most accurately represents the specific anatomy of the cadaver it was prepared from. This leads to the necessity to validate each instrumented model. The model can therefore provide an accurate side by side comparison of the different implants and surgical techniques, neglecting variances in bone density, ligament strength, and anatomy. While this side-by-side comparison is useful in discussing the different implants, it is important to note that this still represents a single case.

Other limitations affecting this study relate to the morphology conforming implant. Since this implant, and its associated surgical technique, were custom developed for this study, it has not yet entered large scale manufacturing and thus only early prototype devices were available. The prototypes featured two main differences from the proposed design. The first was with respect to material. The implants used in this experiment were manufactured using a rapid-prototyping printer which uses plastic, while the design calls for the implants to be made from allograft material. This difference likely resulted in the intact cadaver group having a slightly increased ROM as compared to implants that had been made of bone. This is due to the change in the elastic modulus of the material. The other change between the prototypes that were used and the proposed design is the use of nitinol wire. The wire was absent in the prototypes used in the \textit{in vitro} range of motion study and was not included in the FE model. This wire is
designed to assist surgical conformity to the curvature of the facets, and thus its absence had only minimal effect on the outcomes of this study.

5.5 Conclusion

From a biomechanical perspective, zygapophyseal joint spacers are an effective alternative to performing a posterior spinal fixation with pedicle rods and screws. While they may not provide comparable immediate reduction in motion, they greatly reduce intradiscal pressure which may prevent future disc degeneration and, as a result, alleviate pain associated with stenosis of the foramina. Under most loading conditions (with the exception of flexion), axial decompression, such as that provided by the Z-Lift implant, may further reduce disc pressure.

The fact that these implants reduce motion and disc pressure, provides support for their success in promoting long-term fusion. Spinal segments can be considered as a tripod consisting of the left and right facets and the disc. The load transfer between two vertebra in an intact spine occurs between these three points [64-67]. A decrease in disc pressure without a change in the surface area of the disc means that the load applied at this point of the tripod has also decreased. If the motion between the intact and instrumented spinal segments was the same, the load transfer would shift to the facets, meaning that the stresses present in the facets would increase. Further evidence of this phenomena is shown in the reduction of motion after instrumentation. If motion is decreased under the same load, the load must be absorbed by something. Since the disc pressure decreased, it can be concluded that the stresses induced by the load are being
absorbed by the facets. This was confirmed by the stress analysis. According to Wolff’s law, high stresses within the bones promotes bone growth [68-70]. This bone growth will lead to fusion between the superior and inferior facets as well as between the facets and the implants. Of the implants tested, the morphology conforming implant demonstrated the most consistent reduction in disc pressure, and will therefore most likely result in the best fusion rate, followed by the TruFuse implant and, lastly, the Z-Lift. Since the Z-Lift implant demonstrated high pressures and increased ROM for flexion, it may not be ideal for fusion.

Long-term fusion may afford these implants to become superior to rod and screw fixations at reducing motion. Load transfer resulting from facet spacers provides a key advantage over the traditional method of posterior spinal stabilization. With these facet implants, the load is transferred directly from facet to implant to facet. Since these implants are made of bone, the end result is direct fusion of the superior and inferior facets. Conversely, when using pedicle screws and rods, stress shielding results as the load is transferred from the pedicles to the screws and then to the rods, therein impeding the fusion process. Since the facet devices increase the stresses, fusion may occur faster and more completely than with pedicle screws and rods. Of course, future studies must be conducted to better evaluate this hypothesis.
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Appendix A

Anatomy of the Spine

A.1 Gross Anatomy

The vertebral column of the human spine can be organized into five distinct sections: cervical, thoracic, lumbar, sacrum, and coccyx. The cervical spine consists of seven vertebra, numbered C1 through C7. Their primary function is to protect the cranial nerves, and to support the head while allowing for a large range of motion. This section of the spine has a slight lordosis, or anteriorly convex curve [1]. The thoracic spine immediately follows the cervical spine. Unlike the cervical spine this section has a kyphotic curve and a very limited range of motion. There are twelve thoracic vertebra, T1 through T12, and these serve as the posterior attachment point for the ribs. The lumbar spine consists of five vertebra, L1 through L5, whose primary function is the weight bearing of the torso. These vertebra produce a lordotic curve. Following the lumbar spine is a section of five fused vertebra, which transfer the loads of the body weight from the spine to the ilium. The coccyx, which is commonly referred to as the tailbone, serves as the terminal end of the spine and provides an insignificant role on the biomechanics of the spine.
Figure A-1: The five sections of the human vertebral column. Image obtained from [2].

A.2 The Vertebra

Each vertebra is composed of multiple parts, see Figure A-2. The main portion of each vertebra is the body. The body is comprised mostly of cancellous bone surrounded by a thin layer of cortical bone. The vertebral bodies are the portions of the spine that are connected via the intervertebral discs. Extruding posteriorly from the vertebral body on the left and right side are the pedicles. These are strong bones that often serve as the point
of screw insertion for traditional posterior spinal fixation. [3]. They also serve as the lateral aspects of the spinal canal. The pedicles are connected together by a thin sheet of bone known as the lamina. This bone forms the posterior wall of the spinal canal.

Between the pedicles and the lamina there are lateral boney protrusions. These are the transverse processes and function primarily as anchor points for the muscles in the back. Superiorly and inferiorly to the lamina on each side are the superior and inferior articular processes. These articular surfaces form the zygapophyseal joints, which will be described in a later section. The posterior protrusion from the lamina is the spinous process. When flexing the spine this is the portion of the bone that can be felt through the skin.

Figure A-2: The morphology and anatomical landmarks of a spinal vertebra. This image shows a lumbar vertebra. The top image (A) shows a top-down view and the bottom image (B) shows a lateral view. This image was taken from [4].
The exact characteristics of each vertebra are slightly different depending on which section of the spine it belongs to, and where it is located within each section. The primary differences consist of the size of the vertebral body, the angle of the pedicles, and the orientation of the zygapophyseal joints. While traversing down the spinal column from the rostral end to the caudal end, the relative size of each vertebral body increases. This is due to the increased load bearing requirements of each subsequent vertebra. The pedicle angle can vary greatly within the spine. In the cervical spine the pedicles have an angle of nearly $60^\circ$ [5]. This angle comes close to zero in the thoracic spine with the pedicles oriented almost entirely in the anterior-posterior direction. In the lumbar region the pedicles again flair out to an angle of approximately $15^\circ$. These and other anatomical variation in the spine have been shown to have a strong impact on the biomechanics and can affect the surgical techniques used for spinal fixation [6, 7].

A.3 The Intervertebral Disc

Connecting each of the vertebral bodies together are the intervertebral discs. These discs serve as the shock absorbers within the spine [8]. The disc is composed of two primary parts: the anulus fibrosus and the nucleus pulposus. The anulus fibrosus is a fibrocartilaginous structure with anisotropic properties. The non-uniform material properties are due to the arrangement of the fibers. The anulus fibrosus consists of multiple layers of fibers in alternating direction at an angle of approximately $30^\circ$ to the vertebral body [9]. This arrangement of fibers provides the disc with the ability to resist tensile and rotational forces. The ability to resist compressive forces is due primarily to
the nucleus pulposus. The nucleus pulposus is a fluid filled sac within the disc. It is composed primarily of water and polysaccharides [10]. While in a neutral posture it is in the posterior portion of the disc, however it is believed to move and deform within the disc in response to various loading conditions.

A.4 The Zygapophyseal Joint

The zygapophyseal joints, more commonly called the facet joints, work in conjunction with the disc to transfer loads from segment to segment. These joints exist on the posterior of the spine on both the left and right side. The joints are formed where the inferior articular process of the superior vertebra and the superior articular process of the inferior vertebra come together [11]. They are plane joints, which is a subclass of synovial joints, which only allow a gliding motion between the two surfaces. Since the facets are synovial joints, they contain a joint capsule, synovial fluid, and articular cartilage [12]. An image of this type of joint is shown in Figure A-3. For the facets, the joint capsule is known as the capsulary ligament, see Figure A-5, which surrounds and protects the joint space. This ligament is rather tight and acts to prevent the articular processes from separating [13]. The synovial fluid acts as a lubricant, allowing the two surfaces to glide over each other with very little friction. The articular cartilage serves to cushion the joint during compression and to prevent a bone on bone interaction.
Figure A-3: The anatomy of a synovial joint, such as the zygapophysial joint. Image was obtained from [12].

The facets primary function, in addition to transferring load, is to restrict the motion of the spinal segments. Their orientation changes within the various spinal segments and the differences in morphology correspond to the types of motions allowed in each segment [14-17]. Within the cervical spine the facets are oriented such that all types of motion are allowed. In the thoracic region, the articular processes are contained within the coronal and transverse planes, with curvature in the sagittal plane. This allows for bending and rotation, while restricting flexion and extension. In the lumbar region, however, the facets are oriented within the sagittal plane, with curvature in the transverse plane. This allows primarily for flexion and extension. It also functions to prevent anterior shear of the lumbar vertebra. [18, 19]. The differences between the cervical and lumbar facet orientations are shown in Figure A-4. Within the sacrum, the vertebra are fused and no facets are present.
Figure A-4: The changes in facet morphology in different regions of the spine. (a) Sagittal view of cervical spine. (b) Transverse view of cervical spine. (c) Sagittal view of lumbar spine. (d) Transverse view of lumbar spine. Image obtained from [19].

A.5 The Ligaments

In addition to the disc and facet joints, several ligaments serve to stabilize the spine [20]. The physical locations of each ligament are shown in Figure A-5. Two ligaments are attached to the vertebral bodies. On the anterior surface is the ALL (anterior longitudinal ligament) and on the posterior surface, the anterior wall of the spinal canal, is the PLL (posterior longitudinal ligament). These ligaments run the entire length of the spine. Along the posterior wall of the spinal canal is the ligamentum flavum (LF) which connects the lamina together. Between each of the spinous processes is a ligament known as the interspinous ligament and posterior to that is another ligament that
traverses the entire length of the spine, the supraspinous ligament. These two ligaments function to provide the resistance to flexion of the spine. The last two ligaments are the intertransverse ligaments and the capsulary ligaments, both of which are bilateral. The intertransverse ligament extends between the transverse processes on each side. The capsulary ligament serves as the joint capsule for the facet joints surrounding the inferior articular process of the superior vertebra and the superior articular process of the inferior vertebra.

![Diagram of the spine ligaments](image-url)

Figure A-5: The seven ligaments of the spine. Image obtained from [4].
Appendix B

Individual Specimen Graphs

This appendix contains all of the range of motion graphs for the specimen tested in the *in vitro* experiment. These figures show the analyzed data obtained from the Optotrak system. Results are shown for flexion, extension, left bending, right bending, left rotation and right rotation, flexion with a 400 N preload and extension with a 400N preload. The blue bars show the range of motion for the intact functional spinal units (FSU) and the orange bars show the range of motion after implanting the specimen with the corresponding implant.
Figure B-1: Experimental results for specimen 56770 at the L4-L5 motion segment. The graph compares the intact range of motion to the range of motion present after instrumenting the specimen with the TruFuse implant at a load of 10 N*m.

Figure B-2: Experimental results for specimen 56770 at the L2-L3 motion segment. The graph compares the intact range of motion to the range of motion present after instrumenting the specimen with the TruFuse implant at a load of 10 N*m.
Figure B-3: Experimental results for specimen 56767 at the L4-L5 motion segment. The graph compares the intact range of motion to the range of motion present after instrumenting the specimen with the Z-Lift implant at a load of 10 N*m.

Figure B-4: Experimental results for specimen 57404 at the L4-L5 motion segment. The graph compares the intact range of motion to the range of motion present after instrumenting the specimen with the Z-Lift implant at a load of 10 N*m.
Figure B-5: Experimental results for specimen 64023 at the L4-L5 motion segment. The graph compares the intact range of motion to the range of motion present after instrumenting the specimen with the morphology conforming implant at a load of 10 N*m.

Figure B-6: Experimental results for specimen 64039 at the L4-L5 motion segment. The graph compares the intact range of motion to the range of motion present after instrumenting the specimen with the morphology conforming implant at a load of 10 N*m.
Figure B-7: Experimental results for specimen 64889 at the L4-L5 motion segment. The graph compares the intact range of motion to the range of motion present after instrumenting the specimen with the morphology conforming implant at a load of 10 N*m.
Appendix C

Range of Motion Data Tables

This appendix contains the complete range of motion results for both the in vitro and finite element portions of the study. The graphs are broken up into the intact and instrumented results for each of the experimental groups. These tables show the analyzed data obtained from the Optotrak system and the finite element models at a load of 10 N*m. Results are shown for flexion, extension, left lateral bending, right lateral bending, left axial rotation, right axial rotation, flexion with a 400 N preload, and extension with a 400N preload. All values shown below are in degrees.
Table C.1: Intact results and data analysis for the TruFuse group. This table contains the range of motion results for each specimen in the group, the group average and standard deviation, and the range of motion output for the corresponding finite element model.

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<th>Fix LB</th>
<th>RB</th>
<th>RR</th>
<th>Fix w/ Ext</th>
<th>Fix w/ Ext</th>
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<td>Std. Dev.</td>
<td>Average</td>
<td>Std. Dev.</td>
<td>Average</td>
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Table C.2: Instrumented results and data analysis for the TruFuse group. This table contains the range of motion results for each specimen in the group, the group average and standard deviation, and the range of motion output for the corresponding finite element model.

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Table C.3: Intact results and data analysis for the Z-Lift group. This table contains the range of motion results for each specimen in the group, the group average and standard deviation, and the range of motion output for the corresponding finite element model.

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</table>
Table C.4: Instrumented results and data analysis for the Z-Lift group. This table contains the range of motion results for each specimen in the group, the group average and standard deviation, and the range of motion output for the corresponding finite element model.

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Fix.</th>
<th>Ext.</th>
<th>LB</th>
<th>RB</th>
<th>RR</th>
<th>FFx/w/Ext.w/</th>
<th>FEA</th>
<th>Std. Dev.</th>
</tr>
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<tbody>
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<td>1.85</td>
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<td>3.087</td>
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</tr>
<tr>
<td>Ext.</td>
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<td>4.1564</td>
<td>2.4842</td>
<td>4.2167</td>
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<tr>
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<tr>
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<td>4.2167</td>
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<tr>
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<td>1.4341</td>
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<td>2.7705</td>
<td>1.4341</td>
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</tr>
</tbody>
</table>
Table C.5: Intact results and data analysis for the morphology conforming implant group.

This table contains the range of motion results for each specimen in the group, the group average and standard deviation, and the range of motion output for the corresponding finite element model.

<table>
<thead>
<tr>
<th>Specimen</th>
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<th>Std. Dev.</th>
<th>Average</th>
<th>Flex</th>
<th>Ext</th>
<th>Intact</th>
<th>Lab</th>
<th>RR</th>
<th>Fx w/ Ext.</th>
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</thead>
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</tbody>
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Table C.6: Instrumented results and data analysis for the morphology conforming implant group. This table contains the range of motion results for each specimen in the group, the group average and standard deviation, and the range of motion output for the corresponding finite element model.

<table>
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</table>
Appendix D

Morphology Conforming Implant Design Drawings

This appendix contains the engineering design drawings of the morphology conforming facet implant. The first two drawings show the profile shape of the components of the implant. The first drawing contains the posterior most component and the second drawing contains a description of the anterior two pieces. The third drawing details the ridges that are cut into the implant, as well as the holes that are used for connecting the components together via the nitinol wire.
Figure D-1: Design drawing of the facet spacers that comprise the morphology conforming implant.
Figure D-2: The design drawing for the nitinol wire that is used in the morphology conforming implant.
Figure D-3: The design drawing for the assembled morphology conforming implant.