A Thesis

entitled

Optimization of Pedicle Screw Depth in the Lumbar Spine:
Biomechanical Characterization of Screw Stability and Pullout Strength

by

Laura E. Buckenmeyer

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

Master of Science Degree in Bioengineering

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An Abstract of

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Objective: While much is known about the clinical outcomes of spinal fusion, questions remain in our understanding of the biomechanical strength of lumbar pedicle screw fixation as it relates to screw sizing and placement. Biomechanical analyses examining ideal pedicle screw depth with current pedicle screw technology are limited. In the osteoporotic spine, optimized pedicle screw insertion depth may improve construct strength, decreasing the risk of loosening or pullout. The purpose of this study was to test the pullout strength of transpedicular pedicle screw insertion depth subsequent to cyclic loading, which simulates post-operative loosening in the osteoporotic lumbar spine.

Methods: Ten osteoporotic lumbar spines were dissected free of soft tissue, imaged by computed tomography and potted in polyester resin to ensure rigid fixation. Pedicles were assigned to three experimental groups. Accordingly, screws were inserted to mid-body, pericortical and bicortical depths and underwent cyclic loading and pullout using a custom MTS Bionix servohydraulic testing system. Insertion depth was confirmed by fluoroscopy. Screw insertion depth was randomized between specimens, as well as
vertebral level and side. A pure moment was applied to each screw head to simulate flexion-extension forces prior to pull out. Ten preliminary and ten post-fatigue cycles were run to determine a specimen-specific displacement range and reduction in angular stiffness of the screw-bone interface due to fatigue. A specimen specific range of displacement was determined, and each specimen was cycled through for 5000 cycles at 1 Hz using a fixed displacement rate of 0.25 mm/sec along an 80 mm lever arm until the desired load was reached to apply a ±2 Nm moment. Motion was tracked using 4 infrared light-emitting diodes (irLED) markers attached to each pedicle to determine fulcrum location. To stimulate pull out forces, axial distraction was applied to each screw head at a rate of 5 mm/min for 40 mm. Load-displacement curves were analyzed to determine failure loads and energy absorption.

**Results:** Pre-fatigue and post-fatigue angular stiffnesses were, respectively, 86.4±63.4 Nm/rad and 65.9±58.2 Nm/rad for mid-body screws; 115.0±64.6 Nm/rad and 96.8±62.2 Nm/rad for pericortical screws; and 159.9±84.9 Nm/rad and 141.0±81.0 Nm/rad for bicortical screws. There was a statistically significant difference between the pre-fatigue and post-fatigue cycles for mid-body (p<0.001), pericortical (p<0.001) and bicortical (p<0.001) groups. Angular stiffness reduction for mid-body, pericortical and bicortical groups was 25.6±17.9%, 20.8±14.4%, 14.0±13.0% (p=0.012), respectively. The reduction in angular stiffness was statistically significant between mid-body and bicortical screws (p=0.009). Average pedicle length was measured to be 21.5±2.7 mm. The screw fulcrum point was 25.7±7.9 mm, 24.8±6.1 mm and 14.8±5.1 mm anterior of the insertion point for mid-body, pericortical and bicortical groups (p <0.001),
respectively. Fulcrum position for mid-body and pericortical screw insertion depths was found to be significantly different from the fulcrum position of bicortical screws (p<0.001). The maximum pullout load for mid-body, pericortical and bicortical groups was 583±306 N, 713±321 N, and 797±285 N, respectively. The difference in fixation strength between mid-body and bicortical screws was found to be statistically significant (p=0.005). Energy absorption was not significant between groups (p=0.063).

Conclusion: Increased fixation and decreased loosening were observed with increasing depth of pedicle screw placement in the osteoporotic lumbar spine. We demonstrated that additional purchase of anterior cortex significantly improved fixation strength when compared to mid-body screws that extend halfway through the vertebral body. An understanding of these results may demonstrate a critical advantage in identification of optimal pedicle screw depth for achieving greater screw fixation in the management of osteoporotic patients undergoing spinal surgery.
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List of Abbreviations

ANOVA .................... Analysis of Variance
BMD ......................... Bone Mineral Density
CT .......................... Computed Tomography
DEXA ........................ Dual-energy X-ray Absorptiometry
irLED ........................ Infrared Light-emitting Diode
PMMA ....................... Polymethyl Methacrylate
List of Symbols

cm.................................centimeters

g.................................grams

Hz.................................Hertz

min...............................minutes

mm.................................millimeters

N.................................Newtons

rad...............................radians

s.................................seconds
Chapter 1

Introduction

1.1 Anatomy and Biomechanics

The spine is comprised of 24 vertebrae articulating via intervertebral discs and facet joints. The cervical spine consists of seven vertebrae, the thoracic spine has 12 and the lumbar spine has five. The sacrum, posterior to the lumbar vertebrae consists of several fused vertebrae. The three curvatures of the spine are the cervical lordosis, thoracic kyphosis and lumbar lordosis. The spine functions to maintain stability in the body, allow for support and flexibility, and protect the spinal cord.

1.1.1 Intervertebral Disc

The intervertebral discs (Figure 1-1) are designed for weight bearing and motion. They consist of the cartilaginous endplates, outer annulus fibrosus and inner nucleus pulposus. The endplates are the attachment site to the vertebral bodies and allow for nutrition transfer into the disc. The annulus fibrosus consist of rings of crisscrossing oblique fibers that limit rotation and contain the nucleus. The nucleus pulposus is a semifluid gel that will easily deforms, but is incompressible. There is a high water content within the disc and the combination of these structures allow the disc to handle large compressive loads.
1.1.2 Vertebrae

The vertebra can be divided into two parts – the anterior body and the posterior elements. The anterior body takes most of the compressive loading of the spine. It is comprised of a porous trabecular bone surrounded by a cortical shell. The posterior elements, which consist of the pedicles, lamina, transverse processes and spinoius process, forms a protective arch over the spinal cord that resides posterior of the vertebral body.

1.1.3 Facet Joints

There are two zygapophysial (facet) joints between vertebra. Each vertebra has four articular processes. Two are superior to the pedicles and posterior to the vertebral body, and two are inferior to the pedicles and posterior to the vertebral body. The facet joints are the synovial joint, or diarthrosis, of the spine. It has a fibrous capusule, articular cartilage and synovial fluid. The facet joints limit the amount of motion that each region
of the spine can undergo in six degrees of freedom and can act to transmit loads onto the discs.

1.1.4 Functional Spinal Unit

A functional spinal unit (FSU) consists of two vertebrae, a disc, two facet joints and any other structures that span between these two vertebrae. This is considered the basic functional unit of the spine, and is studied to evaluate the effects disease, degeneration, implants or other procedures have on spinal biomechanics. The disc allows motion in six degrees of freedom, yet motion is limited by the fibers in the disc as well as the ligaments, facet joints and other structures of the spine. Ligaments passively limit tensile moments in the spine and include the anterior and posterior longitudinal ligaments, the infraspinous ligament and supraspinous ligament, among others.

Figure 1-2: The functional spinal unit has six degrees of freedom\(^1\).
1.1.5 Spinal Fusion and Pathology

Spinal fusion (Figure 1-3) is a surgical treatment option for a range of spinal pathologies that include intervertebral disc degeneration, osteoporosis and tumors. Such conditions can compromise the biomechanical integrity of the spine resulting in scoliosis, kyphosis, spondylolisthesis and other conditions that compromise the motion or weight bearing function of the spine. Often such degeneration results in compression of the nerve roots, or even the spinal cord. The goal of fusion surgery is to support the spine, prevent progression of deformity, maintain the anatomical correction, and alleviate or eliminate pain. Surgical intervention typically involves bone graft or an intervertebral spacer of some sort to stabilize motion across the intervertebral space and promote fusion. Posterior stabilization techniques are often used as a secondary stabilization technique to reduce motion until fusion has occurred. The primary attachment point of posterior instrumentation is the posterior elements. In the case of the commonly used screw-rod constructs (Figure 1-4), a pedicle screw's typical trajectory enters at the pars interarticularis between the superior and inferior facets, and traverses the pedicle into the vertebral body.

Figure 1-3: Interbody cage for spinal fusion³.
1.2 Problem Statement

Pedicle screw fixation is among the most common instrumented procedures in the lumbar spine. Since Harrington and Tullos\textsuperscript{4} first reported their technique of transpedicular screw fixation later popularized by Roy-Camille\textsuperscript{5}, the ensuing years since have brought an ever changing landscape of techniques, products and principles that have improved outcomes, while decreasing surgical failures and complications. A review of spinal fusion procedures in the United States between 1998-2008 reveals that the annual number of spinal fusion discharges significantly increased 2.4-fold (137\%) from 174,223 to 413,171 (p<0.001)\textsuperscript{6}. The goal of pedicle screw fixation in such techniques is typically to stabilize the fusion construct following an interbody fusion procedure. Such instrumentation may
be used alone, as part of a posterior construct, or in conjunction with an anterior plate in
the case of a 360 degree construct. Fusion rates have been shown to increase with internal
fixation and the use of pedicle screws, plates and rods allowing the surgeon to direct
attention to the involved diseased segment, while allowing preservation of a patient’s
natural biomechanics. Guidelines have recommended pedicle screw fixation as a
treatment option for patients with low-back pain treated with posterolateral fusion that are
at high risk for fusion failure\textsuperscript{7,8}. Pedicle screw instrumentation has been touted as an
exceptionally utilitarian procedure and as the most popular method in disciplines of
spinal surgery with well accepted advantages in terms of correction and excellent stability
of the reduced deformity\textsuperscript{9,10}.

In a survey by the American Back Society, the rate of screw loosening and breakage
ranges from 0.6\% to 11\% and 0.6\% to 25\%, respectively\textsuperscript{87}. Fixation stability depends on
several variables that include, but are not limited to, screw design, bone mechanical
properties and surgical technique. Osteoporosis and osteopenia are well known risk
factors for loss of surgical construct stability due to screw loosening and loss of fixation.
Osteoporosis has often been cited as a relative contraindication to pedicle screw fixation
during lumbar arthrodesis due to this increased risk\textsuperscript{11,12}. Inherent bone material properties
usually cannot be altered before surgery, although preoperative supplementation with
calcium, vitamins, exercise, alendronate and bone stimulation has been attempted with
inconsistent results\textsuperscript{13}. Bone mineral density and its relationship to screw fixation are
important to consider when an arthrodesis is indicated\textsuperscript{14}. The development of an
enhanced bone-screw interface and solid purchase is critical in achieving construct integrity in all patients, and are even more critical in patients with osteoporosis.

Currently, two major approaches have been employed to address these challenging cases: a) modification of implant design and b) augmentation of vertebral bodies with materials that improve the structural capacity of the compromised tissues. Examples of modified implant design include alterations in thread pitch and screw core geometry, as well as surface modification with coating of hydroxyapatite. These factors have all been asserted to increase bone-screw contact and to reduce screw loosening\textsuperscript{15}. Bone cement and milled bone “matchsticks” have also been utilized as a method of increasing local bone quality, and have demonstrated improved outcomes with decreased construct failure in some patients\textsuperscript{16,17}. However, pedicle screw placement techniques have not changed much over the last several decades.

Optimal pedicle screw depth and orientation using current pedicle screw technology are yet unknown in regards to biomechanical strength and optimal fusion outcome. Typically, skeletal fixation techniques employ the concept of bicortical fixation\textsuperscript{18-28}. By engaging both bony cortices, optimal fixation is achieved. Factors underlying ideal fixation are complex. However, additional bony purchase of screw threads and attachment to stiff cortical bone may improve fixation. Together, reduction in motion that may lead to loosening and improved direct fixation serve to strengthen the bone-screw interface, which may result in increased screw or screw-rod construct pullout strength optimizing the environment for arthrodesis\textsuperscript{29,30}. Alterations to currently accepted screw
placement and trajectory have been proposed to increase the screw-bone purchase of pedicle screws in the lumbar spine \textsuperscript{31-37}. Traditional pedicle screw trajectory follows a transpediculular path along the anatomic axis of the pedicle directed approximately 22 degrees in the cephalocaudal direction in the sagittal plane (e.g. anatomic trajectory), or is instrumented parallel to the superior endplate of the vertebral body in the sagittal plane (e.g. straight-forward trajectory)\textsuperscript{38}. The pedicle screw placement\textsuperscript{39,40} typically engages one cortex at the point of entry of the screw, and many contact the trabecular bone of the vertebral body. Other trajectories, including increased insertion depth to a pericortical or bicortical position have been proposed. Such placement would maintain the same trajectory as a traditional pedicle screw, while also engaging the anterior cortex of the vertebral body. This technique allows for increased cortical bone purchase, which enhances interface strength independent of bone mineral density or a patient’s osteoporosis status\textsuperscript{41,42}.

To evaluate these factors in the human spine, multiple screw insertion depths must be tested in pullout utilizing a model that is inherently vulnerable to such failure\textsuperscript{43,44}. Ideally, vertebrae must be osteoporotic to represent a worst case scenario, and screws must undergo a reasonable degree of cyclic loading designed to simulate the loading conditions experienced prior to the development of a stable fusion mass. Subsequent to bony fusion, motion will be reduced across the instrumented level, screws will be unloaded and potential for pullout will be notably reduced. The ultimate goal is to develop optimal fixation that will survive through a reasonable period during which fusion would likely occur, should the appropriate physiological environment exist. By investigating factors
associated with pedicle screw failure, we may be able to draw conclusions that help produce inherently more stable fixation, thus improving outcomes and patient satisfaction.
Chapter 2

Literature Review

2.1 Osteoporosis

Osteoporosis is a disease characterized by compromised bone strength, causing an increased risk of fracture and musculoskeletal dysfunction\textsuperscript{45}. The presence of osteoporosis makes any necessary orthopaedic procedure riskier and is considered a comorbidity\textsuperscript{45}. Approximately 9\% of adults 50 or older in the United States have osteoporosis and approximately 50\% more have low bone mass and may be at risk\textsuperscript{46}.

2.2 Screw-bone Interface

Pedicle screw-rod constructs are commonly used for the treatment of fractures, tumors and degenerative disease in the spine. When osteoporosis is present, gaining adequate screw purchase during these procedures can be challenging\textsuperscript{14}. The weakened screw-bone interface can be explained by a direct correlation between bone mineral density and pedicle screw fixation\textsuperscript{14,47-49}. Fusion is therefore more difficult to achieve than in healthy bone\textsuperscript{50} causing a longer duration of loading on the instrumentation\textsuperscript{51}, which increases the risk of construct failure.
2.3 Screw Fixation

Screw pullout is the standard method of testing screw fixation within bone. In the spine it gives information on the stability of a pedicle screw-rod construct via screw purchase. Pedicle screw failure, however, typically does not occur with simple pullout. Instead, loosening, due to fatigue, weakens the screw-bone interface leading to pullout. Many pedicle screw pullout studies do not address this and simply pull the screw out at the strongest point of fixation before bony ingrowth. However, more attention is being paid to understanding the role of fatigue in pedicle screw failure. Achieving optimal fixation of the screw-bone interface is vital to clinical outcome.

2.4 Fatigue

Fatigue is a good secondary indication of fixation strength as loosening weakens the screw-bone interface. Fatigue has been reported in cycles to 50% loosening, damage, or as an addition to pullout strength. Increasing the screw length improves the fatigue strength. A straight-ahead trajectory was found to better resist fatigue than the traditional anatomical trajectory, which corresponds with pullout data. Knowledge gained from fatigue studies may directly complement pullout strength and form a well-rounded understanding of pedicle screw purchase within the vertebra. Methods that resist loosening, whether in screw design or insertion technique, will better maintain the screw-bone interface properties during fatigue and decrease the risk of construct failure.
2.5 Optimization of the Screw-bone Interface

To determine the optimal fixation technique for pedicle screws, numerous studies have been undertaken to evaluate how specific factors affect loosening and pullout strength. Among others, researchers and physicians have evaluated insertion techniques, screw characteristics, augmentation, bone quality and morphometry. Generally, a correlation between pullout strength and bone mineral density (BMD)\(^{14,47,48,59,62}\) has been noted by many researchers, although not by all\(^{56}\). This correlation separates bone quality into healthy and osteoporotic bone, and each type has unique needs that should be addressed in screw design and insertion technique. For example, vertebrae from younger bone fractured during pullout, while vertebrae from older, osteoporotic bone did not\(^{60}\).

2.6 Trajectory, Insertion Technique and Screw Characteristics

Trajectory\(^{27,44,48,56,59}\), insertion technique\(^{14,23,58}\), and screw design\(^{39,57,60,64-66}\) have a large affect on screw purchase and may provide a good alternative technique when a surgical limitation is present. The extra-pedicular technique, for example, may be a viable option for patients with morphometry that makes adequate screw purchase a challenge\(^{67}\). There is some debate whether an extra-pedicular screw trajectory decreases fixation strength\(^{44}\) or whether it remains the same\(^{56}\). Differences may be due to sample size, in which a small sample size increases the likelihood of a type II error.

Insertion technique can be altered to optimize fixation strength. Hubbing\(^{23}\) and lateral misdirection\(^{54}\) may increase the likelihood of fracturing the wall of the pedicle and therefore should be avoided. Surgeons may purposefully use a smaller diameter tap or no
tap at all in osteoporotic bone as it decreases fixation strength\textsuperscript{14,68}, however hole preparation did not affect fixation strength in healthy bone\textsuperscript{14}. Hubbing, too, was found to weaken screw purchase\textsuperscript{23}. No correlation was found between insertional torque and pullout strength\textsuperscript{69}.

Pedicle screw design can be enhanced to optimize fixation strength and minimize the likelihood of loosening, pullout or breakage\textsuperscript{39,57,60,64-66}. Screw designs such as expandable screws\textsuperscript{53}, dual lead screws\textsuperscript{55}, and conical screws\textsuperscript{57} may show similar or improved screw purchase compared to conventional screws, and have features beneficial to specific patient populations. Increasing screw diameter in osteoporotic bone does not improve fixation strength\textsuperscript{39}. Knowledge of optimal conditions for each type of screw in either osteoporotic or healthy bone is necessary to obtain good screw purchase and decrease the risk of loosening and failure.

2.7 Augmentation

Augmentation of pedicle screws generally enhances screw fixation in the bone and can be relevant to populations where a weakened bone-screw interface is a concern. Polymethyl Methacrylate (PMMA) has been found to provide substantial fixation compared to an intact screw, salvage procedures involving PMMA, or calcium phosphate cement, including in osteoporotic bone\textsuperscript{16,47,52,53}. Calcium phosphate does provide a good alternative in both revision and augmentation compared to the intact screw\textsuperscript{47}, and is more biocompatible and osteogenic than PMMA. Increasing the volume of cement does not
seem to affect fixation\textsuperscript{52}, while the insertion technique does\textsuperscript{16,47}. Augmentation is an excellent tool for physicians to significantly increase fixation strength.

### 2.8 Screw Length

Increased screw length increases fixation strength of the pedicle screw within the bone\textsuperscript{60,66}. Krag \textit{et al.}\textsuperscript{66} applied a moment in flexion or lateral bending until failure, and found increased strength with increased screw length. Zindrick \textit{et al.}\textsuperscript{60} found no difference in screw purchase between pedicle screws inserted halfway through the body and up to the cortex. However, bicortical pedicle screws significantly increased pullout strength compared to pericortical screws. Cephalocaudal loading showed an increase in number of cycles needed to loosen bicortical screws versus screws inserted halfway into the vertebral body, as well as an increase for bicortical versus pericortical screws\textsuperscript{60}. The pedicle is more important in resisting pullout than the vertebral body\textsuperscript{39}, therefore screw designs should engage the pedicle and the anterior cortex. There has been no study to the author’s knowledge that compares the fatigue and pullout strength in the same sample of osteoporotic lumbar spine between pedicle screws inserted halfway into the vertebral body, up to the cortex and through the cortex.
Chapter 3

Methods

3.1 Specimens
Ten osteoporotic lumbar spines from L1 through L5 were acquired (age 33-66 years old; 5 male, 5 female) and Dual-energy X-ray absorptiometry (DEXA) scans were taken of each specimen to confirm osteoporosis (T-Score=−3.5±0.8; BMD 0.671±.091 g/cm²). Individual vertebrae were dissected out from the spine and cleared of all soft tissue. Each vertebra was potted shallowly along its inferior side in polyester resin to achieve rigid fixation to the testing machine.

3.2 Imaging
Cadaveric pedicle measurements including left and right pedicle diameter, interpedicular distance, spinal canal height, total trajectory and vertebral body size were determined from computed tomography (CT) scans performed on explanted spines from 10 cadaveric specimen. Measurements were obtained after loading raw images onto eFilm image viewing software (Merge Healthcare) and then using standard measurement tools provided in the software controls. Pedicle diameter was determined by measurements
taken at the maximal diameter in the axial plane (medial-lateral). Interpedicular distance was determined at the point of maximal pedicle distance on axial images by measuring the distance between medial most boarders of the pedicles for a given level. Spinal canal height was determined in the axial plane at the point of maximal pedicle diameter by measuring from the most posterior spinal canal border to its most anterior spinal canal border. The total trajectory distance was an assessment of the distance from screw insertion point to the ventral cortical vertebral body wall. It was measured from the point at the intersection of the transverse process and lateral facet at the maximal pedicle diameter to the ventral vertebral body cortical wall. Vertebral body size was determined by taking the measurement from the anterior vertebral cortex to the posterior vertebral cortex at the midpoint interpedicular distance previously determined.

3.3 Experimental Groups

Two Synthes Dual Core – MATRIX monoaxial pedicle screws were inserted in each vertebra (i.e. one per pedicle) to specific depths for cyclic loading and pullout. These screws were selected in part due to the large thread depth of the initial threads in the dual-core design, which facilitated strong purchase at the anterior vertebral cortex. A monoaxial head was used to ensure pure loads were applied to the axis of the screw. Sizing and implantation were completed by a fellowship trained spine surgeon in conjunction with a senior neurosurgical resident.

Screw insertion length used in this study was determined from a combination of pre-operative measurements and surgical experience. Screw placement was randomized
between specimen, screw depth and specimen level/side. Screw depths used in this study were divided among three groups (Table 3.1): mid-body, pericortical and bicortical. Mid-body screws were placed such that insertion lengths passed through approximately 50% of the vertebral body. Pericortical screws were inserted such that the screw tip approached the anterior vertebral body cortical wall, but did not breach the wall. Bicortical screws were inserted such that the tip of the screw passed through the cortical wall of the anterior vertebral body by 5 or fewer screw threads. As screw sizes were available in increments of 5 mm, length was determined based upon the closest screw size that best satisfied the screw depth characteristics of the test group. Screw diameter was maximized based on pre-operative measurements of pedicle geometry from computed tomography. Five pedicles were removed from this study due to errors in loading during testing (e.g. exceeded load limits) and are not included in Table 3.1.

Table 3.1: Testing Matrix

<table>
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<tr>
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<th>Number of Pedicles</th>
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<tr>
<td>Mid-body Screw Placement</td>
<td>32 Pedicles</td>
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<tr>
<td>(50% through the vertebral body)</td>
<td></td>
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<tr>
<td>Pericortical Screw Placement</td>
<td>31 Pedicles</td>
</tr>
<tr>
<td>(screw stops just short of the anterior cortex)</td>
<td></td>
</tr>
<tr>
<td>Bicortical Screw Placement</td>
<td>32 Pedicles</td>
</tr>
<tr>
<td>(at least one turn of thread passes through the anterior cortex)</td>
<td></td>
</tr>
</tbody>
</table>
3.4 Surgical Procedure

Based on anatomic landmarks under direct visualization, a sharp awl was used to penetrate the dorsal pedicle cortex at the approximate junction of the mid-transverse process and lateral facet. Utilizing a straight or curved pedicle probe, a pathway was formed through the cancellous bone of the pedicle into the vertebral body. Gross visualization and tactile sense ensured the desired trajectory. After cannulation, the pedicle probe was placed into the pedicle, and the medial, lateral, rostral and caudal extents of the trajectory was palpated. After the pedicles were probed, the appropriately sized screw was placed into the trajectory that was formed. Care was taken to ensure that each screw would not contact or interfere with the contralateral screw. Fluoroscopic images and photographs were taken to document and confirm screw placement (Figure 3-1). Tapping was not performed since tapping weakens the screw-bone interface\textsuperscript{14,68}.

![Figure 3-1: Fluoroscopic images of a bicortical screw next to a mid-body screw (Left) and a pericortical screw next to a mid-body screw (Right)](image-url)
3.5 Testing Technique

3.5.1 Fatigue

Once potted and instrumented, specimens were secured in a custom fixture (Figure 3-2) in an MTS Bionix servohydraulic testing system (MTS Corporation, Eden Prairie, MN). A universal joint coupled with a hinge joint was attached to the actuator to release any off-axis loads on the screw head. A custom fitting attached the actuator to the head of the screw. Specimens were carefully aligned below the actuator using an x-y table and were rigidly held in place during testing. Ten initial cycles were run to determine the displacement required to create cantilevered loading over a range of ±2 Nm flexion-extension. This was accomplished by loading the fixture at a fixed displacement rate of 0.25 mm/sec along an 80 mm lever arm until the desired load was reached to create a ±2 Nm moment. Peak displacements from the last five cycles were averaged and used to define the range of displacement that each specimen was cycled through for 5000 cycles at 1 Hz. Data were sampled at 100 Hz. A similar method that associated displacement and moment in order to define a displacement based range of cyclic loading was previously reported by Burval et al. Unlike Burval et al., the displacement range used was derived for each specimen, rather than using a typical displacement range to represent a target load level for all specimens. Once complete, the procedure for the initial 10 cycles was repeated. Load-displacement data from the 10 load limited cycles tested before and after cyclic testing were utilized to evaluate how screw fixation rigidity changed over 5000 cycles of cyclic loading. Angular stiffness reduction (1) was compared between groups using a one-way Analysis of Variance (ANOVA) with a post-
hoc Bonferroni analysis at p=0.05, where angular stiffness was defined by equation (2). Pre-fatigue and post-fatigue angular stiffness were compared within groups using paired t-Tests at p=0.05.

Figure 3-2: Custom fixture used for fatigue testing. Specimen was potted and held down by the body using a foam block and metal plate screwed into place. An x-y table allowed the specimen to be properly aligned. A universal joint coupled with a hinge joint ensured the actuator applied a pure moment to the head of the pedicle screw.
\[ \text{angular stiffness reduction} = \frac{(\text{final angular stiffness} - \text{initial angular stiffness})}{\text{initial angular stiffness}} \] (1)

\[ \text{angular stiffness} = \frac{\text{flexion-extension moment range}}{\text{angle of full displacement range}} \] (2)

### 3.5.2 Motion Analysis

A four irLED marker array was attached to each pedicle screw to track motion. The screw fulcrum point (point about which the implanted screw pivots) was calculated and the location within the vertebra was identified. The analysis was conducted by projecting the motion onto a plane and measuring the location of minimal motion via triangulation. The length of the pedicle was the landmark used for comparison and was measured via CT scan as the distance from where the base of the screw head enters the vertebra to the interface between the pedicle and body (Figure 3-3). A One-way ANOVA with a post-hoc Bonferroni analysis was used to compare between groups at p=0.05.

Figure 3-3: CT scan measurement of pedicle length.
3.5.3 Screw Pullout

Each specimen was then re-oriented in the loading frame such that the screw was aligned with the axis of the testing machine and distraction was applied at a rate of 5 mm/min for 40 mm. Data were recorded at 100 Hz and load-displacement curves were analyzed to determine failure loads and energy absorption.

3.5.4 Alternative Statistical Analysis

An alternative statistical analysis was conducted to further evaluate the data set. A paired t-Test was conducted on all screw depth pairs that occurred within individual vertebrae. Screw pullout strength and loosening (angular stiffness reduction) were compared. A regression analysis was conducted to determine the effect pedicle screw diameter had on screw pullout strength and loosening (angular stiffness reduction), if any.
Chapter 4

Results

4.1 Fatigue

During fatigue loading, angular stiffness (Graph 4-1) decreased between the pre-fatigue and post-fatigue cycles for experimental groups. Mid-body screws were found to have a pre-fatigue angular stiffness of $86.4\pm 63.4$ Nm/rad and a post-fatigue angular stiffness of $65.9\pm 58.2$ Nm/rad. Pericortical screws were found to have a pre-fatigue angular stiffness of $115.0\pm 64.6$ Nm/rad and a post-fatigue angular stiffness of $96.8\pm 62.2$ Nm/rad. Bicortical screws were found to have a pre-fatigue angular stiffness of $159.9\pm 84.9$ Nm/rad and a post-fatigue angular stiffness of $141.0\pm 81.0$ Nm/rad. There was a statistically significant difference between the pre-fatigue and post-fatigue cycles for mid-body ($p<0.001$), pericortical ($p<0.001$) and bicortical ($p<0.001$) screws using a paired t-Test. Angular stiffness reduction (Graph 4-2) was $25.6\pm 17.9\%$ for mid-body screws, $20.8\pm 14.4\%$ for pericortical screws and $14.0\pm 13.0\%$ for bicortical screws. The reduction in angular stiffness was statistically significant ($\text{ANOVA} = 0.012$) between
mid-body and bicortical screws (p=0.009), but no significant difference in angular stiffness was observed between pericortical screws and mid-body screws (p=0.635) or bicortical screws (p=0.245).

Graph 4-1: Loosening of pedicle screws during fatigue with flexion-extension cycling. Fatigue causes angular stiffness to decrease significantly for each pedicle screw depth. An asterisk(*) indicates statistical significance.
Graph 4-2: Reduction of angular stiffness from flexion-extension fatigue cycling. The shorter the screw depth the larger the reduction. An asterisk(*) indicates statistical significance.

4.2 Screw Motion Analysis

The screw fulcrum point was 25.7±7.9 mm, 24.8±6.1 mm and 14.8±5.1 mm anterior of the insertion point for mid-body, pericortical and bicortical groups (ANOVA p<0.001), respectively (Graph 4-3). Average pedicle length was measured to be 21.5±2.7 mm. Mid-body and pericortical depths were both significant with bicortical screws (p<0.001). Pericortical and mid-body depths were not significant (p=1.0).
Graph 4-3: The location of the fulcrum point (with respect to the screw insertion point) for each testing group. An asterisk (*) indicates statistical significance.

4.3 Screw Pullout

Screw fixation strength increased based on increasing screw insertion depth (Graph 4-4). The maximum pullout load was 583±306 N for mid-body screws, 713±321 N for pericortical screws, and 797±285 N for bicortical screws. The difference in fixation strength between mid-body and bicortical screws was found to be statistically significant (ANOVA p=0.005), but was not significant between pericortical screws and mid-body screws (p=0.107) or bicortical screws (p=0.278). The energy absorbed during pullout was 1.75±1.983 Nm for mid-body screws, 2.40±1.79 Nm for pericortical screws and 2.97±2.33 Nm for bicortical screws. Significance was not observed between any group
for energy absorption (ANOVA p=0.063). The post-hoc comparison showed a p-value of 0.057 between bicortical and mid-body screws. P-values were greater than 0.5 for pericortical screws compared to bicortical and mid-body screws.

![Graph 4-4: Maximum failure load of pedicle screws during pullout. An asterisk (*) indicates statistical significance.](image)

**4.4 Alternative Statistical Analysis**

Results from the alternative statistical analysis that utilized a paired t-Test can be found in Appendix A.
Chapter 5

Discussion

5.1 Review of Findings

Transpedicular screw fixation of the lumbar spine is commonly used in association with arthrodesis to help achieve stabilization. Arthrodesis of the lumbar spine may be optimized through a variety of mechanisms, which include intrinsic and extrinsic factors. Intrinsic factors may include patient bone quality, pedicle morphology, bone mineral density, age, and smoking status. Extrinsic factors include screw-bone interface, surgical technique, and the use of biologics and other bone substitutes to help achieve an environment promoting arthrodesis. While we are limited in our ability to alter intrinsic factors, extrinsic factors present an opportunity for technique optimization. Pedicle screw pullout strength is highly correlated with bone mineral density\textsuperscript{14,47-49,59,62}. The optimal placement of transpedicular screws to provide a biomechanically advantageous construct remains largely unknown. With an aging population of osteoporotic patients, achieving improved techniques to promote arthrodesis and minimize complications is essential.
Many studies have examined the role of pedicle screw fixation techniques in the thoracolumbar spine. Harington and Luque independently studied their own instrumentation systems to determine effectiveness\textsuperscript{38}. Cortical bone trajectories\textsuperscript{27}, thoracic extra-pedicular screw fixation\textsuperscript{44} and pedicle screw hubbing\textsuperscript{23} have all yielded varied biomechanical results. A comparative study of transpedicular screws, laminar hooks and spinous process wiring was performed by Coe et al.\textsuperscript{11}, who found that pedicle screw fixation had greater resistance to failure in patients with decreased bone mineral density due to osteoporosis, osteomalacia or other forms of metabolic bone disease. Osteoporotic patients undergoing spinal surgery involving pedicle screws have an increased risk of screw and/or construct failure. To minimize this risk, methods of increasing fixation strength and decreasing loosening are being investigated. Knowledge of optimal pedicle screw depth is yet unknown and may provide one method to improve fixation strength.

Physiologic loosening of pedicle screws occurs due to external loads applied to the screw-rod construct during patient movement. The angular stiffness of each screw-bone interface was calculated pre-fatigue and post-fatigue to quantify resistance to loosening of screws with various insertion depths. A large amount of variability exists between vertebral specimens. Factors such as bone mineral density\textsuperscript{14,47,48,59,62} and vertebral morphology\textsuperscript{70,71} notably influence experimental and surgical results. A large sample size (n=95) was required in part due to this variability. Also, offset loading during fatigue was specific to each specimen such that initial loads consistently generated a ±2 Nm moment. Previous studies, have employed a single offset displacement across all specimens.
regardless the resultant moment applied to individual specimen\textsuperscript{16}, which may over- or under-load screws during fatigue cycling.

Multiple pedicle screw diameters were used in this study to ensure proper sizing within the pedicle. There is a great deal of variability in pedicle diameter\textsuperscript{60}, therefore one screw fit was used. Oversized pedicle screws do not necessarily lead to increased stability of the construct in osteoporotic specimen, but may lead to cortical cutout since this technique will result in a thinned cortex and BMD is low in our population of specimens\textsuperscript{39}. Further studies are needed to determine the effects of oversized and undersized screw fit within the pedicle on the pullout strength.

5.1.1 Fatigue

Increased screw insertion depth substantially enhanced screw purchase. Angular stiffness increased with greater screw insertion depth. Maximum stiffness was observed using bicortical fixation. Each screw group loosened significantly during loading (Graph 4-1), which demonstrated the change in the biomechanics of the screw-bone interface due to fatigue. However, the reduction of angular stiffness due to fatigue lessened with increasing screw depth (Graph 4-2). The improved reduction in loosening of the bicortical screw group may be closely related to the greater initial angular stiffness of these screws. The resultant improvement in screw stability produced less motion and resulted in significantly less reduction in angular stiffness compared to the mid-body screw group under cyclic loading. Fluoroscopic images were taken of a screw of each
length post-fatigue demonstrating loosening in flexion compared to the screw's neutral position. (Figure 5-1)

<table>
<thead>
<tr>
<th>Unloaded</th>
<th>Loaded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid-body</td>
<td><img src="image1.png" alt="Image" /></td>
</tr>
<tr>
<td>Pericortical</td>
<td><img src="image2.png" alt="Image" /></td>
</tr>
<tr>
<td>Bicortical</td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
</tbody>
</table>

Figure 5-1: Fluoroscopic images of post-fatigue pedicle screws with (left) and without (right) a downward flexion force. The unloaded mid-body pedicle (top left) was approximately parallel (||) to the superior endplate (α1). By applying a flexion force on the pedicle screw, the angle between the pedicle screw and the superior endplate (α2) changed (top right). Likewise, the angle changes between unloaded (β1) and loaded (β2) for pericortical screws, and unloaded (γ1) and loaded (γ2) for bicortical screws. Note the bending moment present in the loaded pericortical pedicle screw. With increasing screw depth, loosening decreases leading to a decreased difference between the unloaded and loaded angles (Δγ<Δβ<Δα).

5.1.2 Fulcrum

Knowledge of screw motion characteristics within the vertebra may provide insight into optimal screw purchase. Examination of the loading patterns of the screw within the bone may demonstrate how screw insertion technique may be optimized based on vertebral
geometry to resist loosening and failure. While many studies have focused on bending moments applied to pedicle screws within the lumbar vertebra\textsuperscript{72-75}, to our knowledge, few have looked at screw kinematics during fatigue\textsuperscript{63,76}.

Bicortical screws had a fulcrum point about the mid-length of the pedicle, benefitting from the strong cortical shell of the pedicle, which was associated with enhanced screw purchase (Graph 4-3). Mid-body and pericortical screws had a fulcrum point anterior to the pedicle within the trabecular region of the vertebral body, which was associated with increased screw loosening, suggesting a weaker screw-bone interface. Mid-body screw fulcrum location aligns with a study by Law et al.\textsuperscript{63} which found that the fulcrum location was at the "base of the pedicle." Data indicate that bicortical screw placement significantly enhances screw purchase and decreases post-operative screw loosening, which may enhance fusion and improve clinical outcomes.

5.1.3 Screw Pullout

Screw pullout was analyzed to determine the relationship between screw insertion depth and fixation strength. Increasing screw insertion depth was associated with increasing fixation strength (Graph 4-4). While purchase of additional trabecular bone using pericortical screws led to an increase in fixation strength, this change was not significant. However, purchase of the stiff anterior cortex in bicortical screws demonstrated a significant increase in screw fixation strength. Energy absorption of the screws during axial pullout corroborated these findings with increasing energy being required for increasing screw depth. However, no significance was found. Bicortical screws showed a
nearly significant increase in energy absorption in comparison with mid-body screws, whereas the other comparisons were not close. These data suggest that bicortical pedicle screws provide the greatest fixation, which would act to decrease the risks of pedicle screw instrumentation failure in the osteoporotic patient population. Our results compare favorably to similar studies that investigate screw insertion depth\textsuperscript{60,66}.

5.1.4 Alternative Statistical Analysis

In the paired t-Tests between screws paired in individual vertebrae (Table A.1) significance was found between mid-body and pericortical screws for pullout strength and loosening. Significance was also found between mid-body and bicortical screws for loosening. In all cases, including those that did not demonstrate significant differences, the longer screw was associated with increased pullout strength and decreased loosening, particularly compared to mid-body screws. This suggests that pericortical and bicortical screws may provide a good alternative to mid-body screws. Evaluation of the effects of screw diameter on loosening and pullout strength was inconclusive (Table A.2), suggesting that screw diameter has no bearing on the results. This finding also supports the assertion that the fitting of the screws to the pedicles under a single best fit criteria based on a single surgeon sizing all screws did represent a single condition. Alternatively, best fit, oversized and undersized would have represented multiple conditions in terms of selection of screw diameter.

This study design evenly distributed experimental groups between all 10 specimens and all five lumbar vertebral levels. Therefore, the mean values of pullout for each condition
tested should be equally affected by each of these factors. This was not true for the paired analysis, because the study was not designed to equalize these factors between experimental groups. Further, sample size was smaller when only vertebra-paired comparisons were utilized, which may have made experimental groups more susceptible to outlying data points under the reduced sample size. While care was taken to standardize the surgical technique, it is always possible that unaccounted human error or variability may have played a role. Although paired analysis has certain advantages, experimental groups with an equal distribution by level and bone mineral density in these revised statistical groups would have been needed to make the paired comparisons analogous to the unpaired comparisons that were conducted.

5.1.5 Limitations and Risks

Risks associated with pedicle screw fixation have become more prevalent with increased use of this technology. The most common complications of pedicle screws include misplacement, nerve root impingement, cerebrospinal fluid leak, pedicle fracture, screw loosening, and hardware fracture/malfunction. The effects of these complications is usually not of great clinical significance, however, misplaced instrumentation has been implicated in cases of delayed instability and pseudoarthrosis. When considering pedicle screws insertion depth, one must also be aware of the vascular implications. Several cases have been reported in the literature whereby pedicle screw instrumentation is found to be in contact with the great vessels or have led to vessel injury such as pseudoaneurysm or rupture. These cases are rare, and it is unclear what implications a bicortical screw may have on the retroperitoneal vascular anatomy, if any. When found
post-operatively, the decision for replacement and repositioning must be weighed against the relative risk of leaving the screw in place\textsuperscript{80}. A retrospective review by of 182 patients undergoing thoracic, lumbar and lumbar-sacral pedicle screw fixation was performed by Foxx \textit{et al}.\textsuperscript{81} who found that of the 680 pedicle screws placed, 66 screws were found to be in contact with a major vessel. No patients had clinical or radiographic complications up to 44 months after surgery suggesting a more conservative strategy for these patients could be indicated. Currently used pedicle screws are predominantly blunt tipped with larger diameters making vascular injury even more unlikely. Further, the bicortical screws placed in this study were no more than 5 threads (or 2mm) through the anterior cortex. Certainly, the benefits and risks of placement of pedicle screws should be considered carefully and individualized for each patient. The authors do not advocate widespread bicortical pedicle screw placement. However, we have provided compelling evidence of increased biomechanical stability when using this technique in the osteoporotic lumbar spine. Future anatomic studies for safety could be considered if this technique were to be used in selected patients.

Several limitations of our study were identified. \textit{In vivo} investigation may provide additional insight beyond \textit{in vitro} biomechanical testing. Without accompanying soft tissue, which also provides fixation to the healing spine after surgery, our data must be interpreted with care and caution. Similar protocols have been used in previous studies. However, these may not ideally replicate \textit{in vivo} biomechanics. Further biomechanical and \textit{in vivo} testing with increased sample size and the inclusion of healthy spines as controls should be performed.
5.2 Review of Technique

5.2.1 Screw Pullout

Pedicle screw pullout study techniques vary widely and often depend on the needs of the study. However, these variations make it difficult to compare between studies. Also, achieving consistent positioning and alignment of the screw for testing adds complexity. The identification and adherence to key factors in study design can provide more consistent results and aid comparisons between studies, facilitating the clinical implementation of bench top research.

5.2.1.1 Screw Diameter

Pedicle diameter ranges widely\(^6\), yet many studies use the same pedicle screw diameter regardless of pedicle geometry\(^{14,16,23,35,44,47,52,55-60,62,66}\). Zindrick et al.\(^6\) measured the pedicle isthmus in the transverse plane and found a wide range in diameters. For example, L1 specimens ranged from 4.5 to 13.0 mm and L2 ranged from 4.0 to 13.0 mm. They observed that the pedicle failed in pullout via fracture in younger specimens and without fracture in older, osteoporotic specimens. Pedicle screws in osteoporotic patients do not gain good purchase of cortical bone in the pedicle due to deformation\(^6\), so it is a safe assumption that pedicle deformation occurs during pullout in osteoporotic vertebrae. In addition, larger screws do not lead to increased stability of the construct in osteoporotic specimen, but may lead to cortical cutout since the cortex has thinned and BMD is low\(^3\). Using a pedicle screw diameter that is outside established surgical guidelines could severely affect the fixation strength of the screw-bone interface, particularly in osteoporotic patients.
5.2.1.2 Pullout Displacement Rate

Pedicle screw pullout studies in the literature report varying displacement rates ranging from 1 to 30 mm/min\textsuperscript{16,44,47,52-54,61}. Inceoglu \textit{et al.}\textsuperscript{61} tested four different pullout rates from 0.1 to 50 mm/min and found that displacement rates affect the mechanisms of pullout strength. However, no general pattern of increasing or decreasing strength was found between studies. This observation suggests the need to better characterize the effects of displacement rate on pullout strength. In our study 5 mm/min was used based on the ASTM F 543 standard\textsuperscript{82} in order to facilitate comparisons to other studies as much as possible.

5.2.1.3 Specimen Alignment

Alignment of the specimen in a fixture for pullout can prove challenging. It is important to ensure a pure pullout load along the screw axis so as not to introduce off-axis loading. However, the geometry of the specimen is complex and the angle of the screw in relation to the specimen can vary greatly. This creates many difficulties for applying an axial (or off-axis) load to the screw head.

5.2.1.3.1 Potting

Potting of spine specimens in polyester resin or a similar substance is common. This method has many benefits for simplifying the geometry used to attach the potted specimen complex to the test fixture. However, it is challenging to rigidly orient a vertebra without interfering with pullout.
There are many techniques for potting a vertebra depending on the need of the study. A common technique involves placement of the vertebral body in polyester resin, PMMA or similar substance\textsuperscript{14,16,23,27,35,44,47,48,52-55,57,60,61}. Ensuring that the pedicles and lamina are not reinforced by the potting material is also important, as pullout strength may be affected. In addition, some investigators utilize clay, putty or similar materials along key aspects of the vertebral body to keep the potting material from penetrating into the bone or preventing expansion of the vertebral body during pullout thereby increasing screw pullout strength\textsuperscript{49}. The exothermal process may cause degradation of tissue, so proper care must be taken to use as little potting material as possible. With care, potting of the vertebral body provides solid fixation of the specimen to the fixture.

### 5.2.1.3.2 Alternate Methods of Specimen Fixation

Another technique to fix the vertebral specimen involves clamping the vertebral body between two plates. Several techniques can be employed to avoid a point load on the vertebral body. Our method potted the specimen at its base to conform with the anatomy of the vertebra and then applied compression to the other end of the specimen with a compliant foam material to prevent expulsion of the potted vertebra during loading. Hasegawa et al.\textsuperscript{62} used a small amount of plaster on the endplates to even out the surface. While leaving part of the disc attached may simplify the geometry, it may be of compliant to allow for an adequately rigid fixation.
Santoni et al.\textsuperscript{27} and Demir et al.\textsuperscript{83} used a fixture that surrounds the vertebra with a narrow slot for the pedicle screw to pass through, while restraining the vertebra. The prominent bony structures near the insertion site may result in a poor interface with the fixture. Any off-axis loading may realign the specimen as increased distraction deforms the prominent posterior elements of the specimen that interface with this fixture.

5.2.1.4 Loading Fixture

Custom-designed fixtures are often used to attach the specimens to the material testing machines\textsuperscript{16,27,44,48,54,55,57,59,61,62,84,85}. Many of these are designed to readily align the specimen. Cook et al.\textsuperscript{53} and Halvorson et al.\textsuperscript{14} used a universal joint and platen, which allows both rotation and translation about the x- and y-axes. Crawford et al.\textsuperscript{54}, Paik et al.\textsuperscript{23}, and Burval et al.\textsuperscript{16} used a bench vise. Jacob et al.\textsuperscript{55} used a fixture that employed a rod through the potting and another at the head of the screw that allowed only rotation in the transverse plane, but no other motion. This configuration may not assure proper alignment for pullout along the axis of the screw. Abshire et al.\textsuperscript{57} used a custom device consisting of a sliding block on a hinge to allow for medial-lateral translation and rotation. Santoni et al.\textsuperscript{27} employed an x-y table for translation. Paik et al.\textsuperscript{23} hooked a rod that attached to the screw head. Many studies, however, may mention a custom device and the ability for adjustment, but clear details or photographs were not provided\textsuperscript{44,47,48,52,56}. Some studies fail to mention how they dealt with alignment\textsuperscript{52,60}. 
5.2.1.5 Off-axis pullout

Not all loads in the pedicle screw-rod construct are axial. The forces and moments applied to the screw-bone interface are complex and cannot be completely accounted for using axial pullout. To account for these conditions, some pullout studies involve off-axis loading. Several studies\textsuperscript{23,44,48} utilize parasagittal pullout. However, there is no way to account for angle and variations in geometry. Therefore, such an experimental design may not be reproducible. A study by Santoni \textit{et al.}\textsuperscript{27} used a rigid fixture to pull pedicle screws out with a moment arm. A review of this work suggests that the rod may be over-constrained at the interface of the grips with the testing machine. Matching off-axis loading constraints with those of \textit{in vivo} screw loading is challenging.

5.2.1.6 Synthetic Bone Pullout Tests

Pullout studies with synthetic bone (e.g. foam block with specified properties) are an excellent method to understanding the fundamentals of an idealized screw-bone interface. The effects of varying bone densities can be controlled, but this does not account for all of the factors associated with an implanted screw under typical conditions.

5.2.1.7 Sample Size

Most studies employ a small sample size, allowing for an immense influence from highly variable vertebral geometry and strength properties. Many studies have relatively small sample sizes\textsuperscript{14,16,27,35,44,47,53,54,56-58,60,61,66}. A larger sample size decreases the probability of a type II error and more accurately reflects the mean. However, an excessive sample size may simply be a waste of resources\textsuperscript{86}. We included a sample size of 100 pedicles split
between three groups in order to minimize any bias from the variation between specimens.

5.2.2 Fatigue

5.2.2.1 Load and Displacement Control

For most pedicle screw fatigue studies displacement control is utilized for cyclic loads. This is often due to the challenges of load control. Typically studies have applied the same displacement to all specimens, despite variations in density or augmentation\textsuperscript{16,60}. Therefore, the moment applied to each specimen may vary greatly, biasing screw fixation strength. Load control is a specimen-specific option used in many studies\textsuperscript{23,35}. However, it may be difficult to gain stable control over long periods of cyclic loading, especially when tissue breakdown is a factor. Several studies applied displacement control up to a specific load\textsuperscript{61,62}, which may allow for the best resolution while ensuring that fatigue is at a reasonable level for a wide range of specimens.

5.2.2.2 Flexion-Extension Versus Other Modes of Loading

Loading on the screw head \textit{in situ} is a complex combination of multiple axes of loading. Many investigators have simulated post-implantation loosening about a variety of axes. Burval \textit{et al.}\textsuperscript{16}, Hasegawa \textit{et al.}\textsuperscript{62} and Zindrick \textit{et al.}\textsuperscript{60} utilize cephalocaudal loading. Zindrick \textit{et al.}\textsuperscript{60} also studied fatiguing in the medial-lateral direction. Paik \textit{et al.}\textsuperscript{23} and Sterba \textit{et al.}\textsuperscript{35} applied caudal loading. Inceoglu \textit{et al.}\textsuperscript{61} tested pre-yield fatigue axially. Such variations in methodology complicate comparisons across multiple studies.
5.2.2.3 Offset Loading for Fatigue

The length of offset loads in fatigue studies are highly variable. These offset may be measured from either the head of the screw\textsuperscript{16,62} or from the point of initial bony contact\textsuperscript{35,60} making offset distance difficult to compare between studies.

Application of offset loads varies by group. Sterba \textit{et al.}\textsuperscript{35} used a cylindrical loading rod to apply a load at a given distance from the vertebra. Burval \textit{et al.}\textsuperscript{16} used a hinge and vice to apply fatigue loading. Hasagewa \textit{et al.}\textsuperscript{62} used a loop around a rod attached to the head of the screw. Inceoglu \textit{et al.}\textsuperscript{61} applied axial fatigue and therefore simply potted the specimen. This range of methods makes it difficult to evaluate how specimen positioning and fixation influence experimental data.
Chapter 6

Conclusion

6.1 Testing Conclusion

Increased screw depth in the osteoporotic lumbar spine led to increased fixation and decreased loosening. Improved screw purchase of the stiff anterior cortex led to significant improvements compared to mid-body screws that extend halfway through the vertebral body. These results may prove to be a critical advantage in achieving optimal pedicle screw fixation in the management of osteoporotic patients undergoing spinal surgery.

6.2 Technique Conclusion

Proper alignment of a vertebral specimen during screw pullout and fatigue can be challenging due to the complex geometry and potential for interference in screw fixation. The development of a custom fixture that allows x-y translation and rotation may minimize these difficulties. The addition of fatigue may provide further insight into the screw-bone interface, as such loading mimics loosening that may underlie surgically observed failure.
References


Appendix A

Alternative Statistical Analysis

Table A.1: Paired t-Test of Pedicle Screw Pairs within Individual Vertebrae. An asterisk (*) indicates statistical significance.

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Pullout Strength: Failure Load</th>
<th>p-Value</th>
<th>Loosening: Angular Stiffness Reduction</th>
<th>p-Value</th>
<th>Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid-body vs. Pericortical</td>
<td>609±238 N vs. 751±248 N</td>
<td>0.019*</td>
<td>-29.6%±16.6% vs. -15.3%±10.2%</td>
<td>0.030*</td>
<td>14</td>
</tr>
<tr>
<td>Pericortical vs. Bicortical</td>
<td>740±390 N vs. 751±338 N</td>
<td>0.860</td>
<td>-24.8%±17.6% vs. -18.4%±12.4%</td>
<td>0.148</td>
<td>14</td>
</tr>
<tr>
<td>Mid-body vs. Bicortical</td>
<td>744±216 N vs. 826±279 N</td>
<td>0.166</td>
<td>-28.0%±16.8% vs. -12.0%±14.6%</td>
<td>0.016*</td>
<td>13</td>
</tr>
</tbody>
</table>

Table A.2: Regression Analysis of the Effect of Diameter on Pullout Strength and Loosening. An asterisk (*) indicates statistical significance.

<table>
<thead>
<tr>
<th>Screw Depth</th>
<th>Pullout Strength: Failure Load (slope)</th>
<th>p-Value</th>
<th>Loosening: Angular Stiffness Reduction (slope)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid-body</td>
<td>-63.2</td>
<td>0.081</td>
<td>0.0275</td>
<td>0.323</td>
</tr>
<tr>
<td>Pericortical</td>
<td>-19.5</td>
<td>0.685</td>
<td>0.0556</td>
<td>0.006*</td>
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<tr>
<td>Bicortical</td>
<td>-33.4</td>
<td>0.504</td>
<td>-0.0213</td>
<td>0.222</td>
</tr>
</tbody>
</table>