OSTEOPOROTIC SPINE FIXATION:
A BIOMECHANICAL INVESTIGATION

by

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Abstract

Intervertebral fusion of the aging spine is a common surgical procedure for a wide range of clinical problems including trauma, deformity and degeneration. Spinal instrumentation is often used to stabilize the spinal column and help facilitate the fusion. The main problems of using spinal instrumentation in elderly patients (many with osteoporosis) are loss of fixation due to loosening and adjacent segment effects. The objectives of this thesis were to compare existing techniques of osteoporotic spine fixation using in vitro biomechanical models and to investigate new surgical strategies, so as to provide information to the spine surgeon to decrease the incidence of implant loosening and reduce degenerative changes at the adjacent levels in elderly patients.

Pedicle screw loosening is common in patients with poor bone quality. Augmentation of pedicle screws with laminar hooks, sublaminar wires and/or cement are techniques used clinically to minimize pedicle screw loosening. A novel testing configuration was developed to apply physiologic load in relevant magnitudes and directions to study pedicle screw motion in cadaveric vertebrae. Twenty-four lumbar vertebrae (L3-L5) were divided into three groups and instrumented bilaterally with pedicle screws. A model of loosened screws was created by overdrilling the pedicle screw trajectory. Two techniques of screw augmentation, using laminar hooks, sublaminar wires and/or calcium phosphate cement, were carried out within each group of specimens. Paired comparisons of screw motion magnitudes at the screw head and screw tip, and overall motion patterns were carried out. Screws augmented with cement exhibited primarily rotational motion patterns with minimal translational motion, and most closely resembled the motion pattern of screws in high density bone. All three augmentation techniques resulted in a 50% mean reduction in screw motion. No significant differences in motion magnitudes were found between the different augmentation techniques. The results suggested that augmentation of pedicle screws with calcium phosphate cement might provide enhanced fixation over laminar hook and sublaminar wire augmentation.

Anterior interbody device subsidence is another clinical problem that leads to implant loosening. Ninety-six thoracolumbar cadaveric vertebrae were compressed to failure using various shaped indentors. The focus was primarily on the superior endplate. In forty-eight specimens, the purpose was to determine the effect of cage shape and cage size on cage-vertebra interface properties. In the remaining forty-eight specimens, the effects of pedicle screw insertion and cement augmentation of screws on cage-vertebra interface properties were determined for various shapes and sizes of devices. Failure load, failure strength and stiffness
were compared. In the first part, larger sized devices (with 40% endplate coverage versus with 20%) resulted in 75% higher failure load. Clover-leaf shaped devices also resulted in at least 45% higher failure load and failure strength over kidney or elliptical shaped devices. Trabecular failure was found to occur in a semi-elliptical zone beneath the interbody device. In the second part, pedicle screw insertion disrupted the underlying trabecular bone and reduced cage-vertebral interface strength. Cement augmentation of pedicle screws structurally reinforced the underlying trabeculae, and resulted in an improvement in cage-vertebra interface strength. No differences were found between cement augmented anterior vertebral body screws and pedicle screws. There were also no differences in interface strength between indenter shapes following screw insertion, with and without cement augmentation. Larger sized interbody devices and cement augmentation of vertebral screws might reduce the incidence of interbody device subsidence in the osteoporotic spine.

Cement augmentation of pedicle screws and extension of posterior instrumentation are two techniques to improve the stabilization of spinal fixation in the presence of osteoporosis. Using the traditional flexibility protocol and a new hybrid test technique, intersegmental range of motion within the fused segment and at adjacent levels following cement augmentation of pedicle screws and extension of posterior rods were compared using an in vitro biomechanical thoracolumbar model. Twelve T9-L3 segments were tested in a repeated measures fashion to determine the effects of posterior rod extension and cement augmentation. Intact flexibility tests under 5 Nm pure moments were first carried out in axial rotation, lateral bending, and flexion extension. The initial test configuration included a T11 corpectomy and reconstruction with an extendable cage, and pedicle screws instrumentation from T10-T12. Flexibility tests were carried out randomly on 1) the initial test configuration, 2) with additional posterior rod extension to L1 using standard rigid rods and 3) extension using flexible acetal rods. The T12 and L1 pedicle screws trajectory were overdrilled as before to simulate loosening in the osteoporotic spine. Following flexibility tests under these three fixation methods, the T12 and L1 screws were augmented with cement. The flexibility tests were repeated for the three conditions in randomized order again. Three-dimensional motion of each vertebra was measured using an optoelectronic camera system. Intersegmental ROM at the fusion level was normalized and compared under the same applied moment in the flexibility protocol. Vertebral body strains and intersegmental ROM at the adjacent segments were compared under the same overall T9-L3 ROM in the hybrid protocol. Using the flexibility protocol, cement augmentation resulted in better fixation at the fusion level than with posterior rod extension. Using the hybrid protocol, posterior rod extension reduced ROM at the adjacent level but resulted in increased ROM and
strain at the remaining non-instrumented levels. The use of flexible rods resulted in lesser increase in ROM and strain at these remaining non-instrumented levels than with rigid rods. Flexible rod extension might provide a better alternative than with rigid rod extension, when extension rods are necessary to prevent adjacent level effect at the extension level.

The findings in this thesis support the use of cement in the osteoporotic spine to 1) improve fixation strength at the pedicle screw-vertebra interface, 2) improve fixation strength at the interbody device-vertebra interface and 3) increase overall structural stiffness (decrease motion) at the fusion level. Larger interbody devices should be used in the osteoporotic spine to further enhance construct stiffness. Extension of posterior instrumentation with flexible rods might prevent adjacent level disease at the extension level, but it should be used with caution as it might aggravate the remaining non-instrumented levels and postpone the adjacent level diseases to these levels.
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Co-Authorship Statement

Sections of this thesis have been submitted as multi-authored papers in refereed journals. The research was performed by me except for surgical procedures which were carried out by a spine surgeon in each study. Detailed design of all studies was presented to the co-authors for approval prior to the experiments being carried out. Data analyses and manuscript preparation were carried out by me and the co-authors contributed in editing the manuscripts for submission to refereed journals. The original ideas in a Canadian Institutes of Health Research (CIHR) grant, titled “Enhancement of Osteoporotic Spine Fixation”, submitted jointly by the Principal Investigators, Drs Oxland, Dvorak and Fisher in September 2000, provided the research topic and the grant provided funding.

______________________________ Juay Seng Tan

Published Papers


Authors' contribution: Juay Seng Tan was jointly responsible for the original ideas behind the paper, conducting the experiments, data analyses, presentation of the findings, and writing and editing of the original paper. Dr Brian Kwon conducted the surgical procedures. Mr Dinesh Samarasekera conducted a preliminary pilot study. Dr Marcel Dvorak and Dr Charles Fisher stimulated discussion. Dr Thomas Oxland was jointly responsible for the original ideas, provided supervision, and was the key editor on this paper.


Authors' contribution: Juay Seng Tan was responsible for the final proposal (based on the original ideas), conducting the experiments, data analyses, presentation of the findings, and writing and editing of the original paper. Dr Brian Kwon conducted the surgical procedures, stimulated discussion and provided editorial assistance. Dr Marcel Dvorak and Dr Charles Fisher were jointly responsible for the original ideas behind this paper, stimulated discussion and provided editorial assistance. Dr Thomas Oxland was jointly responsible for the original ideas behind this paper, provided supervision, and was the key editor on this paper.

Authors’ contribution: Juay Seng Tan was responsible for the final proposal (based on the original ideas), designing the indentors, preparing the test setup, conducting the experiments, data analyses, presentation of the findings, and writing and editing of the original paper. Dr Christopher Bailey conducted the surgical procedures, stimulated discussion and provided editorial assistance. Dr Marcel Dvorak and Dr Charles Fisher were jointly responsible for the original ideas behind this paper, stimulated discussion and provided editorial assistance. Dr Thomas Oxland was jointly responsible for the original ideas behind this paper, provided supervision, and was the key editor on this paper.

**Papers Submitted**

4. **Tan JS, Bailey CS, Dvorak MF, Fisher CG, Cripton PA, Oxland TR.** Cement augmentation of vertebral screws enhances the interface strength between interbody device and vertebral body. Submitted to *Spine* (7 Nov 2005).

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**Papers in Preparation**

5. **Tan JS, Singh S, Zhu QA, Dvorak MF, Fisher CG, Oxland TR.** Spinal stabilization in the osteoporotic spine following posterior rod extension and cement augmentation of screws using a flexibility protocol. In preparation for submission to *Spine*.

6. **Tan JS, Singh S, Zhu QA, Dvorak MF, Fisher CG, Oxland TR.** Adjacent level effects in the osteoporotic spine following posterior rod extension and cement augmentation of screws using a hybrid protocol. In preparation for submission to *Spine*.

Authors’ contribution: Juay Seng Tan was responsible for the final proposal (based on the original ideas), overhauling the spine machine, preparing the test setup, conducting the experiments, data analyses, presentation of the findings, and writing and editing of the original paper. Dr Sandeep Singh conducted the surgical procedures, stimulated discussion and provided editorial assistance. Dr Qing-An Zhu assisted in data collection and in conducting the experiments. Dr Marcel Dvorak and Dr Charles Fisher were jointly responsible for the original ideas behind these 2 papers, stimulated discussion and provided editorial assistance. Dr Thomas Oxland was jointly responsible for the original ideas behind these 2 papers, provided supervision, and was the key editor on these papers.
Chapter 1

Introduction

Overview

The populations of the developed nations are aging. Degenerative conditions such as degenerative spondylosis, spondylolisthesis, spinal stenosis and degenerative spinal lumbar kyphosis and scoliosis, and other disabling conditions such as trauma or the presence of tumours, are conditions in older individuals and they often require stabilization with spinal implants. Osteoporosis is a condition of reduced bone density that could result in loss of bone strength and cause pain, deformity and loss of function for the patient. While vertebral osteoporotic fractures do not often necessitate surgery, the presence of diminished bone quality complicates spinal stabilization surgery when spinal implants are used. The weakened bone in the osteoporotic spine results in poor bone-implant interface properties and brings about surgical challenges such as loosening of pedicle screws and subsidence of interbody devices. Currently available spinal instrumentation devices that would otherwise be beneficial often loosen when used in the aging spine. Moreover, the increased stiffness within the fused segments could also lead to early failure of adjacent levels in the elderly patients due to altered biomechanics such as increased load and motion demands, and may necessitate further surgery. The objective of this thesis was to provide insights into both the problems of implant loosening and adjacent level effects in the aging spine.
1. Introduction

1.1 Overview

The current generation of spinal implants are often not specifically designed for use in the elderly patient. As the quality of the bone in the elderly spine is commonly compromised with degenerative conditions such as spondylosis and osteoporosis, spinal implant loosening is a common cause of failure in these patients. To compound the problem, elderly patients are prone to adjacent level disease, a spinal condition believed to be caused by altered biomechanics at the levels adjacent to the implanted levels. These two problems complicate spinal instrumentation in the osteoporotic patient. Many elderly patients who would otherwise benefit from currently available spinal instrumentation devices are denied the treatment due to their compromised bone quality.

The absolute number and proportion of elderly people in the population are projected to increase in the next few decades. With the projected increase in the number of elderly patients with osteoporosis requiring spinal surgery, it is in the interest of spinal implant companies to develop devices that would cater to this rising demand in the market. There are however no initiative to develop spinal devices specifically for this patient group, according to the author's knowledge.

In recent years, motion preservation devices have been conceived as the next generation of spinal implants and many implant companies are jostling for market share. Motion preservation devices could become a solution for preventing adjacent level diseases in the younger patients. Also in recent years, bone cement has become more popular to improve the implant-bone interface. Bone cement holds much promise to address the issue of device loosening in patients with compromised bone. The use of motion preservation devices with bone cement could thus be the future solution for preventing both device loosening and adjacent level diseases. However, further research would be necessary before they could be indicated for elderly patients with compromised bone quality.

Further understanding of the biomechanics of spinal device loosening and adjacent level diseases are necessary in order to solve both issues together. A current surgical solution that could address both issues is needed for osteoporotic elderly patients. It is the goal of this thesis to provide further biomechanical input into the problems of spinal device loosening and adjacent level disease and to propose feasible solutions to these issues so as to improve quality of life for the elderly patients.
1.2 The Normal Spine

1.2.1 Basic Anatomy and Physiology

The human spinal column consists of 24 mobile vertebrae: 7 cervical vertebrae (C1-C7), 12 thoracic vertebrae (T1-T12), and 5 lumbar vertebra (L1-L5), and the relatively immobile sacrum (S1-S5) and coccyx. Except for C1 and C2, the other mobile vertebrae consist anteriorly of a vertebral body, and posteriorly of a neural arch formed by the pedicles and the laminae (Figure 1.1). Where the laminae meet at the posterior midline, a spinous process emerges. At the junction between the pedicle and the lamina, the transverse process projects laterally. The superior and inferior articular processes connect to corresponding articular processes of adjacent vertebral bodies, forming the facet joints.

![Diagram of a vertebra and a functional spinal unit](image)

**Figure 1.1** (Top) Schematic diagram of a vertebra viewed from above, showing the vertebral body and the neural arch. (Below) Schematic diagram of a functional spinal unit (FSU) viewed from the side, showing a pair of vertebrae, the intervertebral disc (cross-section), and a facet joint (the other facet joint is blocked from view).
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The spinal column can be considered to be made up of a series of functional spinal units (FSUs). Each FSU consists of two adjoining vertebrae and its connecting soft tissues (Figure 1.1). An intervertebral disc and a pair of facet joints transmit load and allow motion of the FSU.

The vertebral body is mainly made up of trabecular bone (also known as cancellous bone), with a thin shell of cortical bone on its outer surface. The posterior elements, consisting of the pedicles, transverse processes, laminae, spinous process, superior articular processes, and inferior articular processes, are mainly made up of cortical bone, with some cancellous bone within. At the interfaces between the vertebral body and the superior and inferior intervertebral discs are the vertebral endplates. The endplate in the adult consists of an osseous layer integrated with the vertebral body, and a thin cartilaginous layer in contact with the nucleus pulposus and annulus fibrosus. The endplate is not vascularized and it prevents blood flow into the intervertebral disc.

The intervertebral disc consists of a gelatinous nucleus pulposus surrounded by concentric layers of annulus fibrosus (Figures 1.1 and 1.2). The gelatinous nucleus pulposus behaves like an incompressible fluid material. The fibres in the annulus are oriented approximately between 20° to 30° with the horizontal plane, with alternating directions between concentric layers, making it strong in resisting the hydrostatic pressure of the nucleus pulposus.

![Figure 1.2 Schematic diagram of a vertebral body with an intervertebral disc. The vertebral body is made up mainly of trabecular bone, with a thin cortical shell.](image-url)
shell. The intervertebral disc consists of a gelatinous nucleus pulposus, surrounded by concentric layers of annulus fibrous. The fibres in the annulus are oriented between 20° to 30° with the horizontal plane, with alternating directions between layers.

The physiological purpose of the intervertebral disc is to transmit load from the superior vertebral body to the inferior vertebral body, while allowing motion for the FSU. Under compression, a uniform hydrostatic pressure is created in the nucleus of the healthy disc, which in turn exerts a radial stress onto the annulus fibrosus (Figure 1.3). One important role of the annulus is thus to enclose and contain the nucleus during load and motion. Superior and inferior to the intervertebral disc, the endplates and underlying trabecular bone resist the hydrostatic pressure in the nucleus pulposus during motion. During sideward or forward bending, the annulus on the concave side is placed under compression, while the opposite region of the annulus is under tension. Load acting from the vertebral body in bending is also transmitted through the pressurized nucleus to the next level, and the resultant forces are noted to push the nucleus pulposus away from the concave side [Benzel 1995, Tsantrizos et al. 2005]. During axial rotation motion, the concentric layers of the annulus with its oriented fibre directions withstand the stresses created. Loads from the vertebral body acting on the intervertebral discs are more commonly a combination of compression, bending, axial torsion, and shear. Together, the nucleus pulposus and the annulus fibrosus provide the strength for the intervertebral disc to withstand compressive, bending and torsional loads.

Figure 1.3 Schematic diagram of a functional spinal unit (FSU) under compressive load and during bending. A uniform hydrostatic pressure is created in the nucleus, which in turn exerts a radial stress onto the surrounding annulus.
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*During bending, the annulus on the bending side is placed under compression while the opposite annulus is under tension.*

The inferior articular process of the superior vertebra and the superior articular process of the inferior body are connected by a synovial joint, and this joint is commonly called the facet joint (also the apophyseal, the zygapophyseal, or the posterior intervertebral joint) (Figure 1.1). The facet joints connect the FSU posteriorly and together with the intervertebral disc transmit loads and allow motion. Under pure compression, the pair of facet joints in the lumbar spine withstands approximately 20% of the load while the intervertebral disc withstands approximately the remaining 80% [Lorenz et al. 1983, Yang and King 1984]. Higher amount of load is transmitted through the intervertebral disc in forward flexion, while more load is transmitted through the facet joints in extension motion. In axial rotation, one facet joint is generally in compression while the opposing facet is generally in tension and shear. One important role of the facet joints is to prevent excessive motion of the FSU with a bone-on-bone mechanical stopper between the articular processes. The differing orientations of the facet articulations across the cervical, thoracic and lumbar spine, and the subtle differences within each of these regions, results in different ratio of load sharing with the intervertebral disc and in different range of motion (ROM) for each level.

Several ligaments connect vertically across the FSU (Figure 1.4). The role of ligaments is to enhance stability by restricting excessive motion. The anterior longitudinal ligament (ALL) attaches firmly to the anterior surface of the vertebral body and is stretched during extension motion. The posterior longitudinal ligament (PLL) attaches to the posterior surface of the vertebral body and lies anterior to the spinal canal. Both the interspinous ligament (ISL) and the supraspinous ligament (SSL) connect between spinous processes and are stretched during flexion motion. The ligamentum flavum (LF) connects between laminae and lies posterior to the spinal canal. Lastly, the facet capsular ligament (CL) connects across adjacent articular processes and prevents excessive motion of the facet joint. Several other ligaments are present in the thoracic spine which connects across the costovertebral joints between the rib and the vertebra.
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Figure 1.4 Schematic diagram showing the ligaments, muscles, spinal canal and intervertebral foramen in the lumbar spine. Ligaments restrict excessive motion while muscles are the prime movers. The spinal cord is protected by bony structures of the vertebra. The spinal cord passes through the spinal canal while the spinal roots exit through the intervertebral foramen. Ligaments: anterior longitudinal ligament (ALL), posterior longitudinal ligament (PLL), ligamentum flavum (LF), capsular ligament (CL), interspinous ligament (ISL), supraspinous ligament (SSL). Muscles: psoas major (PM), quadratus lumborum (QL), iliocostalis lumborum (IL), longissimus thoracis (LT), multifidus muscle (M).

Muscles are the prime movers of joints in the body. The major muscles that make up the extensor group includes the multifidus muscle (M), longissimus thoracis (LT) and the iliocostalis lumborum (IL) (Figure 1.4). The latter two (LT and IL) together are also known as the erector spinae. Deep intrinsic flexor muscles include the psoas major (PM) and the quadratus lumborum (QL), while extrinsic flexor muscles of the abdominal wall include the external oblique (EO), internal oblique (IO) and the rectus abdominis (RA). Lateral bending and axial rotation of the thoracolumbar spine is through the unilateral action of deep muscles (IL, LT, M, QL) and abdominal muscles (EO, IO), with contraction of muscles at the opposite side.

1.2.2 Basic Biomechanics

The definition of stability in the engineering field is well established and could be represented pictorially by a cone on a flat surface or a ball on curved or flat planes (Figure 1.5). When perturbed by an external force, the unstable object would 'topple'. The neutral object does not topple, but could be displaced and is thus not stable. The stable object would not
Instability of the spine however is hard to define and a single definition does not exist [Crisco 1989]. Instability is a term vaguely used to describe some biomechanical spinal dysfunction involving excessive or abnormal movements of the spine [Adams et al. 2002]. Identification of the unstable spine is important clinically as it can be an indication for surgical intervention. One interpretation of clinical instability defined it as “the inability of the spine under physiologic loads to limit patterns of displacement so as not to damage or irritate the spinal cord or nerve roots and, in addition, to prevent incapacitating deformity or pain due to structural changes” [White and Panjabi 1990].

![Unstable Neutral Stable](image)

**Figure 1.5** Engineering definition of stability as illustrated by a cone on a flat surface and by a ball on curved or flat surfaces. All objects are in equilibrium initially. When perturbed by an external force, the unstable object would 'topple'; the neutral object and stable objects would not topple but the stable object would return to its initial position. [Adapted from Crisco 1989 and Adams et al. 2002]

The three fundamental biomechanical functions of the spine are 1) to allow motion between levels, 2) to transfer load across levels, and 3) to protect the spinal cord and spinal roots [White and Panjabi 1990]. The unstable spine could become incompetent in performing one or more of these functions.

The cervical, thoracic, lumbar and sacral regions of the spine perform these functions with different degrees of emphasis. The lumbar region, for example, is subjected to larger loads than the thoracic and cervical spine, and provides most of the motion in flexion-extension for the trunk [White and Panjabi 1990]. In contrast, the cervical region protects the central nervous
system that connects the brain to the body and limbs, withstands a much smaller load as compared to the thoracic and lumbar spine and which in most instances is equal to the weight of the head, and provides a wide ROM for the head and neck.

Motion between vertebral levels from the second cervical vertebra to the sacrum is made possible by a three-joint complex at each level, made up of the intervertebral disc and a pair of facet joints that connect adjacent vertebral bodies. Rotational motions are the predominant modes of motion across these FSUs. Translational motion in the normal spine exists as part of the coupled motions during rotational motion. For example, a mean forward translation of the lumbar FSU of between 2.3 to 3.3 mm was measured during full flexion-extension [Schneider et al. 2005], together with 2° of coupled axial rotation and 3° of coupled lateral bending [Pearcy et al. 1984, Pearcy 1985].

The rotational ROM at each FSU differs between regions of the spine and also between individual levels in each region. The lumbar spine, for example, has a rotational ROM of about 12° to 17° in flexion and extension, while the thoracic spine has about 4° to 12° [White and Panjabi 1990]. In axial rotation, the lumbar spine has a rotational ROM of about 1° to 2° unilaterally while the thoracic spine has between 2° to 9°. The rotational ROMs in lateral bending are about the same for FSUs in the thoracic and the lumbar spine, and range between 5° to 8°. While motion across individual FSU is limited, the cumulative rotational ROM of the spinal column allows for substantial motion of the trunk and head.

Load transfer across vertebral levels and with active muscle stabilization is necessary in order for the spinal column to remain erect in static and dynamic situations. Stabilization of the spinal column can be compared to the stabilization of an inverted-pendulum (Figure 1.6). The inverted pendulum, depicted as a long pole on a hinge, can be stabilized with guy wires pulling from both sides. This inverted pendulum model of the spinal column without the guy wires is unstable like the inverted cone in Figure 1.5. In the spinal column, muscle activation act like guy wires to help stabilize the column and the lost of active muscle in the asleep or dead person results in the spinal column not being capable of remaining upright. Coactivation of the agonist and antagonist muscles is necessary in order to maintain a neutral position [Cholewicki et al. 1997]. As a result, compressive loads are applied onto and transmitted across vertebral levels.
Figure 1.6 Analogy of the stabilization of the spinal column to an inverted pendulum. A long pole can stand vertically if stabilized with guy wires. Changes in the applied forces in each wire would result in change in inclination of the pole. In the spinal column, a combination of muscle forces creates motion in the spine. Coactivation of the agonist and antagonist muscles are necessary for motion and stability. Between vertebral levels, an intervertebral disc and a pair of facets act as spacers to provide distraction, and to allow for load transfer as well as motion. Surrounding ligaments further stabilize the spine and prevent excessive motion. The shaded arrows indicate compressive loads through the structures, as a result of tension from the guy wires, muscle forces and reaction forces. [Adapted from Daggfeldt and Thorstensson 1997 and Cholewicki et al. 1997]

Load transfer across spinal levels mainly passes as compressive forces through the facet joints and intervertebral disc, onto the adjacent vertebrae. Surrounding ligaments and both agonist and antagonist muscles provide counteracting forces to stabilize the spine and prevent excessive motion. The external forces necessary to create motion are provided by the agonist muscles. Activation of the agonist muscle creates motion towards it while concurrent relaxation of the antagonist muscle allows the agonist to effect movement. The antagonist muscles works in coordination with the agonist muscles to achieve mechanical stability [Cholewicki et al. 1997]. During backward trunk extension, for example, the erector spinae (extensor) muscle is the agonist, the psoas major (flexor) muscle the antagonist, and the anterior longitudinal ligament and the intervertebral disc help stabilize the joint (Figure 1.7). Using a free body diagram, the forces acting on the FSU must be in equilibrium [Daggfeldt and Thorstensson 1997].
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Figure 1.7  Free body diagrams of a functional spinal unit (FSU) during extension and during flexion. The extension muscles are agonist muscles during extension motion, while the flexor muscles are antagonist muscles. Other counter forces could be contributed by gravity, the ligaments (L), and the disc.

The vertebral column protects the spinal cord as it descends from the brain. The spinal cord passes through the spinal canal, and exits as spinal roots through the intervertebral foramen (Figure 1.4). Bony protection of the spinal cord anteriorly is provided by the vertebral body and posteriorly by the spinous process and laminae. Laterally, the spinal cord is protected by the transverse process and the pedicle. The posterior longitudinal ligament lies anterior and the ligamenta flava lies posterior to the spinal cord, and they both help to provide further protection to the cord.
1.3 The Aging Spine

1.3.1 Epidemiology

The populations of the developed nations are aging, with a projected increase in absolute numbers and proportions of elderly people in the population. With low fertility levels (1.56 children per women in 2005-2010) and higher life expectancy (75 years in 1995-2000 and 82 years in 2045-2050), the proportion of the population in developed nations aged 60 years or above will increase from 19% in 2000 to 32% in 2050 [UN Population 2003].

In Canada, the trend of lower fertility levels and higher life expectancy reflect the world trend for developed nations. The average number of children per woman is projected to be about 1.5 from 2000 to 2025. Life expectancy at the same time is projected to increase from 78.7 years in 1995-2000 to 83.3 in 2045-2050 [UN Population 2003]. The proportion of the population above 65 years in 2000 was 12.7% and was projected to increase to 21.4% by 2026 and 25.4% by the year 2051 [Statistics Canada 2001] (Figure 1.8). The number of people aged above 65 years will increase from 3.9 million in 2000 to 7.8 million in 2026 and to 9.4 million in 2051. At the same time, the number of people aged above 80 years will increase from 0.9 million in 2000 to 1.9 million in 2026 and 3.3 million in 2051 [Statistics Canada 2001].

![Population distribution of Canada by age and sex, 1971 and 1996](image)

Figure 1.8 Population distribution of Canada in 1971 and 1996, from Statistics Canada (www.statcan.ca). The proportions of the Canadian population 65 years and above will reach 25.4% of the total population in 2051.
With an aging population, total health expenditure will be proportionally higher. In 1994, Canada was already spending 40% of its total health spending on the 12.8% of the total population above 65 years old [Anderson and Hussey 2000]. A higher proportion of GNP will need to be spent on healthcare in the next few decades in order to maintain the current quality of care.

1.3.2 Age Related Degenerative Pathology

There are several physical degenerative changes that could occur in the aging spine [Vernon-Roberts 1992, Prescher 1998, Ferguson and Steffen 2003]. These changes affect various structures in the FSU, such as the vertebral body, facet joints, endplate, nucleus pulposus, and the annulus fibrosis (Figure 1.9), individually or collectively. Osteoporosis is also a degenerative condition of the aging spine, and will be discussed separately in the next section (Section 1.3.3).

![Degenerative changes in the aging spine](image)

Figure 1.9 Degenerative changes in the aging spine could result in a smaller intervertebral foramen space, loss of disc height, loss of vertebral height, and a kyphotic posture. The vertebral body is generally larger in size.
anteriorly and laterally in the degenerated spine. Osteophytes (6) are commonly seen growing at the anterolateral and posterolateral regions. The vertebral body could also suffer from an osteoporotic fracture (8). Nucleus degeneration (10) would result in loss of intervertebral disc height, which could lead to bridging osteophytes (9) forming at the anterolateral vertebral rim. Vertebral fracture and loss of disc height could result in excessive loading on the facet joint, resulting in facet osteophytes (1) and facet osteoarthritis (2). Endplate degeneration and annulus lesion (7) are commonly found in the degenerated disc. If the nucleus remains fairly hydrated but the surrounding endplate or annulus is degenerated, Schmorl's node (4) and disc bulge/prolapse (3) could result from nucleus migration. With a hydrated nucleus and weak adjacent bone, the endplate could become more concave (5).

Vertebral rim osteophytosis [Nathan et al. 1994a] and facet joint osteophytosis [Tischer et al. 2005] are two common degenerative conditions of the vertebra. The cause of osteophyte formation is attributed to adaptation of bone tissues to abnormal strains observed [Nathan et al. 1994b]. These osteophytes could compress surrounding nerves [Matsumoto et al. 2002], resulting in pain, loss of function and/or loss of sensation. A classification describing four degrees of vertebral osteophytes was previously defined [Nathan et al. 1994a], ranging from only isolated points of hyperostosis to fused osteophytes across adjacent vertebrae. The prevalence of osteophytosis is higher in men than in women [Kinoshita et al. 1998, Pye et al. 2004]. Osteophytes with second degree or higher occurs in 90% of men and in 64% of women above 60 years old [Kinoshita et al. 1998]. The incidence of osteophytosis is also associated with increasing age [Pye et al. 2004].

Facet joint degeneration occurs after disc or vertebral body degeneration [Butler et al. 1990]. The prevalence of facet osteoarthritis occurs in 14% of men and women above 60 years old [Kinoshita et al. 1998]. In most cases, disc degeneration would occur without the presence of facet degeneration, while facet degeneration would only occur in the presence of disc degeneration. The cause of facet degeneration is possibly due to altered load patterns within the facet joint, such as loading location and increased magnitudes [Nathan et al. 1994b]. Disc degeneration also results in a change in the instantaneous axis of rotation of the FSU [Rousseau et al. 2005] and an increase in the facet forces. As a result of an increase in load magnitudes and a change in loading location in the facet joints, adaptive remodelling within the facet could lead to enlarged facets, facet osteophytes and facet osteoarthritis [Taylor and Twomey 1986, Berlemann et al. 1998].

In the vertebral endplates, fissure formation, fractures and horizontal cleft formation are some early degenerative changes observed [Vernon-Roberts 1992]. In later stages, increase in
vascular penetration, extension of calcification and ossification from the bony endplate, loss of cartilaginous endplate thickness and microscopic intrusion of nucleus material through the endplate are observed. Biomechanically, decreased strength at the central location of endplates in degenerated disc has been measured experimentally [Grant et al. 2002]. The cranial or caudal migration of nucleus material through these endplates, which would develop into a Schmorl's node, takes place in vertebrae with weakened endplates and underlying trabeculae. In a study involving 100 T1-L5 cadaveric specimens from donors aged 43 to 93 years old, Schmorl's nodes were found in 58% of the specimens, with 41% of the specimens having multiple nodes [Pfirrmann and Resnick 2001].

Degeneration of the intervertebral disc is another physiological change that occurs in the aged spine. It is generally associated with a loss of disc height and is found to occur in 67% of those above 60 years old [Jones et al. 1995]. The annulus fibrosis and the nucleus pulposus could develop signs of degeneration independently of each other in the aging spine. Annulus lesions are observed as early as the third decade, before nucleus degeneration occurs, while concentric tears and delamination are also observed in later stages of the degenerated annulus [Vernon-Roberts 1992]. Disc bulge and disc prolapse (disc herniation) commonly occur at the posterolateral region, as the annulus is thinnest in this area compared to the anterior or lateral regions, while the posterior longitudinal ligament prevents prolapse through the central posterior annulus [Vernon-Roberts 1992].

Degeneration of the nucleus pulposus is considered to be due to a loss of nutrients that it receives through the vertebral endplates [Buckwalter 1995]. Subsequently, the nucleus losses water content with age [Urban and McMullin 1988], and the disc pressure is decreased. A uniform disc pressure is present in the healthy spine and is lost in the degenerated spine, resulting in higher magnitudes of pressures at the peripheral regions [McNally et al. 1996]. Nucleus degeneration and loss of disc height results in excessive load through the annulus and also the facet joints, and could trigger degenerative responses at these sites. A four group classification of the grade of degeneration of the disc has been established, based on the status of the nucleus [Nachemson 1960]. In group 1, there are no changes visible to the naked eye. In group 2, some fibrous tissue in the nucleus pulposus could be seen, while the annulus remains intact. In group 3, there are some fibrous tissues in the nucleus, with isolated fissures in the annulus fibrosis. In group 4, fissures and cavities are present in both nucleus and annulus, and osteophytes are commonly found in the adjoining vertebrae.
1.3.3 Osteoporosis in the Aging Spine

Osteoporosis was defined at a 1993 consensus conference as "a systemic skeletal disease characterized by low bone mass and microarchitectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture" [Consensus 1993]. More recently, osteoporosis was defined as "a skeletal disorder characterized by compromised bone strength predisposing a person to an increased risk of fracture" [NIH 2001].

The World Health Organisation (WHO) established an operational definition of osteoporosis based on the bone mineral density (BMD) measurement compared to the mean for a normal young adult population of the same sex and race [WHO 1994, Kanis et al. 1994]. A "t-score" is assigned to the patient, where t-score corresponds to the number of standard deviations above or below the mean BMD for normal young adults. A patient is considered to be osteoporotic if the t-score is less than -2.5, and osteopenic if the t-score is between -1.0 and -2.5 (Figure 1.10). Normal bone is defined as a t-score between +2.5 and -1.0. These definitions were adopted in Canada [Brown et al. 2002a], in the United States [NOF 1998, NIH 2001], and in Europe [WHO 1994, Kanis et al. 2000].

![Figure 1.10](image)

*Figure 1.10* Typical variation of bone mineral density (BMD) with age in a population (in bold, mean BMD). Bone accrual usually occurs up to 30 years old, is maintained from 30-50 and is rapidly lost after 50 years of age. The mean BMD of the 25 year olds is usually used as a reference point (X) and the t-score is assigned based on the number of standard deviation from the mean. Osteoporosis is defined as having a t-score less than -2.5 (below the lower dashed line). Osteopenia is defined as having a t-
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score between -1 and -2.5 (between the dashed lines). Normal BMD is defined as a t-score between +2.5 and -1. [Adapted from Bartl and Frisch 2004]

A strong correlation is found between osteoporosis and fracture risk [Melton et al. 1993, Ross et al. 1996, Legrand et al. 1999]. In a recent study in Canada on fracture risk of women older than 50 years, it was reported that one in four will suffer one or more osteoporotic fractures in her remaining lifetime [Lorrain et al. 2003]. The lifetime risk of sustaining a fracture from 50 years old onward is estimated at 11-18% for women and about 5-6% for men [Lips 1997, Lorrain et al. 2003]. As many osteoporotic patients are aged and frail, they have an increased rate of falls due to weakness, poor balance, poor eyesight or other co-morbidity [Lord et al. 1994, Arnold et al. 2005]. Since osteoporotic patients have a higher chance of fracture from a fall, their risk of fracture increases with age. With increased life expectancy, this lifetime fracture risk will further increase.

In adults at age 50, lifetime risk of fracture of the vertebra is the highest compared to risk of fracture of the hip or of the wrist [Melton et al. 1993, NOF 1998]. Unlike fracture of the hips or wrists where the bone breaks into two and the patient usually needs to be hospitalised for treatment, the majority of vertebral fractures are unsymptomatic and are thus undiagnosed. It is estimated that only about 30% of vertebral fracture/deformities come to clinical attention [Cooper et al. 1993, Lips 1997]. Vertebral fracture is however a clinical marker for subsequent fractures [Papaioannou et al. 2002] and a sign for osteoporosis in the patient. Patients normally have complaints in the later stages of fracture when they present with kyphosis, loss of anterior body height of more than 20%, or fracture at other sites. As prevalence of vertebral fracture is associated with a five-fold increase in risk of sustaining a further vertebral fracture [Black et al. 1999], many osteoporotic patients have multiple vertebral fractures when presented at the clinic.

Vertebral osteoporosis commonly presents as vertebral compression fracture on radiographs. The prevalence of vertebral compression fracture increases with age and osteoporosis [Cortet et al. 2002]. Vertebral compression fracture could present as 1) concaved endplate, 2) decreased vertebral height, 3) wedge shaped vertebral body, or in combination (Figure 1.11) [Genant et al. 1993, Lenchik et al. 2004]. Wedged fractures are most common from T5-L2, while an overall decrease in vertebral height are most common in L1-L4 [De Smet et al. 1988]. Vertebral compression fracture affects the overall spinal curvature, and spinal deformity such as kyphosis and scoliosis could develop following compression fracture in the osteoporotic spine [Healey and Lane 1985, Cortet et al. 2002].
Figure 1.11 Vertebral compression fracture commonly present with a) concaved endplates, b) decreased vertebral height, c) wedge shaped vertebral body, or in combination (d-g). [Adapted from Genant et al. 1993 and Lenchik et al. 2004]

Pain, physical impairment, functional impairment and quality of life are issues associated with osteoporotic vertebral compression fractures [Hall et al. 1999, Nevitt et al. 1998, Lips et al. 1999]. Vertebral osteoporotic fracture is termed “a silent killer” as microfractures occur without symptoms or sometimes with symptomatic pain that will subside after 3-4 weeks. Patients with vertebral osteoporotic fractures often complain of back pain and require one to five days of bed rest and an additional 12 to 44 days of limited activities per year [Nevitt et al. 1998]. There might be no obvious radiologic evidence of vertebral fracture at the initial onset of the fracture and radiologic assessment could be subjective. Conservative treatments at this early stage are common and patients recover after bed rest and limited activity [Nevitt et al. 1998]. Surgical intervention is thus not necessary even if there is evidence of vertebral fracture, mainly because the pain would normally go away and there is usually no chronic neurological deficit. In recent years, some studies reported the use of percutaneous vertebroplasty, where calcium phosphate cement or PMMA cement are injected bilaterally through the pedicles into one or more levels, to
alleviate pain resulting from vertebral fracture and to prevent further vertebral fractures [Mehbod et al. 2003, Phillips 2003].

On a smaller scale, changes in the trabecular bone are observed in the aging spine [Inoue and Chao 2002, Keaveny and Yeh 2002]. Trabecular strut thickness, length and connectivity are typically reduced in the osteoporotic spine [Barger-Lux and Recker 2002]. Thinning and loss of horizontal struts in the trabecular lattice are often also observed [Mosekilde 1988, Thomsen et al. 2002], which makes the remaining vertical struts susceptible to buckling failure [Schnitzler 2003].

To prevent osteoporosis, a lifelong approach is required. Bone accrual in the young should be maximized, bone in adults should be maintained and bone loss in elderly should be prevented. In the young, the rate of bone mineral accrual is found to be highest before menarche in girls [McKay et al. 1998]. This increased accumulation of bone mineral in the young is related to increased bone mass in later life and would result in reduced fracture risk [Matkovic et al. 1979, Barr et al. 1998, Khan et al. 2000]. It is recommended that children, particularly those entering and passing through puberty, should be encouraged to participate in sports [Brown et al. 2002a]. In adults, exercise is found to maintain BMD of early postmenopausal women [Engelke et al. 2005]. Without exercise, the benefits of BMD gains in athletes are found to be lost after three to five decades of retirement [Karlsson 2004]. In the elderly, a combination of exercise and pharmacologic interventions had been shown to prevent bone loss [NIH 2001, Brown et al. 2002a, Kannus et al. 2005].

Pharmaceutical agents such as biphosphonates, calcitonin and selective estrogen-receptor modulators (SERMs), are recommended by National Agencies for inhibiting the resorption of bone in osteoporotic patients [NOF, 1998, NIH 2001, Brown et al. 2002a]. Treatment to promote bone growth in the elderly using anabolic agents such as parathyroid hormone (PTH) is a new direction to treat osteoporosis [Neer et al. 2001, Rosen and Bilezikian 2001, Rubin and Bilezikian 2002].

Osteoporosis is not considered to be an age dependent disease as it can affect people of all ages, and it can be prevented in the elderly [NIH 2001]. The proportion of the population with t-score less than -2.5, however, increases exponentially with age (Figure 1.10) [Kanis et al. 1994]. This is due, in part, to the fact that loss of bone mineral increases rapidly following menopause in women. Other factors such as genetics [Rhalston 2005], exercise and diet [Lunt et al. 2001] are important factors on BMD for the elderly patients.

Studies indicate varying rates of osteoporosis in different populations [Lunt et al. 1997]. The prevalence of osteoporosis among women aged above 50 years varies from 10.9% in
Taiwanese women [Yang et al. 2004] to 20% in white American women [Looker et al. 1997, Mazess and Barden 1999]. Among Canadian women above 50 years old, 12.1% were diagnosed with osteoporosis in 2000 [Tenenhouse et al. 2000]. In the United Kingdom, among all women above the age of 50, 22.5% were diagnosed as osteoporotic in the hip while the proportion increased to 58.7% among those above the age of 80 [Kanis et al. 1994]. The rate of osteoporosis in Europe is consistently higher than 50% for those above 80 years of age [Melton 1997, Kanis et al. 1994].

While men tend to have higher bone mass, they are also at risk for osteoporosis. Using a cut-off value of 0.545 g/cm\(^2\) in femoral neck BMD to define osteoporosis, 6% of European men and 23% of women above 50 years old were estimated to be osteoporotic [Kanis et al. 1994]. Consistent with this, a separate study carried out in the United States using a cut-off of 0.56 g/cm\(^2\) in femoral neck BMD to define osteoporosis, estimated the rates of osteoporosis in men and women above 50 years old to be 4% and 20% respectively [Looker et al. 1997]. The use of peak bone mass in the female populations to define osteoporosis in male is however controversial [Lombardi and Ross 2001]. Using the same cut-off values in male and female, the rate of osteoporosis was underestimated in men [Melton et al. 1998, Melton 2001, Lombardi and Ross 2001].

With an aging population in Canada and the rest of the world, the number of people affected by osteoporosis will definitely increase in the near future [Papadimitropoulos et al. 1997, Brown et al. 2002a]. In Canada, where 1.2 million women and 0.7 million men are expected to be above 80 years old by 2026 [Statistics Canada 2001], 0.6 million women and a conservative estimate of 0.1 million men in this age range alone would be osteoporotic. By 2051, with 2.0 million women and 1.3 million men above 80 [Statistics Canada 2001], there will be 1.0 million osteoporotic women and at least 0.2 million osteoporotic men from this age range alone.

A total of 109,502 hospitalization days due to osteoporosis and osteoporosis related vertebral fractures, involving 4,033 males and 23,657 females, were recorded in 1993 [Goeree et al. 1996]. The acute care cost for vertebral fractures was estimated at CDN$72 million (1993) dollars, while the total direct costs due to osteoporotic fractures including hospitalization, drugs, long-term and chronic care to the Canadian health care system in 1993 was estimated to be CDN$1.3 billion [Goeree et al. 1996]. The cost of health expenditure on osteoporosis related fractures will increase proportionally with the increase in absolute number of osteoporotic elderly in the population [Wiktorowicz et al. 2001].
1.3.4 Spinal Degeneration and Osteoporosis

Osteoporosis and disc degeneration are generally mutually exclusive in the elderly spine. While osteoporosis of the spine is commonly associated with changes to the vertebral body, it could lead to other degenerative conditions involving the disc and facet joints (Figure 1.12). Alteration of stresses in the osteoporotic spine was postulated as a pathway leading to disc degeneration [Margulies et al. 1996]. For example, with a weak endplate and underlying bone, Schmorl's nodes could result from local stresses exceeding the material strength of the endplate. Increased endplate concavity, common in the osteoporotic spine, could also lead to increased stresses in the annulus fibrosus. Spinal deformity such as kyphosis following vertebral compression fracture, increased load in the facet and altered load distribution, and leaded to facet degeneration and facet osteoarthritis.

Disc degeneration is associated with loss of disc height, facet degeneration, disc bulge, and osteophyte growth. Disc bulge and tension in the anterior longitudinal ligament was postulated to result in stresses in the local area, and together with adaptive bone remodelling, results in osteophyte growth [Kumaresan et al. 2001].

Disc degeneration could also lead to an altered load transmission path through the spine (Figure 1.12). In discs with a hydrated nucleus, load transmission passes through the nucleus and the central region of the vertebral. In degenerated discs, load transmission through the nucleus diminishes and load transmission is transferred through the annulus, onto the peripheral regions of the vertebral body [Horst and Brinckmann 1981, Kurowski and Kubo 1986, Adams et al. 1996]. In support of this observation, a finite element model simulating a degenerated disc also found a shift in load path towards the peripheral regions of the vertebral body [Polikeit et al. 2004].

As a result of the different load path through the intervertebral disc in the degenerated spine, the facet joints sustain a higher compressive load during erect standing [Pollintine et al. 2004]. Stress-shielding could occur within the anterior column, and could subsequently lead to a decrease in compressive strength, stiffness and modulus of the trabecular bone at the central regions of the vertebral body [Keller et al. 1989]. Subsequently, the weakened anterior column is susceptible to a higher risk of osteoporotic compression fracture.

A negative correlation between disc degeneration and low BMD was noted in the literature [Jones et al. 1995, Harada et al. 1998, Nanjo et al. 2003, Pye et al. 2006]. In other words, disc degeneration would be more common in patients with high BMD, and conversely, patients with low BMD would be less likely to have disc degeneration. Furthermore, an inverse relation was found to exist between vertebral body deformity and intervertebral disc narrowing.
[Okawa et al. 1996]. Also, an inverse relation between osteoporosis and spondylosis was reported [Miyakoshi et al. 2003]. Therefore, these studies further support the two different pathways of spinal degeneration for the elderly reported in the literature (Figure 1.12). In the first condition, there is a healthy disc and weak bone, while in the second condition there is a degenerated disc and healthy bone. In the first condition, spondylosis was not present in later stages. In the second scenario of normal bone mass and degenerated disc, spondylosis developed in the later stages.

![Diagram of spinal degeneration](image)

**Figure 1.12** Progression of spinal degeneration in the elderly spine from weak bone [Margulies et al. 1996] or from degenerated disc [Vernon-Roberts 1992]. The vertical arrows indicate load paths through the anterior and posterior regions of the functional spinal unit (FSU) in compression. (Top row): The combination of a healthy disc with weak vertebra bone could result in osteoporotic compression fracture and Schmorl's node. Further compression fracture could result in a wedged vertebra with kyphosis of the spinal column. The increased load at the facet joint could lead to facet arthritis. Disc bulge could also result with a hydrated disc. (Bottom row): A degenerated nucleus would result in a loss of disc height, increased disc bulge and a shift in load path through the annulus and facet joints. Disc bulge and tension in the anterior longitudinal ligament could be the cause for osteophytes to grow at the anterolateral regions of the vertebral rim. The increased peripheral load, as a result of loss of disc pressure, could cause buckling of the vertebral cortex. Further loss...
of disc height and osteophyte growths could result in bridging osteophytes. The increased load at the facet joint could again lead to facet degeneration. A decrease in bone mass at the core of the vertebral could result from decreased loading through the nucleus following adaptive bone remodelling.

1.3.5 Biomechanics of the Aged Spine

Biomechanical properties of the spine, such as its kinematics and the overall load bearing capacity, are affected in the elderly patients with spinal degeneration and/or osteoporosis. These changes to the biomechanical properties could be attributed in part to changes in geometric properties (Figures 1.9 and 1.11) and also to material properties [Aspden 2003]. The three fundamental roles of allowing motion, bearing load and protecting the spinal cord could subsequently become undermined in the aged spine due to these changes in biomechanics.

Changes to the kinematics of the FSU such as its stiffness, laxity (neutral zone) and ROM have been reported in the literature. Stiffness of cadaver FSUs initially decreases during early disc degeneration and increases with severe disc degeneration [Brown et al. 2002b]. In a separate animal study, the stiffness of degenerated disc is higher than in intact disc when subjected to cyclic loading [Kaigle et al. 1998]. Higher joint laxity is present in degenerated spines than in normal spines in a flexibility study of 47 cadaveric lumbar FSUs in axial rotation [Mimura et al. 1994]. In another study, the neutral zone of degenerated mouse tail discs increases by 33% in flexion following compressive overloading to induce degeneration [Lotz et al. 1998]. ROM of degenerated discs has been found to increase with increasing severity in degeneration grades, but decrease for the worst degeneration grade in two separate cadaver studies [Fujiwara et al. 2000, Tanaka et al. 2001]. It appears that the overall change to mechanics of the degenerated disc is an increase in stiffness and joint laxity, with changes to the ROM dependent on the grade of degeneration.

Geometric changes of the vertebral body in the elderly have been reported. In general, the elderly vertebra has larger overall dimensions in the antero-posterior direction [Evans et al. 1993] and has smaller vertebral heights [Diacinti et al. 1995]. This increase in antero-posterior dimension could increase load bearing area in the elderly. Changes in geometric properties on bone strength have been studied in the long bone [Aspden 2002, Russo et al. 2006] and in the spine [Duan et al. 2001, 2005]. Age related increase in cross sectional area and decrease in volumetric BMD of the vertebral body increases the risk of vertebral fracture [Duan et al. 2001, 2005].
Geometric changes of the spinal column, such as kyphosis, could also affect the load applied to the lumbar vertebrae. The centre of gravity of the upper body is located more ventrally in a kyphotic patient and a larger flexion moment is experienced in the lumbar region [Rohlmann et al. 2001]. This change in load pattern in the kyphotic patient affects the overall load bearing capacity of the spine.

Material properties of the bone and surrounding soft tissues have been observed to degrade in elderly patients. The trabeculae in the osteoporotic spine are oriented more vertically while trabeculae in normal bone are more isotropic [Inoue and Chao 2002]. This results in the vertebrae of the aged being strong in axial compression only, but weak in all other loading directions. Ligament and muscle strength are also generally weaker in elderly patients. Elastic modulus of the anterior longitudinal ligament has been reported to increase by 135% with aging (from 21 to 79 years old), while it's tensile strength decreases by 55% [Neumann et al. 1994]. Similarly, the elastic modulus and tensile strength of the L4-L5 spinous process and supraspinous/interspinous ligament complex has been reported to decrease by about 50% with aging [Iida et al. 2002]. Moreover, sarcopenia, the loss of skeletal muscle mass and strength in the elderly, has a 30% prevalence among the population above 60 years old [Doherty 2003].

1.3.6 Clinical Problems of the Aging Spine

Back pain is a major factor affecting physical health status in many adults and remains a problem in the elderly [Hartvigsen et al. 2003]. Any sites in the spine could be the source of back pain, and it could arise from any structure that receives an innervation, including any ligament, muscle, fascia, joint or disc [Adams et al. 2002]. The three general areas in the spine where pain could originate from are: A) deep and originating in the FSU, B) superficial and emanating from skin, fascia, and muscles, and C) from the spinal roots protected by the spinal column [O'Brien 1984]. Deep pain originating from within the FSU is a problem in the degenerated spine. The degenerated disc, facets and vertebra are potential sources of deep spinal pain [Martin et al. 2002, Benoist 2003].

Spinal cord or root compression results in severe pain, sensory loss and/or loss of function of the extremities. As a result of an impingement on the spinal cord or spinal roots, the motor and/or sensory function of the central nervous system could be compromised and surgical intervention is often necessary to resolve the problem. Impingement on the dorsal root could result in loss of sensation, an impingement on the ventral root could result in loss of motor function and impingement of more distal spinal roots could result in loss of both motor and sensory function. Surgical intervention to alleviate the pain and restore the motor and sensory
functions would often involve surgical disruption of some of the spine's structure in order to access the relevant impingement sites. As a result, the normal motion and load transfer function of the affected FSU may be compromised.

Back pain causes disability and results in reduction in productivity at the work place [Kopec and Esdaile 1998]. The patient's ability to bear load could also be diminished by back pain and in some cases there is also inability to stand or walk a short distance. Neural deficit, diminished ROM and diminished load bearing roles are common in patients with back pain. Surgical intervention may alleviate the chronic pain and associated disability [Dawson and Bernbeck 1998].

Instability is another problem in the aging spine. Spondylolisthesis is an example of spinal instability that occurs commonly at the lumbosacral level (L4-L5 and L5-S1), when one vertebra shifts forward upon another. The spine is unstable, in such a case, as the ligaments, discs and facets are unable to prevent forward shearing of the superior vertebral level (L5) against the sacrum [DeWald 2002].

Degenerative conditions in the thoracolumbar spine often result in spinal pain, instability and deformity. Degenerative spondylolysis, spondylolisthesis [Bassewitz and Herkowitz 2001, Herkowitz and Kurz 1991], spinal stenosis [Sengupta and Herkowitz 2003, Postacchini 1999] and adult degenerative spinal kyphosis and scoliosis [Healey and Lane 1985] are common degenerative conditions that may affect the elderly. Degenerative spondylolysis is the condition associated with disc degeneration and growth of osteophytes in the elderly, resulting in an increase in vertebral body dimensions, posterior disc bulge and occasionally leading to spinal stenosis [Vernon-Roberts 1992]. Degenerative spondylolisthesis is the condition where there is excessive forward translation of a spinal level against the next as a result of degeneration primarily in the facet joints but also in the discs. Canal stenosis is the narrowing of the spinal canal resulting in constriction of the spinal cord or cauda equina, while intervertebral stenosis is the narrowing of the spinal canal resulting in constriction or compression of the spinal nerve roots [Cinotti et al. 2002]. Compression to the spinal cord or spinal nerve roots results in pain and loss of lower limb function and surgical intervention would be necessary to stabilize the affected segment [Sengupta and Herkowitz 2005].

Spinal deformity such as kyphosis and scoliosis could also affect the well-being of the elderly. Adult spinal deformity often occurs with vertebral deformity involving one or more levels. Kyphosis is generally the result of vertebral compression fracture with loss of anterior body height, while adult degenerative scoliosis results from lateral wedge vertebral compression fracture or asymmetric disc narrowing [Healey and Lane 1985, De Smet et al. 1988, Hu 1997b].
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Kyphosis could also result from degenerative disc disease or osteoarthritis, with no vertebral fracture or osteoporosis [Osman et al. 1994, Schneider et al. 2004].

Osteoporotic fractures, described in an earlier section, could lead to the deformity of one or more vertebral bodies in the elderly. The prevalence of at least one vertebral deformity in those aged 65 years or older was reported to be 39%, and similar in both elderly men and women [Pluijm et al. 2000]. Vertebral deformity is associated with impairment, functional limitations, disability and poor self-perceived health [Lyles et al. 1993, Burger et al. 1997, Pluijm et al. 2000]. Vertebral deformity in older women is also associated with significant back pain [Lau et al. 1998], and also with increased risks of mortality and hospitalization [Ensrud et al. 2000].

1.4 Surgical Management of the Aging Spine

1.4.1 Conditions Requiring Spinal Stabilization

In a recent special issue of the Journal of Neurosurgery in 2005, titled “Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine”, detailed guidelines were comprehensively presented. In one recommendation, for example, “Lumbar fusion is recommended as a treatment for carefully selected patients with disabling low back pain due to one- or two-level degenerative disease without stenosis or spondylolisthesis” [Resnick et al. 2005].

The compromise of one or more of the three fundamental roles of protection, load bearing and motion of the degenerated spine are the underlying principles where surgical intervention might be necessary. Alleviation of pain and return of neurological functions for the patients are usually reasons for surgical intervention [Postacchini 1999, Bassewitz and Herkowitz 2001, Sengupta and Herkowitz 2003]. Pain is closely related to a loss in function (motion and load bearing) and could be caused by spinal root compression (loss of protection). Loss of neurological function on the other hand is a result of spinal root compression and could result in pain and also loss of function.

Other conditions that are not limited to the elderly population, such as trauma [Nguyen et al. 2003] and metastatic diseases [Fisher et al. 2005], could also result in the loss of performance by the spine of its fundamental roles and would also necessitate surgical intervention.

Surgical treatments are often necessary for such conditions and spinal stabilization is often indicated to provide stability. Spinal fusion in patients with degenerative spinal disorders
could result in improved spinal stability and improved neurological function [Vaccaro and Ball 2000].

1.4.2 General Surgical Approach

Spinal arthrodesis (fusion) is a common strategy carried out in patients with severe instability for the various problems of the aging spine [Postacchini 1999, Vaccaro and Ball 2000, Bassewitz and Herkowitz 2001, Sengupta and Herkowitz 2003]. In the surgical treatment of these patients, osteophytes and any protruding disc material causing nerve root compression are identified and removed. As patients with spondylosis often have degenerated discs, resulting in diminished disc height and intervertebral stenosis, interbody devices are often implanted into the intervertebral disc space to restore disc height.

The objective in spinal fusion is to restore intervertebral disc heights, to create bone growth across vertebral bodies of unstable levels, to return to normal neurological function, and to provide relief of pain. Cancellous bone grafts are commonly inserted into and around with the interbody devices to promote bony fusion. Bony fusion is usually completed in three to six months.

Spinal stabilization with rigid instrumentation devices such as pedicle screws and rods, or anterior body screws and plates, is often necessary to provide structural support. The posterior surgical approach for example would require removal of posterior bony structures and the remaining structure would be structurally unsound following implantation with the interbody device alone. Pedicle screw instrumentation (Figure 1.13) is thus commonly used with interbody devices to maintain stability and alignment so that bony fusion could occur. Spinal fusion carried out with rigid fixation such as pedicle screws has been reported to promote fusion [Kim et al. 1990, Zdeblick 1993, Thomsen et al. 1997, Bjarke et al. 2002].
The immediate post-operative rigidity of the instrumented level is important for the fusion process to take place [Benzel 1995]. Either too little load transmitted through or too much motion of the bone grafts could result in suboptimal conditions for osteointegration to take place [Bauer and Muschler 2000]. Non-fusion in the long run may result in implant loosening or fatigue failure due to the cyclical loadings and reliance on implants to bear loads [Babat et al. 2004]. The challenge of achieving post-operative rigidity is confounded in the osteoporotic patients due to the weak bone-implant interface.

1.4.3 Clinical Problems with Surgical Management

The low bone quality in the osteoporotic elderly patient makes surgical intervention with spinal implants a challenge [Oxland et al. 1996, Diwan et al. 2003b, Glassman and Alegre 2003]. Potential problems include hardware loosening and subsequent adjacent level effects.

Hardware loosening was reported to result in failure of the surgical procedure [Paramore et al. 1996, Babat et al. 2004]. Hardware loosening is caused by failure at the bone-implant interface and is an issue in the osteoporotic patient [Andersson et al. 2000]. An increase in stresses at the bone-implant interface following surgery results in localised failure of surrounding trabeculae and in subsequent device loosening. In particular, failure at the pedicle screw-bone interface could result in pedicle screw pullout [Paramore et al. 1996, Babat et al. 2004].
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2004], while failure at the interbody cage-bone interface could result in cage subsidence into the vertebra [Gercek et al. 2003, Polikeit et al. 2003].

Pedicle screw loosening is a clinical problem in the osteoporotic patient [Hu 1997b, Okuyama et al. 2001]. As cancellous bone is more affected by osteoporosis, loosening of pedicle screws commonly occurs within the vertebral body. Moreover, higher stress is also concentrated at the distal end of the pedicle screw. The failure pattern of pedicle screw loosening has been described as a butterfly-shaped void within the pedicle tract [Law et al. 1993]. The pedicle acts as a fulcrum point for the pedicle screw under toggle loads. In a clinical study of 52 patients who underwent pedicle screw fixation, the mean BMD of patients with radiographic screw loosening was significantly lower than those without loosening [Okuyama et al. 2001]. Moreover, the mean BMD of patients with non-union of the fusion procedure was significantly lower than those with successful union. In vitro studies had similarly demonstrated the association between stability of pedicle screws and low vertebral BMD [Bennett et al. 1997, Coe et al. 1990, Halvorson et al. 1994, Okuyama et al. 1993, Soshi et al. 1991, Wittenberg et al. 1993, Yamagata et al. 1992].

Interbody device subsidence is another problem with spinal fusion in osteoporotic bone. As in the case for pedicle screws, the post operative increase in stresses at the interbody device-bone interface results in trabecular failure and subsequent device loosening. Subsidence of interbody devices into adjacent endplates has been identified to involve failure of the subchondral trabecular bone [Hasagawa et al. 2001]. Thus failure at the bone-implant interface rather than failure of the implant results in subsidence of interbody fusion device. Local compressive strength of the endplate decreases with vertebral BMD [Grant et al. 2002], and both parameters play an important role in preventing interbody device subsidence. BMD was highly correlated with failure loads of interbody cages in the lumbar spine in an in vitro study [Jost et al. 1998]. Other in vitro studies also found strong correlation between BMD and failure loads of interbody devices [Closkey et al. 1993, Hasegawa et al. 2001, Lim et al. 2001, Steffen et al. 2000, Tsantrizos et al. 2000].

Subsequent failure at the adjacent segments following spinal fixation is another challenge faced by the spine surgeon in the elderly patients [Eck et al. 1999]. Adjacent segments normally refer to one or two levels cephalad or caudal to the instrumented levels. The terms 'adjacent level effects' and 'adjacent segment biomechanics' have been used to refer to the biomechanical changes observed at the segments adjacent to a spinal fusion [Ha et al. 1993, Kumar et al. 2001, Panjabi 2002, Panjabi and Goel 2005], while 'adjacent segment degeneration' and 'adjacent segment disease' have been used to refer to the radiographically or
clinically observed degenerative changes and related new symptoms [Eck et al. 1999, Park et al. 2004, Hilibrand and Robbins 2004]. Accelerated failure of adjacent levels has been reported following rigid spinal fixation [Lee 1988]. This was attributed to both the degenerative progression in the elderly and to the increased demands placed on these adjacent levels following spinal fixation [Hilibrand and Robbins 2004]. Biomechanical changes such as increased load, mobility and intradiscal pressure in adjacent segments after fusion had been shown in biomechanical and radiographic studies and outlined in recent review articles [Eck et al. 1999, Park et al. 2004]. It is the interest of the biomechanical engineer to reduce these biomechanical changes which contribute towards adjacent level effects.

Pedicle screw loosening and interbody device subsidence could result in surgical failure and would require revision surgery. Accelerated failure at the adjacent segment could also necessitate revision surgery to address the new affected levels. Further details on pedicle screw loosening are discussed in Chapter 3, further details on interbody device subsidence are discussed in Chapters 4 and 5, further discussion on increasing overall construct stiffness of a spinal fixation are in Chapter 6, and further discussion on adjacent level effects are in Chapter 7.

The rate of revision surgery following spinal fusion was reported at about 10% [Hu et al. 1997a, Diwan et al. 2003a], 13% [Greiner-Perth et al. 2004] and 18% [Malter et al. 1998]. Pseudoarthrosis at the initial fusion level was reportedly a main indication for revision surgery. Adjacent level failures, such as juxtafusion kyphosis, scoliosis or degeneration, or a combination of these problems, were also cause for revision surgery [Diwan et al. 2003a, 2003b]. Augmentation to existing fusion and extension of the fusion to adjacent segment(s) were common indications for revisions. Revision surgery in the osteoporotic spine poses a higher level of complexity than the initial surgery [Dvorak and Fisher 1999]. The presence of fibrous scar tissue, altered anatomy and poor vascularity can predispose patients to higher rates of complications. Increased length of surgery, more extensive exposure, higher rates of dural tears and infections complicate revision spine surgery [Diwan et al. 2003a, 2003b]. In order to reduce the number of revision surgeries in frail osteoporotic patients, an effective surgical technique needs to be identified such that the problems of implant loosening and adjacent level effect are addressed at the same time. No technique currently available is capable of addressing both implant loosening and adjacent level effects in the osteoporotic spine.
1.4.4 Current Surgical Strategies

There are currently two concepts to address adjacent level effects. In the first concept, internal fixation is used across multiple segments to reduce motion across all levels that could potentially develop adjacent level effects [Hu 1997b, Inaoka et al. 2002]. This concept is currently used to prevent adjacent segment disease. The other concept is to maintain motion of the spine with spinal arthroplasty rather than spinal fusion [Robertson et al. 2005, Regan 2005]. The use of spinal arthroplasty is however a recent concept. Further discussions of this concept for the elderly spine are in the next section.

Current surgical strategies adopted by spine surgeons to address device loosening can be broadly categorized into two groups. To prevent pedicle screw loosening, one technique is to increase the number of anchor points [Hu 1997b, Inaoka et al. 2002]. Another technique that has become popular is the cement augmentation of screws, which was shown to biomechanically improve fixation strength at the screw-bone interface [Cameron et al. 1975, Zindrick et al. 1986, Wittenberg et al. 1993, Lotz et al. 1997, Moore et al. 1997, Yerby et al. 1998, Ignatius et al. 2001, Bai et al. 2001, Sarzier et al. 2002, Schultheiss et al. 2004, Cook et al. 2004, Renner et al. 2004].

In recent years, the use of cements such as polymethylmethacrylate (PMMA) and calcium phosphate cement are increasingly used in osteoporotic patients. The use of cement in osteoporotic patients reportedly improved fixation in the osteoporotic hip [Urist 1975], knee [Larsson and Bauer 2002] and shoulder [Friedman 1998]. In the spine, cement is used in the procedures of kyphoplasty [Rhyne et al. 2004] and vertebroplasty [Barr et al. 2000]. Patients with osteoporotic compression fractures of the spine are injected with cement percutaneously with much clinical success. A recent clinical review also reported the use of cement in augmenting screw fixation and in preventing interbody device subsidence [Heini 2005].

The long term side effects of cement, if any, are not known. A known complication with cement use is the extrusion of cement into the foramina or blood vessels during insertion. Cement is thus contraindicated when there is a breach of the pedicle wall during screw insertion. Real-time imaging during cement injection greatly improves the safety of injecting cement into the spine. The exothermic chemical reaction during the in situ curing of the cement could also cause damage to neighbouring cells. Calcium phosphate cement is used recently in place of PMMA because of the lower curing temperature and also because calcium phosphate is the basic mineral in bone and might be more biocompatible.
1.4.5 New Surgical Strategies

Research directions that could become part of future surgical techniques to improve fixation of the osteoporotic spine include the use of bone growth factors and motion preservation devices.

Bone morphogenetic protein (BMP) had been shown to promote bone growth in animal models [Lovell et al. 1989, Alden et al. 2002]. In humans, the use of recombinant human BMP type 2 (rhBMP-2) with threaded fusion cages was also shown to result in consistent osteoinduction in single level lumbar fusion [Boden et al. 2000]. Other clinical trials with humans also reported successful osteoinduction with fusion cages [Burkus et al. 2002, Haid et al. 2004, Boden et al. 2002]. The use of rhBMP-2 to fill the fusion cages resulted in reduced pain for the patient as it replaced the need to harvest bone grafts from the iliac crest. The use of BMP in spinal fusion has not been carried out in osteoporotic patients to date and future studies in this area would be important. The administration of rhBMP-2 to osteopenic mice was found to prevent bone loss [Turgeman et al. 2002] and thus its potential in osteoporotic patients to promote bone growth is encouraging. The use of BMP might, in the future, be a solution to prevent implant loosening in the osteoporotic patients.

Spinal arthroplasty, as mentioned earlier, has been recently reported to prevent adjacent segment disease [Robertson et al. 2005]. Spinal arthroplasty can be considered to be a new surgical technique as its use has not been widespread. The Charité Artificial Disc is indicated for the treatment of degenerative disc disease and has been in use for the longest time as compared to all other spinal arthroplasty devices. In a recent 17 years follow-up on the performance of the Charité, the authors reported an 11% reoperation rate in 53 patients [Putzier et al. 2005]. A prospective randomized control trial of the Charité in the US demonstrated equivalent quantitative clinical outcome as compared with the BAK fusion device and the authors recommended it as "a safe and effective alternative to fusion for the surgical treatment of symptomatic disc degeneration in properly indicated patients" [Blumenthal et al. 2005]. The use of motion preservation devices, while not currently indicated in the elderly population, might become a possible solution to prevent adjacent level disease in the near future.

1.4.6 Problem with Device Evaluation

Current spinal devices are not designed for the osteoporotic patient group. Implant manufacturers design their products to meet the requirements stipulated in test standards, so as to gain approval for marketing their products. Test standards usually include testing the properties of the implants per se, such as static failure strength, fatigue life, and biocompatibility.
issues. One such test standard is the ASTM Standard for the test of pedicle screws (ASTM F1717) to determine failure strength and fatigue lifespan [ASTM 2001]. The rationale for such a test is that pedicle screws should have sufficiently long fatigue lifespan in clinical use. In order to attain the required fatigue lifespan and failure strength, pedicle screws systems are typically rigid as compared to the stiffness of neighbouring bone. High stresses at the interface with neighbouring bone results in localized trabecular bone failure. Implant loosening is thus common in the osteoporotic patient group.

Current spinal device test standards do not include the investigation of rigid spinal implant on the interface with neighbouring bone. For example, no equivalent test standard focuses on the effect of rigid implant systems on the failure of surrounding bone. Further detail on this issue of bone density is discussed in Chapter 2.

In a consensus meeting on treatment of osteoporosis in 1997, spinal instrumentation in osteoporotic patients was considered not advisable, and a need for new instrumentation that would allow for rigid fixation and bone healing without affecting adjacent levels was identified [Andersson et al. 1997]. The success of polymethylmethacrylate (PMMA) and other bone cement in reinforcement of osteoporotic vertebral fractures in more recent years had been promising [Heini 2005].

1.5 Motivation

Spinal degeneration and osteoporosis can negatively affect the quality of life of the elderly. Deformity, fracture and degeneration of the spine can produce substantial pain and disability which results in a diminished quality of life. Surgical intervention in the spine is often necessary when there is neurological deficit or chronic pain. The main goal of surgical treatment is to achieve early ambulation and pain relief. Unfortunately, the issues of implant loosening and adjacent level effects in the spine remain a problem in the aging spine.

This study is motivated by the desire to provide biomechanical input to the spine surgeon in their treatment of the elderly patients using spinal fusion techniques. Specifically, the objective of this research is to enable the spine surgeon to prevent pedicle screw loosening, interbody device subsidence, and subsequent adjacent level disease. Firstly, the implant-bone interfaces should be sufficiently strong to withstand the loads transmitted and not result in subsidence or loosening. Secondly, the surgical intervention should not result in further complications such as adjacent level effects with the necessity to follow up with another surgery. The surgery should ideally achieve satisfactory results with the initial surgical intervention that would outlast the lifespan of the osteoporotic patient.
Chapter 1  Introduction

1.6  Objectives

The main objective of this thesis is to provide insights and directions in the use of devices to address both the problems of implant loosening and adjacent level effects in the aging spine. This is accomplished with the following specific goals:

i) To highlight the importance of vertebral bone density in pedicle screw fixation (Chapter 2).

ii) To compare three pedicle screws augmentation techniques, using calcium phosphate cement, laminar hooks and sublaminar wires, as a mean of preventing implant loosening (Chapter 3).

iii) To compare two interbody sizes and three shapes as a mean of preventing device subsidence (Chapter 4).

iv) To determine the effects of screw fixation and cement augmentation of screws on interbody device subsidence (Chapter 5).

v) To compare two current surgical techniques, using cement augmentation of pedicle screws or using posterior rod extension, as means of achieving adequate stabilization in the osteoporotic patients (Chapter 6).

vi) To compare three posterior rod extension conditions, using rigid rods, flexible rods or without extension rods, as means of preventing adverse accelerated degeneration at the adjacent levels (Chapter 7).

1.7  Scope

This thesis is limited to the study of the thoracolumbar spine using in vitro biomechanical tests. The first two sections on pedicle screws were carried out using single vertebral bodies with simulated physiological loads applied to the screw heads. Chapter 2 addresses the issue of pedicle screw testing adopted by the ASTM and the effects of BMD. Chapter 3 compares three current clinical techniques of improving pedicle screw fixation: calcium phosphate cement, laminar hooks and sublaminar wire augmentation.

The next two chapters on interbody device subsidence were also carried out using single vertebral bodies. Superior endplates of thoracolumbar vertebrae were loaded to failure under axial compressive load. Chapter 4 provides suggestions to improve the bone-implant interface of interbody devices with different cage shape and sizes. Chapter 5 provides further ideas to reduce interbody device subsidence with vertebral screws and cement augmentation of screws.

In the last two chapters, multisegmental thoracolumbar spines (T9-L3 or T8-L2) were used. Chapter 6 addresses the issue of motion after fixation of a corpectomy in the osteoporotic spine and compares between cement augmentation of screws and extension of posterior
instrumentation. Chapter 7 compares adjacent level motion and strains following cement augmentation and extension of posterior instrumentation.

1.8 References


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Chapter 2

Importance of Vertebral Bone Density in Pedicle Screw Testing

Overview

This chapter highlights the importance of vertebral bone density in pedicle screw fixation and testing. Current ASTM assessment methods, particularly the ASTM F1717, use synthetic elements as vertebral surrogates and do not address important in vivo performance and failure characteristics. The effectiveness of spinal implants in fixation is dependent upon the bone-implant interface, and thus on vertebral bone density.

The results in this study was presented to the American Standards of Testing and Materials (ASTM) Committee F04 on Medical and Surgical Materials and Devices at the "Symposium on Spinal Implants: Are We Evaluating Them Appropriately?" held in Dallas, Texas, Nov 6-7 2001. It was subsequently published as a peer reviewed article:

2. Importance of Vertebral Bone Density in Pedicle Screws Testing

2.1 Introduction

Spinal instrumentation is commonly used to stabilize the spine in conditions of trauma, tumor, deformity, and degeneration. Various implant types are in existence, including pedicle screws, pedicle and laminar hooks, wires, cables, rods and plates, as well as anterior devices such as interbody cages. The pre-clinical assessment of these devices may involve many different types of testing, as described previously [Panjabi 1988, Ashman et al. 1989]. Within the last decade, ASTM standard test methods for spinal implants have been developed. One such Standard is the ASTM Test Methods for Static and Fatigue for Spinal Implant Constructs in a Corpectomy Model (F1717) [ASTM 2001]. The focus of this article is to address the relevance of F1717 to the clinical situation.

In general, spinal instrumentation is effective in correcting deformity and stabilizing the spine, however, failures do occur. Clinical mechanisms of instrumentation failure are varied, but include intra-operative, or early post-operative fixation failure, late development of pseudoarthrosis with concomitant implant loosening, and disc or vertebra failure adjacent to the instrumentation [Paramore et al. 1996, McAfee et al. 1999, Eck et al. 2001, Uzi et al. 2001]. Ideally, testing methods would address these failure mechanisms, but this can be a significant challenge. For example, adjacent segment effects represent both a biological and mechanical problem that may be difficult to simulate in a pre-clinical model. However, early fixation failure represents a series of failure modes that can be evaluated in a pre-clinical model, including both failure of the specific device or the interface between the device and the spine. Clinical investigation suggests that it is the interface between the device and the spine that is the most common site of early failure [Paramore et al. 1996, Eck et al. 2001]. Essentially, this represents failure of the bone-implant interface.

Biomechanical studies have demonstrated that bone mineral density, and more so the presence of osteoporosis, is a critical factor in the success of achieving rigid fixation both for pedicle screws [Zindrick et al. 1986, Soshi et al. 1991, Wittenberg et al. 1991, Yamagata et al. 1992, Okuyama et al. 1993, Halvorson et al. 1994, Pfeiffer et al. 1996] and interbody cages [Oxland et al. 1996, Lund et al. 1998]. In general, pedicle screw pull-out strength and toggle amplitude as well as interbody cage subsidence resistance and overall stabilisation have been shown to be linearly correlated to BMD.

The F1717 uses synthetic elements as vertebral surrogates and therefore does not address the bone-implant interface. The F1717 does evaluate the mechanical properties of the screw-rod constructs, particularly in fatigue failure. However, such failure is not a common
mode of clinical failure [Paramore et al. 1996, McAfee et al. 1999, Eck et al. 2001, Uzi et al. 2001]. Since cancellous bone has an elastic modulus that ranges between 0.01 to 1.0 GPa, whereas UHMWPE has a modulus of 1 GPa, the construct would be expected to behave differently if the bone was included in the assessment.

The primary purpose of this study was to contrast the mechanical behaviour of pedicle screws under short-term cyclic physiologic loads when inserted in cadaveric vertebrae versus synthetic surrogates. Secondarily, the effect of bone mineral density on the pedicle screw behaviour was investigated, as was a novel model of simulating a situation where the screw-bone interface is recognised as being poor. In essence, we are questioning whether the fixation at the bone-implant interface can be measured during short-term cyclic testing.

2.2 Materials and Methods

2.2.1 Specimen Preparation

Eight lower lumbar cadaveric vertebrae (three L3s, three L4s, two L5s) from a previous endplate indentation study [Grant et al. 2001] were used in this study. All specimens had intact pedicles. Lateral DEXA bone mineral density (BMD) ranged from 0.30 to 1.04 g/cm$^2$ with a mean of 0.70 g/cm$^2$.

Pedicle screws of uniform size (Universal Spinal System, USS diameter 6 mm and length 45 mm, Stainless Steel, Synthes Spine, Paoli, PA) were inserted into each pedicle. A single spine surgeon (Dr Brian Kwon) carried out all screw insertions for the specimens. Two types of pedicle screw hole preparation were carried out in a randomised manner for each specimen. One side was prepared in the normal recommended fashion using a blunt pedicle probe to a depth of approximately 50 mm. The other side was prepared with an overdrilled hole using a 15/64 inch (5.95 mm) drill bit to a depth of 50 mm. The latter method was an attempt to create a "loosened" screw model. Accuracy of insertion was checked by direct palpation of the pedicle walls. Radiographs were taken in the cephalo-caudad (axial) direction to verify screw placement through the pedicle. Specimens were defrosted at room temperature for 4 to 5 hours before screw insertions were carried out. After the screws had been inserted, the specimens were soaked in saline solution and submerged in a water bath maintained at 37 °C for 16 to 24 hours before being tested.

2.2.2 Pedicle Screw Loading

A custom built jig was used to test the pedicle screws with loads simulating physiological conditions. The basic test configuration was similar to the ASTM standard (F1717), but a
cadaveric vertebra replaced the inferior block and the dimensions were modified to reflect recent in vivo load data [Rohlmann et al. 1997, Rohlmann et al. 2000]. To allow comparison between screw fixation in a vertebra and UHMWPE, an inferior block of UHMWPE was used in other tests. A vertical connecting rod of length 140 mm was attached to the two pedicles screws, which were inserted in a UHMWPE block and in the pedicle of a cadaveric specimen respectively (Figure 2.1). The inferior blocks and specimens were clamped rigidly to the base of the testing machine, which is a different setup from the ASTM standard. This fixation method was selected to prevent the specimen breakdown that would probably occur if a single loading point had been used for the vertebra. The design of a rigid inferior mount results in somewhat different moments being applied to the screw-vertebra interface, depending upon the vertebral material. A two-dimensional finite element analysis demonstrated this effect (Figure 2.2).

Figure 2.1  (a) Lateral and (b) frontal view of the testing jig. A single vertical rod connects the two pedicle screws, which in turn are inserted into a UHMWPE block superiorly and into the pedicle of a cadaveric specimen inferiorly. Other tests included a UHMWPE block inferiorly as well. The pedicle screws were placed parallel to each other and the connecting rod was aligned vertically before every test. The vertebral body was securely clamped to the base of the testing machine, whereas the UHMWPE was allowed to pivot about an axis 35 mm away from the vertical rod.
Figure 2.2 A two-dimensional finite element analysis determined the variation in ground reaction moments as a factor of elastic modulus of the lower block. The lower block was rigidly fixed in translation and rotation while the upper block was allowed to rotate freely.

The initial position of the specimen was such that the pedicle screw was in a horizontal position (Figure 2.1). The upper segment of the testing apparatus was attached to the actuator arm of the testing machine and was hinged to the UHMWPE block, allowing the block to freely rotate about a single axis. The horizontal distance between the hinge and the vertical rod was 35 mm. Liquid levels were used to ensure that the vertical connecting rod was in an absolute vertical position prior to toggle tests. A single UHMWPE block was used and the same pedicle screw was inserted in the block throughout all the tests.

The vertical load acting on the setup was cycled between an axial compression of 300 N and tension of 30 N at a rate of 0.5 Hz for 100 cycles using a servohydraulic test system (Instron 8874, Instron Corporation, Canton, MA). The moment arm of 35 mm resulted in a bending moment (300 N x 35 mm = 10.5 Nm) in the connecting rod in addition to the cephalo-caudad force. This ratio of axial load to bending moment was based upon in vivo measurements [Rohlmann et al. 1997, Rohlmann et al. 2000].

2.2.3 Kinematics

Motion of the pedicle screws with respect to the inferior UHMWPE and the cadaveric specimens was detected using a high precision optoelectronic system (Optotrak 3020, Northern Digital Inc., Waterloo Canada) at a rate of 10 Hz, which gave twenty data points for each cycle. Two sets of marker carriers, each with four infrared LEDs, were mounted onto the rigid bodies:
pedicle screw and bone or pedicle screw and UHMWPE block (Figure 2.3). The set of marker carriers on the bone was mounted onto the posterior elements, such as the lamina or the superior articular process, so as to be close to the screw and pedicle. The bone was assumed to be moving as a rigid body. The three dimensional motion of these two rigid bodies with respect to one another was post processed.

![Marker carrier attached to bone and marker carrier fixed to screw](image)

**Figure 2.3** Two marker carriers, each with four infrared LEDs, were mounted onto the two rigid bodies, (a) pedicle screw and vertebral specimen, and (b) pedicle screw and UHMWPE block. A high precision optoelectronic system was used to capture the motion of each rigid body with time. Subsequent post processing determines the relative motion of the pedicle screw in bone and of the pedicle screw in UHMWPE.
Chapter 2  Bone Density and Pedicle Screw Testing

A Cartesian local coordinate system was specified to describe the motion of the pedicle screws. The origin of the local coordinate system laid along the axis of the screw at the point where the connecting rod was attached to the pedicle screw. The z-axis always pointed away from the screw tip. The y-axis was parallel to the connecting rod and pointed upwards toward the direction of the superior pedicle screw. The direction of the x-axis was the vector cross product of the y- and z-axes.

The relative motions between the pedicle screw and the UHMWPE and between the pedicle screw and the vertebral bone were post processed from the three-dimensional motion data using custom software. The range and offset of the motion of the pedicle screw head were obtained from the average of the last five cycles (96th to 100th). These parameters gave an indication of dynamic motion under repetitive loading (range) and of settling or subsidence (offset). As the applied loads were in the sagittal plane (parallel to the pedicle screws), the resultant motions were primarily y translation and x rotation (Figure 2.4). Furthermore, the translation of the screw tip was also calculated, which when combined with the translation of the screw head, allowed for an estimation of the instantaneous axis of rotation to be made.

2.2.4 Statistical Analysis

The range and offset of the motion of the pedicle screw head were compared between the three types of insertion: UHMWPE, normal insertion and overdrilling. An unpaired t-test was used to determine if there was any difference between the translation and rotation ranges and offsets between screws in UHMWPE and screws in bone inserted in the normal fashion. A paired t-test was used to compare between pedicle screws in normal and in overdrilled holes. Effects of BMD on translation and rotation offsets and ranges were determined for both normal insertion and overdrilling by calculating Pearson product-moment correlation coefficients between these factors and BMD. Statistical significance was assumed to be at the 95 % level.
Figure 2.4 The (a) relative translations and (b) rotations between pedicle screw and bone in all six degrees of freedom for the first twenty seconds are presented in these two graphs. Translations in y of the screw head and rotations in x were the main motions measured, since the applied loads were in that plane. The other translations and rotations were not deemed significant as their magnitudes were much smaller. The range and offset of the y translation and x rotation are as shown on the graphs. Range and offset of the motion of the pedicle screw head were obtained from the average of the last five cycles (96th to 100th).
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2.3  Results

2.3.1  Motion of Pedicle Screw

The motions reported here consist of the sagittal plane rotation of the screw with respect to the vertebra and the axial translation of the screw head. The other rotations and translations were measured, but were very small and therefore not deemed significant.

The range of motion of the pedicle screw in the UHMWPE block was small, averaging 0.2 mm and 0.9°. The range of motion in the bone was significantly higher, averaging 1.4 mm and 2.4° for normally inserted screws and 2.4 mm and 2.7° for screws in overdrilled holes (Table 2.1 and Figure 2.5).

Table 2.1  Range and offset of translation and rotation in the sagittal plane.

<table>
<thead>
<tr>
<th></th>
<th>Y Translation-Range (mm)</th>
<th>X Rotation-Range (degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Screw in UHMWPE (n=8)</td>
<td>Normal Insertion (n=8)</td>
</tr>
<tr>
<td>Mean</td>
<td>0.2</td>
<td>1.4</td>
</tr>
<tr>
<td>s.d.</td>
<td>0.02</td>
<td>1.0</td>
</tr>
<tr>
<td>Max</td>
<td>0.3</td>
<td>3.1</td>
</tr>
<tr>
<td>Min</td>
<td>0.2</td>
<td>0.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Y Translation-Offset (mm)</th>
<th>X Rotation-Offset (degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>-0.1</td>
<td>0.4</td>
</tr>
<tr>
<td>s.d.</td>
<td>0.02</td>
<td>0.8</td>
</tr>
<tr>
<td>Max</td>
<td>-0.1</td>
<td>0.0</td>
</tr>
<tr>
<td>Min</td>
<td>-0.1</td>
<td>-1.6</td>
</tr>
</tbody>
</table>

The offset of translation of pedicle screws in the UHMWPE block was -0.1 mm whereas the offset of the pedicle screws in bone was -0.5 mm and in the overdrilled holes was -1.2 mm. The offset of the rotation of pedicle screws in UHMWPE was 0.4° whereas the offset of the pedicle screws in bone was 0.4° and in overdrilled holes was 0.3°. Offset of the pedicle screws in bone resulted in enlarged insertion holes. There was a significant difference in translation range (p < 0.005), translation offset (p < 0.05) and rotation range (p < 0.001) between motion of screw in UHMWPE and bone, while rotation offsets were not different (p > 0.95). There was no significant difference in translation range (p = 0.15), translation offset (p = 0.47), rotation range (p = 0.33) and rotation offset (p = 0.89) between pedicle screws in normal and overdrilled holes.
Chapter 2  Bone Density and Pedicle Screw Testing

Figure 2.5  The range and offset of the motion of the screw heads for screws inserted in a) UHMWPE, b) bone with normal insertion and c) bone with overdrilling. Error bars denote the standard deviation. N = 8 for each group.

2.3.2 Motion of Pedicle Screw in Bone; Effects of BMD

The correlation between bone mineral density and the range and offset of motion of the pedicle screw inserted in the normal fashion (Table 2.2 and Figure 2.6) was not statistically significant. There was, however, a trend that the specimens with higher bone mineral density generally had lower translation and rotation ranges, whereas these ranges tended to be higher for specimens with lower bone mineral densities.

No direct correlation between magnitude of translation or rotation with BMD was found for the pedicle screws inserted into the overdrilled holes.

Table 2.2  Correlation between range and offset of translation and rotation against BMD.

<table>
<thead>
<tr>
<th></th>
<th>p value</th>
<th>Correlationa</th>
<th>Correlation coefficient, r²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Translation range</td>
<td>0.15</td>
<td>No</td>
<td>0.37</td>
</tr>
<tr>
<td>Translation offset</td>
<td>0.26</td>
<td>No</td>
<td>0.24</td>
</tr>
<tr>
<td>Rotation range</td>
<td>0.12</td>
<td>No</td>
<td>0.35</td>
</tr>
<tr>
<td>Rotation offset</td>
<td>0.69</td>
<td>No</td>
<td>0.03</td>
</tr>
</tbody>
</table>

aA 95 % confidence level (p < 0.05) was used to decide if the data were significantly correlated.
Figure 2.6  Scatterplots of screw head translation and rotation ranges versus BMD for pedicle screws inserted with normal hole preparation. No significant linear correlations in translation range ($p=0.15$, $r^2=0.369$) or rotation range ($p=0.12$, $r^2=0.350$) with BMD were found but there was a trend of lower translations and rotations for specimens with higher BMD. No correlations were found for pedicle screws inserted in overdrilled holes.

2.3.3 Center of Rotation

The kinematics of the pedicle screw in bone could be broadly categorised into two groups. For specimens with higher bone mineral density, the screws were pivoting about a point located somewhere between the screw tip and the screw head. Translations and rotations were generally smaller (Figures 2.6 and 2.7). For specimens with lower bone mineral density, the motion of the screws underwent two stages. In the first stage, screw motion was characterized by vertical rigid body translation, with the screw head and screw tip both translating along the y-axis together. In the second stage, the screw demonstrated a rotational motion, with the screw head and tip moving in opposite directions, indicative of a center of rotation somewhere between the screw tip and the screw head.

Overdrilling did not alter the kinematic patterns of the pedicle screws in the specimens. With overdrilling, pedicle screws in specimens with higher bone mineral density were observed to be pivoting about a point, without the translations as observed in the overdrilled specimens with lower bone mineral density. This was in spite of the observation that the magnitudes of range and offset in the overdrilled holes were not correlated with BMD.
Figure 2.7  Typical motion of pedicle screws inserted in the normal fashion at the screw head and screw tip during the last 5 cycles for specimens (a) with low BMD and (b) with high BMD. The motion pattern for screws in low BMD bone was in two stages, a rigid body translation and a rigid body rotation. While in high BMD bone, the screws were mainly in rigid body rotation, oscillating about a point some distance between the screw head and screw tip.

2.4  Discussion

The testing methodology in this study applied similar loads and boundary conditions onto the two pedicle screws, one inserted in bone and the other inserted in UHMWPE. The results of this study showed clearly that the motion of the pedicle screw with respect to bone was significantly higher than its motion in a homogeneous block of UHMWPE. The higher stiffness of the UHMWPE results in less rotation of the screws and rod construct. Inspection of the specimens indicated that the pedicle screws caused permanent enlargement of the insertion
holes of the pedicles. On the other hand, the pedicle screws inserted in the UHMWPE did not result in any observable damage to the latter.

The motion of the pedicle screw with respect to the UHMWPE at the screw head could be attributed to a) motion of the screw within the UHMWPE and b) bending of the screw outside the UHMWPE. Indeed, a combination of both scenarios, motion within and bending outside the UHMWPE, could have occurred. While no gross permanent damage to the UHMWPE was observed, such motion could also be partially attributed to load application within the elastic limit of the UHMWPE. As the portion of the pedicle screw embedded within the UHMWPE was not substantially loaded, it could be postulated that fatigue fracture of pedicle screws tested in UHMWPE would occur at the neck of the screw.

Motion of the pedicle screw with respect to the vertebra was largely attributed to the rigid body motion of the screws within the bone and not to the bending of the screw itself. This rigid body motion of the screw against the bone resulted in enlargement of the insertion hole and permanent damage to the internal trabecular structure of the vertebral body. The kinematics of the pedicle screws in the bone was consistent with the presence of a fulcrum between the head and tip about which the pedicle screws were oscillating. Description of this clinically relevant mode of failure may aid in the development of improved techniques of spinal fixation.

Bone mineral density appeared to have an effect on the kinematics of the pedicle screws. Although translation and rotation ranges were not significantly correlated with bone mineral density in this study, there was a trend to suggest this association. The small sample size in this study could have contributed to the failure to demonstrate a statistically significant correlation. Moreover, the BMD values used in the statistical analysis were of the vertebral bodies and did not include the quality of bone in the pedicle region. The same trend against BMD was observed in pull-out tests by many researchers [Soshi et al. 1991, Wittenberg et al. 1991, Yamagata et al. 1992, Okuyama et al. 1993, Halvorson et al. 1994, Pfeiffer et al. 1996]. In those studies, specimens with higher BMD had higher pull-out force, while in the current study, there was a trend of lower translation and rotation ranges for specimens with higher BMD.

By studying the motion of the screw tip and screw head, it was revealed that for screws in vertebrae with higher bone mineral density, the screws were pivoting about a point between the screw head and the screw tip. For screws in vertebrae with lower bone mineral density, the screws underwent a rigid body translation followed by a pivoting motion. The former group of pedicle screws inserted in vertebrae with higher BMD could be considered to have achieved satisfactory early bone-implant fixation and they, in addition to the screws inserted in the
UHMWPE, would have passed the ASTM test protocol. The latter group of pedicle screws inserted in vertebrae with lower BMD mimicked the clinical scenario of intra-operative or early post-operative bone-implant interface failure. Thus, bone mineral density indeed influenced short-term fixation and early failure of pedicle screws. This would not have been detected using the F1717 test protocol [ASTM 2001]. The damaging effects of metallic implants on bone have not been fully characterized or addressed in the F1717. It is possible that some designs of pedicle screws could result in more damage to the trabecular structure than others. Therefore the fatigue life of an implant does not appear to be correlated to the ability of an implant to successfully develop a strong bone implant interface.

Overdrilling did not result in significantly higher translation or rotation ranges and offsets as compared to the screws inserted in the normal fashion. The kinematics of the pedicle screws was also not affected by overdrilling. Overdrilling furthermore caused the translation and rotation ranges and offsets to be independent of BMD, eliminating the trend of BMD effect observed for the normal screw insertions. Overdrilling the insertion holes resulted in a loosened screw model which otherwise could be achieved by a high number of cyclic motions on a screw inserted in a normal fashion.

2.5 Conclusion

This study contrasted, under short-term cyclic physiologic loads, the mechanical behavior of pedicle screws inserted in cadaveric vertebrae versus synthetic surrogates. The kinematics of the screws inserted in bone and in UHMWPE were found to be different in terms of the range of motion, pivoting and bending points of the screws and in terms of the effects of bone mineral density. The kinematics of the screws in bone is more relevant to clinical modes of failure. The fixation at the bone-implant interface can be quantified during short-term cyclic testing when an appropriate model is used, as demonstrated in this study.

2.6 References

Chapter 2  Bone Density and Pedicle Screw Testing


Chapter 3
Augmentation of Pedicle Screws in Osteoporotic Spine

Overview

This chapter addresses the issue of pedicle screw loosening in the osteoporotic spine by comparing three existing techniques of pedicle screw augmentation in the osteoporotic spine. The motion patterns and motion magnitudes of pedicle screws following augmentation with laminar hooks, sublaminar wires or calcium phosphate cement were contrasted.

The results in this study were presented at national and international conferences:

It was also recently published in a refereed journal:
3. **Augmentation of Pedicle Screws in Osteoporotic Spine**

3.1 **Introduction**

Pedicle screws are commonly used for a variety of indications to achieve segmental fixation within the lumbosacral spine [Lin et al. 1983, Cloward 1985, Lin 1999, Lowe and Tahernia 2002]. Despite being the most rigid form of posterior instrumentation, pedicle screws sometimes achieve poor initial fixation primarily in patients with low bone mineral density (BMD) [Okuyama et al. 2001]. Furthermore pedicle screw constructs in the lumbosacral spine can loosen with time, particularly at the ends of a long fusion and in weaker bone. Augmentation of pedicle screws in patients with poor bone quality may be necessary to enhance the rigidity of the construct [Weinstein et al. 1992, Bostrom and Lane 1997, Okuyama et al. 2001].

The common clinical methods to improve the fixation of pedicle screws within the osteoporotic spine include the addition of laminar hooks or sublaminar wires to the fixation construct, or the supplementation of the pedicle channel with polymethylmethacrylate (PMMA) or calcium phosphate cement [An et al. 2002]. Other novel augmentation methods suggested in the literature include the use of a bushing, a plate [Law et al. 1993], an expansive pedicle screw design [Cook et al. 2000, Cook et al. 2001], an expandable anchor [McKoy and An 2001a] and an interlocking screw [McKoy et al. 2001b]. The use of laminar hooks concurrently with pedicle screws *in vitro* has been shown to enhance the rigidity of pedicle screw fixation [Halvorson et al. 1994, Hilibrand et al. 1996, Hasegawa et al. 1997, Liljenqvist et al. 2001]. The use of sublaminar wires in a variety of configurations has also been shown to improve fixation in the osteoporotic spine [Coe et al. 1990, Butler et al. 1994, Hu 1997, Heller et al. 1998]. In recent years, various bone cements have been shown to increase pedicle screw fixation strength [Soshi et al. 1991, Wittenberg et al. 1993, Lotz et al. 1997, Moore et al. 1997, Yerby et al. 1998, Ignatius et al. 2001, Sarzier et al. 2002]. Few comparative studies between these various methods have been conducted.

The fixation strengths of sublaminar wires, hooks, and screws, when used alone, have been contrasted [Coe et al. 1990, Butler et al. 1994]. However the use of sublaminar wires, laminar hooks, and cement to augment pedicle screw fixation have not been compared.

The purpose of this study was to compare three methods of pedicle screw augmentation (laminar hooks, sublaminar wires, and calcium phosphate cement) in an *in vitro* biomechanical model of a loose pedicle screw in an osteoporotic spine. Specifically, we sought to determine the effects of these augmentation techniques on both the pattern and the magnitude of screw motion under physiologic loading conditions.
3.2 Methods

3.2.1 Specimens

Twenty-four lumbar vertebrae (8-L3, 7-L4 and 9-L5) from eleven human cadavers were used in this study. The ages ranged between 48 to 90 years, with a mean of 74.5 years. Three were female and eight were male. All specimens were previously utilized in an experiment to determine the structural properties of the endplate [Grant et al. 2001]. Although the testing protocol of this previous study involved only the endplates, each specimen was carefully visually inspected for structural damage. All specimens had intact posterior elements, and in particular, the pedicles were intact.

Bone mineral density from lateral DXA scans in the twenty-four specimens ranged between 0.28 and 1.30 g/cm$^2$. The specimens were arranged into three groups of eight to ensure a comparable distribution of bone mineral densities amongst the groups (i.e. each group averaged approximately 0.7 g/cm$^2$).

3.2.2 Augmentation Methods

Within each group of eight specimens, two augmentation methods were compared in a paired experimental design. The first group compared wire versus hook, the second compared hook versus calcium phosphate cement, and the third compared calcium phosphate cement versus wire.

The loosening of pedicle screws within an osteoporotic spine was simulated by drilling an oversized pedicle channel, thus creating “loose screws” without subjecting the specimens to large numbers of cyclic loads. This technique of mimicking loose pedicle screws was validated in a previous study (Chapter 2) [Tan et al. 2003]. Some of the specimens from this initial validation study were used in the current study (wire-hook group). Using the standard posterior landmarks for pedicle screw placement, the pedicle was drilled to a depth of 50 mm with an oversized drill bit measuring 6.35 mm (1/4 inch) in diameter.

For the specimens in which hooks and wires were tested, a stainless steel pedicle screw, 6.0 mm in diameter, 45.0 mm in length (Universal Spine System, Synthes, Paoli, PA) was then inserted into the pedicle and connected to a 6.0 mm by 140 mm stainless steel hard rod with the standard caps (Synthes Spine, Paoli PA). For sublaminar wire augmentation, two smooth 18 gauge Luque wires (Zimmer, Warsaw, IN), were wrapped around the pedicle screw and rod construct and tightened independently to secure the screw and rod construct to the laminar (Figure 3.1). For laminar hook augmentation, a medium or large laminar hook was attached to the rod distal to the screw with a 15 or 25 mm transverse connector (Synthes Spine,
Paoli, PA) and then compressed against the pedicle screw (Figure 3.1). For the calcium phosphate cement augmentation, the cement (Norian CRS, Norian Corporation, Cupertino, CA) was mixed in the manufacturer's pneumatic mixer, and approximately 2 ml were injected in a retrograde fashion into the oversized pedicle drill hole. A 6.0 mm by 45.0 mm stainless steel pedicle screw was inserted into the cement-filled pedicle channel, and the specimen was then immediately immersed into a 37 °C isotonic saline bath for 16 to 24 hours to allow the cement to harden completely and achieve its maximal compressive strength [Lotz et al. 1997]. Specimens with sublaminar wire or laminar hook augmentation were also placed in the saline bath so that consistency in the condition of the vertebral bodies was maintained. All pedicle screw insertions and augmentation procedures were carried out by a single spine surgeon (Dr Brian Kwon) in order to minimize variation in technique.

**Figure 3.1** Augmentation with laminar hook (left) and with sublaminar wires (right). The wires were twisted separately (inset). Compression between the pedicle screw and the transverse connector of the laminar hook pulled the head of the pedicle screw down inferiorly (rotating the tip of the screw in a superior direction). Tightening of the sublaminar wires pulled the screw head medially, rotating the screw tip laterally. The rotation of the screw in the vertical plane by this external force creates a "three-point contact" along the length of the screw.
Radiographs of each specimen were taken in the axial and lateral directions to verify position of the implants. Drilling to a depth of 50 mm did not perforate the anterior cortical wall and none of the 45 mm screws penetrated the anterior cortex.

![Figure 3.2](image)

**Figure 3.2** (a) The resultant forces on the inferior screw consisted of a compression and a flexion bending moment. (b) Two sets of marker carriers with four infrared LEDs each were rigidly attached to the pedicle screw and the superior articular process so as to capture the rigid body screw motion during cyclic test. The marker carrier was attached to the pedicle screw using a 4 mm bolt. Rigid connection between the superior articular process and marker carrier was provided by a 4-prong stiff braided wire, and attached using a bone screw.

### 3.2.3 Mechanical Testing

Testing methodology used in this study was the same as in the previous study (Chapter 2). The pedicle screws were subjected to a flexion bending moment by applying a cephalo-caudad force with an offset to the rigidly connected vertical rods (Figure 3.2a). The magnitudes of these forces were analogous to loads experienced during walking [Rohlmann et al. 1997, Rohlmann et al. 2000]. The vertebral bodies with the augmented pedicle screw and rod constructs were rigidly clamped to the base of the testing machine during tests. The rod was
connected 120 mm superiorly to a pedicle screw inserted into a polyethylene (PE) block. The PE block was hinged 35 mm anterior to the rod. A servo-hydraulic testing machine (Instron 8874, Instron Corporation, Canton, MA) was used to cyclically apply forces between 300 N of compression and 30 N of tension using a sinusoidal waveform. This load transformed into a compressive force (300 N) and a bending moment (10.5 Nm) at the inferior pedicle screw. Each screw was tested for 100 cycles at a rate of 0.5 Hz. At the completion of these tests, the fixation was removed from the specimen, and the process of pedicle screw insertion and augmentation was repeated on the contralateral pedicle with new screws and the comparison augmentation technique.

An optoelectronic camera system (Optotrak 3020, Northern Digital Inc., Waterloo, Canada) was used to monitor the rigid body motion of the pedicle screws and the vertebral bodies. Two “marker carriers”, each mounted with four infrared LEDs, were rigidly attached to the head of the pedicle screw and to the superior articular process of the vertebra being tested (Figure 3.2b). The capture rate of the camera system was at 10 Hz, which gave 20 data points for each loading cycle.

Figure 3.3  The motion of the screw head in the vertical direction during the last 10 cycles is presented in this figure. The translation range was defined as the difference between the maximum and minimum displacement between the 96th to the 100th cycles. Translation offset was defined as the change in mean position between the first five to the last five cycles.
3.2.4 Data Analyses

The translation range and translation offset were analyzed for the screw tip and screw head with respect to the vertebral body. All analyses, particularly the determination of screw tip motion, assumed that the pedicle screws underwent rigid body motion. Motion of the screws during the first and last five cycles of the total 100 cycles was used to determine the translation range and translation offset (Figure 3.3). The translation range was defined as the difference between the maximum and minimum displacement in the axial (Y) direction averaged between the 96th to 100th cycles (Chapter 2) [Tan et al. 2003]. Translation offset was defined as the change in mean position between the first five to the last five cycles. Both the translation range and offset were analysed for motion at the screw tip and screw head for all forty-eight screws. Since the direction of applied loads was restricted to the vertical plane alone, the primary motions observed were translation and rotation within that plane. The translation and rotation motion subsequently discussed referred to motion in this vertical plane only.

As well as comparing the magnitudes of translation at the screw head and screw tip, the patterns of motion for each screw were also categorised as a) pure rotation, b) translation, c) rotation-translation or d) double rotation (Figure 3.4) by inferring from the motion of the screw head and screw tip over time. Frequencies of occurrence of these motion patterns were compared between augmentation types.

3.2.5 Statistical Analysis

Non-parametric analyses using Wilcoxon signed-rank tests were carried out within each group of specimens to determine whether the two different augmentation methods resulted in a difference in translation offsets and ranges at both the screw head and screw tip. Pearson product-moment correlations between translation offsets and ranges with BMD were determined for all three augmentation methods. Chi-squared tests were used to compare the observed frequencies of occurrence of each motion pattern between augmentation methods. Analysis of variance was carried out to compare the current study with augmentation against a previous study (Chapter 2) [Tan et al. 2003] with normally inserted pedicle screws (without overdrilling). Statistical significance was assumed at the 95% level.
Figure 3.4 Schematic diagram of the screw positions at three or four instances of time during one loading cycle, starting with the screw head at the superior position (position 1). The screw head was displaced downwards through position 2 to the inferior position (positions 3 or 4) and back through position 2 to position 1. Four patterns of motion in the vertical plane were observed for the screws after augmentation with one of three techniques and these could be broadly characterised as a) pure rotation, b) translation, c) rotation-translation or d) double rotation. In (a), (b) and (c) the motions were mostly planar while in (d) there was out of plane motion.
3.3 Results

One specimen in the wire-hook group was rejected as a result of loosening of the transverse bar connecting the laminar hook to the vertical rod during cyclic testing. Thus, the sample size was seven for the wire-hook group and eight for the hook-cement and wire-cement groups. The screw motions after augmentation resulted in a maximum translation offset and range of \(-3.2\, \text{mm}\) and \(3.0\, \text{mm}\) respectively (Figures 3.5 and 3.6).

![Graph showing translation offset at screw head and screw tip for the three groups of specimens.](image)

**Figure 3.5** Mean and standard deviation of translation offsets at the screw head and screw tip for the three groups of specimens. There were no significant differences between any of the pairs within each group, using the Wilcoxon signed-rank test.
The mean translation offset and range for all forty-seven screws following augmentation were 0.0 mm (s.d. = 0.4) and 0.7 mm (s.d. = 0.7 mm) at the screw head and were -0.4 mm (s.d. = 0.7) and 0.7 mm (s.d. = 0.5) at the screw tip respectively. In our previous study (Chapter 2) [Tan et al. 2003], the corresponding translation offset and range at the screw head without any augmentation were -1.2 mm (s.d. = 1.3) and 2.4 mm (s.d. = 0.9) with an overdrilled hole and were -0.5 mm (s.d. = 0.5) and 1.4 mm (s.d. = 1.0) with a normal screw hole preparation using a standard blunt pedicle probing technique.

Figure 3.6  Mean and standard deviation of translation ranges at the screw head and screw tip for the three groups of specimens. There were no significant differences between any of the pairs within each group using the Wilcoxon signed-rank test.
Table 3.1  P-values analysed using the non-parametric Wilcoxon signed-rank tests between two augmentation methods within the same specimen.

<table>
<thead>
<tr>
<th></th>
<th>Wires - Hooks (n = 7)</th>
<th>Hooks - Cement (n = 8)</th>
<th>Wire - Cement (n = 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Translation offset, screw head</td>
<td>0.47</td>
<td>0.19</td>
<td>0.42</td>
</tr>
<tr>
<td>Translation offset, screw tip</td>
<td>0.11</td>
<td>0.37</td>
<td>0.53</td>
</tr>
<tr>
<td>Translation range, screw head</td>
<td>0.34</td>
<td>0.32</td>
<td>0.10</td>
</tr>
<tr>
<td>Translation range, screw tip</td>
<td>0.15</td>
<td>0.32</td>
<td>0.47</td>
</tr>
</tbody>
</table>

Comparisons were made between translation offsets and ranges at the screw heads and screw tips. No statistically significant differences were determined between augmentation methods, at the 95% significance level. The small sample sizes in each group could have contributed to a Type II error.

3.3.1 Paired Comparison between Augmentation Methods

Comparing between the two augmentation methods for each of the three groups of specimens (wire-hook, hook-cement, wire-cement), no significant differences were observed between translation ranges and translation offsets at the screw head and screw tip (Figures 3.5 and 3.6). P-values for the Wilcoxon analyses are presented in Table 3.1.

3.3.2 Correlation with BMD

After augmentation with sublaminar wires, there was poor correlation between BMD and the translation ranges and offsets at the screw tip and screw head (Table 3.2). Following augmentation with calcium phosphate cement, there was a linear correlation (p = 0.017) between BMD and translation ranges at the screw tip. The positive correlation coefficient (r) of 0.58 (Figure 3.7) indicated that higher translation ranges were observed with higher bone mineral densities. Subsequent to augmentation with laminar hooks, there was a negative linear correlation (p = 0.049) between BMD and translation ranges at the screw head.

Table 3.2  Pearson correlation coefficient, r, of translation offset and range against BMD.

<table>
<thead>
<tr>
<th></th>
<th>Laminar Hooks (n = 15)</th>
<th>Sublaminar Wires (n = 16)</th>
<th>Calcium Phosphate Cement (n = 16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Translation offset, screw head</td>
<td>0.02</td>
<td>0.17</td>
<td>0.23</td>
</tr>
<tr>
<td>Translation offset, screw tip</td>
<td>0.39</td>
<td>-0.03</td>
<td>0.17</td>
</tr>
<tr>
<td>Translation range, screw head</td>
<td>-0.51*</td>
<td>-0.13</td>
<td>-0.24*</td>
</tr>
<tr>
<td>Translation range, screw tip</td>
<td>-0.35</td>
<td>-0.09</td>
<td>0.58*</td>
</tr>
</tbody>
</table>

* p < 0.05, indicating linear correlation. Screws were pooled into laminar hooks, sublaminar wires or calcium phosphate cement augmentation.
Figure 3.7  For the 16 screws augmented with calcium phosphate cement, the translation range at the screw tip was linearly correlated with BMD ($r = 0.58, p = 0.017$). Specimens with lower BMD had lower translation range and vice versa. This could be the result of better infiltration of the calcium phosphate cement into the more porous cancellous bone for specimens with lower BMD. All translation ranges at the screw tip were relatively small (less than 0.8 mm).

3.3.3 Motion Patterns

The motion pattern of thirteen of the sixteen (81%) screws augmented with calcium phosphate cement was that of pure rotation (Table 3.3 & Figure 3.8). Chi-squared analyses determined this observation to be significant ($p < 0.01$) (Table 3.3). In contrast, pure rotation was seen in only seven of sixteen screws (44%) augmented with sublaminar wires and three of fifteen screws (20%) augmented with laminar hooks. None of the sixteen screws augmented with calcium phosphate cement demonstrated a translational motion pattern, while this was seen in seven of fifteen screws (47%) augmented with laminar hooks and four of sixteen screws (25%) augmented with sublaminar wires.
Chapter 3  Pedicle Screw Augmentation

Table 3.3  Frequency and percentage of the number of screws that underwent pure rotation, translation, rotation-translation and double rotation.

<table>
<thead>
<tr>
<th></th>
<th>Laminar Hooks (n = 15)</th>
<th>Sublaminar Wires (n = 16)</th>
<th>Calcium Phosphate Cement (n = 16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pure Rotation</td>
<td>3 (20 %)**</td>
<td>7 (44 %)</td>
<td>13 (81 %)*</td>
</tr>
<tr>
<td>Translation</td>
<td>7 (47 %)*</td>
<td>4 (25 %)</td>
<td>0 (0 %)**</td>
</tr>
<tr>
<td>Rotation-Translation</td>
<td>5 (33 %)</td>
<td>2 (13 %)</td>
<td>3 (19 %)</td>
</tr>
<tr>
<td>Double Rotation</td>
<td>0 (0 %)</td>
<td>3 (19 %)*</td>
<td>0 (0 %)</td>
</tr>
</tbody>
</table>

** Significantly lower number of occurrence than expected (p < 0.05),
* Significantly higher number of occurrence than expected (p < 0.05), Chi-squared test.

Screws were pooled into laminar hooks, sublaminar wires or calcium phosphate cement augmentation.

![Graphs](image)

Figure 3.8  (a) The motion at the screw tip and screw head during the last five cycles is presented. Different modes of screw motion are demonstrated in these two specimens. The figure above exemplifies a pedicle screw undergoing rigid body rotation, with the screw head and screw tip being 180 degrees out of phase. The figure below demonstrates a screw undergoing mainly rigid body translation, with the screw head and screw tip moving in phase. Notice that the absolute motions are small (less than 1 mm). Screws augmented with calcium phosphate cement generally demonstrated a rotational pattern of rigid body motion (81%) with higher translation magnitude at the screw tip (in 8 of 13 pure rotations). While those with
hooks often demonstrated rigid body translation (47%) with similar translation magnitudes at the screw head and screw tip (3 cases with higher magnitude at screw head, 2 cases with higher magnitude at screw tip and 2 cases with somewhat similar magnitudes at screw head and screw tip). (b) Two other modes of motion were identified. They were categorised as the rotation-translation and the double rotation modes. The screws in the rotation-translation mode moved in rigid motion translation for some period until an impingement (possibly within the pedicle) caused the screw tip to move in the opposite direction as the screw head. All three augmentation methods presented with some cases of this mode. The double rotation mode was mainly observed with wire augmentation. Loosened sublaminar wires could have resulted in loss of ability to pull the screw head medially and allowed for this out of plane motion. At the extreme positions of the screw, the wires were again taut and the screws were pulled medially.

3.4 Discussion

Osteoporosis and poor bone mineral density present a significant challenge for internal fixation within the lumbosacral spine. A number of augmentation strategies exist to enhance the rigidity of the pedicle screw-bone interface, but comparative evaluations of their biomechanical efficacy are rare. In the current study, we evaluated one innovative and two common augmentation techniques and compared both the magnitudes and patterns of motion at the screw head and tip under loading conditions that simulate those experienced in vivo. Using a similar biomechanical testing paradigm, we have compared the motion of pedicle screws inserted in the normal fashion, to the motion of pedicle screws in an overdrilled hole but without any form of augmentation (Chapter 2) [Tan et al. 2003]. The motion of the screws observed in the current study of three augmentation methods was significantly less than that observed previously in normally inserted pedicle screws (without overdrilling) and with overdrilling. The reduction in motion after augmentation is supported by the fact that the eight specimens in the previous study were used for the wire-hook group in the current study. Furthermore the reduction in motion that we observed with these augmentation techniques is consistent with previously published studies on individual augmentation methods [Coe et al. 1990, Soshi et al. 1991, Wittenberg et al. 1993, Butler et al. 1994, Halvorson et al. 1994, Hilibrand et al. 1996, Hu 1997, Lotz et al. 1997, Moore et al. 1997, Hasegawa et al. 1997, Yerby et al. 1998, Heller et al. 1998, Ignatius et al. 2001, Liljenqvist et al. 2001, Sarzier et al. 2002].

In the current study, paired comparisons of the displacement magnitudes at the screw head and screw tip did not identify any one of the three augmentation methods to be superior to the others. It is recognised that our observation of no significant differences in translation
offsets and ranges amongst the three augmentation techniques could represent a Type II error related to the sample size of each group.

When motion patterns were analysed, screws augmented with calcium phosphate cement revealed more frequent rotational motion with minimal translation. On the other hand, translation was the primary motion observed for screws augmented with sublaminar wires (25 %) or laminar hooks (47 %). Determining the clinical significance of these differences in translation and rotation is somewhat speculative, however we note from our previous study (Chapter 2) [Tan et al. 2003] that screw motion in specimens with higher bone mineral densities tends to involve primarily rotation while screw motion in lower bone mineral density is both rotational and translational (similar to rotation-translation in Figure 3.8b).

Characterizing the patterns of pedicle screw motion within osteoporotic vertebrae under physiologic loading may be important to our understanding of how such fixation loosens in the osteoporotic spine and how to most effectively prevent this occurrence. By testing pedicle screws under cephalo-caudad loads, Law et al (1993) demonstrated a rotational pattern of pedicle screw motion, with a fulcrum point at the base of the pedicle. This created localized failure of the cancellous bone within the vertebral body and pedicle, creating a "butterfly-shaped" bony defect. More recently, we have described the motion of pedicle screws under cyclic axial compression and flexion bending moment to consist of both rigid body translation and rotation, with a center of rotation located somewhere between the screw tip and screw head (Chapter 2) [Tan et al. 2003]. These detailed motion patterns of the screw within the vertebral body may provide substantial insight into the effectiveness of different augmentation methods, but to date, the clinical significance of these patterns of movement at the bone-implant interface are unknown.

The *in vitro* simulation of osteoporosis in human cadaveric vertebral bodies (beyond the pre-existing attenuation in bone mineral density of elderly donors) is difficult to do in a clinically meaningful manner. In this regard, the overdrilling of the pedicle canal (6.35 mm drill for a 6.0 mm diameter screw) creates a model of a loosened pedicle screw, representing a somewhat extreme form of bone compromise at the screw-bone interface. While a loosened screw model could be generated by cyclically loading a screw over an extended period of time, overdrilling creates a more consistent bony deficit which facilitates the comparison of different augmentation techniques. It is reasonable to assume that a pedicle screw inserted into a merely osteoporotic vertebral body would have greater contact with cancellous bone and thus less motion initially than if inserted into an overdrilled hole. Over time, however, with failure of the surrounding trabecular bone, this distinction between true osteoporosis and an overdrilled hole would be
expected to diminish. The motion of screws in the current study may therefore be a reasonable model of the long-term motion patterns of screws in osteoporotic bone \textit{in vivo}.

Previous work on pedicle screw motion suggested an association between poor bone mineral density and the magnitude of motion, reflecting the intuitive notion that the biomechanical loading of a pedicle screw in osteoporotic bone will result in greater motion than in robust bone [Coe et al. 1990, Soshi et al. 1991, Halvorson et al. 1994, Bennett et al. 1997, Okuyama et al. 2001, Tan et al. 2003]. After augmentation with sublaminar wires, the magnitude of pedicle screw motion did not correlate significantly with the bone mineral density of the specimen. This lack of correlation between magnitudes of motion and BMD implies that this technique negated the deleterious effect of osteoporosis on pedicle screw fixation rigidity. Interestingly, we noted a positive correlation between BMD and the translation range at the screw tip after calcium phosphate cement augmentation, suggesting that the motion was actually less in the more osteoporotic bone. This somewhat counter-intuitive observation may be attributable to the more osteoporotic and porous cancellous bone allowing for better, and possibly more distal, cement infiltration upon injection, which could provide a more stable bone-implant interface when hardened. While this result implies that calcium phosphate cement augmentation might provide better fixation in osteoporotic bone than in denser bone, the differences between true osteoporosis and the overdrilled pedicle should be considered before arriving at strong conclusions about this observation.

Numerous studies that have assessed the fixation strength of pedicle screws \textit{in vitro} have utilized the pullout test [Coe et al. 1990, Soshi et al. 1991, Butler et al. 1994, Halvorson et al. 1994, Hilibrand et al. 1996, Moore et al. 1997, Yerby et al. 1998, Cook et al. 2000, Liljenqvist et al. 2001, McKoy and An 2001a, Sarzier et al. 2002]. It is well recognized, however, that the loads applied to pedicle screws in pullout tests are not entirely representative of the loads that lumbar pedicle screws are subjected to \textit{in vivo}. Rohlmann et al. (1997, 2000) measured the \textit{in vivo} loads transmitted through spinal fixators during walking and determined that the main load components transmitted to the pedicle screw head consisted of an axial compressive force together with a flexion bending moment. Such \textit{in vivo} loads could be simulated \textit{in vitro}, as utilized in this study, by applying a cephalo-caudad compressive force with an offset so that the resultant forces acting on the pedicle screw head consist both of axial compression and a flexion bending moment [Cunningham et al. 1993, Tan et al. 2003]. The American Society for Testing and Materials (ASTM) has since proposed a similar testing methodology in their assessment of pedicle screw constructs [ASTM 2001]. These applied loads however did not
include loads on the pedicle screw system during axial rotational motion, a possible mode of motion for the bedridden patient in recovery after surgery.

Within the context of comparing the motion magnitudes and patterns between the three augmentation techniques, it is worth noting the differences in how each method augments the fixation of the loosened screw. The sublaminar wires pull the pedicle screw head medially, while compression between the screw and laminar hook pulls the screw head inferiorly towards the transverse bar (Figure 3.1). This application of an external force (albeit from different directions) onto the pedicle screw head creates a "three-point contact" along the length of the screw. As for augmentation using calcium phosphate cement, the cement is in contact with the screw presumably along its entire length, enhancing the interface between the screw threads and the cancellous bone. The cement does not, however, provide any direct fixation to the screw head. In view of these differences, one could speculate that cement augmentation together with hook or wires might be the best way to deal with all forces to enhance fixation.

3.5 Conclusion

This study compared the effectiveness of three augmentation methods in stabilizing a pedicle screw in a model of osteoporotic screw loosening. Compared to the results of the previous study (Chapter 2) [Tan et al. 2003] of screw motion without augmentation, all three of the augmentation methods were successful in stabilizing the fixation, as reflected by a reduction in the magnitude of pedicle screw motion. There were, however, no statistically significant differences in the magnitudes of pedicle screw motion when the three augmentation methods were compared. The deleterious effect of low bone mineral density was offset by the addition of sublaminar wires. Differences in the motion patterns suggested that calcium phosphate cement augmentation might provide enhanced fixation over the other two techniques. The applicability of these findings to the clinical management of osteoporotic patients undergoing pedicle screw fixation in the lumbosacral spine, however, requires further in vivo study.

3.6 References


Chapter 3  Pedicle Screw Augmentation


Chapter 4
Interbody Device Shape and Size on Bone-Implant Interface Strength

Overview

This chapter addresses the interbody device subsidence in the osteoporotic spine by comparing interface strength of interbody device with different shapes and sizes. Interbody devices that are larger in size and extend to the stronger peripheral regions of the endplates were found to result in stronger interface properties. Failure of underlying trabeculae was found to be isolated to the immediate region under the interbody devices.

The results in this study were presented at national and international conferences:
2) 50th Annual Meeting of the Orthopaedic Research Society, Mar 7-10, 2004, San Francisco, California, USA.

It was also recently published in a refereed journal:
Chapter 4  Interbody Device Shape and Size on Interface Strength

4.  Interbody Device Shape and Size on Bone-Implant Interface Strength

4.1  Introduction

The use of interbody devices for spinal fusion procedures is well established [Weiner and Fraser 1998, Zdeblick and Phillips 2003]. Implant subsidence is a concern with the majority of these devices, particularly in the osteoporotic patient, where lower bone mineral density (BMD) is associated with lower bone strength [Jost et al. 1998, Steffen et al. 2000, Lim et al. 2001, Grant et al. 2002]. To avoid implant subsidence, the strength of the vertebra-device interface must exceed the applied loads.

Recent studies on regional endplate strength of lumbar and thoracic specimens have determined some consistent variability, with higher strength posterolaterally and closer to the periphery [Grant et al. 2001, 2002, Bailey 2003]. In addition, a recent finite element model concluded that the placement of implants in the central area of the vertebral body may lead to early failure [Polikeit et al. 2003]. The same study proposed that cages should be designed to rely on the strong peripheral part of the endplate to reduce the risk of subsidence. Placement of interbody fusion devices on these stronger regions of the endplate would result in a stronger bone-implant interface. A study comparing three different cage positions on the surface of the end-plate, suggested that cages placed in the posterolateral aspect of the endplate were 20% stronger than cages placed centrally [Labrom 2002]. Rather than varying the position of interbody fusion devices, it may also be possible to increase the vertebra-device interface strength by designing devices to lie on the strongest regions of the vertebrae. Previous biomechanical comparisons between interbody device shapes [Rapoff et al. 1997, Jost et al. 1998, Lund et al. 1998, Tsantrizos et al. 2000, Steffen et al. 2000, Krammer et al. 2001, Murakami et al. 2001] have found no differences between designs; however, these studies did not specifically focus on the effect of different cross-sectional shapes.

A better understanding of some of the factors that lead to interbody device subsidence is necessary in order to address the problem effectively. Interbody fusion device subsidence results from failure at the bone-implant interface, rather than failure of the implant per se. We postulated that the region of bony failure under the various device shapes would provide clues regarding future strategies to prevent this complication.

We hypothesize that interbody fusion devices with novel cross sectional shapes that extend over the stronger regions of the endplates will result in a stronger bone-implant interface. The primary purpose of this study, therefore, was to compare the in vitro failure load, strength, and stiffness of three cage shapes with comparable cross-sectional areas when compressed axially into superior thoracolumbar vertebral endplates. Two novel cage shapes, kidney and
clover-leaf, were compared against a standard elliptical shape. The secondary purpose of this study was to document the pattern of failure of the endplate and its adjacent trabecular bone. We anticipated that there would be zones of trabeculae densification in the vertebral body, signifying the location of bone failure as it was compressed under the interbody devices.

4.2 Methods
4.2.1 Specimens
Forty-eight thoracolumbar vertebrae (T9-L2) were used in this study. These specimens were dissected from 19 cadavers and stored fresh frozen at -20 °C. There were 11 male and 7 female (one unknown gender) donors with a mean age of 77 years (max = 93, min = 58). Specimens were chosen to represent osteoporotic vertebrae in an attempt to create a 'worst case scenario' for our indentor testing.

Radiographs and BMD scans (DXA, QDR 4500W, Hologic Inc., Bedford, MA) from both anterior-posterior and lateral projections were carried out on dissected T9-L2 spinal segments. The average lateral BMD of the vertebral bodies was 0.46 g/cm² (max = 0.92, min = 0.25). Exclusion criteria for specimens were 1) acute fracture, 2) vertebral body lysis or deformity secondary to remote fracture or other pathology (tumor), and 3) end-plate irregularity such as a significant Schmorl's node.

4.2.2 Test Groups
The three indentor shapes compared in this study were termed: a) kidney, b) elliptical, and c) clover-leaf. Five sizes of each indentor shape were custom-manufactured. These indentors had solid indentation surfaces and the shapes were designed with equivalent cross-sectional areas (Figure 4.1, Table 4.1). The cross-sectional area of each indentor was measured using imaging software (Image Pro 4.5, Media Cybernetics, Silver Spring, MD) and areas between indentor shapes were within 2% of each other, except for sizes 1 and 2 for the clover-leaf indentors. The higher area for these two indentors was due to the limitation of machining the desired inner radii for the smaller clover-leaf indentors.

The forty-eight vertebrae were allocated into six groups of eight specimens. Each group had a similar mean lateral DXA BMD value of approximately 0.46 g/cm². In the first three groups, only vertebral bodies from T10, T12 and L2 were included (Table 4.2). In the last three groups, vertebral bodies from levels T9 to L2 were included.
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Figure 4.1  
The kidney, elliptical and clover-leaf shaped indentors. All indentors have a solid flat indentation surface. The indentors shown are all "Size 3", with an average cross-sectional area of 323 mm².

Table 4.1  
Average cross-sectional areas (mm²) of each solid indentor.

<table>
<thead>
<tr>
<th>Size</th>
<th>Size 2</th>
<th>Size 3</th>
<th>Size 4</th>
<th>Size 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>125</td>
<td>219</td>
<td>326</td>
<td>417</td>
</tr>
<tr>
<td>Elliptical</td>
<td>122</td>
<td>221</td>
<td>320</td>
<td>418</td>
</tr>
<tr>
<td>Clover-leaf</td>
<td>141</td>
<td>232</td>
<td>324</td>
<td>418</td>
</tr>
</tbody>
</table>

For each size, the cross-sectional areas between indentor shapes were within 2% of each other except for sizes 1 & 2 clover-leaf.

Table 4.2  
The 48 vertebral bodies distributed into 6 groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>20%, kidney</th>
<th>20%, elliptical</th>
<th>20%, clover-leaf</th>
<th>40%, kidney</th>
<th>40%, elliptical</th>
<th>40% clover-leaf</th>
</tr>
</thead>
<tbody>
<tr>
<td>T9</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>T10</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>T11</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>T12</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>L1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>L2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Average BMD (g/cm²)

Group 1; 20%, kidney | 0.463
Group 2; 20%, elliptical | 0.462
Group 3; 20%, clover-leaf | 0.468
Group 4; 40%, kidney | 0.460
Group 5; 40%, elliptical | 0.444
Group 6; 40% clover-leaf | 0.460

Groups 1-3 consisted of only T10, T12 and L2 and had comparable numbers of each level distributed. Groups 4-6 consisted of T9, T10, T11, T12, L1 and L2.
The lateral DXA BMD in each group averaged between 0.44 and 0.47 g/cm²

In the comparison between cage shapes, two percentages of coverage area of the indentors over the endplates were included: 20% and 40%. The endplate areas were calculated from the maximum AP and lateral dimensions by approximating the endplate as an elliptical shape [Panjabi et al. 1991, 1992, Higgins 2003]. Endplate areas of the 48 thoracolumbar vertebrae ranged between 477 mm² to 1602 mm² with an average of 895 mm². The indentor size which best approximated the desired endplate coverage percentage was chosen and the distribution in each test group is shown in Table 4.3.
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Table 4.3 Distribution of indentor size used in each test group.

<table>
<thead>
<tr>
<th>Group</th>
<th>Indentor Size</th>
<th>Size 1</th>
<th>Size 2</th>
<th>Size 3</th>
<th>Size 4</th>
<th>Size 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1: 20%, Kidney</td>
<td>XXX</td>
<td>XXXX</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2: 20%, Elliptical</td>
<td>XXX</td>
<td>XXXX</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 3: 20%, Clover-leaf</td>
<td>XXXX</td>
<td>XXX</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 4: 40%, Kidney</td>
<td>XXXX</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 5: 40%, Elliptical</td>
<td>XX</td>
<td>XXXX</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 6: 40%, Clover-leaf</td>
<td>XX</td>
<td>XXXXX</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Each 'X' represents one test. There were 8 specimens in each Group. Two specimens were rejected and not included in this Table.

4.2.3 Test Protocol

Specimens were thawed in room temperature for between 4 to 8 hours before tests were carried out. Both superior and inferior discs were sharply excised without damaging the underlying endplates. The cartilaginous endplates were removed. Each vertebra was individually secured in a custom built clamping device with the superior endplate aligned to the horizontal plane (Figure 4.2). The specimen was then centered within the testing machine using a weighted bob such that the geometric centre of the indentor face was aligned to the centre of the vertebral body. This centre was determined from the mid-point of the maximum anterior-posterior and lateral dimensions. The test jig was designed to allow for free rotation (frontal, lateral and axial rotations) of the indentors, about a centre of rotation located at the same geometric centre of the indentor face. This free rotation of the indentors will facilitate initial settling of the indentors onto the uneven geometry of the endplate, which will be reflected as an initial toe region in the load-displacement curve. The free rotation was achieved by a pair of opposing smooth articulating spherical concave and convex surfaces within the test jig (Figure 4.2). The concave surface was made out of UHMWPE and the convex surface was stainless steel.

The indentor was compressed axially over the endplate at a rate of 0.2 mm/s to a depth of 20% of the vertebral body height, using a servohydraulic testing machine (Instron 8874, Instron Corporation, Canton, MA). Axial compressive force and displacement were measured. All endplates failed within this indentation depth.
Figure 4.2 The test jig was designed with a pair of matching spherical concave and convex surfaces to allow for three dimensional rotations of the indentors about a centre of rotation located at the geometric centre of the indentor face (marked X). The specimen was rigidly clamped with the superior endplate lying in the horizontal plane. A rigid post (A) inserted through the vertebral foramen restricted posterior motion while a V-shape block (B) prevented anterior and lateral motion.

Failure load (in Newtons, N) and construct stiffness (in N/mm) were extracted from the load-displacement curves (Figure 4.3). Failure load was the maximum load before the gradient of the curve changes from positive to negative while stiffness was the slope of the linear portion of the load-displacement curve before failure occurred. Failure strength (in, N/mm²) was determined by dividing the failure load by the indentor area.

Motion of the indentor and the vertebral body were measured during tests using an optoelectronic camera system (Optotrak 3020, Northern Digital Inc., Waterloo, Canada). The relative rotations of the indentor with respect to the vertebra were resolved into the anatomical planes of the specimen and defined as flexion-extension, axial rotation and lateral bending angles. These relative motions were summarised as rotation ranges in each of these planes, where rotation ranges were defined as the difference between the maximum and minimum angles for the test duration.
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![Graph](image)

**Figure 4.3** Typical load-displacement curves where failure load was the maximum load before the gradient of the curve changes from positive to negative while stiffness was the slope of the linear portion of the curve before failure occurred. In 73% of the vertebrae tested, failure load was also the maximum load (a), while higher load beyond failure was measured in the other 27% of the tests (b).

4.2.4 Peripheral Quantitative Computer Tomography

Peripheral quantitative computer tomography (pQCT) scans (XCT2000, Stratec Medisintechochnik, Pforzheim, Germany) were carried out on all specimens pre and post indentation test. A single 2.5 mm wide cut was scanned through the mid-sagittal plane at a resolution of 0.2 mm by 0.2 mm.

The density profile in the vertebral body from the superior to the inferior endplates within this mid-sagittal slice was compared graphically between pre and post test pQCT scans to identify zones of trabeculae densification. Trabecular densification indicated permanent failure of the trabeculae. The percentage increases in bone mineral densities in these zones corresponding to a 20% applied strain were quantified and compared between indentor sizes. A pilot study carried out previously determined that the scan protocol and analysis was repeatable within a 4% coefficient of variation.

In order to distinguish the effect of indentor size on permanent loss of vertebral height, we compared the changes in vertebral height following indentation tests. All specimens were
indented to a strain of 20% and when unloaded some amount of permanent deformation resulted. Percentages of permanent deformation were calculated and compared between the two indentor sizes (20% and 40%) for all three indentor shapes. Vertebral heights were measured from pQCT images.

4.2.5 Statistical Analysis

Two-way factorial ANOVA was used to determine significant differences between cage shape and size. Post hoc Student’s Newman-Keuls tests were carried out to determine the significant factors, with a significance level of 95%.

Unpaired Student’s t-tests were used to compare the increase in 1) bone mineral densities and 2) permanent deformation between tests with 20% and 40% indentor coverage area over endplate area, with a significance level of 5%.

4.3 Results

Failure load was significantly affected by cage shape \( (p = 0.0005) \) and percentage of endplate covered by the indentor \( (p = 0.000003) \) (Figure 4.4). The failure loads for the larger clover-leaf indentor (40% endplate coverage) were observed to be 54% and 45% higher when compared to the kidney and elliptical shapes respectively. The failure loads for the smaller clover-leaf indentor (20% endplate coverage) were observed to be 62% and 60% higher when compared to the kidney and elliptical shapes respectively. No significant difference in failure load was found between the kidney and the elliptical shapes \( (p = 0.72) \) for both indentor sizes. The failure loads observed with the larger indentor were 75% greater than those for the smaller indentors. This was most significant for the elliptical shape (83%) and less so for the kidney (75%) and the clover-leaf (66%).

Failure strength, defined as the failure load divided by the indentor area, was not significantly different between the large and small indentors for any of the three indentor shapes \( (p = 0.65) \) (Figure 4.5). Cage shape remained a significant factor \( (p = 0.0004) \), with a significantly higher failure strength for the clover-leaf shaped indentor. The failure strength for the larger clover-leaf indentor were observed to be 59% and 49% higher compared to the kidney and the elliptical shapes respectively. The failure strength for the smaller clover-leaf indentor were observed to be 79% and 85% higher compared to the kidney and the elliptical shapes respectively. No significant difference in failure strength was found between the kidney and the elliptical shapes \( (p = 0.87) \).
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![Graph showing mean failure load for different shapes: kidney, elliptical, and clover-leaf, with 20% and 40% endplate coverage.](image)

**Figure 4.4** Mean failure load for the kidney, elliptical and clover-leaf indentor groups, with 20% and 40% endplate coverage. Failure load for the clover-leaf shaped indentors were significantly higher than both kidney and elliptical shapes for both indentor sizes. Failure load was significantly higher for larger indentors. Error bars indicate standard deviation.

![Graph showing mean failure strength for different shapes: kidney, elliptical, and clover-leaf, with 20% and 40% endplate coverage.](image)

**Figure 4.5** Mean failure strength for the kidney, elliptical and clover-leaf indentor groups, with 20% and 40% endplate coverage. The clover-leaf shaped indentors have significantly higher failure strength than both kidney and elliptical shapes. Error bars indicate standard deviation.

Stiffness of the construct was significantly affected by cage shapes \((p = 0.0004)\) but not by the surface area of end-plate coverage by the indentor \((p = 0.13)\) (Figure 4.6). Consistent with failure load and failure stress, the clover-leaf shaped indentor resulted in higher construct
stiffness over the kidney and the elliptical shapes. The stiffnesses for the larger clover-leaf indentor were observed to be 47% and 50% higher compared to the kidney and the elliptical shapes respectively. The stiffnesses for the smaller clover-leaf indentor were observed to be 79% and 35% higher compared to the kidney and the elliptical shapes respectively. No significant difference in stiffness was found between the kidney and the elliptical shapes (p = 0.32).

![Figure 4.6](image)

**Figure 4.6** Mean stiffness for the kidney, elliptical and clover-leaf indentor groups, with 20% and 40% endplate coverage. Higher stiffnesses were found with clover-leaf shaped indentors. Error bars indicate standard deviation.

Peripheral-QCT results indicated that densification of trabeculae occurred directly beneath the indentors, leaving the osseous endplate and immediate underlying cancellous bone intact (Figure 4.7). The zone with densified trabeculae in the sagittal plane for all three cage shapes had a semi-elliptical shape. Increase in bone mineral density in this region was quantified by comparing densities within the boxed region in Figure 4.7 before and after indentation (Figure 4.8). Increase in bone mineral density was significantly higher (p = 0.0001) for the smaller indentors with 20% endplate coverage (by 39%, s.d. = 14%) than for the larger indentors with 40% endplate coverage (by 24%, s.d. = 10%).
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Figure 4.7  Images of a specimen indented with an elliptical indentor through the mid sagittal plane a) pre and b) post indentation tests using peripheral quantitative computer tomography (pQCT). Zones of trabecular densifications occurred beneath the indented endplate for all three indentor shapes in a semi-elliptical pattern. The osseous endplate and immediate underlying cancellous bone was subsided but remained intact. Density in the boxed region was compared quantitatively. c) A 2 mm slice of the same specimen with a semi-elliptical trabecular densification pattern (arrows) under the indented endplate.

Figure 4.8  Density profile across the vertebral body from superior endplate (left) to inferior endplate (right) at the mid-sagittal plane. Each point on the graph represents the average density of a column of pQCT data points within the boxed region. Densification of trabeculae (circled) was observed.
under the indented endplate only and did not involve other regions in the vertebral body. This observation was consistent for all three indentor shapes.

The permanent deformation of the vertebrae under the smaller indentors (20% endplate coverage) was significantly higher (p < 0.02) than with larger indentors (40% coverage) after 20% applied strain for all three indentor shapes (Table 4.4). This higher permanent deformation for the smaller indentors occurred with associated lower failure loads (Figure 4.4). Permanent deformation for kidney and clover-leaf shaped indentors were not significantly different from the elliptical indentors for both percentages of endplate coverage.

Table 4.4 Permanent deformation after 20% applied strain, determined by comparing the vertebral height before and after indentation tests at the mid sagittal plane from pre and post test pQCT scan data.

<table>
<thead>
<tr>
<th></th>
<th>Kidney</th>
<th>Elliptical</th>
<th>Clover-leaf</th>
</tr>
</thead>
<tbody>
<tr>
<td>20% coverage</td>
<td>16.6%*</td>
<td>14.2%*</td>
<td>12.9%*</td>
</tr>
<tr>
<td></td>
<td>(1.8)</td>
<td>(3.0)</td>
<td>(3.8)</td>
</tr>
<tr>
<td>40% coverage</td>
<td>9.9%</td>
<td>9.1%</td>
<td>6.8%</td>
</tr>
<tr>
<td></td>
<td>(5.7)</td>
<td>(4.1)</td>
<td>(4.0)</td>
</tr>
<tr>
<td>p-value</td>
<td>0.01</td>
<td>0.01</td>
<td>0.02</td>
</tr>
</tbody>
</table>

* significantly higher than corresponding value in 40% coverage, at 95% level. Permanent deformation is presented as the percentage change in vertebral height from the original height. Values in parenthesis denote standard deviation. Permanent deformations were significantly higher with the smaller indentors (p < 0.02). Note that the applied load was different in each test.

The rotational motions of the indentors were not significantly different between cage shapes or between sizes. The rotation in the three planes of motion were small, with indentors rotating most profoundly in the sagittal plane; an average of 1.5° (flexion-extension), with no preferential direction between flexion or extension. Axial rotation of the indentor with respect to the vertebral body averaged 0.4° and was much less than flexion-extension or lateral bending. Lateral bending of the indentors averaged 0.9°, with a trend to less motion when the kidney shaped cages were tested (0.6°).

The results from two vertebrae (same donor, female, age = 58) were rejected as the failure loads (2516 N and >3000 N) were 500% and 587% higher than the means of the respective groups (504 N ± 157 N and 511 N ± 203 N). These two were clear outliers as their failure loads were at least twelve standard deviations above the respective means. These two specimens had the highest BMD amongst the 48 vertebrae and lowest age amongst the donors and clearly did not fit our inclusion criterion which was to include vertebral bodies that were somewhat osteoporotic.
4.4 Discussion

The purpose of this study was to compare two novel cage shapes with a standard elliptical shape using an axial compressive test model. The current study indicates that the novel clover-leaf shape results in improved bone-implant interface properties in vitro. These properties of the clover-leaf design may modify the clinical behaviour of an intervertebral implant with this foot-print, and may potentially reduce implant subsidence when compared to the standard elliptical shape.

The average failure loads of 504-1358 N for the various indentors in this study were comparable to the values reported by Hollowell et al. (1996) (262-1473 N) and Hasegawa et al. (2001) (510-1335 N). The average construct stiffness of 396-805 N/mm in this current study also compared reasonably with the values reported by Hasegawa et al. (2001) (385-541 N/mm). Jost et al. (1998) and Lund et al. (1998) both reported greater amounts of flexion-extension and less axial rotation of the interbody devices they tested. This is consistent with our results. The lower values of indentor motion in our study may be due to the single vertebrae to which we applied the indentor and the alignment carried out before each test. Whereas in the studies of Jost et al. (1998) and Lund et al. (1998) an interbody device was placed within a functional spinal unit and thus one would expect a larger amount of motion.

A secondary purpose of this study was to document the pattern of failure of the endplate and/or sub-endplate trabecular bone when compressed by an indentor. It is by understanding the pattern of trabeculae failure that we can begin to address the issue of implant subsidence. The current study documented the pattern of failure of the trabecular bone beneath the indentor device and identified a semi-elliptical zone of trabecular densification and permanent damage occurring beneath an intact osseous end-plate and beneath some intact sub-cortical trabecular bone.

Hasegawa et al. (2001) observed trabeculae failure directly beneath the cage. Their result was consistent with our study, as the zone of trabecular densification did not extend into the central region of the vertebral body. A similar semi-ellipsoidal shaped zone of trabecular densification under the endplate was previously described in an in vitro model with titanium mesh cages and pedicle screws [Labrom 2002]. That model used functional spinal units and thus mimicked the in vivo situation more closely. The shape of the failure zone in Labrom’s study is similar to our findings. The mode of trabecular failure is similar to that seen when there is shear failure of horizontal struts under the edge of the indentors together with buckling of vertical struts under the indentors. This zone of trabecular failure could potentially be reinforced in selected patients to increase failure load and reduce implant subsidence.
We recognize several limitations in the current study. *In vitro* biomechanical models such as ours do not take into account the remodelling that occurs following surgery. *In vivo* bone growth or resorption occurs depending on the load experience by the bone. Thus the current study is applicable to the immediate post-operative period before any biological changes have occurred. Furthermore, our model, which utilizes individual vertebral bodies does not take into account the dynamic load sharing which occurs within a functional spinal unit *in vivo* or from the addition of posterior instrumentation. While we used a compression model with unrestricted rotation, the *in vivo* load could be more compression-flexion or compression-extension etc., depending on the level, use of posterior instrumentation or patient’s activity. Despite these limitations, we believe that the compressive model in this study served its intended purpose of a biomechanical comparison between indentor shapes.

In order to focus on our primary research question and limit the number of variables, we decided on the use of solid indentors. A recent study assessed the axial compressive strength of interbody devices with full as opposed to peripheral contact and found similar mechanical strength [Steffen et al. 2000]. Using thin walled indentors with synthetic bone graft surrogates would most closely represent the *in vivo* situation, but such indentors would add several variables to the comparison, such as the indentor surface area, graft area, and thickness of the wall of the hollow indentor.

The comparison between indentor shapes was carried out with indentors of the same cross-sectional areas in order to control the potentially confounding influence of indentor area. To address the effect of varying the area of the indentor, we included indentors with surface areas of 20% and 40% of the endplate area. Moreover, we compared failure strength, where failure strength is failure load normalised to indentor areas. By using percentage of endplate coverage, we also took into consideration the fact that endplate sizes varied between individuals and between spinal levels. Our results indeed indicated that larger indentor surface area resulted in higher failure loads.

The cross sectional area of the largest clover-leaf cages which can be placed on the endplates is smaller that the cross sectional area of the largest elliptical cage. Thus one could argue that the failure load of the largest elliptical cage (assuming a size equivalent to 60% endplate coverage) could approach or even exceed the failure load of the largest clover-leaf cage (Figure 4.4). Failure strength data, however, indicated that the clover-leaf shape devices exhibited higher strength, regardless of coverage area (Figure 4.5). Attempts to minimize the contact area of the intervertebral device serve to increase the end-plate area outside the device available for bone grafting and eventual fusion. When intervertebral device designs attempt to
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balance the strength profile of the device by maximizing contact area and the opportunity for bone growth on the outside of the intervertebral device, the true benefits of this novel device shape may provide some assistance. However it is not sure if the fusion process would be compromised with the use of a clover-leaf shaped device with peripheral excursion. Moreover, the increased construct stiffness with this device shape (Figure 4.6) might be detrimental to the fusion process.

4.5  **Conclusion**

The results of the current study support an earlier proposal [Polikeit et al. 2003] that cages should be designed with more peripheral excursion to sit above the stronger regions of the endplates. We conclude that a clover-leaf shaped indentor was biomechanically superior to both elliptical and kidney shaped indentors of similar surface areas, and could potentially influence implant subsidence. Moreover, larger devices should be used to increase contact area and subsequently increase failure load and therefore reduce device subsidence. Failure of the underlying trabeculae was isolated to the immediate region under the indentor and thus it seems logical that future intervertebral devices should extend over the stronger regions of the endplate to reduce implant subsidence.

4.6  **References**


Chapter 4  Interbody Device Shape and Size on Interface Strength


Chapter 5
Cement Augmentation of Vertebral Screws
Enhances the Resistance to Subsidence of Interbody Device

Overview

This chapter addresses the effects of cement augmentation of screws on interbody device-vertebral body interface properties. Pedicle screw insertion was found to disrupt the underlying trabecular bone and reduce the interbody device-vertebral body interface properties. Cement augmentation of pedicle screws restored and further improved cage-vertebra interface properties. No differences in interface properties were found between cement augmented anterior vertebral body screws and pedicle screws. Cement augmentation of screws could reduce interbody device subsidence in the osteoporotic spine.

The results of this study were presented at:
1) 5th Combined Meeting of the Orthopaedic Research Societies of the USA, Canada, Japan and Europe, Oct 10-13, 2004, Banff, Alberta, Canada.

It was also submitted for publication in a refereed journal:
JS Tan, CS Bailey, MF Dvorak, CG Fisher, PA Cripton, TR Oxland. Cement augmentation of vertebral screws enhances the interface strength between interbody device and vertebral body. Submitted to Spine (7 Nov 2005).
5. Cement Augmentation of Vertebral Screws Enhances the Resistance to Subsidence of Interbody Devices

5.1 Introduction

The prevalence of osteoporosis, vertebral fracture [EPOS 2002] and spinal deformity [Jackson et al. 2000] is known to be associated with age. With the percentage of total population aged 65 and older projected to increase by 24% to 54% between 2000 and 2020 in the world’s industrialized nations [Anderson and Hussey 2000], the number of patients presenting with osteoporotic fracture and deformity will become more frequent. Surgical stabilization of the osteoporotic spine is indicated in the presence of significant neurological deficit, instability, deformity, or in revision surgery [Dvorak and Fisher 1999]. Both pedicle screw and anterior vertebral body screw fixation [Wuisman et al. 2000, Kostuik and Shapiro 2003, Heini 2005], have been used in these situations to supplement anterior interbody devices.


Surgical strategies to enhance the resistance of interbody devices (cages) to subsidence in the osteoporotic spine have received less attention than has augmentation of screw fixation. We recently reported that cage-vertebra interface failure loads could be increased by greater than 45% by using uniquely shaped interbody devices that engaged the peripheral regions of the endplate [Tan et al. 2005 (Chapter 4)]. In that study, trabecular bone failure occurred in a semi-elliptical zone underlying the interbody devices. That failure region led us to hypothesize that local cement augmentation could increase the strength at the cage-vertebra interface. The effects of pedicle screws, anterior vertebral body screws or cement placed within the vicinity of that zone of damage on cage-vertebra interface strength has not been previously studied.
Clinically, cement has been injected into vertebral bodies with the intention of reducing interbody device subsidence [Heini 2005]. However, we are not aware of any biomechanical study that addresses cage-vertebra interface strength when underlying pedicle or vertebral body screw are inserted with or without cement augmentation.

The main purpose of this study was to determine if cement augmentation of pedicle screws could improve interface properties of interbody devices, and therefore their resistance to subsidence. The secondary purpose was to determine any differences between pedicle screws with cement augmentation and anterior vertebral body screws with cement augmentation. We investigated these questions with both elliptical and clover-leaf shaped interbody devices, for three screws and cement configurations: 1) pedicle screws only, 2) pedicle screws with cement and 3) anterior vertebral body screws with cement.

5.2 Methods

5.2.1 Experimental Protocol

Individual vertebra was prepared with 1 of 3 different screw and cement configuration and axially compressed with 1 of 2 shaped indenter onto the superior endplate until failure. Failure load and failure strength were compared.

5.2.2 Specimens

Forty-eight thoracolumbar vertebrae (T9-L2) from 21 human cadavers were used in this study. The donors' ages ranged between 62 and 93 years with a mean age of 77 years. There were 13 male and 7 female donors (one unknown gender). All specimens were kept frozen at -20 °C after harvesting from donors in the University of British Columbia Tissue Donation Program. This study was approved by our Institutional Clinical Research Ethics Board.

Areal bone mineral densities (aBMD) of the vertebral bodies were measured from the lateral projection of dissected T9-L2 spinal segments using a dual-energy x-ray absorptiometry (DXA) machine (QDR 4500W, Hologic Inc., Bedford, MA) with methodology previously described by our group in detail [Sran et al. 2005]. The specimens were sectioned and divided into six groups with 8 vertebral bodies per group such that each group had similar mean BMD, standard deviation and comparable distribution of spinal levels (Table 5.1). Mean BMD for the 48 vertebrae was 0.46 g/cm² and ranged between 0.29 and 0.72 g/cm².

Exclusion criteria for specimens were 1) acute fracture, 2) vertebral body lysis or deformity secondary to remote fracture or other pathology (tumor), and 3) end-plate irregularity such as a significant Schmorl's node or fracture.
Table 5.1 Distribution of spinal levels and mean bone mineral density (BMD) in each group.

<table>
<thead>
<tr>
<th>Screw Configuration</th>
<th>Indentor Shape</th>
<th>Number of Specimens</th>
<th>Average BMD, g/cm² (s.d.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pedicle screw alone</td>
<td>elliptical</td>
<td>T9 1 T10 1 T11 3</td>
<td>0.467 (0.10)</td>
</tr>
<tr>
<td>Pedicle screw alone</td>
<td>cloverleaf</td>
<td>T12 1 L1 2 L2 1</td>
<td>0.462 (0.14)</td>
</tr>
<tr>
<td>Pedicle screw + cement</td>
<td>elliptical</td>
<td>T9 1 T10 1 T11 3</td>
<td>0.462 (0.12)</td>
</tr>
<tr>
<td>Pedicle screw + cement</td>
<td>cloverleaf</td>
<td>T12 1 L1 2 L2 1</td>
<td>0.463 (0.12)</td>
</tr>
<tr>
<td>Anterior body screw + cement</td>
<td>elliptical</td>
<td>T9 1 T10 3 T11 1 L1 2</td>
<td>0.469 (0.10)</td>
</tr>
<tr>
<td>Anterior body screw + cement</td>
<td>cloverleaf</td>
<td>T12 1 L1 2 L2 1</td>
<td>0.463 (0.08)</td>
</tr>
</tbody>
</table>

s.d. = standard deviation

5.2.3 Test Groups

The experiment was designed to test the main effects and two way interaction between three different screw-cement combinations: i) pedicle screws only, ii) pedicle screws with cement, and iii) anterior vertebral body screws with cement, and two different interbody device shapes: i) elliptical, and ii) clover-leaf. The 6 groups of vertebrae (Table 5.1) were assigned to a screw-cement configuration and cage shape.

5.2.4 Compression Failure Tests

The specimens were tested under compression with a shaped indenter over the superior endplate of each vertebra. The test setup and protocol used was similar to our previous study on interbody device shape and size [Tan et al. 2005 (Chapter 4)]. Four different sizes of each custom-shaped stainless steel indenter, with cross sectional areas of approximately 519, 418, 322 and 227 mm², were used (Figure 5.1). Indenter size for each test was chosen such that they covered an area as close to 40% of the endplate area as possible. Endplate areas were calculated from the maximum anterior-posterior (AP) and lateral dimensions by approximating the endplate as an elliptical shape [Panjabi et al. 1991, 1992, Higgins 2003]. Cross-sectional areas of the superior endplate of the 48 thoracolumbar vertebrae ranged between 517 mm² to 1493 mm² with an average of 951 mm². The distribution of indenter size used for the tests was similar between the size groups (Table 5.2). Overall mean percentage endplate coverage achieved was 40% with means in the 6 groups ranging from 38% to 42%.
Figure 5.1  Four sizes of clover-leaf and elliptical shaped indentors were used for the tests. Cross-sectional areas were similar for each size.

5.2.5  Test Procedure

Specimens were thawed at room temperature (23°C ± 2°C) for between 4 to 8 hours before screw insertion and cement injection. Both superior and inferior discs were sharply excised without damaging the underlying endplates, and the cartilaginous endplates were dissected away. Anterior vertebral body screws and pedicle screws (CD Horizon, Medtronic Sofamor-Danek and Moss Miami, DePuy Spine) were implanted by a fellowship trained spine surgeon (Dr Chris Bailey) in clinically relevant orientations. Screw diameters were 6 mm and screw lengths were 40-55 mm. Screws from both manufacturers were randomly used in all groups. Anterior vertebral body screws were inserted with bicortical purchase on lateral cortices
while pedicle screws were inserted to 80% of the vertebral body depth. Radiographs in the axial and lateral projections confirmed proper positioning of screws.

Table 5.2 Distribution of indentor size used in each test group and mean percentage area of endplate coverage achieved.

<table>
<thead>
<tr>
<th>Screw Configuration</th>
<th>Indentor Shape</th>
<th>Indentor Size (Indentor Area)</th>
<th>Mean Percentage Area of Endplate Coverage (s.d.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pedicle screw alone</td>
<td>elliptical</td>
<td>XXX</td>
<td>41% (4%)</td>
</tr>
<tr>
<td>Pedicle screw alone</td>
<td>cloverleaf</td>
<td>XXX</td>
<td>40% (5%)</td>
</tr>
<tr>
<td>Pedicle screw + cement</td>
<td>elliptical</td>
<td>XXX</td>
<td>38% (3%)</td>
</tr>
<tr>
<td>Pedicle screw + cement</td>
<td>cloverleaf</td>
<td>XXX</td>
<td>42% (3%)</td>
</tr>
<tr>
<td>Anterior body screw + cement</td>
<td>elliptical</td>
<td>XXX</td>
<td>40% (5%)</td>
</tr>
<tr>
<td>Anterior body screw + cement</td>
<td>cloverleaf</td>
<td>XXX</td>
<td>42% (1%)</td>
</tr>
</tbody>
</table>

Each 'X' represents one test. There were 8 specimens in each group. One test was rejected as a result of metal-on-metal contact between the indentor and the custom built specimen clamps and was not included in this Table.

In the cemented groups, approximately 2 ml of polymethylmethacrylate (PMMA) bone cement (Osteobond, Zimmer, Warsaw, IN) was injected into the screw tracts after removal of a normally inserted screw. The same screw was immediately reinserted after cement injection. This method of cement injection into a screw tract is used clinically [Wuisman et al. 2000] and has been applied experimentally [Soshi et al. 1991, Lotz et al. 1997]. The cement was allowed to cure for 1 to 2 hours before indentation tests were carried out. The vertebral bodies were consistently considered as the inferior body of a fusion construct where the interbody device was in contact with the superior endplate of the vertebral body being tested.

For each test, the vertebra was secured in a custom built clamp and the superior endplate was aligned in the horizontal plane with the aid of an adjustable vise (Figure 5.2). Following that, the specimen was centred within the testing machine using a weighted bob such that the geometric centre of the indentor face was aligned with the centre of the vertebral body. The centre of the vertebral body was determined from the mid-point of the maximum AP dimension in the mid-sagittal plane. The test jig was designed to simulate a spherical joint and
to allow for unconstrained rotation in the frontal, lateral and transverse planes of the indentor, about a centre point located at the geometric centre of the indentor face. A pair of opposing smooth articulating spherical concave and convex surfaces within the test jig made up the spherical joint. The concave surface was made out of UHMWPE and the convex surface was stainless steel. The compression stiffness of this indentor setup was established experimentally to be 5140 N/mm. Free rotation of the indentor during application of the compression load facilitated initial settling of the indentors onto the uneven geometry of the endplate, which was reflected as an initial toe region in the load-displacement curve.

![Custom-built clamps](image)

**Figure 5.2** Custom-built clamps were used to secure the specimen and an adjustable vise was used to align the superior endplate in the horizontal plane. A pair of concave-convex surfaces was used to create a non-constraining spherical joint through which the compression was applied.

All tests were carried out using a servohydraulic testing machine (Instron 8874, Instron Corporation, Canton, MA) and axial compressive force and displacement were collected by the machine at 20 Hz. The indentor was compressed axially at a constant rate of 0.2 mm/s to a depth of 30% of the vertebral body height. Vertebral body height was measured directly using a pair of Vernier calipers.
Failure load (in Newtons, N) and construct stiffness (N/mm) were extracted from the load-displacement curves (Figure 5.3). Failure load was interpreted as the maximum load before the slope on the load-displacement curve first changed from positive to negative. All specimens failed within the indentation depth of 30% of vertebral body height. Failure strength (MPa) was determined by dividing the failure load by the indentor area. Stiffness was determined to be the maximum slope of the load-displacement curve before failure occurred. To account for the fact that failure load was assumed to be a factor of BMD, specimen size and indentor size, we distributed the specimens such that their BMD and spinal level characteristics were evenly distributed among the 6 groups, and we matched indentor size to specimen size to obtain 40% of endplate coverage. To further account for differences associated with specimen and indentor size, we compared normalized failure load with indentor area (failure strength).

5.2.6 Statistical Analysis

Two-way factorial ANOVA was used to determine significant differences due to cage shape and method of fixation. Post hoc Student’s Newman-Keuls tests were carried out to determine the differences between groups, with a significance level of 95%.

Figure 5.3 Typical load-displacement curves where failure load was the maximum load before the gradient of the curve changed from positive to negative, while stiffness was the maximum slope of the curve before failure occurred. In 55% of the vertebrae tested, failure load was also the maximum load while a higher load beyond failure was measured in the other 45% of the tests.
5.3 Results

Mean failure loads ranged from 741 N for specimens inserted with pedicle screws alone to 1919 N for specimens inserted with anterior vertebral body screws augmented with cement, both tested with clover-leaf shaped indentors (Figure 5.4). Failure load was significantly affected by the method of fixation ($p = 0.001$) and not by indentor shape ($p = 0.20$), and there was a significant 2-way interaction ($p = 0.009$). In the post-hoc analyses between groups with pedicle screws, the use of cement significantly increased mean failure load ($p = 0.002$), with mean increases of 54% for elliptical shaped indentors and 121% for clover-leaf shaped indentors. There was no significant difference in failure load between pedicle screws with cement and anterior vertebral body screws with cement ($p = 0.41$). The significant 2-way interaction was attributed to the 89% higher mean failure load for clover-leaf shaped indentors compared to elliptical shaped indentors with anterior vertebral body screws ($p = 0.02$), but not with pedicle screws.

![Figure 5.4](image_url)  

**Figure 5.4**  Mean failure loads for elliptical and clover-leaf shaped indentors with i) pedicle screws only, ii) pedicle screws with cement, and iii) anterior vertebral body screws with cement. Error bars denote standard deviation.

Mean failure strengths ranged from 1.9 MPa for specimens inserted with pedicle screws alone to 4.6 MPa for specimens inserted with anterior vertebral body screws augmented with cement, both tested with clover-leaf shaped indentors (Figure 5.5). Similar to failure load,
failure strength was also significantly affected by the method of fixation ($p = 0.0001$) and not by indentor shape ($p = 0.33$), with a borderline significant 2-way interaction ($p = 0.05$). In the post-hoc analyses between groups with pedicle screws with and without cement, use of cement significantly increased mean failure strength ($p = 0.0002$), with mean increases of 69% for elliptical shaped indentors and 137% for clover-leaf shaped indentors. There was no significant difference in failure strength between pedicle screws with cement and anterior vertebral body screws with cement ($p = 0.16$). Similar to failure load, the significant 2-way interaction was attributed to a higher (53%, $p = 0.08$) mean failure strength for clover-leaf shaped indentors compared to elliptical shaped indentors with anterior vertebral body screws, but not with pedicle screws.

![Figure 5.5](image)

**Figure 5.5**  Mean failure strengths for elliptical and clover-leaf shaped indentors with i) pedicle screws only, ii) pedicle screws with cement, and iii) anterior vertebral body screws with cement. Error bars denote standard deviation.

Mean stiffnesses ranged from 476 N/mm to 703 N/mm for all groups (Figure 5.6). Stiffness was not significantly affected by method of fixation ($p = 0.72$) or by indentor shape ($p = 0.47$). There was a significant 2-way interaction ($p = 0.04$) caused by the trend of higher stiffness with clover-leaf shaped devices when used with anterior vertebral body screws, but a trend of lower stiffness with pedicle screws.
Results from one test were rejected as metal-on-metal contact of the test jig with the specimen holder was noted during test.

![Graph showing mean stiffnesses for elliptical and clover-leaf shaped indentors with i) pedicle screws only, ii) pedicle screws with cement, and iii) anterior vertebral body screws with cement. Error bars denote standard deviation.](image)

**Figure 5.6** Mean stiffnesses for elliptical and clover-leaf shaped indentors with i) pedicle screws only, ii) pedicle screws with cement, and iii) anterior vertebral body screws with cement. Error bars denote standard deviation.

### 5.4 Discussion

The purpose of this study was to determine the effects of cement augmentation of screws on cage-vertebra interface properties. Results from this study clearly indicated an increase in cage-vertebra strength when cement was used with pedicle or anterior vertebral body screws versus with using the screws alone. These results suggest that interbody device subsidence may be reduced in osteoporotic patients if cement is used to augment pedicle screws or anterior vertebral body screws.

The improved cage-vertebra interface strength in this study was determined for the superior vertebral endplates, and similar results could not be implied for the inferior endplates as pedicle screws are placed further from the inferior endplate than superior endplate. Another limitation of this study was the use of a single vertebra experimental model, where the pedicle screws were not connected to posterior rods and thus the screw heads were not under load. Based on current literature, it is unclear whether this difference from the clinical scenario would have an effect on our results as there is contradictory information of the effect of posterior
instrumentation on the compressive failure load of functional spinal units with interbody fusion devices [Jost et al. 1998, Tsantrizos et al. 2000, Cripton et al. 2000]. Finally, only compression loads were applied in this study while loads in vivo include bending moments and shear forces. However, compression load is the predominant load expected to be transmitted through interbody devices, and thus we find that this is clinically germane.

Clinical usage of bone cement in the spine has been primarily focused on the techniques of vertebroplasty and kyphoplasty as treatments for osteoporotic compression fracture [Barr et al. 2000, Kostuik and Shapiro 2003, Phillips 2003, Heini 2005]. Biomechanically, vertebroplasty resulted in increased vertebral compression failure load ranging from 100% [Bai et al. 1999] to 300% [Belkoff et al. 2000]. Clinically, significant pain relief has been seen in numerous studies [Barr et al. 2000, Wuisman et al. 2000, Fourney et al. 2003, Kostuik and Shapiro 2003, Heini 2005]. The use of cement as an augmentation technique for spinal implants in osteoporotic patients has been described for pedicle screws [Wuisman et al. 2000, Kostuik and Shapiro 2003, Heini 2005] in an attempt to address concerns of poor screws purchase, screws loosening, and screws pullout. The ability to improve local screw purchase, and thus achieve adequate construct stability in patients with low bone mass, has made cement use a viable option in osteoporotic spine patients.

The effect of pedicle screws and/or cement on cage-vertebra interface strength has not previously been reported to our knowledge. Compared to our earlier study where no screws or cement were used [Tan et al. 2005 (Chapter 4)], failure load and failure strength after inclusion of the pedicle screws were not significantly affected for elliptical shaped devices, but were significantly decreased with clover-leaf shaped devices (Table 5.3). Cement augmentation of vertebral screws restored or even increased failure load and failure strength. A direct comparison could be made to results from this previous study as the specimen characteristics, such as age, vertebral levels and BMD range were similar, and the test protocol used was identical.

We speculate that the decrease in failure strength with pedicle screws only for the clover-leaf devices was due to the disruption of the trabecular structure of underlying bone beneath the interbody device. Due to different seating of the interbody devices over the endplate, the disruption of bone by the screws had a variable effect on cage-vertebra interface strength (Figure 5.7). Trabecular disruption associated with pedicle screw insertion included the posterolateral region of the vertebral body, which was the same region where the clover-leaf shaped indentor harnessed the higher interface strength. Pedicle screw insertion therefore had a direct effect on reducing interface strength for clover-leaf shaped indentors. Cage-vertebra
interface strength for the elliptical shaped device was less affected with pedicle screw insertion, due to the smaller overlap of the elliptical indentor with the pedicle screw trajectory.

**Table 5.3 Effects of pedicle screws insertion on failure load and failure strength.**

<table>
<thead>
<tr>
<th></th>
<th>Failure Load, N (s.d.)</th>
<th>Failure Strength, MPa (s.d.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Elliptical</td>
<td>Clover-leaf</td>
</tr>
<tr>
<td>No Screw/ Cementa</td>
<td>936 (238)</td>
<td>1358 (327)</td>
</tr>
<tr>
<td>Pedicle Screws Inserted</td>
<td>1051 (199)</td>
<td>741 (328)</td>
</tr>
<tr>
<td></td>
<td>p* = 0.31</td>
<td>p* = 0.002</td>
</tr>
<tr>
<td></td>
<td>Elliptical</td>
<td>Clover-leaf</td>
</tr>
<tr>
<td>No Screw/ Cementa</td>
<td>2.9 (1.0)</td>
<td>4.4 (0.8)</td>
</tr>
<tr>
<td>Pedicle Screws Inserted</td>
<td>2.6 (0.8)</td>
<td>1.9 (0.4)</td>
</tr>
<tr>
<td></td>
<td>p* = 0.45</td>
<td>p* = 0.00002</td>
</tr>
</tbody>
</table>

*From previous study [Tan et al. 2005]
*p-value using un-paired t-tests.
s.d. = standard deviation

Cement injection into the pedicle tracts resulted in structural reinforcement to surrounding trabeculae. We speculate that the stiffer cement-bone composite block together with its closer vicinity to the superior endplate, redistributed load onto larger volumes of supporting trabecular bone beneath the screws and cement (Figure 5.8), and increased failure strength.

As an *ex situ* DXA measurements of 0.29 g/cm² could differ by 43% from *in situ* scans with soft tissue present [Svendsen et al. 1995], the clinical definitions of osteoporosis and osteopenia, and the use of t-scores, are not applicable on *ex situ* specimens. Thus the bone quality of our dissected specimens could not be classified as normal, osteopenic or osteoporotic. We could, however, infer from the donors' age range of 62 to 93 years that the specimens would most likely be osteopenic or osteoporotic. In comparison to previous studies, the mean AP DXA BMD in a study with 16 T9-L4 specimens aged above 65 was 0.486 g/cm² (range: 0.416 to 0.586 g/cm²) [Bai et al. 2001], the mean AP DXA BMD in another study involving 16 T12-L1 specimens aged 60 to 96 was 0.56 g/cm² [Belkoff et al. 2001b], while the mean lateral DXA BMD in a third study with 9 L3-S1 specimens aged 72 to 93 was 0.486 g/cm² (range: 0.185 to 1.025 g/cm²) [Labrom et al. 2005]. Accounting for differences due to specimen levels, age range, scan direction and scan machines, the DXA BMD range in these previous studies were comparable to the current study.
Figure 5.7  Pedicle screw insertion resulted in disruption of trabecular bone at the posterolateral region of the vertebral body and along the screw. Without pedicle screws, trabecular bone failure was found to occur in a semielliptical zone underlying the interbody devices (hatched area) [Tan et al. 2005 (Chapter 4)]. Due to the different seating of the elliptical and clover-leaf shaped devices over the endplate and over the screw trajectories, the disruption of bone by the screws had different outcome on device-vertebral body interface strength.

In a recent biomechanical study the mean compressive failure load of vertebral bodies following kyphoplasty or vertebroplasty with PMMA and calcium phosphate cement ranged between 1083 N to 1533 N [Tomita et al. 2003]. In a separate study [Bai et al. 1999], the mean compressive failure load after vertebroplasty with calcium phosphate cement was 1063 N while with PMMA it was 1036 N. Both of these studies compressed the vertebral bodies via a movable hinge to create wedge fractures. Comparatively, compressive failure load for vertebrae with cement augmentation in the current study ranged with means of 1013 N to 1919 N. In spite of the differences in compressive test setup, cement type, cement volume and specimens related characteristics, the range of failure loads obtained in the current study was
Figure 5.8 (A) Underlying trabeculae supports the applied load from the interbody device. Failure strength is lower in the weaker osteoporotic bone. The hatched area represents the critical zone of trabeculae found to collapse at failure. (B) Pedicle screws disrupt the trabecular architecture in this critical zone beneath the interbody device, resulting in lower failure strength. (C) Cement injection into the pedicle tracts results in structural reinforcement to the trabeculae. The injected cement could penetrate towards the superior endplates and interbody device and the cured cement-bone composite blocks are stiffer than the surrounding trabecular bone. A larger volume of bone around this composite block prevents its subsidence, which in turn prevents subsidence of the interbody device.
combination of these factors results in higher failure strength following cement augmentation of pedicle screws.

5.5 Conclusion

In conclusion, cement augmentation of pedicle screws was found to increase cage-vertebra interface strength. There were no significant differences between pedicle and anterior vertebral body screws when cement augmentation was used. With the use of cement augmented screws, the increased cage-vertebra interface strength could reduce interbody device subsidence in the osteoporotic spine.

5.6 References


Chapter 5  
Screws and Cement on Interbody Device Interface Strength


Chapter 5  
Screws and Cement on Interbody Device Interface Strength


Chapter 6
Enhancing Fixation of the Osteoporotic Spine in a Corpectomy Model:
The Effect of Cement Augmentation and Posterior Instrumentation Extension

Overview

This chapter compares the enhancement of osteoporotic spine fixation by 1) cement augmentation of pedicle screws and 2) extension of posterior instrumentation, using the flexibility test protocol. Both techniques are available to surgeons to obtain improved fixation in the osteoporotic spine. Cement augmentation was found to consistently reduce intersegmental motion at the destabilized level while posterior rod extension reduced intersegmental motion in the absence of cement.

The next study (Chapter 7) was carried out in parallel with the current study.

The results of this study were presented at these national and international conferences:
1) 52nd Annual Meeting of the Orthopaedic Research Society, Mar 19-22, 2006, Chicago, Illinois, USA.
2) 40th Annual Meeting of the Canadian Orthopaedics Research Society, Jun 2-4, 2006, Toronto, Ontario, Canada.

A manuscript on the results of this study is being prepared for publication in the refereed journal *Spine*. 
Chapter 6

Rod Extension and Cement on Destabilized Level

6 Enhancing Fixation of the Osteoporotic Spine in a Corpectomy Model: The Effect of Cement Augmentation and Posterior Instrumentation Extension

6.1 Introduction

Reconstruction of the anterior spinal column is necessary after vertebral body resection in the thoracic and lumbar spine in cases with substantial instability such as following severe trauma or resection of a tumor [Vahldiek and Panjabi 1998, Vieweg et al. 2003, Dvorak et al. 2003, Thongtrangan et al. 2003, Pflugmacher et al. 2004, Fisher et al. 2005, Holman et al. 2005]. Structural allografts [Bridwell et al. 1995, Molinari et al. 1999], autografts [Buttermann et al. 1997], bone cement [Harrington 1988], titanium cages [Akamura et al. 2002] or expandable cages [Vieweg et al. 2003, Thongtrangan et al. 2003] are used clinically to reconstruct the anterior column. Supplementary posterior or anterior instrumentation is necessary to enhance the structural stability of the spinal column [Vahldiek and Panjabi 1998].

Immediately following surgery, the implants are expected to provide sufficient stability for spinal fusion to occur. The implants are thus subjected to full load bearing during the immediate post-operative period, with minimal load transmitted through the remaining facet joints. The bone-implant interfaces are consequently placed under high stresses during this immediate post-operative period. The challenge of maintaining bone-implant interfaces and initial rigidity is even greater when such surgery is to be carried out in patients with low bone density [Vieweg et al. 2003, Babat et al. 2004]. Failure at the pedicle screw-bone interface, and/or the interbody device-vertebra interface could result in failure of bony fusion and the loss of correction in spinal alignment (Figure 6.1).

To achieve initial rigidity, the surgeon aims to prevent both pedicle screw loosening and cage-vertebra subsidence. One technique to prevent pedicle screw loosening is to increase the number of anchor points [Hu 1997, Hasegawa and Hirano 2002], such as extending the pedicle screws two or more levels above and below the immediate fusion level. Another technique that has become popular is the cement augmentation of screws, which was shown to biomechanically improve fixation strength at the screw-bone interface [Cameron et al. 1975, Zindrick et al. 1986, Wittenberg et al. 1993, Lotz et al. 1997, Moore et al. 1997, Yerby et al. 1998, Ignatius et al. 2001, Bai et al. 2001, Sarzier et al. 2002, Schultheiss et al. 2004, Cook et al. 2004, Renner et al. 2004, Tan et al. 2004]. No biomechanical study has directly compared these two approaches to our knowledge.
Increased motion at adjacent non-instrumented levels following rigid spinal fixation has been suggested to be the cause of adjacent segment diseases [Lee 1988, Shono et al. 1998]. Adjacent segment failure in 4 out of 7 patients included progressive kyphosis with pseudoarthrosis following instrumented fusion in a retrospective study on patients with Parkinson's disease [Babat et al. 2004]. One solution utilised by surgeons to prevent adjacent segment disease is to extend the rigid posterior instrumentation to adjacent levels [Hu 1997]. Extending the rigid posterior instrumentation, however, could simply bring the adjacent segment disease to the next level where the extension rod ends. To prevent such adjacent segment effect, we conceptualized that this extension of instrumentation to an adjacent level should result in a more gradual gradient in resultant motion from the fusion construct, through the
extension level, and to the non-instrumented levels. With no sudden increase in motion at the junction to a fusion construct or extension level, mechanically induced adjacent segment disease could possibly be reduced. One technique to achieve this gradual gradient in resultant motion would be to use flexible extension rods of appropriate flexural modulus in place of rigid rods. In a study investigating change in range of motion (ROM) at the adjacent segment after a solid fusion and after implantation of a flexible stabilization device (Dynesys, Centerpulse Orthopedics) at the adjacent segment, ROM at L4-L5 increased following rigid instrumentation at L5-S1, but reduced with implantation of a flexible transition device at L4-L5 [Goertzen et al. 2003]. The effect on ROM at the immediate surgical level (L5-S1) in that study was however not reported.

This study is the first of a two-part study on addressing both initial construct fixation and adjacent level effects in the osteoporotic spine. In Part I (Chapter 6), enhancement of initial construct fixation with cement augmentation of pedicle screws is contrasted against extension of posterior instrumentation to the next level. In Part II (Chapter 7), adjacent level kinematics is contrasted between cement augmentation and posterior instrumentation extension. The purposes of Part I and Part II are to determine if cement augmentation and/or posterior rod extension could 1) enhance stability at the immediate surgical level, and 2) modulate motion at the adjacent vertebral level, respectively. For the current study, it is hypothesized that both cement augmentation of pedicle screws and extension of posterior fixation to the next level could enhance stabilization to the immediate surgical level. The kinematics of the immediate surgical level (T10-T12) in a T9-L3 cadaveric model with T11 corpectomy following: 1) cement augmentation of pedicle screws, and 2) extension with flexible or rigid posterior rods to L1, under the same applied moment of 5Nm, were contrasted.

### 6.2 Methods

#### 6.2.1 Specimens

Twelve 7-vertebrae thoracolumbar cadaveric specimens (T8-L2 or T9-L3) were utilised in this study. The donors' ages ranged between 64 and 84 years with a mean of 75 years (ages of 4 donors unknown). There were 3 male and 7 female donors (gender of 2 unknown). All specimens were harvested from unembalmed donors from the University of British Columbia Tissue Donation Program and stored frozen at -20 °C. This study was approved by our Institution's Clinical Research Ethics Board.

Surrounding soft tissues such as muscles were carefully dissected, without damaging the intervertebral ligaments and discs. All ribs were removed by dissecting through the
costovertebral and costotransverse joints. Thereafter, areal bone mineral densities (aBMD) of the 5 middle vertebral bodies (T9-L1 of T8-L2 segments and T10-L2 of T9-L3 segments) were measured from the lateral projection of dissected (T8-L2 or T9-L3) spinal segments using a dual-energy x-ray absorptiometry (DXA) machine (QDR 4500W, Hologic Inc., Bedford, MA) and using methodology previously described in detail [Sran et al. 2005]. The lateral dimension of each vertebral body was physically measured using a pair of vernier calipers and the volumetric BMD (vBMD) was subsequently calculated by approximating the vertebral body as an elliptical cylinder [Sran et al. 2005]. Average aBMD and vBMD for each spinal segment was calculated from the 5 middle vertebral levels. Mean aBMD and vBMD for the 12 spines was 0.420 g/cm$^2$ (s.d. = 0.090) and 0.151 g/cm$^3$ (s.d. = 0.034) respectively (Figure 6.2). Specimens with 1) bridging osteophytes resulting in bony fusion, and 2) vertebral body fracture, were excluded from this study. Two specimens included in the study had third degree (bird's beak shaped) osteophytes [Nathan et al. 1994] at T10 and T11, while one specimen had third degree osteophytes at L1 and L2.

![Figure 6.2](image)

Figure 6.2 Distribution of areal bone mineral density (aBMD) and volumetric bone mineral density (vBMD) among the 12 specimens in this study. The aBMD data were obtained directly from the DXA machine output, derived from dividing bone mineral content (BMC) by the projection area (2-dimensional area). The vBMD data were calculated from dividing the BMC by the estimated volume of the vertebral body. aBMD is the traditional technique of presenting BMD data but is less accurate as it uses the projected area in its calculation while vBMD is more accurate as it considers the total volume.
6.2.2 Anterior and Posterior Instrumentation Configurations

The experiment was conducted in a repeated measures fashion to test two main effects with interactions, between 1) cement augmentation of screw fixation and 2) posterior rod extension (rigid and flexible). The three surgical conditions in a T9-L3 (T8-L2) spinal segment (Figure 6.3) involved:

(A) T11 (T10) corpectomy, interbody implant bridging across T10 to T12 (T9 to T11), pedicle screws and rigid rod fixation bridging across T10 to T12 (T9 to T11) (Figure 6.3A),
(B) surgical condition A) and with rigid rod bridging across T10 to L1 (T9 to T12) (Figure 6.3B), and
(C) surgical condition A), with rigid rod bridging across T10 and T12 (T9 to T11) and with flexible rod bridging across T12 and L1 (T11 to T12) (Figure 6.3C).

Figure 6.3 Schematic diagram of different surgical conditions tested in a repeated measures fashion in a T9-L3 spine segment. (I): Intact spine. (A): T11 corpectomy, a vertebral body replacement device inserted and rigid posterior instrumentation across T10 and T12. (B): Previous condition, with rigid rod across T10 to L1. (C): Previous condition, but with flexible rod between T12 and L1. The T10 screw fixations were augmented with bone cement in all surgical test conditions.

Stainless steel pedicle screws (USS, Synthes Spine, Mississauga, ON) were implanted by a single spine surgeon (Dr Sandeep Singh), by the following clinical protocol. Screws of uniform diameter (5mm), with lengths of 35 mm, 40 mm, 45 mm or 50 mm, were used. The
pedicle screws were inserted to approximately 80% of the vertebral body depth and the length of the pedicle screws used varied between specimen and spinal level.

An expandable vertebral body replacement device (Synex, Synthes Spine, Mississauga, ON) was used to bridge across the T10-T12 (T9-T11) space following corpectomy to restore and maintain the intervertebral height. The device was inserted in the un-expanded state, aligned and expanded in situ with the accompanying tool (Synthes Spine), and engaged the endplates at both ends. A smaller vertebral body replacement device expandable from 23-31 mm was used in 9 spines, and a larger device expandable from 26-36 mm was used in the remaining 3 spines. Measured heights at the anterior edges (Figure 6.4) of the expanded devices ranged from 27 mm to 36 mm, with a median height of 29.5 mm. Both sizes of the device had endplate contact area of 25x28 mm and zero degrees of endplate angulation. No bone grafts were inserted into or around the vertebral body replacement device.

Figure 6.4  Measured height of the expandable vertebral body replacement device excluded the spiked protuberances at both ends. The end dimensions of the device contact areas are 25x28 mm. The devices included in this study had zero degrees of endplate angulation.
Connection of the extending rigid and flexible rods to the next distal level was carried out using a "parallel rod connector" and a "transverse connector" (Synthes Spine) (Figure 6.5). The average length of the extended rod segments was 76% (s.d. = 7%) of the length of the T10-T12 (T9-T11) rods. Similar lengths of rigid and flexible extension rods were used in surgical conditions (B) and (C). Using three-point bending tests, the ratio of the stiffness of the flexible rods (diameter 6.35 mm) to the stiffness of the rigid stainless steel rods (diameter 6 mm) was determined to be 1:37. The flexible rods are made of polyacetal (Trade name Delrin®, Industrial Plastics and Paints, Vancouver, BC) a biocompatible material used in heart valves and hip prostheses [McKellop et al. 1996]. The use of these rods for this application in the spine is not clinically approved to our knowledge. They are used in this study as a matched comparison to the rigid rods to test the concept of flexible posterior instrumentation.

Figure 6.5  Extending rigid and flexible posterior rods from T12 to L1 of T9-L3 segments (T11-T12 in T8-L2 segments) were carried out using a "parallel rods connector" and a "transverse connector" on each side. Both rigid and flexible extending rods' lengths were adjusted to three-quarter of the length of the T10-T12 (T9-T11) rod. The length of the T10-T12 rod was measured between screw heads while the length of the extension rod was measured between the parallel and transverse connectors. The extension rods (black in colour) shown in this figure are the 'flexible rods' made of polyacetal.
6.2.3 Test Protocol

Intact flexibility tests in axial rotation (AR), lateral bending (LB) and flexion-extension (FE) were carried out in a randomized order with applied pure moments ranging between +5 Nm and -5 Nm. FE flexibility tests were carried out with and without 400 N of compressive follower-load (FL) based on the method previously described [Patwardhan et al. 1999]. The FL apparatus consists of components attached individually to each vertebral (Figure 6.6) and the compressive load remains tangential to the curvature of the spine during motion. A FL was not used in AR and LB as the current concept of using bilateral cables to simulate muscle loads is not generally accepted in these directions [Goel 2005].

All tests were conducted using a custom spine testing machine (Figure 6.6) capable of applying pure moments [Goertzen et al. 2004]. This spine tester was retrofitted in March 2005 with a new actuator arm that has a lower torsional compliance (0.6 degree/Nm), and with new universal joints to eliminate the issues of slippage previously experienced [Niosi et al. 2005]. The actuator was rotated at a rate of 2 degrees/second between a maximum of 5 Nm and a minimum of -5 Nm for 3 cycles. A servohydraulic actuator (Instron A591-4, Instron Corporation, Canton, MA) was used to apply and maintain the constant 400 N of FL.

Following testing in the intact condition, the three surgical conditions were carried out in a randomized order by a trained surgeon (Dr Sandeep Singh). Cement was used to augment only the T10 (T9 in T8-L2 segments) screws at this stage. In order to simulate the worst case scenario of loosened screws in the osteoporotic spine, the T12 and L1 (T11 and T12) pedicle screw tracts were over-drilled with a 5 mm diameter drill prior to the insertion of the pedicle screws [Tan et al. 2004 (Chapter 3)]. Flexibility tests similar to those in the intact state were repeated following each of the three surgical conditions. The flexibility tests in AR, LB, FE and FE+FL, were again carried out in a randomized order.

After all tests for the non-cemented state were completed, the T12 and L1 (T11 and T12) pedicle screws were augmented with cement, and the tests for the cemented state carried out. Each pedicle screw was removed, then about 2 cm³ of cement (Palacos R, Biomet Merck, Kerzers, Switzerland or Simplex, Stryker, Hamilton, ON) was injected in the pedicle screw tract and lastly the same screw was reinserted. This method of cement injection into a screw tract is used clinically [Wuisman et al. 2000] and was evaluated experimentally [Soshi et al. 1991]. Both cements were randomly used among the 12 specimens.

The cement was allowed to cure and the same three surgical conditions (A), (B) and (C) were then randomly carried out, and with flexibility tests conducted in a randomized order for each surgical condition.
Figure 6.6  The custom spine testing machine used to apply pure moments to the specimen. The follower load (FL) apparatus consists of components attached to each vertebra and with bilateral eyelets where the compressive load is guided through.

Three-dimensional kinematics of all vertebral bodies (except the corpectomy level) was collected during each flexibility test using an optoelectronic camera system (Optotrak 3020, Northern Digital Inc., Waterloo, Canada). The data for motion and applied moment was synchronised and recorded at 20 Hz for the duration of each test. Intersegmental and overall
range of motion (ROM) and neutral zones (NZ) (Figure 6.7) were determined from the flexibility curves at the third (last) cycle. A lower ROM at the destabilized level between surgical techniques would indicate better fixation stabilization. An increase in ROM at the adjacent level indicates potential accelerated adjacent level effects. A constant ROM at the non-instrumented level would indicate application of pure moments. Increase in NZ across spinal segment(s) indicates injury [Oxland and Panjabi 1992] and increased instability at the level(s).

6.2.4 Statistical Analysis

One-way repeated measures ANOVA, with Newman-Keuls post-hoc tests, were carried out to determine significant differences between intact and surgical conditions. Two-way repeated measures ANOVA, with Newman-Keuls post-hoc analyses, were carried out to determine significant effects of cement augmentation (factor 1) and posterior rod extension (factor 2). ROM and NZ were normalized against its intact condition for the two-way ANOVA to reduce effects of inter-specimen differences. An alpha of 0.01 was chosen as multiple two-way ANOVAs were carried out independently across 5 spinal levels and 3 test directions.

Figure 6.7 Flexibility curve of the T8-L2 spine in flexion-extension (FE) of a typical specimen (3 cycles shown), following cement augmentation of all pedicle screws and with rigid posterior rod extension. Overall range of motion (ROM) and neutral zone (NZ) were determined from the third (last) cycle.
6.3 Results

6.3.1 Flexibility across Destabilized Level

The mean ROMs across the destabilized level in the intact state (T10-T12 in T9-L3 segments) in AR, LB and FE were 9.3°, 7.8° and 6.2° respectively (Table 6.1). The corresponding mean NZs in AR, LB and FE were 0.5°, 0.7° and 0.4° respectively. In the 1-way ANOVA analyses, AR, LB and FE ROMs and NZs were significantly affected by surgical intervention (all p < 0.001). The mean ROMs at the destabilized level were significantly reduced with the basic surgical procedures carried out (no cement, no extension), in LB to 5.1° (by 35%, p < 0.001) and in FE to 4.5° (27%, p < 0.001), but with a marginal reduction in AR to 7.9° (16%, p = 0.06). Conversely, surgical intervention without cement or rod extension increased mean NZ at the destabilized level from its intact state in AR by 248% to 1.6° (p < 0.001), in LB by 40% to 1.0° (p = 0.02), and in FE by 92% to 0.8° (p < 0.001).

Table 6.1 Range of motion and neutral zone across destabilized levels for different surgical conditions in the respective test directions.

<table>
<thead>
<tr>
<th></th>
<th>Range of Motion, mean (s.d.)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AR</td>
<td>LB</td>
<td>FE</td>
<td>FE+FL</td>
</tr>
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<td>7.8° (2.8°)</td>
<td>6.2° (1.9°)</td>
<td>6.2° (1.8°)</td>
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<td>*5.1° (2.2°)</td>
<td>*4.5° (2.5°)</td>
</tr>
<tr>
<td></td>
<td>Flexible extension</td>
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<td>*3.3° (1.9°)</td>
</tr>
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</tr>
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<td>Cemented</td>
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<td>*1.9° (1.1°)</td>
<td>*2.3° (1.1°)</td>
</tr>
<tr>
<td></td>
<td>Flexible extension</td>
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<td>*1.3° (1.3°)</td>
<td>*1.8° (0.9°)</td>
</tr>
<tr>
<td></td>
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<td>*1.2° (1.1°)</td>
<td>*1.5° (0.7°)</td>
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<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
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<table>
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<tr>
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<td></td>
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<td>LB</td>
<td>FE</td>
<td>FE+FL</td>
</tr>
<tr>
<td>Intact</td>
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<td>0.7° (0.4°)</td>
<td>0.4° (0.3°)</td>
<td>0.4° (0.3°)</td>
</tr>
<tr>
<td>Not cemented</td>
<td>No extension</td>
<td>*1.6° (1.5°)</td>
<td>1.0° (0.6°)</td>
<td>*0.8° (0.7°)</td>
</tr>
<tr>
<td></td>
<td>Flexible extension</td>
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<td>0.6° (0.6°)</td>
<td>0.4° (0.3°)</td>
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<tr>
<td></td>
<td>Rigid extension</td>
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<td>0.5° (0.5°)</td>
<td>0.3° (0.2°)</td>
</tr>
<tr>
<td>Cemented</td>
<td>No extension</td>
<td>0.5° (0.4°)</td>
<td>*0.3° (0.2°)</td>
<td>0.2° (0.1°)</td>
</tr>
<tr>
<td></td>
<td>Flexible extension</td>
<td>0.5° (0.3°)</td>
<td>*0.3° (0.3°)</td>
<td>0.1° (0.1°)</td>
</tr>
<tr>
<td></td>
<td>Rigid extension</td>
<td>0.4° (0.3°)</td>
<td>*0.2° (0.3°)</td>
<td>0.1° (0.08°)</td>
</tr>
<tr>
<td>p-values from 1-way ANOVA</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

* - significantly different from corresponding intact value, alpha = 0.01.

In the 2-way ANOVA analyses, mean ROMs and NZs at the destabilized level in all directions were reduced significantly by cement augmentation and rod extension (Table 6.2, Figures 6.8 to 6.11). In general, cement augmentation resulted in greater percentage decrease
Chapter 6  Rod Extension and Cement on Destabilized Level

in ROM than did flexible posterior rod extension in all loading directions, and greater than or similar percentage decrease in ROM than did rigid posterior rod extension. In all cases, rigid posterior rod extension resulted in greater reduction in ROM at the destabilized level than flexible rod extension. There was a significant 2-way interaction between cement and posterior rod extension on ROM in all directions and on NZ in LB and FE. Without cement augmentation of screws, rod extension significantly reduced ROM and NZ at the destabilized level; however, the effects of rod extension were not or were less significant in the presence of cement augmentation.

### Table 6.2 2-way ANOVA results on normalized ROM and NZ between cement (factor 1) and rod extension (factor 2) at destabilized levels.

<table>
<thead>
<tr>
<th></th>
<th>Range of Motion (ROM)</th>
<th>Neutral Zone (NZ)</th>
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<tbody>
<tr>
<td></td>
<td>AR</td>
<td>LB</td>
</tr>
<tr>
<td>Factor 1: Cement</td>
<td>0.002</td>
<td>0.003</td>
</tr>
<tr>
<td>Factor 2: Extension</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Interactions</td>
<td>0.01</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

In AR, cement augmentation with no rod extension resulted in a 38% decrease in normalized ROM (from 87% of intact ROM to 49%). Rigid rod extension decreased ROM by 10% (p = 0.03) with cement and by 26% (p < 0.001) without, while flexible rod extension decreased ROM by only 2% with cement and by 13% without. Overall, cement augmentation resulted in higher percentage decreases in ROM (22% to 38%) than posterior rod extension (2% to 26%). A borderline interaction between cement augmentation and posterior rod extension (p = 0.01) was the result of significant effects of posterior rod extension when cement was not used and a non significant effect of posterior rod extension with cement. Of note was that cement augmentation of the baseline condition (no cement, no extension) resulted in smaller ROM (49% of intact) than with rigid (61%) rod extension (p = 0.003).
Figure 6.8  Mean normalized range of motion (ROM) of the destabilized level in AR. Error bars indicate standard deviation.

Figure 6.9  Mean normalized range of motion (ROM) of the destabilized level in LB. Error bars indicate standard deviation.

In LB, cement augmentation decreased ROM between 15% (with rigid rod) and 44% (without rod extension), while rigid rod extension resulted in 38% decrease without cement but only 9% with cement. A significant interaction between cement augmentation and posterior rod extension was observed, wherein posterior rod extension significantly decreased ROM only
when cement was not used. Of note was that cement augmentation of the baseline condition resulted in smaller ROM (27% of intact) than with rigid rod extension (33%), although the difference was not significant (p = 0.07).

In FE, cement augmentation decreased ROM between 12% (with rigid rod) and 35% (without rod extension), while rigid rod extension resulted in 37% decrease without cement and in 14% with cement. A significant interaction between cement augmentation and posterior rod extension was observed, and this was again due to the differences between effects of posterior rod extension with and without cement. Cement augmentation of the baseline condition resulted in a ROM (38% of intact) similar to ROM with rigid rod extension (36%) (p = 0.61).

Figure 6.10  Mean normalized range of motion (ROM) of the destabilized level in FE. Error bars indicate standard deviation.
6.3.2 Flexibility across Rod Extension Level

The mean ROM across the rod extension level (T12-L1 in T9-L3 segments) in the intact state in AR, LB and FE were 2.7°, 4.6° and 4.0° respectively (Table 6.3). The corresponding mean NZs at the rod extension level were 0.1°, 0.4° and 0.3° respectively. In the 1-way ANOVA analyses, AR, LB and FE ROMs were significantly affected by surgical intervention (p < 0.001). With no posterior rod extension, with or without cement, the mean ROMs at the rod extension level were not significantly different from intact, while rod extension significantly reduced ROMs in all test directions (Table 6.3). NZs at the rod extension level were generally unaffected as no injury was created at that level, such as removal of disc matter, when posterior rod extension was included.

In the 2-way ANOVA analyses, mean ROMs at the rod extension level in all flexibility test directions were significantly reduced after inclusion of extension rods, regardless on the presence of cement (Tables 6.3 and 6.4, Figures 6.12 to 6.15). In general, posterior rod extension resulted in greater percentage decrease in ROM across the rod extension level than did cement augmentation in all loading directions. A noteworthy point was that cement augmentation without posterior rod extension did not result in increased motion at the rod extension level. In all cases, rigid posterior rod extension resulted in greater reduction in ROM at the rod extension level than flexible rod extension. There was no significant 2-way interaction between cement augmentation and posterior rod extension on ROM or NZ in all directions.
Table 6.3  Range of motion and neutral zone across extension level for different surgical conditions in the respective test directions.

<table>
<thead>
<tr>
<th></th>
<th>Range of Motion, mean (s.d.)</th>
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<th>LB</th>
<th>FE</th>
<th>FE+FL</th>
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<tbody>
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<td><strong>Intact</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>No extension</td>
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<td>4.6° (1.9°)</td>
<td>4.0° (1.8°)</td>
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<td></td>
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<td>2.8° (1.1°) *</td>
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<td>2.3° (1.1°) *</td>
<td>1.8° (1.0°) *</td>
<td>1.6° (0.9°) *</td>
</tr>
<tr>
<td><strong>Not cemented</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td></td>
<td>2.4° (1.6°)</td>
<td>4.6° (1.3°)</td>
<td>3.7° (1.3°)</td>
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<td>Flexible extension</td>
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<td>1.7° (0.5°) *</td>
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<td><strong>Cemented</strong></td>
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* - significantly different from corresponding intact value, alpha = 0.01.

Table 6.4  2-way ANOVA results on normalized ROM and NZ between cement (factor 1) and rod extension (factor 2) at the rod extension level (below destabilized level).

<table>
<thead>
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<th>Range of Motion (ROM)</th>
<th>AR</th>
<th>LB</th>
<th>FE</th>
<th>FE+FL</th>
</tr>
</thead>
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<tr>
<td><strong>Factor 1: Cement</strong></td>
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<td>0.01</td>
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<tr>
<td><strong>Factor 2: Extension</strong></td>
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<td>&lt; 0.001</td>
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In AR, cement augmentation with no extension resulted in an 11% decrease in normalized ROM (from 105% of intact ROM to 94%). Rigid rod extension decreased ROM by 49% with cement and by 45% without, while flexible rod extension decreased ROM by 31% with cement and 26% without. Overall, posterior rod extension resulted in higher percentage decreases in ROM (26% to 49%) than cement augmentation (11% to 16%). There was no interaction between cement augmentation and posterior rod extension.
Figure 6.12 Mean normalized range of motion (ROM) at the extension level in AR. Error bars indicate standard deviation.

In LB, the trend of higher percentage decrease in ROM with posterior rod extension (50% to 76%) than with cement augmentation (8% to 22%) was again observed. Cement augmentation decreased ROM by 8% without rod extension, by 21% with flexible rod and by 22% with rigid rod. Rigid rod extension decreased ROM by 62% without cement and by 76% with cement, while flexible rod extension decreased ROM by 50% without cement and by 63% with cement. There was no interaction between cement augmentation and posterior rod extension.

In FE, posterior rod extension again resulted in higher percentage decrease in ROM (53% to 72%) than cement augmentation (15% to 23%). Cement augmentation decreased ROM by 15% without rod extension, by 23% with flexible rod and by 21% with rigid rod. Rigid rod extension decreased ROM by 66% without cement and by 72% with cement, while flexible rod extension decreased ROM by 53% without cement and by 61% with cement. There was no interaction between cement augmentation and posterior rod extension.
Figure 6.13  Mean normalized range of motion (ROM) at the extension level in LB. Error bars indicate standard deviation.

Figure 6.14  Mean normalized range of motion (ROM) at the extension level in FE. Error bars indicate standard deviation.
6.3.3 Flexibility across Non-Instrumented Levels

At the non-instrumented levels of T9-T10 (1 level above destabilized level), AR, LB and FE ROMs were significantly increased by surgical intervention (p < 0.001) (Table 6.5). Corresponding NZs at T9-T10 were also increased in LB (p < 0.001), and FE (p < 0.001), but not in AR (p = 0.2). Compared to intact values, the basic surgical procedures carried out (no cement, no extension) significantly increased mean ROMs at T9-T10, in AR from 5.1° to 6.1° (18 %, p = 0.002), in LB from 4.5° to 5.6° (25 %, p < 0.001), and in FE from 3.0° to 4.0° (35 %, p < 0.001) (Table 6.5, Figures 6.16 – 6.19). These increases in ROMs and NZs were unexpected, as pure moments were applied. On the other hand, ROMs and NZs at the distal non-instrumented levels of L1-L2 (2 levels below) and L2-L3 (3 levels below) were generally unaffected by surgical intervention (Tables 6.6 and 6.7, Figures 6.16 – 6.19).

Figure 6.15  Mean normalized range of motion (ROM) at the extension level in FE+FL. Error bars indicate standard deviation.

- **Not Cemented**
- **Cemented**

- p < 0.001
- p = 0.002
- p = 0.001
- p = 0.1

**Figure 6.15**  Mean normalized range of motion (ROM) at the extension level in FE+FL. Error bars indicate standard deviation.
### Table 6.5 Range of motion and neutral zone across level above destabilized level (T9-T10) for different surgical conditions in the respective test directions.

<table>
<thead>
<tr>
<th></th>
<th>Range of Motion, mean (s.d.)</th>
<th>Neutral Zone, mean (s.d.)</th>
</tr>
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<tr>
<td></td>
<td>AR</td>
<td>LB</td>
</tr>
<tr>
<td><strong>Intact</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>*6.1° (1.5°)</td>
<td>*5.6° (1.7°)</td>
</tr>
<tr>
<td>Flexible</td>
<td>*6.0° (1.5°)</td>
<td>*5.7° (1.8°)</td>
</tr>
<tr>
<td>Rigid</td>
<td>*6.0° (1.5°)</td>
<td>*5.5° (1.6°)</td>
</tr>
<tr>
<td><strong>Cemented</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>*6.2° (1.5°)</td>
<td>*5.9° (1.8°)</td>
</tr>
<tr>
<td>Flexible</td>
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<td>*5.7° (1.9°)</td>
</tr>
<tr>
<td>Rigid</td>
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</tr>
<tr>
<td>p-values from 1-way ANOVA</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

* - significantly different from corresponding intact value, alpha = 0.01.

### Table 6.6 Range of motion and neutral zone at 2 levels below destabilized level (L1-L2) for different surgical conditions in the respective test directions.

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<tr>
<td>Not cemented</td>
<td></td>
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<tr>
<td>No extension</td>
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<tr>
<td>Flexible</td>
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<td>6.0° (2.0°)</td>
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<tr>
<td>Rigid</td>
<td>1.9° (1.7°)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>No extension</td>
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<td>6.1° (2.1°)</td>
</tr>
<tr>
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* - significantly different from corresponding intact value, alpha = 0.01.
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<td>LB</td>
<td>FE</td>
<td>FE+FL</td>
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<tr>
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<tr>
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<table>
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<td>LB</td>
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<td>FE+FL</td>
</tr>
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<td>0.8° (0.5°)</td>
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</tr>
<tr>
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<td>0.1</td>
</tr>
</tbody>
</table>

Values in parenthesis denote standard deviation.
* - significantly different from corresponding intact value, alpha = 0.01.

In the 2-way ANOVA analyses, mean AR, LB and FE ROMs and NZs at all 3 non-instrumented levels were not significantly different between surgical procedures carried out at the instrumented and extension levels (Figures 6.16 – 6.19).
Figure 6.16 Mean normalized range of motion (ROM) and neutral zone (NZ) of each mobile level and instrumented segment in AR. Posterior rod extension involved the first level below the destabilized level. No significant differences were found at the non-instrumented levels (1 level above, 2 below or 3 below from destabilized level) between surgical conditions.
Figure 6.17 Mean normalized range of motion (ROM) and neutral zone (NZ) of each mobile level and instrumented segment in LB. There were no significant differences in ROM between surgical conditions, at the non-instrumented levels.
Chapter 6  Rod Extension and Cement on Destabilized Level

Flexion-Extension ROM

Flexion-Extension NZ

* - significant effect of cement and significant effect of rod extension,
** - significant effect of extension only, within the level.

Using 2-way repeated measures ANOVA, alpha = 0.01.
Error bars indicate standard deviation.

Figure 6.18  Mean normalized range of motion (ROM) and neutral zone (NZ) of each mobile level and instrumented segment in FE. There were no significant differences in ROM between surgical conditions, at the non-instrumented levels.
Chapter 6  Rod Extension and Cement on Destabilized Level

Figure 6.19  Mean normalized range of motion (ROM) and neutral zone (NZ) of each mobile level and instrumented segment in FE+FL. There were no significant differences in ROM between surgical conditions, at the non-instrumented levels.
6.4 Discussion

The main purpose of this study was to determine the relative effect of cement augmentation of screws and posterior rod extension on spinal motion in the osteoporotic spine. This study focused on the destabilized level, but other levels were also addressed. An in vitro multi-segmental spine model was adopted, so as to compare the immediate post-operative kinematics following different surgical conditions. Less motion at the destabilized level is desirable so as to achieve better fusion, while motion at the adjacent levels should remain similar to the intact state so as to avoid adjacent level effects.

6.4.1 Limitations

A common limitation associated with repeated measures in vitro studies where extensive surgical procedures and tests were carried out on the same specimen was the deterioration of the tissues over the duration of the test, which could result in device loosening or soft tissues damage. This was addressed by randomizing the sequence of rod extension configurations and the order of flexibility tests. To mitigate the effects of differences between specimens, comparisons were made within specimens and normalized against its intact values. As a prudent measure, all tests on a specimen were carried out on the same day to minimise the effect of refreezing and the specimens were sprayed with saline and water at intervals to keep the tissues moist during tests. To further alleviate the issue of tissue deterioration, cement augmentation of screws were conducted in the later half of each test day, which resulted in significantly lower ROM at the instrumented and extension levels, and mitigated any adverse effects of device loosening over time. The fact that ROMs at the non-instrumented levels were not significantly affected over time demonstrated minimal damage to its biomechanical integrity.

Although the testing machine was designed to apply pure moments of the same magnitudes in each test, there were some limitations inherent with the spine machine (Figure 6.6). The balance weight of 4.3 N located 0.14 m from the midline was balanced for the neutral position. During operation, the length of the ball spline extends and retracts by as much as 0.02 m in each direction. As a result, the change in moment by weight of the actuator arm could vary by about 0.08 Nm. This moment acts in an orthogonal plane to the plane of applied moment. For example in flexion-extension tests, this 0.08 Nm is applied in the lateral bending direction. A second limitation with the testing machine is with the counter weight system, which hung on a passive swivel system that has some inherent friction. From the angle of the hanging wires and the mass of the counter weight, it can be estimated that a 2 N force was necessary to overcome the friction in the swivel. This resulted in a counteracting moment, with smaller magnitudes.
(about 0.2 Nm) applied to the upper most spinal segment and higher magnitudes (about 0.5 Nm) to the lowest spinal segment. These errors were however consistent in every specimen and surgical condition, and should not affect the overall result and conclusion.

6.4.2 Destabilized Level

Posterior instrumentation together with vertebral body replacement cage has been found to provide greater rigidity at the destabilized levels than the intact state in vertebral body replacement surgeries [Vahldiek and Panjabi 1998, Pflugmacher et al. 2004, Schultheiss et al. 2004]. The ROM following stabilization with vertebral bone replacement cages and posterior instrumentation in an *in vitro* study was about 10% of intact values in FE and LB and about 40% in AR [Pflugmacher et al. 2004]. In another *in vitro* study, the ROM was 12.5% of intact values in FE, 40% in LB and was not different from intact in AR [Vahldiek and Panjabi 1998].

In the current study, the minimal surgical configuration without cement or posterior rod extension did not substantially reduce ROM in FE (73% of intact), LB (65%) and AR (84%). This was an expected findings as the condition in an osteoporotic spine was simulated with loosened screws at T12. Following cement augmentation and/or posterior rod extension, ROM at the destabilized level was reduced. With cement augmentation, ROMs were reduced in FE (37% of intact), LB (24%) and AR (47%). With both cement augmentation and rigid rod extension, ROMs were further reduced in FE (24% of intact), LB (15%) and AR (38%). These values were comparable to the literature [Vahldiek and Panjabi 1998, Pflugmacher et al. 2004], and thus the data supports the use of cement and/or posterior rod extension to improve fixation in the osteoporotic spine. Figures 6.20 and 6.21 summaries the results in this study.

6.4.3 Rod Extension Level

Increased biomechanical demand at levels adjacent to a rigid construct were previously found to cause significant degenerative changes at these adjacent levels in clinical studies [Axelsson et al. 1997, Oda et al. 1999, Kumar et al. 2001a, 2001b]. At the rod extension level in this study, ROMs were found to be significantly reduced with the use of rigid or flexible rod extension, but less so with cement. The use of posterior rod extension could thus be a feasible technique to suppress the potential increase in demands following rigid fixation. The use of rigid posterior rod extension resulted in 45% to 55% reduction in motion at the rod extension level in AR, LB and FE. Flexible rod extension on the other hand resulted in 26% reduction in motion in AR, 39% in LB and 42% in FE. No related data is available in the published literature for comparison, according to our knowledge.
Figure 6.20  Summary of changes in ROM across levels and directions, for the non-cemented conditions.
Figure 6.21  Summary of changes in ROM across levels and directions, for the cemented conditions.
6.4.4 Other Levels

Compared to the respective intact states, the initial surgical intervention resulted in 23% increase in AR ROM, 29% in LB and 42% in FE at the upper most level (T9-T10) (Table 6.5). These increases were unexpected as pure moments were applied. Injury to the T9-T10 motion segment during the initial surgery could have caused these increases in ROMs. As the dimensions of T9-T10 were the smallest within the test specimen, the 5 Nm applied moment could also have caused soft tissue damage at this level but not at the more distal levels. A further check of the data revealed that 2 of 12 specimens had higher increases in ROM with the initial surgical condition than the average of the other 10 specimens, which inflated the overall average increase. One specimen had 151% increase in AR, a second specimen had 94% increase in LB, and in FE these two specimens had increases of 215% and 115% respectively. Omitting the data from these outliers, the average increase in ROMs would have been more moderate at 11% in AR, 23% in LB and 29% in FE. Other factors that could have affected kinematics at T9-T10 included changes within the motion segment. The injection of cement into T10 followed by insertion of pedicle screws could have affected normal deflection of the superior T10 endplate, and changes to the T9-T10 disc pressure. As cement was used in all T10 screws, it could have consistently affected kinematics at the T9-T10 level in all specimens. In a finite element study, cement injection of vertebral bodies was found to increase disc pressure in adjacent discs, endplate deflection, stresses and strains [Polikeit et al. 2003].

Cement augmentation or posterior rod extension did not result in changes in ROMs at the all non-instrumented levels, and were consistent with expectation when the flexibility protocol was used.

6.4.5 Spinal Fusion and Adjacent Level Effect

The role of spinal instrumentation and interbody fusion devices are to provide initial rigidity for bony fusion to occur [Evans 1985]. It is known that too much motion could be detrimental to the fusion process, and granulation tissue and fibrosis would develop from the bone grafts [Bauer and Muschler 2000], leading to pseudoarthrosis, implant loosening, and possibly in subsequent fatigue failure of instrumentation [Babat et al.2004]. Wolff's law on bone remodelling or the interfragmentary strain theory used in fracture fixation of long bones [Chao and Aro 1997] could probably be used to describe the bone remodelling or growth that takes place within the bone grafts in spinal fusion. In short, the bone grafts need to be loaded in order for bone remodelling to occur, while too much motion may inhibit the fusion process. Less motion at the destabilized level is therefore desirable in order to achieve better fusion.
One solution to address adjacent level effects was to increase the extent of the fixation to include multiple segments [Hu 1997, Babat et al. 2004]. There was concern, however, that rod extension might result in postponement of adverse adjacent level effects to the level beyond the extension rods [Hu 1997, Diwan et al. 2003, Kostuik and Shapiro 2003, Babat et al. 2004]. The use of flexible rod extension to maintain motion at the extension level theoretically could result in no further increase in demand at remaining non-instrumented levels and might resolve this issue of postponement of adverse adjacent level effects. Ideally, the flexible extension rods would provide a transition zone between the rigid spinal fixation to the non-instrumented levels, from minimal motion at the fixation level and with gradual increase in motion at the flexible rod extension level(s) to the first non-instrumented level. Motion at the adjacent levels should thus remain similar to the intact state in order to avoid adjacent level effects.

This study demonstrated that flexible rod extension resulted in moderate reduction in motion at the adjacent level when compared with rigid rod extension. The optimal range of stiffness and other physical properties of the flexible extension rod to most successfully address adjacent level effects, however, would require further investigation, and this was not within the scope of the thesis.

The use of both cement augmentation of pedicle screws and extension of posterior rods to adjacent level could potentially result in an optimal fixation construct in the degenerated and/or osteoporotic spine, addressing both issues of device loosening and adverse adjacent level effects.

6.4.6 Testing Methodology

This study used the flexibility protocol of testing. This method uses a pure moment applied to a spine specimen with the resultant vertebral motions measured. The applied moment across all segments remained a pure moment of the same magnitude and thus the flexibility protocol could not be used to ascertain biomechanical changes at the adjacent levels following rigid spinal fixation. The hybrid flexibility-stiffness protocol should be used [Panjabi and Goel 2005], and it will be presented and discussed in more detail in Chapter 7. In this study however, it was sufficiently demonstrated using the flexibility protocol that the concept of posterior rod extension could reduce motion at the adjacent level.

6.4.7 Cement Augmentation versus Posterior Rod Extension

Cement augmentation of pedicle screws has been found previously to enhance fixation of screws in bone [Cameron et al. 1975, Zindrick et al. 1986, Wittenberg et al. 1993, Lotz et al.
1997, Moore et al. 1997, Yerby et al. 1998, Ignatius et al. 2001, Bai et al. 2001, Sarzier et al. 2002, Schultheiss et al. 2004, Cook et al. 2004, Renner et al. 2004, Tan et al. 2004]. The injected cement penetrated through the porous trabeculae, and formed a stronger composite of bone and cement when the cement hardened. The rigid screw and surrounding cement-impregnated bone composite together can be considered as a single "implant", with enlarged size and larger surface area for interface area with surrounding trabeculae. As a wider infiltration of cement was found to be possible when injected into more porous low density bone, the size of the "implant" would be larger. Moreover, the screw-composite bone interface could be assumed to be rigid as both materials have high stiffness as compared to bone. As the previously weak screw-bone interface in low density bone was replaced by a larger "implant", and with a stronger "implant"-bone interface following cement augmentation, better fixation strength was thus achieved (Figure 6.22).

In the combined anterior-posterior fixation construct, the overall structural stability of the reconstructed spinal column depended on both the anterior interbody device's interface and the posterior pedicle screw instrumentation's interface with the neighbouring bone (Figure 6.1).

Posterior rod extension results in an increase in the number of fixation points for the rigid posterior rods in order to improve fixation (Figure 6.23B). As the posterior instrumentation does not directly improve the interbody device-vertebral interface, bending of the long rods could result in subsidence of the cage into the endplates. Not only does posterior instrumentation not improve fixation strength of the anterior construct, pedicle screw insertion was found in our
earlier study to disrupt trabecular bone and decrease interbody device-bone interface strength [Chapter 5]. The use of posterior rod extension thus directly enhanced 2 out of 4 of the interfaces (A and B in Figure 6.1) in the fusion construct.

Cement augmentation of pedicle screws, on the other hand, directly improved overall structural stability to the posterior [Tan et al. 2004 (Chapter 3)] device-bone interfaces. Cement augmentation of pedicle screws was also found in our previous study to increase interface strength at the interbody device-inferior vertebral bone interface [Chapter 5] (interface D in Figure 6.1). The use of cement augmentation of pedicle screws thus enhanced at least 3 out of 4 of the interfaces (A, B and D in Figure 6.1) in the combined anterior-posterior fusion construct (Figures 6.1 and 6.23A). Cement augmentation should thus, theoretically, result in more stable constructs over posterior rod extension, and probably better condition for bony fusion.

Figure 6.23 (A) Schematic diagrams of rigid instrumentation following corpectomy, with cement augmentation of pedicle screws. Cement could directly reduce pedicle screw loosening, and reduce interbody device subsidence. (B) Schematic diagrams of rigid instrumentation following corpectomy, with extension of posterior instrumentation to the inferior adjacent vertebral level. Increasing the number of fixation points for the posterior instrumentation directly reduced pedicle screw loosening. Posterior instrumentation does not directly improve cage-vertebra interface and bending of the long rods under load could result in cage subsidence.
6.4.8 Advantages and Disadvantages

Cement use in the spine is commonly associated with the techniques of vertebroplasty and kyphoplasty in patients with vertebral compression fractures [Barr et al. 2000, Kostuik and Shapiro 2003, Phillips 2003, Berlemann et al. 2004, Rhyne et al. 2004, Heini 2005]. Alleviation of pain and correction of deformity were achieved. Cement was also used in revision surgeries [Yerby et al. 1998, Dvorak and Fisher 1999]. At other sites, cement was also used to improve screw fixation in bone with low bone mass [Cameron et al. 1975, Larsson 2002, Kwon et al. 2002].

The disadvantages and complications associated with the use of cement were previously highlighted. The heat created during the exothermic polymerization of PMMA cement and presence of toxic non-polymerized monomer could cause necrosis of neighbouring cells [Kim et al. 2004] and affect normal bone healing [Santin et al. 2004]. This problem was reduced with the use of alternate bone cement, made of materials such as calcium phosphate [Bai et al. 1999, Lim et al. 2002]. Cement leakage was reportedly a potential issue during injection, which could result in neurological deficit [Ratliff et al. 2001, Shapiro et al. 2003, Nakano et al. 2005]. The use of radiologic guidance during injection of cement improved safety of the technique [Barr et al. 2000, Laredo and Hamze 2005]. Cement also has the disadvantage of not being easily removable after impregnation into porous trabecular bone, which could be problematic in cases with severe infection and the need for implant removal. Drilling and tapping a screw hole in cement is nearly impossible and patients with prior vertebroplasty have fewer surgical options in follow-up. The effect of the cement impregnated bone on bone growth and spinal fusion is also unclear. As bone needs vascularization for growth, it is not known currently if cement within the vertebrae would affect the fusion process at the adjacent fusion mass.

Long posterior rods were most commonly used in fixation of deformity such as scoliosis and kyphosis. Extension rods were also used in patients with low bone mass, to improve spinal fixation in the osteoporotic patients [Hu 1997, Kostuik and Shapiro 2003, Babat et al. 2004]. They were used to bridge across unsymptomatic degenerated adjacent levels to prevent juxtafusion degeneration or kyphosis in spinal fixation [Hu 1997, Babat et al. 2004] and in revision surgeries [Dvorak and Fisher 1999, Diwan et al. 2003]. The disadvantages and complications associated with the use of long rigid posterior rod extension included the postponement of adjacent level effects to the levels where the rod extension ends [Babat et al. 2004], and the disadvantage of immobilization of otherwise functional motion segments.
6.5 Conclusion

Cement augmentation resulted in better fixation of the osteoporotic spine at the immediate surgical level than with posterior rod extension. On the other hand, adjacent level motion was significantly reduced with posterior rod extension and less so with cement augmentation. Flexible rod extension resulted in significantly lower ROM at the extension level than without extension and higher ROM than with rigid extension. In conclusion, a combination of cement augmentation and flexible rod extension could provide the optimum solution to both issues of device loosening in the osteoporotic spine and adjacent level effects.

6.6 References


Chapter 6  Rod Extension and Cement on Destabilized Level


Chapter 6   Rod Extension and Cement on Destabilized Level


Chapter 7

Adjacent Level Effects: Consequence of Extension of Posterior Instrumentation and Cement Augmentation of Pedicle Screws

Overview

This chapter addresses the issue of adjacent level effects following extension of posterior instrumentation and cement augmentation of pedicle screws, using the hybrid flexibility-stiffness test protocol. Both surgical techniques are available to surgeons to obtain improved fixation in the osteoporotic spine, however, adverse adjacent level effects could result following rigid fixation. Effects of both cement augmentation and posterior rod extension were evaluated. The effects of flexible extension rods on the adjacent level were compared against rigid extension rods and against no extension rods. Cement augmentation of pedicle screws resulted in increased ROM and vertebral strain at adjacent levels. Posterior rod extension resulted in reduced ROM at the extension level but increased ROM and strain at the next non-instrumented level. Flexible extension rod resulted in lesser degree of adjacent level effects at the remaining non-instrumented levels than with rigid rods. Extension with flexible rods might be a solution to prevent adjacent level effect at the extension level while minimizing the effect at remaining non-instrumented levels.

This study was carried out in parallel with the previous study (Chapter 6), using the same 12 specimens.

The results of this study, together with results in Chapter 6, were presented as a single study at these national and international conferences:

1) 52nd Annual Meeting of the Orthopaedic Research Society, Mar 19-22, 2006, Chicago, Illinois, USA.

2) 40th Annual Meeting of the Canadian Orthopaedics Research Society, Jun 2-4, 2006, Toronto, Ontario, Canada.


A manuscript on the results of this study is being prepared as the second of a two-part paper for publication in the refereed journal Spine.
Chapter 7  Adjacent Level Effects

7  Adjacent Level Effects: Consequence of Extension of Posterior Instrumentation and Cement Augmentation of Pedicle Screws

7.1 Introduction

Degenerative changes at adjacent segments following spinal fusion surgery have been observed in patients for many years [Eck et al. 1999, Park et al. 2004, Hilibrand and Robbins 2004]. The most common clinical complication after spinal fusion at the adjacent segment appears to be disc degeneration and vertebral fracture, while other clinical observations such as lysthesis, hypertrophic facet joint arthritis, herniated nucleus pulposus and stenosis are also attributed to fusion [Park et al. 2004]. The etiology of these clinical observations has been attributed to two main factors: 1) biomechanical changes and 2) natural progression of degeneration [Eck et al. 1999, Park et al. 2004, Hilibrand and Robbins 2004]. The focus of this study was on determining the biomechanical changes at the adjacent levels.

The terms adjacent level effects and adjacent segment biomechanics have been used to refer to the altered load bearing and motion characteristics observed at the segments adjacent to a spinal fusion [Ha et al. 1993, Kumar et al. 2001, Panjabi 2002], while adjacent segment degeneration and adjacent segment disease have been used to refer to the radiographically or clinically observed degenerative changes and related new symptoms [Eck et al. 1999, Park et al. 2004, Hilibrand and Robbins 2004].

Many experimental studies have provided supporting evidence to show increased motion, increased intradiscal pressure, and altered stress states to the adjacent spinal segment(s) after fusion, which might explain the early degenerative changes observed radiographically or clinically. Past biomechanical studies using human cadaveric models have demonstrated that fusion was associated with increased disc pressure [Weinhoffer et al. 1995, Chow et al. 1996, Cunningham et al. 1997, Eck et al. 2002], segmental motion [Quinnell and Stockdale 1981, Chow et al. 1996, Esses et al. 1996, Fuller et al. 1998, Bastian et al. 2001, Eck et al. 2002, Akamaru et al. 2003, DiAngelo et al. 2003], facet loads [Lee and Langrana 1984] and vertebral strain at the adjacent segments. However, a critical review of these studies has not been carried out.

Cunningham et al (1997) found increased intradiscal pressures at adjacent segments (L2-L3 and L4-L5) after instrumentation at L3-L4 when eleven L1-S1 specimens were tested under 12.5 degrees of flexion and extension. Similarly, Weinhoffer et al (1995) found increased intradiscal pressures at adjacent non-instrumented discs (L3-L4 and L4-L5) after instrumentation from L5-S1 and from L4-S1 when six specimens (L2-S1) were tested under flexion to 20 degrees. Chow et al (1996) also carried out single level (L4-L5) and double levels
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(L4-S1) instrumentation and found increased intradiscal pressures at adjacent non-instrumented discs (L1-L2, L2-L3, L3-L4 and L5-S1) and increased segmental motions when six specimens (L1-S1) were tested under 15 degrees of flexion and 10 degrees of extension. Eck et al (2002) compared intradiscal pressure and segmental motion at C4-C5 and C6-C7 under 20 degrees of flexion and 15 degrees of extension between intact specimens and after anterior cervical plating at C5-C6 using six cervical spines (C3-T1). These studies demonstrated biomechanical changes at adjacent spinal segments following rigid fixation that might cause adjacent segment diseases.

It is believed that these altered biomechanics at the adjacent level affect the natural progression of the disease at the adjacent levels. Cyclic pressure differentials in the intervertebral discs are believed to be associated with metabolic production and fluid exchanges, and increased intradiscal pressure associated with early disc degeneration [Cunningham et al. 1997]. Increased segmental motions were associated with increased vertebral strain and facet loads and could lead to early degenerative changes such as trabecular fracture and hypertrophic facet joint arthritis. Changes to segmental rotation centre [Lee and Langrana 1984] and lordotic angles [Umehara et al. 2000, Akamaru et al. 2003, Sudo et al. 2003] were some other biomechanical factors attributed as related causes for the radiographically or clinically observed adjacent level effects. Adjacent segments that were beginning to develop or were in the early stages of natural degenerative changes might be more adversely affected by the biomechanical changes than other healthy segments. The abnormal loading conditions on the adjacent degenerated segments can produce tissue trauma and/or adaptive changes that may result in more severe degenerative stages [Stokes and Latridis 2004]. The effect of altered disc metabolism and vertebral strain on the adjacent segment with early degenerative changes could also be factors that lead to an accelerated degenerative process. These same abnormal loading conditions might have a slower rate of effect or no adverse effect on the tissues in healthy neighbouring segments. The natural progression of degeneration and biomechanical changes at adjacent segments are two inseparable factors that could be equally important to adjacent level disease.

In contrast to earlier studies, some recent biomechanical studies using cadaveric specimens claimed no adverse biomechanical effects at the adjacent spinal segments [Rohlmann et al. 2001, Lindsey et al. 2003, Swanson et al. 2003, Schmoelz et al. 2003]. These recent studies typically used load controlled testing methodologies in which pure moments of the same magnitude were applied to the intact and instrumented models and parameters at the adjacent non-instrumented levels were compared. Of note are the findings in Chapter 6 where
Chapter 7  
Adjacent Level Effects

kinematics at the inferior non-instrumented levels under the same applied loads were not significantly different between the intact and various instrumented conditions. Similarly, in finite element studies with the same applied muscle loads to the intact and instrumented model, no significant adverse biomechanical effects at the adjacent segments were found [Rohlmann et al. 1999, Zander et al. 2003]. Lindsey et al (2003) and Swanson et al (2003) tested seven L2-L5 specimens under flexion-extension (FE), axial rotation (AR) and lateral bending (LB) with 7.5 Nm bending moment and 700 N compression in both the intact state and after implantation of an interspinous device at L3-L4. They found no significant difference in range of motion (ROM) [Lindsey et al. 2003] and intradiscal pressure [Swanson et al. 2003] in all three rotations between intact and implant states for both adjacent non-instrumented levels (L2-L3 and L4-L5) and concluded that the implant did not significantly affect the ROM and intradiscal pressure at adjacent levels. Schmoelz et al (2003) tested six L2-L5 specimens with pure moments of 10 Nm in FE, AR and LB in 1) the intact state, 2) after implantation of a dynamic stabilizing device and 3) after implantation of an internal fixator, across L3-L4. The ROM and neutral zone of the adjacent segments (L2-L3 and L4-L5) were not found to be affected under the applied loading conditions. Rohlmann et al (2001) tested seven lumbar specimens (4 L1-L5 and 3 T12-L4) under pure moments of 3.75 Nm in FE, AR and LB in the intact state and after fixation of the middle three verteabrae leaving one intact segment above and below the implant. The changes in intradiscal pressure and intersegmental rotation at the adjacent levels were small under the applied load-controlled (pure moments) conditions. Using a non-linear finite element model of the lumbosacral spine (L2-S1), Zander et al (2003) evaluated the stresses in the intervertebral discs, facet joint forces and intradiscal pressure at the adjacent level (L3-L4) after simulated facetectomy and laminectomy at L4 and L5. Muscle forces were applied to simulate physiological loads experienced while standing and forward bending. With the same loading conditions in the intact and surgical states, they found negligible effect on these parameters at L3-L4. In an earlier similar finite element study by Rohlmann et al (1999) on the lumbar spine (L1-L5), stresses in adjacent intervertebral discs (L1-L2 and L4-L5) after fixation of the L2-L4 levels were compared against the intact state. Muscle forces were simulated for standing and flexion postures. The result was also similar, in that, the internal fixators had only minor influence on stresses at the adjacent discs. The application of pure moments was the common denominator in these studies and was why no significant differences were found at the adjacent non-instrumented levels.

Various other different testing protocols were used in the past to show these biomechanical adjacent level effects. The strengths, limitations and underlying assumptions of
these testing methods however were not clear to the clinicians and biomechanical engineers alike. The technique of applying a pure moment and measuring the resultant three translations and three rotations was referred to as the ‘flexibility’ protocol [Panjabi and Goel 2005]. The flexibility protocol had been used to determine if a particular instrumentation was overly flexible immediately post surgery as compared to its intact state or against established surgical techniques [Panjabi et al. 1976, Panjabi 1988, Abumi et al. 1990]. Pure moments were applied in three orthogonal directions in flexibility tests: commonly in FE, AR and LB. The applied moments were usually of the same magnitude so that the resultant displacements could be directly compared between intact and instrumented state. Specimens with a single functional spinal unit (FSU) were commonly used for such tests [Oxland et al. 1996, Lund et al. 1998, 2000, Nydegger et al. 2001, Le Huec et al. 2002]. The flexibility test was well suited to compare flexibility at the implanted level between intact and instrumented states and also for comparison between novel techniques against existing instrumentation techniques. Following the recommendations that length of specimens should have at least one free segment on either end of the instrumented levels [Wilke et al. 1998], recent tests were carried out with three or more FSUs. With the longer test specimens in more recent studies, the flexibility of the adjacent segments was included in the results of these studies [Rohlmann et al. 2001, Lindsey et al. 2003, Schmoelz et al. 2003, Chapter 6]. Readers of these studies could interpret the results for the insignificant effect at the adjacent segments in two ways. Firstly, the reader could wrongly interpret that the instrumentation eliminated the adverse biomechanical effects at the adjacent segments. Alternatively, the reader in understanding that pure moment was applied in the intact and instrumented states, would expect the biomechanical parameters at the adjacent segments to be the same. And as the results showed insignificant effect at the adjacent segments, it inversely implies that pure moment was successfully applied.

An understanding of the underlying mechanics would allow the reader (and authors) to appreciate the latter interpretation as correct (Figure 7.1). In Figure 7.1a, when pure moments were applied at the ends of a long beam, any section throughout the beam experienced the same moment. Following reinforcement of a section with the same moment applied (Figure 7.1b), any section throughout the beam would still experience the same moment. With pure moments, the only difference would be a reduction in motion at the reinforced section. In the above mentioned in vitro studies where the same pure moment was applied to the intact and instrumented states, the moments experienced at the adjacent segments were of the same magnitude. One would thus expect no significant changes to adjacent level kinematics under these same loading conditions. These studies indeed were in agreement with theory and thus
we knew that pure moments were successfully applied. The flexibility protocol is thus unsuitable for assessing gross kinematic changes in the adjacent segments. Some studies on the other hand supposedly applied 'pure moments' of same magnitudes to the specimens in the intact and instrumented state but found adjacent level biomechanical changes at the non-instrumented adjacent levels [Bastian et al. 2001, Untch et al. 2004]. It can only be assumed that the moments applied might not be 'pure' and the test setup might not have provided 'unrestricted' motion as claimed.

![Diagram showing the application of pure moments at the ends of a beam.](image)

**Figure 7.1** When pure moments were applied at the ends of a beam, the moment experienced in any section throughout the beam was the same even when a section was reinforced. (a) Bending moments applied at the ends of a uniform beam. The moments in any section of the beam were the same. (c) A section of the same beam was now reinforced and the same pure moment applied at the ends of the beam. The moment experienced at any section of the reinforced beam remained the same.

Another test protocol called the 'stiffness' protocol was used to assess if a particular instrumentation was overly less stiff immediately post surgery as compared to its intact state or against established surgical techniques. In the stiffness protocol, individual translations and rotations in three orthogonal directions are applied and the resulting six load components are measured. A problem with using the stiffness protocol surrounds the difficulty of applying a
single component motion while disallowing the other five motion components [Panjabi 2002].
As coupled motions are commonly seen in the FSU, the stiffness test in applying a pure rotation
is too restrictive and can result in excessive resultant loads. Another issue is in pre-determining
the centre of rotation of the spine for the mode of motion under test as the centre of rotation
shifts with rotation angle [Yoshioka et al. 1990]. Furthermore, the problem of locating a centre
of rotation would be more pronounced if the test segment was much longer such as in the study
by Stanley et al. (2004) and in the current study. For studying adjacent level effects, the
stiffness protocol was difficult to implement and less repeatable between different laboratories.

Many studies mentioned earlier that showed increased intradiscal pressure or motion at
the adjacent segments made use of a simplified stiffness protocol [Lee and Langrana 1984,
Weinhoffer et al. 1995, Chow et al. 1996, Eck et al. 2002]. These studies applied the same
magnitude of flexion/extension rotation by displacing an anterior/posterior offset point by a fixed
vertical displacement. In other studies, moments of same magnitudes were applied using the
same technique of applying a point load with a fixed anterior/posterior offset [Esses et al. 1996,
Shimamoto et al. 2001, Akamaru et al. 2003]. The problem of locating a centre of rotation was
bypassed as the centre of the vertebral body was used as the reference point for the
anterior/posterior offset. The motion of the specimen however was found to not reflect in vivo
motion, especially when more segments were tested. Buckling and instability of the test
specimen was also a problem and was more pronounced when longer specimens were tested.
More importantly, the moment applied at each segment became ambiguous as the moment arm
changed with motion of the specimen [Panjabi 1988, Panjabi and Goel 2005].

With the inherent problems associated with both the flexibility and the stiffness protocols,
a new protocol called the hybrid flexibility-stiffness protocol was recently proposed [Panjabi
2002]. The hybrid protocol has an underlying assumption that patients would assume the same
overall ROM in their daily routine after a solid fusion. This hybrid protocol was further described
in detail recently [Panjabi and Goel 2005]. In the hybrid protocol, the application of a pure
moment in the flexibility protocol was married to the application of a fixed displacement in the
stiffness protocol. Flexibility tests were first carried out on the intact specimen to determine the
ROM of the whole segment under a physiologic moment. After instrumentation, the same
flexibility tests were carried out until the same main motion corresponding to the test direction
was achieved. The main difference of the hybrid protocol from the stiffness protocol was that
the test was carried out with applied pure moments instead of displacement control, while the
difference from the flexibility protocol was that the hybrid test was carried out until the intact
ROM was achieved instead of to the same moment. The intradiscal pressures, vertebral strains
and/or kinematics of the adjacent segments at the same overall ROM were compared between intact and instrumented states. However, the assumption of the same overall ROM after fusion with the hybrid protocol would remain a controversial topic for discussion [Schmoelz et al. 2003]. It was countered that the application of pure moments as suggested in the hybrid protocol in a study would not provide an explanation to the clinical observations of adjacent level degeneration occurring at the immediate one or two adjacent segments to the instrumentation. Based on the underlying assumption of same overall ROM, the reduced motion at the instrumented level would have to be contributed by the other mobile levels. In order to achieve this higher motion at the other mobile levels with rigid fixation, the necessary applied moment would be substantially higher. As all adjacent non-instrumented segments in the test model would be subjected to the same increase in applied pure moment, a proportional increase in measured biomechanical parameters would be expected.

Another problem with the hybrid protocol as proposed [Panjabi and Goel 2005] is the possibility of excessive loads necessary to reach the same baseline ROM especially with the inclusion of rigid fixations. Our solution is to apply the same maximum pure moments (3.75 Nm for cervical, 5 Nm for thoracic and 7.5 Nm for lumbar) to the various instrumentation configurations in the experimental stage, but to make comparisons at the same baseline ROM during data analyses. The baseline ROM would correspond to the stiffest construct within the study. A similar analysis protocol and hybrid test protocol has been recently reported in a conference abstract [Goertzen et al. 2003].

Despite the above mentioned problems associated with the hybrid protocol, it is the current state of the art in in vitro spine testing for studying adjacent level effects, and is a more coherent methodology than either the flexibility or the stiffness protocols. Moreover, the hybrid protocol remains a technique that has not been published in refereed journal. The initial objective of this study was to demonstrate that the proposed hybrid test protocol could be used to assess biomechanical changes at adjacent levels. The main purpose of this study was to determine, using the hybrid protocol, if flexible posterior extension rods in combination with cement augmentation of pedicle screws could reduce adjacent biomechanical effects following spinal fixation. Motion and strains at adjacent segments were compared between flexible, rigid and no posterior extension rods, and with and without cement augmentation of pedicle screws.
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7.2 Methods

The experiment in Chapters 6 and 7 were carried out concurrently, on the same 12 specimens. Specimen conditions were described in Section 6.2.1.

The same repeated measures experimental protocol to test the two way interaction between cement augmentation and posterior rod extension was also carried out concurrently for both studies. Details on experimental protocol were described in Section 6.2.2.

The test protocol, described in Section 6.2.3, was also carried out concurrently for both studies. Post-test analyses using the hybrid protocol of the kinematic data was used to determine adjacent level effects. In addition to the measurement of kinematic data, vertebral body strains were also measured.

7.2.1 Hybrid Flexibility-Stiffness Analyses

Motions in three-dimensional space of all vertebral bodies (T9, T10, T12, L1, L2 and L3 in a T9-L3 segment, except the corpectomy level) were collected using an optoelectronic camera system (Optotrak 3020, Northern Digital Inc., Waterloo, Canada). Data for motion and applied moment was synchronised and recorded at 20 Hz for the duration of each test.

In the post-test analyses, overall (T9-L3) AR, LB, and FE ROM in both positive and negative directions were first determined from the flexibility curves at the third (last) cycle for all surgical conditions. The smallest ROM under +/-5 Nm applied moment (in both positive and negative directions), which corresponded to the most rigid fixation, was identified for each flexibility test direction (Figure 7.2). In the example in Figure 7.2, cement augmentation and rigid rod extension resulted in the most rigid fixation and the baselines overall +ROM and -ROM were 16.4° and -11.5°. Corresponding parameters, such as applied moment, vertebral strains and intradiscal pressure, between surgical conditions were compared at these baseline ROMs in the hybrid protocol.

In order to compare changes at the adjacent levels using the hybrid protocol, the applied moments (in both positive and negative directions) necessary to achieve these baseline ROMs for each surgical condition needed to be first determined. For the example in Figure 7.2, the moments applied to the intact spinal segment necessary to achieve the baseline ROMs were 0.6 Nm and -0.6 Nm respectively. Corresponding vertebral strains and segmental ROMs were determined at these moments for the intact state and compared against other surgical states. These moments for each surgical condition were different and needed to be individually determined for all flexibility test directions and surgical conditions.
Figure 7.2  Flexibility curves at the third cycle for all surgical conditions were compared to determine the baseline (smallest) positive and negative range of motion (+ROM and -ROM) and corresponding applied moment. This baseline ROM was used for further comparison, and was based on the underlying assumption in the hybrid flexibility-stiffness protocol that the patient would assume the same overall ROM in their daily routine after fusion surgery. In this specimen, the baseline +ROM and -ROM were 16.4° and -11.5° respectively, with cemented screws and rigid posterior extension. The positive moments (in increasing order) necessary to create this baseline +ROM for each surgical condition were 0.6, 1.3, 1.9, 2.2, 3.1 and 4.1 Nm respectively. The negative moments (in decreasing order) necessary to create this baseline -ROM for each surgical condition were -0.6, -1.4, -1.7, -2.4, -2.9 and -4.4 Nm respectively.

Using these moments, the corresponding intersegmental ROMs (both positive and negative) could be determined from the intersegmental flexibility curves. The positive and negative intersegmental ROMs at each level were summed to obtain the overall (in both positive and negative directions) intersegmental ROM for the level. Intersegmental ROM was normalized against its intact condition so as to reduce effects of inter-specimen differences. The normalized intersegmental ROMs at the adjacent levels were compared between surgical conditions. These changes at the adjacent levels, under the same overall ROM, were the
underlying assumptions in the hybrid protocol. Changes in vertebral body strains using this analysis protocol were also carried out in this study.

7.2.2 Vertebral Body Strains

Single axis strain gauges (TML FLG-02-23, Tokyo Sokki Kenkyujo, Tokyo, Japan) were attached to 2 distal vertebral bodies in all tests. The L1 and L2 in T9-L3 spinal segments and the T12 and L1 vertebral bodies in T8-L2 segments were each attached with 3 strain gauges: two on the lateral aspects of each vertebral body and one on the left surface of each spinous process (Figure 7.3). Strain data was recorded in synchronisation with applied moment and motion data at 20 Hz for the duration of each test (Figure 7.4).

Figure 7.3 Two strain gauges were attached onto the lateral aspects of the body and one strain gauge attached onto the left surface of the spinous process, on 2 distal vertebral bodies to the corpectomy level (T12 and L1 in T8-L2). Gauges 1-4 were attached to the vertebral bodies and gauges 5 and 6 to the spinous processes. Positive strain gauge values represented tensile strain.

During post-test analyses, the hybrid protocol was used and strain values corresponding to the positive and negative baseline ROMs were determined. The overall change in strain from the positive baseline ROM to the negative baseline ROM was calculated and normalized against the corresponding intact ranges for each test. Changes in strain readings at the same overall ROM indicate possible adjacent level effects following cement augmentation or posterior extension.
Strain data were collected for the full duration of each test. The data was passed through a low pass filter, which removed noise in the data.

For FE tests, all strain gauges were compared between the different surgical conditions. In LB, only gauges attached to the vertebral bodies were compared. Gauges attached to the spinous process were ignored in LB as they were not sensitive to changes during LB tests. Similarly, in AR motion, the changes in all gauges were not sensitive to this test direction and thus were not compared. As gauges 1 and 3 were mounted on the same vertebra (T12) and gauges 2 and 4 on the adjacent vertebra (L1), some symmetry in results could be expected in FE.

7.2.3 Statistical Analysis

One-way repeated measures ANOVA with Newman-Keuls post-hoc tests were carried out to determine significant difference within specimens between intact and surgical conditions. Two-way repeated measures ANOVA analyses, with Newman-Keuls post-hoc analyses, were carried out to determine the effect of cement augmentation (factor 1) and posterior rod extension (factor 2) on (i) normalized applied moment, (ii) intersegmental ROMs and (iii) normalized vertebral strains, for each flexibility test direction. An alpha of 0.01 was chosen.
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7.3 Results

7.3.1 Overall Flexibility

The overall ROMs (across T9-L3 or T8-L2) in both positive and negative directions in the intact and surgical states in AR, LB and FE were determined from the flexibility curves (Figure 7.5). The surgical configuration with the smallest ROM in each specimen and test direction was used for baseline comparison.

Of note, the mean overall ROMs were the smallest with cement augmentation and rigid extension in all directions (Table 7.1), but within individual specimen overall ROM was not always the smallest with any particular surgical configuration.

![Axial Rotation - H1022](image)

*Figure 7.5  Typical flexibility curves of the T8-L2 spine of a specimen under AR motion, in the intact and various surgical intervention states.*

7.3.2 Baseline Range of Motion and Minimum Moment

Baseline ROM corresponded to the stiffest surgical construct within each specimen at 5 Nm of applied moment. The baseline ROM+ and ROM- occurred most frequently with rigid extension rods and cement (70%), followed by rigid extension rods without cement (17%) and by flexible extension rods with cement (9%) (Table 7.2).
Table 7.1  Mean overall range of motion (across T9-L3 or T8-L2) for different surgical conditions in the respective test directions at 5 Nm applied moment.

<table>
<thead>
<tr>
<th></th>
<th>Range of Motion, mean (s.d.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AR</td>
</tr>
<tr>
<td>Intact</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>22.0° (6.6°)</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>19.4° (7.2°)</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>17.3° (6.6°)</td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>17.5° (5.5°)</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>16.4° (4.9°)</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>15.1° (4.8°)</td>
</tr>
</tbody>
</table>

Table 7.2  Baseline ROM+ and ROM- for the 12 specimens.

<table>
<thead>
<tr>
<th>Specimen</th>
<th>AR</th>
<th>LB</th>
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<tbody>
<tr>
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<td>a</td>
<td>c</td>
<td>a</td>
<td>b</td>
</tr>
<tr>
<td>2</td>
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</tr>
<tr>
<td>12</td>
<td>a</td>
<td>a</td>
<td>c</td>
<td>a</td>
</tr>
<tr>
<td>Mean</td>
<td>8.3°</td>
<td>11.7°</td>
<td>8.8°</td>
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<table>
<thead>
<tr>
<th>Specimen</th>
<th>ROM+</th>
<th>ROM-</th>
<th>ROM+</th>
<th>ROM-</th>
<th>ROM+</th>
<th>ROM-</th>
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<tbody>
<tr>
<td>1</td>
<td>a 16.4°</td>
<td>-11.5°</td>
<td>a 18.0°</td>
<td>-13.6°</td>
<td>a 12.7°</td>
<td>-a 11.6°</td>
</tr>
<tr>
<td>2</td>
<td>a 6.6°</td>
<td>-6.2°</td>
<td>a 10.6°</td>
<td>c -9.3°</td>
<td>a 7.5°</td>
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</tr>
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<td>-7.6°</td>
<td>b 13.2°</td>
<td>b -10.3°</td>
<td>b 8.8°</td>
<td>-b 6.4°</td>
</tr>
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<td>a 10.8°</td>
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<td>a 8.5°</td>
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<td>a 11.1°</td>
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<td>c 14.4°</td>
<td>-a 9.7°</td>
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<tr>
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<td>a 8.2°</td>
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<td>a 11.3°</td>
<td>a -9.4°</td>
<td>a 6.0°</td>
<td>-a 7.0°</td>
</tr>
<tr>
<td>12</td>
<td>a 6.1°</td>
<td>-5.8°</td>
<td>a 7.2°</td>
<td>-7.0°</td>
<td>a 8.2°</td>
<td>-a 5.7°</td>
</tr>
</tbody>
</table>

The applied moment necessary to achieve the baseline +ROM and -ROM for the stiffest construct would be +5 Nm and -5 Nm respectively, while the applied moment necessary to achieve the same baseline ROMs on other surgical conditions within the same specimen would depend on its overall stiffness. In each specimen, these applied moments differed for the intact spine and each surgical condition (Table 7.3).
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Table 7.3  Applied moments that created the baseline ROMs in specimen 1.

<table>
<thead>
<tr>
<th>Baseline ROMs from Table 7.2</th>
<th>AR+</th>
<th>AR-</th>
<th>LB+</th>
<th>LB-</th>
<th>Flexion</th>
<th>Extension</th>
</tr>
</thead>
<tbody>
<tr>
<td>16.4°</td>
<td>18.0°</td>
<td>-11.5°</td>
<td>12.7°</td>
<td>-13.6°</td>
<td>-11.6°</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Applied Moment (Nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
</tr>
<tr>
<td>Not cemented</td>
</tr>
<tr>
<td>No extension</td>
</tr>
<tr>
<td>Flexible extension</td>
</tr>
<tr>
<td>Rigid extension</td>
</tr>
<tr>
<td>Cemented</td>
</tr>
<tr>
<td>No extension</td>
</tr>
<tr>
<td>Flexible extension</td>
</tr>
<tr>
<td>Rigid extension</td>
</tr>
</tbody>
</table>

In the 2-way ANOVA analyses, the minimum applied moments at the same baseline ROMs were generally higher for surgical conditions with cement augmented screws and with posterior extension rods, in both the positive and negative directions (Table 7.3, Figures 7.6 to 7.9). Applied moments were significantly higher with cement augmentation in AR+ (by between 74% to 94% of intact), AR- (71-77%) and LB+ (50-62%), but not in LB- (30-57%), FE+ (28-53%) and FE- (21-61%) (Table 7.4, Figures 7.6 to 7.9). Applied moments were also significantly affected by configuration of posterior rod extension. Applied moments were significantly higher with rigid rods in AR+ (72-92%), AR- (84-90%), LB+ (92-104%), LB- (102-126%), FE+ (128-142%) and FE- (77-117%). Applied moments were also significantly higher with flexible rods in AR+ (36-40%), AR- (32% with cement), LB+ (66-76%), LB- (61-88%), FE+ (67-92%) and FE- (51-70%). As rigid extension rods resulted in stiffer constructs than with flexible extension rods, significantly higher moments were necessary in order to achieve the same baseline ROM.

Table 7.4  2-way ANOVA results on normalized moment between cement (factor 1) and posterior rod extension (factor 2) under the same baseline ROM.

<table>
<thead>
<tr>
<th></th>
<th>AR+</th>
<th>LB+</th>
<th>Flexion</th>
<th>Flexion+FL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor 1: Cement</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>0.03</td>
<td>0.04</td>
</tr>
<tr>
<td>Factor 2: Extension</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Interactions</td>
<td>0.1</td>
<td>0.7</td>
<td>0.7</td>
<td>0.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>AR-</th>
<th>LB-</th>
<th>Extension</th>
<th>Extension+FL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor 1: Cement</td>
<td>0.003</td>
<td>0.02</td>
<td>0.06</td>
<td>0.13</td>
</tr>
<tr>
<td>Factor 2: Extension</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Interactions</td>
<td>0.9</td>
<td>0.3</td>
<td>0.2</td>
<td>0.2</td>
</tr>
</tbody>
</table>

AR+: positive axial rotation, AR-: negative axial rotation, LB+: positive lateral bending, LB-: negative lateral bending, FL: Follower Load.
Figure 7.6 Mean normalized applied moment in AR at baseline ROM. Error bars indicate standard deviation.

Figure 7.7 Mean normalized applied moment in LB at baseline ROM. Error bars indicate standard deviation.
Figure 7.8  Mean normalized applied moment in FE at baseline ROM. Error bars indicate standard deviation.

Figure 7.9  Mean normalized applied moment in FE with follower-load at baseline ROM. Error bars indicate standard deviation.
7.3.3 Intersegmental Range of Motion

At the same baseline ROM, intersegmental ROMs were not evenly distributed across levels in the thoracolumbar segments, and ROM across each level was affected by different surgical configurations (Table 7.5, Figure 7.10). Magnitudes of intersegmental ROM in the positive and negative directions were not symmetrical but trends of changes following cement or rod extension were similar. The overall intersegmental ROM was summed from the magnitudes of the intersegmental ROM+ and ROM-, and normalized against the intact overall intersegmental ROM for further comparison.

Table 7.5 Intersegmental ROM+, intersegmental ROM- and overall intersegmental ROM in axial rotation for specimen 1. Intersegmental ROM+ and ROM- corresponded to baseline ROM+ and ROM-. Overall intersegmental ROM was summed from the intersegmental ROM+ and ROM-magnitudes.

<table>
<thead>
<tr>
<th>Applied Moment (Nm)</th>
<th>1 level above D (T9-T10)</th>
<th>D (T10-12)</th>
<th>Rod extension level (T12-L1)</th>
<th>2 levels below D (L1-L2)</th>
<th>3 levels below D (L2-L3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>1.9</td>
<td>3.7°</td>
<td>5.6°</td>
<td>1.0°</td>
<td>2.8°</td>
</tr>
<tr>
<td>Not cemented</td>
<td>No ext</td>
<td>0.6</td>
<td>3.0°</td>
<td>7.9°</td>
<td>0.1°</td>
</tr>
<tr>
<td></td>
<td>Flex ext</td>
<td>1.3</td>
<td>3.8°</td>
<td>6.5°</td>
<td>0.2°</td>
</tr>
<tr>
<td></td>
<td>Rigid ext</td>
<td>2.2</td>
<td>4.1°</td>
<td>5.0°</td>
<td>0.2°</td>
</tr>
<tr>
<td>Cemented</td>
<td>No ext</td>
<td>3.1</td>
<td>4.8°</td>
<td>2.5°</td>
<td>1.3°</td>
</tr>
<tr>
<td></td>
<td>Flex ext</td>
<td>4.1</td>
<td>5.1°</td>
<td>2.5°</td>
<td>0.7°</td>
</tr>
<tr>
<td></td>
<td>Rigid ext</td>
<td>5.0</td>
<td>5.5°</td>
<td>2.3°</td>
<td>0.5°</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intertsegmental ROM-</th>
<th>Intact</th>
<th>-1.7</th>
<th>-2.5°</th>
<th>-3.8°</th>
<th>-1.2°</th>
<th>-2.3°</th>
<th>-2.3°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not cemented</td>
<td>No ext</td>
<td>-0.6</td>
<td>-2.2°</td>
<td>-5.9°</td>
<td>-0.6°</td>
<td>-2.0°</td>
<td>-1.5°</td>
</tr>
<tr>
<td></td>
<td>Flex ext</td>
<td>-1.4</td>
<td>-2.3°</td>
<td>-4.4°</td>
<td>-0.6°</td>
<td>-2.3°</td>
<td>-2.1°</td>
</tr>
<tr>
<td></td>
<td>Rigid ext</td>
<td>-2.9</td>
<td>-3.1°</td>
<td>-3.2°</td>
<td>-0.6°</td>
<td>-2.6°</td>
<td>-2.5°</td>
</tr>
<tr>
<td>Cemented</td>
<td>No ext</td>
<td>-2.4</td>
<td>-3.2°</td>
<td>-2.0°</td>
<td>-1.4°</td>
<td>-2.6°</td>
<td>-2.8°</td>
</tr>
<tr>
<td></td>
<td>Flex ext</td>
<td>-4.4</td>
<td>-3.4°</td>
<td>-2.0°</td>
<td>-1.1°</td>
<td>-2.9°</td>
<td>-2.8°</td>
</tr>
<tr>
<td></td>
<td>Rigid ext</td>
<td>-5.0</td>
<td>-3.5°</td>
<td>-1.8°</td>
<td>-0.8°</td>
<td>-3.0°</td>
<td>-2.9°</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Overall intersegmental ROM</th>
<th>Intact</th>
<th>6.3°</th>
<th>9.4°</th>
<th>2.2°</th>
<th>5.0°</th>
<th>5.3°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not cemented</td>
<td>No ext</td>
<td>5.2°</td>
<td>13.8°</td>
<td>0.7°</td>
<td>4.0°</td>
<td>4.3°</td>
</tr>
<tr>
<td></td>
<td>Flex ext</td>
<td>6.1°</td>
<td>10.9°</td>
<td>0.9°</td>
<td>4.8°</td>
<td>5.3°</td>
</tr>
<tr>
<td></td>
<td>Rigid ext</td>
<td>7.2°</td>
<td>8.2°</td>
<td>0.9°</td>
<td>5.5°</td>
<td>6.1°</td>
</tr>
<tr>
<td>Cemented</td>
<td>No ext</td>
<td>8.0°</td>
<td>4.5°</td>
<td>2.7°</td>
<td>5.9°</td>
<td>6.7°</td>
</tr>
<tr>
<td></td>
<td>Flex ext</td>
<td>8.5°</td>
<td>4.6°</td>
<td>1.9°</td>
<td>6.3°</td>
<td>6.8°</td>
</tr>
<tr>
<td></td>
<td>Rigid ext</td>
<td>9.0°</td>
<td>4.1°</td>
<td>1.3°</td>
<td>6.5°</td>
<td>7.0°</td>
</tr>
</tbody>
</table>

D: destabilized level, No ext: No extension rods, Flex ext: Flexible extension rods, Rigid ext: rigid extension rods.
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Figure 7.10  Distribution of overall intersegmental range of motion (ROM) in axial rotation for specimen 1 (corresponds to data in Table 7.5). Increase in ROMs at non-instrumented levels and decrease in ROMs at instrumented levels were generally observed.

Mean normalized intersegmental ROMs across all levels for the 12 specimens were affected by cement augmentation and/or posterior rod extension (Figures 7.11 to 7.14). Reflecting the results for specimen 1 (Figure 7.10), mean normalized intersegmental ROM at the destabilized and extension level were reduced by posterior rod extension and cement augmentation of screws, while intersegmental motions at the non-instrumented levels were increased in order to maintain the overall ROM. Detailed 2-way ANOVA analyses for each level and flexibility test direction are presented in the Appendix.
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Figure 7.11 Normalized intersegmental range of motion (ROM) in AR. Detailed 2-way ANOVA analyses for each level presented in Appendix.

Figure 7.12 Normalized intersegmental range of motion (ROM) in LB. Detailed 2-way ANOVA analyses for each level presented in Appendix.
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**Figure 7.13** Normalized intersegmental range of motion (ROM) in FE. Detailed 2-way ANOVA analyses for each level presented in Appendix.

**Figure 7.14** Normalized intersegmental range of motion (ROM) in FE+FL. Detailed 2-way ANOVA analyses for each level presented in Appendix.
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Rod Extension Level

In the 1-way ANOVA analyses, ROMs at the rod extension level (1 level below destabilized level, T12-L1 in T9-L3 segments) were significantly affected by surgical intervention in all directions (Table 7.6). The initial surgical configuration (no cement, no rod extension) was not significantly different from intact in all directions, while posterior rod extension significantly reduced ROMs from corresponding intact values in LB and FE (Tables 7.6 and 7.7).

In the 2-way ANOVA analyses, cement augmentation significantly affected ROM at the rod extension level in FE only, but not in AR and LB, while posterior rod extension significantly reduced ROM in all directions (Table 7.8, Figures A.9 to A.12 in Appendix A). There were significant 2-way interactions in all directions, which were probably due to higher ROMs in the cemented and with no rod extension state.

Table 7.6  Mean ROM across rod extension level for different surgical conditions using the hybrid protocol.

<table>
<thead>
<tr>
<th></th>
<th>Range of Motion, mean (s.d.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AR</td>
</tr>
<tr>
<td>Intact</td>
<td>1.6° (1.4°)</td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>1.5° (1.3°)</td>
</tr>
<tr>
<td>Flexible</td>
<td>1.3° (1.0°)</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>1.2° (0.8°)</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>2.0° (1.3°)</td>
</tr>
<tr>
<td>Flexible</td>
<td>1.5° (1.0°)</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>1.2° (0.9°)</td>
</tr>
<tr>
<td>p-values from 1-way ANOVA</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* - significantly different from corresponding intact value, alpha = 0.01.

Table 7.7  Percentage difference in ROM from intact and statistical significance, for rod extension level.

<table>
<thead>
<tr>
<th></th>
<th>Percentage Difference from Intact, p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AR</td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>-11%, 0.5</td>
</tr>
<tr>
<td>Flexible</td>
<td>-19%, 0.3</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>-26%, 0.09</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>22%, 0.04</td>
</tr>
<tr>
<td>Flexible</td>
<td>-9%, 0.4</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>-27%, 0.1</td>
</tr>
</tbody>
</table>

Table 7.8  2-way ANOVA results on normalized ROM between cement (factor 1) and posterior rod extension (factor 2) using the hybrid protocol for rod extension level.

<table>
<thead>
<tr>
<th></th>
<th>AR</th>
<th>LB</th>
<th>FE</th>
<th>FE+FL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor 1: Cement</td>
<td>0.3</td>
<td>0.1</td>
<td>0.002</td>
<td>0.008</td>
</tr>
<tr>
<td>Factor 2: Rod extension</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Interactions</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>0.006</td>
<td>0.006</td>
</tr>
</tbody>
</table>
2 Levels below Destabilized Level

In the 1-way ANOVA analyses, ROMs at 2 levels below destabilized level (L1-L2 in T9-L3 segments) were significantly affected by surgical intervention in LB and FE (Table 7.9). The initial surgical configuration (no cement, no extension) was not significantly different from intact in all directions, while posterior rod extension and cement augmentation significantly increased ROMs from corresponding intact values in LB and FE (Tables 7.9 and 7.10).

In the 2-way ANOVA analyses, cement augmentation marginally increased ROM at 2 levels below destabilized level in LB, but not in AR and FE (Table 7.11, Figures A.13 to A.16 in Appendix A). Posterior rod extension significantly increased ROM in all directions. There were no significant 2-way interactions.

Table 7.9 Mean ROM at 2 levels below destabilized level (L1-L2) for different surgical conditions using the hybrid protocol.

<table>
<thead>
<tr>
<th></th>
<th>Range of Motion, mean (s.d.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AR</td>
</tr>
<tr>
<td>Intact</td>
<td>1.5° (1.4°)</td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>1.2° (1.2°)</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>1.4° (1.4°)</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>1.6° (1.5°)</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>1.7° (1.5°)</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>1.8° (1.7°)</td>
</tr>
<tr>
<td>p-values from 1-way ANOVA</td>
<td>0.03</td>
</tr>
</tbody>
</table>

* - significantly different from corresponding intact value, alpha = 0.01.

Table 7.10 Percentage difference in ROM from intact and statistical significance, for 2 levels below destabilized level.

<table>
<thead>
<tr>
<th></th>
<th>Percentage Difference from Intact, p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AR</td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>-17%, 0.4</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>-6%, 0.6</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>10%, 0.4</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>17%, 0.5</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>12%, 0.6</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>23%, 0.3</td>
</tr>
</tbody>
</table>

Table 7.11 2-way ANOVA results on normalized ROM between cement (factor 1) and posterior rod extension (factor 2) using the hybrid protocol, for 2 levels below destabilized level.

<table>
<thead>
<tr>
<th></th>
<th>AR</th>
<th>LB</th>
<th>FE</th>
<th>FE+FL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor 1: Cement</td>
<td>0.06</td>
<td>0.01</td>
<td>0.02</td>
<td>0.09</td>
</tr>
<tr>
<td>Factor 2: Rod extension</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Interactions</td>
<td>0.2</td>
<td>0.5</td>
<td>0.02</td>
<td>0.06</td>
</tr>
</tbody>
</table>
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3 Levels below Destabilized Level

In the 1-way ANOVA analyses, ROMs at 3 levels below destabilized level (L2-L3 in T9-L3 segments) were significantly affected by surgical intervention in all directions (Table 7.12). The initial surgical configuration (no cement, no rod extension) was not significantly different from intact in all directions, while posterior rod extension and cement augmentation generally increased ROMs from intact values in LB and FE (Tables 7.12 and 7.13).

In the 2-way ANOVA analyses, ROMs at 3 levels below destabilized level were generally increased with cement augmentation and posterior rod extension, except in FE (Table 7.14, Figures A.17 to A.20 in Appendix A). There were no significant 2-way interactions.

<table>
<thead>
<tr>
<th>Table 7.12</th>
<th>Mean ROM at 3 levels below destabilized level (L2-L3) for different surgical conditions using the hybrid protocol.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range of Motion, mean (s.d.)</td>
<td>AR</td>
</tr>
<tr>
<td>Intact</td>
<td>2.1° (1.6°)</td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>1.8° (1.0°)</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>2.0° (1.2°)</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>2.3° (1.4°)</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>2.7° (1.8°)</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>2.6° (1.5°)</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>2.9° (1.6°)</td>
</tr>
<tr>
<td>p-values from 1-way ANOVA</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

* - significantly different from corresponding intact value, alpha = 0.01.

<table>
<thead>
<tr>
<th>Table 7.13</th>
<th>Percentage difference in ROM from intact and statistical significance, for 3 levels below destabilized level.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage Difference from Intact, p-values</td>
<td>AR</td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>-17%, 0.3</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>-6%, 0.6</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>7%, 0.5</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>26%, 0.1</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>22%, 0.1</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>35%, 0.02</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 7.14</th>
<th>2-way ANOVA results on normalized ROM between cement (factor 1) and posterior rod extension (factor 2) using the hybrid protocol, for 3 levels below destabilized level.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AR</td>
</tr>
<tr>
<td>Factor 1: Cement</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Factor 2: Rod extension</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Interactions</td>
<td>0.2</td>
</tr>
</tbody>
</table>
Level above Destabilized Level

In the 1-way ANOVA analyses, ROMs at the level above destabilized levels (T9-T10 in T9-L3 segments) were significantly increased by surgical intervention in all directions (Table 7.15). Cement augmentation and posterior rod extension increased ROMs from intact values in all directions, except for the initial surgical configuration in AR (Tables 7.15 and 7.16).

In the 2-way ANOVA analyses, both cement augmentation and posterior rod extension significantly increased ROMs at the level above destabilized level (Table 7.17, Figures A.1 to A.4 in Appendix A). There were no significant 2-way interactions.

<table>
<thead>
<tr>
<th>Table 7.15</th>
<th>Mean ROM across level above destabilized level (T9-T10) for different surgical conditions using the hybrid protocol.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Range of Motion, mean (s.d.)</td>
</tr>
<tr>
<td></td>
<td>AR</td>
</tr>
<tr>
<td>Intact</td>
<td>4.1° (1.3°)</td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>4.8° (1.6°)</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>*5.2° (1.5°)</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>*5.5° (1.7°)</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>*5.7° (1.7°)</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>*5.8° (1.5°)</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>*6.1° (1.6°)</td>
</tr>
<tr>
<td>p-values from 1-way ANOVA</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

* - significantly different from corresponding intact value, alpha = 0.01.

<table>
<thead>
<tr>
<th>Table 7.16</th>
<th>Percentage difference in ROM from intact and statistical significance, for level above destabilized level.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Percentage Difference from Intact, p-values</td>
</tr>
<tr>
<td></td>
<td>AR</td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>17%, 0.02</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>25%, 0.002</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>33%,&lt;0.001</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>38%,&lt;0.001</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>42%,&lt;0.001</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>48%,&lt;0.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 7.17</th>
<th>2-way ANOVA results on normalized ROM between cement (factor 1) and posterior rod extension (factor 2) using the hybrid protocol, for level above destabilized level.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor 1: Cement</td>
<td>0.009</td>
</tr>
<tr>
<td>Factor 2: Rod extension</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Interactions</td>
<td>0.5</td>
</tr>
</tbody>
</table>
Destabilized Level

In the 1-way ANOVA, ROMs at the destabilized levels (T10-T12 in T9-L3 segments), were significantly affected by surgical intervention in all directions (Table 7.18). Cement augmentation and posterior rod extension generally decreased ROMs from intact values in all directions, except in AR and without cement (Tables 7.18 and 7.19).

In the 2-way ANOVA analyses, both cement augmentation and posterior rod extension significantly decreased ROMs at the destabilized level (Table 7.20, Figures A.5 to A.8 in Appendix A). The significant 2-way interactions in LB and FE were due to significant effect of posterior rod extension without cement, while cement augmentation resulted in non-significant effects of posterior rod extension.

Table 7.18  Mean ROM across destabilized levels for different surgical conditions using the hybrid protocol.

<table>
<thead>
<tr>
<th></th>
<th>AR</th>
<th>LB</th>
<th>FE</th>
<th>FE+FL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>6.6° (2.0°)</td>
<td>5.7° (1.7°)</td>
<td>4.3° (1.2°)</td>
<td>3.8° (0.8°)</td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>6.2° (3.2°)</td>
<td>*4.3° (1.8°)</td>
<td>*3.4° (1.8°)</td>
<td>*1.7° (1.4°)</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>5.6° (2.5°)</td>
<td>*2.7° (2.0°)</td>
<td>*2.6° (1.3°)</td>
<td>*0.9° (0.7°)</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>4.9° (2.1°)</td>
<td>*2.1° (1.7°)</td>
<td>*1.8° (1.0°)</td>
<td>*0.7° (0.5°)</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>*3.8° (1.3°)</td>
<td>*1.7° (1.1°)</td>
<td>*1.4° (0.8°)</td>
<td>*0.7° (0.7°)</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>*3.9° (1.5°)</td>
<td>*1.3° (1.2°)</td>
<td>*1.6° (0.8°)</td>
<td>*0.6° (0.6°)</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>*3.6° (1.5°)</td>
<td>*1.2° (1.1°)</td>
<td>*1.4° (0.7°)</td>
<td>*0.5° (0.7°)</td>
</tr>
<tr>
<td>p-values from 1-way ANOVA</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

* - significantly different from corresponding intact value, alpha = 0.01.

Table 7.19  Percentage difference in ROM from intact and statistical significance, for destabilized level.

<table>
<thead>
<tr>
<th></th>
<th>Percentage Difference from Intact, p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AR</td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>-6%, 0.5</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>-16%, 0.1</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>-26%, 0.01</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>No extension</td>
<td>-43%, &lt;0.001</td>
</tr>
<tr>
<td>Flexible extension</td>
<td>-41%, &lt;0.001</td>
</tr>
<tr>
<td>Rigid extension</td>
<td>-46%, &lt;0.001</td>
</tr>
</tbody>
</table>

Table 7.20  2-way ANOVA results on normalized ROM between cement (factor 1) and posterior rod extension (factor 2) using the hybrid protocol, for destabilized level.

<table>
<thead>
<tr>
<th></th>
<th>AR</th>
<th>LB</th>
<th>FE</th>
<th>FE+FL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor 1: Cement</td>
<td>0.003</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>0.009</td>
</tr>
<tr>
<td>Factor 2: Rod extension</td>
<td>0.008</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Interactions</td>
<td>0.04</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>0.001</td>
</tr>
</tbody>
</table>
Chapter 7  Adjacent Level Effects

7.3.4 Vertebral Body Strains

Flexion-Extension

Strains for gauges attached to the vertebral bodies (gauges 1-4) were negative in magnitude during flexion (in compression) and positive during extension, as expected, while strains for gauges attached to the spinous processes (gauges 5 and 6) were positive in magnitude during flexion (in tension) and negative during extension (Table 7.21). Noise level of the strain data was minimal (Figure 7.4).

In the 1-way ANOVA analyses, overall change in strains in gauges 2, 4, 5 and 6 were significantly affected by surgical intervention in FE (Tables 7.21 and 7.22, Figure 7.15).

Table 7.21 Mean (standard deviation) strain gauge values (in microstrain) at baseline ROM in flexion and in extension.

<table>
<thead>
<tr>
<th></th>
<th>Strain in Flexion, mean (s.d.)</th>
<th>Strain in Extension, mean (s.d.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gauge 1</td>
<td>Gauge 2</td>
</tr>
<tr>
<td>Intact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>-156 (114)</td>
<td>-120 (96)</td>
</tr>
<tr>
<td>Flex ext</td>
<td>-100 (75)</td>
<td>-88 (80)</td>
</tr>
<tr>
<td>Rigid ext</td>
<td>-186 (98)</td>
<td>-179 (120)</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>-141 (87)</td>
<td>-116 (98)</td>
</tr>
<tr>
<td>Flex ext</td>
<td>-192 (119)</td>
<td>-161 (97)</td>
</tr>
<tr>
<td>Rigid ext</td>
<td>-224 (132)</td>
<td>-207 (139)</td>
</tr>
</tbody>
</table>

Strain in Flexion-Extension, mean (s.d.)

<table>
<thead>
<tr>
<th></th>
<th>Strain in Flexion, mean (s.d.)</th>
<th>Strain in Extension, mean (s.d.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gauge 1</td>
<td>Gauge 2</td>
</tr>
<tr>
<td>Intact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>-343 (292)</td>
<td>-327 (245)</td>
</tr>
<tr>
<td>Flex ext</td>
<td>-301 (182)</td>
<td>-373 (268)</td>
</tr>
<tr>
<td>Rigid ext</td>
<td>-308 (228)</td>
<td>-341 (266)</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>-438 (276)</td>
<td>*-558 (436)</td>
</tr>
<tr>
<td>Flex ext</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid ext</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

p-values from 1-way ANOVA

|                     | 0.03 | < 0.001 | 0.5 | < 0.001 | < 0.001 | < 0.001 |

No ext: No extension rods, Flex ext: Flexible extension rods, Rigid ext: rigid extension rods.

* significant difference from corresponding intact value, p < 0.01.
Table 7.22  Percentage difference in strain from intact during flexion-extension and statistical significance.

<table>
<thead>
<tr>
<th></th>
<th>Percentage Difference from Intact, p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gauge 1</td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>-29%, 0.4</td>
</tr>
<tr>
<td>Flex ext</td>
<td>-12%, 0.9</td>
</tr>
<tr>
<td>Rigid ext</td>
<td>-2%, 0.9</td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>-10%, 0.8</td>
</tr>
<tr>
<td>Flex ext</td>
<td>18%, 0.3</td>
</tr>
<tr>
<td>Rigid ext</td>
<td>28%, 0.2</td>
</tr>
</tbody>
</table>

Figure 7.15  Mean changes in strain values between flexion and extension at respective baseline ROM. Negative strain values correspond to flexion (compression).

In the 2-way ANOVA analyses, mean normalized vertebra strains in FE were not significantly affected by cement augmentation, except for gauge 4 (Table 7.23, Figure 7.16). On the other hand, posterior rod extension significantly increased strain values in all gauges except gauge 3. There were no significant 2-way interactions in all gauges.
Table 7.23 2-way ANOVA results on normalized vertebral strain between cement (factor 1) and posterior rod extension (factor 2) using the hybrid protocol.

<table>
<thead>
<tr>
<th></th>
<th>Flexion-Extension</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gauge 1</td>
</tr>
<tr>
<td>Factor 1: Cement</td>
<td>0.05</td>
</tr>
<tr>
<td>Factor 2: Rod extension</td>
<td>0.01</td>
</tr>
<tr>
<td>Interactions</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Changes in Strain during Flexion-Extension using Hybrid Flexibility-Stiffness Protocol

---

*significant effects of cement and extension. **significant effect of extension only.
Error bars indicate standard deviation.

**Figure 7.16** Normalized changes in strain values during FE at respective baseline ROM.

**Lateral Bending**

In right LB, strains for gauges on the right vertebral surfaces (gauges 1 and 2) were negative (compression side) while strains for gauges on the left vertebral surfaces (gauges 3 and 4) were positive (tension side) just as expected (Table 7.24). In left LB, the signs of the strains were all reversed.

In the 1-way ANOVA analyses, overall change in strains in gauges 1 to 4 were significantly affected by surgical intervention in LB (Tables 7.24 and 7.25, Figure 7.17).
### Table 7.24
Mean (standard deviation) strain gauge values (in microstrain) at baseline ROM in right lateral bending and in left lateral bending.

<table>
<thead>
<tr>
<th></th>
<th>Strain in Right Lateral Bending, mean (s.d.)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gauge 1</td>
<td>Gauge 2</td>
<td>Gauge 3</td>
<td>Gauge 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>-353 (202)</td>
<td>-258 (139)</td>
<td>784 (519)</td>
<td>551 (292)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>-317 (150)</td>
<td>-238 (104)</td>
<td>728 (363)</td>
<td>528 (246)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flex ext</td>
<td>-370 (175)</td>
<td>-344 (160)</td>
<td>889 (327)</td>
<td>800 (295)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid ext</td>
<td>-447 (192)</td>
<td>-403 (162)</td>
<td>1015 (426)</td>
<td>931 (323)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>-409 (186)</td>
<td>-323 (131)</td>
<td>1097 (491)</td>
<td>796 (321)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flex ext</td>
<td>-467 (186)</td>
<td>-447 (152)</td>
<td>1167 (547)</td>
<td>1119 (342)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid ext</td>
<td>-482 (217)</td>
<td>-510 (217)</td>
<td>1154 (463)</td>
<td>1222 (350)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Strain in Left Lateral Bending, mean (s.d.)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gauge 1</td>
<td>Gauge 2</td>
<td>Gauge 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>762 (491)</td>
<td>572 (360)</td>
<td>-451 (284)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>751 (378)</td>
<td>546 (290)</td>
<td>-456 (311)</td>
<td>-329 (196)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flex ext</td>
<td>877 (466)</td>
<td>784 (445)</td>
<td>-532 (224)</td>
<td>-433 (170)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid ext</td>
<td>976 (538)</td>
<td>906 (564)</td>
<td>-589 (393)</td>
<td>-510 (388)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>847 (370)</td>
<td>688 (360)</td>
<td>-495 (283)</td>
<td>-378 (182)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flex ext</td>
<td>955 (450)</td>
<td>1013 (524)</td>
<td>-622 (312)</td>
<td>-569 (291)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid ext</td>
<td>981 (400)</td>
<td>1106 (567)</td>
<td>-707 (361)</td>
<td>-642 (378)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Strain in Lateral Bending, mean (s.d.)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gauge 1</td>
<td>Gauge 2</td>
<td>Gauge 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>-1115 (671)</td>
<td>-830 (473)</td>
<td>1235 (761)</td>
<td>872 (452)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>-1068 (502)</td>
<td>-784 (371)</td>
<td>1184 (548)</td>
<td>857 (296)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flex ext</td>
<td>-1247 (568)</td>
<td>-1128 (557)</td>
<td>1422 (506)</td>
<td>*1233 (322)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid ext</td>
<td>-1424 (666)</td>
<td>-1309 (692)</td>
<td>1604 (649)</td>
<td>*1441 (449)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>-1255 (505)</td>
<td>-1011 (460)</td>
<td>1591 (664)</td>
<td>*1174 (375)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flex ext</td>
<td>-1421 (585)</td>
<td>-1461 (642)</td>
<td>*1789 (780)</td>
<td>*1688 (499)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid ext</td>
<td>*-1463 (572)</td>
<td>*-1616 (728)</td>
<td>*1860 (721)</td>
<td>*1864 (580)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>p-values from 1-way ANOVA</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

No ext: No extension rods, Flex ext: Flexible extension rods, Rigid ext: rigid extension rods.

* significant difference from corresponding intact value, \( p < 0.01 \).

### Table 7.25
Percentage difference in strain from intact during lateral bending and statistical significance.

<table>
<thead>
<tr>
<th></th>
<th>Percentage Difference from Intact, p-values</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gauge 1</td>
<td>Gauge 2</td>
<td>Gauge 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not cemented</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>-4%, 0.7</td>
<td>-6%, 0.7</td>
<td>-4%, 0.7</td>
<td>-2%, 0.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flex ext</td>
<td>12%, 0.2</td>
<td>36%, 0.01</td>
<td>15%, 0.1</td>
<td>41%, 0.002</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid ext</td>
<td>28%, 0.03</td>
<td>58%, &lt;0.001</td>
<td>30%, 0.02</td>
<td>65%, &lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cemented</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ext</td>
<td>13%, 0.4</td>
<td>22%, 0.08</td>
<td>29%, 0.02</td>
<td>35%, 0.004</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flex ext</td>
<td>27%, 0.02</td>
<td>76%, &lt;0.001</td>
<td>45%, &lt;0.001</td>
<td>93%, &lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid ext</td>
<td>31%, 0.01</td>
<td>95%, &lt;0.001</td>
<td>51%, &lt;0.001</td>
<td>114%, &lt;0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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Figure 7.17  Mean changes in strain values during LB at respective baseline ROM. Negative strain values correspond to right lateral bending (compression).

In the 2-way ANOVA analyses, mean normalized vertebra strains in LB were significantly increased by both cement augmentation and posterior rod extensions, except for gauge 1 (Table 7.26, Figure 7.18). There were no significant 2-way interactions in all gauges.

Table 7.26  2-way ANOVA results on normalized vertebral strain between cement (factor 1) and posterior rod extension (factor 2) using the hybrid protocol.

<table>
<thead>
<tr>
<th>Lateral Bending</th>
<th>Gauge 1</th>
<th>Gauge 2</th>
<th>Gauge 3</th>
<th>Gauge 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor 1: Cement</td>
<td>0.06</td>
<td>0.003</td>
<td>0.002</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Factor 2: Rod extension</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Interactions</td>
<td>0.2</td>
<td>0.4</td>
<td>0.4</td>
<td>0.3</td>
</tr>
</tbody>
</table>
Chapter 7  
Adjacent Level Effects

Changes in Strain during Lateral Bending using Hybrid Flexibility-Stiffness Protocol

*significant effects of cement and extension. **significant effect of extension only.
Error bars indicate standard deviation.

Figure 7.18  Normalized changes in strain values during LB at respective baseline ROM.

7.4 Discussion

The purpose of this study was to determine biomechanical changes at adjacent levels following spinal fixation, and specifically to assess the effects of posterior rod extension and cement augmentation of pedicle screws on these biomechanical changes. The hybrid flexibility-stiffness test protocol was successfully utilised to assess changes in ROM and vertebra strains at adjacent levels. Both flexible and rigid extension rods reduced ROM at the rod extension level and generally did not increase vertebra strains at the first adjacent level; on the other hand, there were increased ROM and vertebra strains beyond the rod extension (Figures 7.19 and 7.20). Cement augmentation also resulted in increased ROM and vertebra strains at adjacent levels in some directions.
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Axial Rotation  Lateral Bending  Flexion-Extension

(a) no cement, no extension

(b) no cement, flexible rods extension

(c) no cement, rigid rods extension

Legend

↑ Increased ROM
↓ Decreased ROM
⇔ No change in ROM
↑ Increased Strain
⇔ No change in Strain

Figure 7.19  Summary of changes in ROM and strains across levels and directions, for the non-cemented conditions.
Figure 7.20 Summary of changes in ROM and strains across levels and directions, for the cemented conditions.
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7.4.1 Limitations

The same limitations described in Section 6.4.1 also applies to this chapter and will not be repeated. The inherent assumption of same ROM in the hybrid test protocol posed another limitation to this study with regards to specimen length.

The present study on adjacent level effect was carried out with a long human cadaveric specimen length which was comprised of 7 vertebral bodies. The use of such a long cadaveric specimen length in studying adjacent level effects was unprecedented. While a long test specimen (T8-L2 or T9-L3) was used, cement augmentation only resulted in 3 remaining mobile segments below while posterior rod extension resulted in 2 segments. The reduced motion at the destabilized and rod extension levels was compensated with increased motion in these remaining mobile segments. With more remaining mobile segment, there were higher percentages and more significant increases following posterior rod extension then with cement augmentation. Direct comparison between these 2 surgical interventions in the current study should thus be carried out with this limitation in mind.

Increasing the total number of spinal segments to the test model might make the comparison of increased ROM and vertebra strains between posterior rod extension and cement augmentation less biased. It was suggested that the entire thoracolumbar spine should be included in experiments addressing adjacent level effects [Panjabi 2002]. Availability of suitable test specimens is an issue in in vitro spine testing and to use even longer specimens in one study will remain a limitation for future research.

With the current specimen length, we were able to isolate end effects due to proximity to the potting cement [Wilke et al. 1998, Kettler et al. 2000], while still able to address the effects of surgical intervention the remaining adjacent levels. Changes at the levels immediately proximal to both superior and inferior dental stone potting could be due to end effects such as absence of connection of supraspinous ligaments to the dental stone [Dickey and Kerr 2003]. The observed changes at the most superior level in this study were compounded by this end effect and the surgical intervention at the next level. With only one non-instrumented level above the destabilized level in the current study, interpretation of results at this level should be made with caution.

With the current specimen length, increased intersegmental ROM at the distal non-instrumented levels was found in the current study using the hybrid protocol. The applied loads resulted in sufficiently high changes in ROM and strains, with the limited number of specimens, for observing significant differences. Thus the specimen level used in this study was sufficient to study adjacent level effects. The use of longer multisegmental specimens would result in
increased complexity. Interpretation of current results for the distal levels should be similarly applicable to the levels superior to the fusion construct.

7.4.2 Comparison with Existing Results

The basic surgical procedure (no cement, no extension) did not decrease motion at the destabilized level in AR, but resulted in smaller ROM than intact in LB and FE. This observation is consistent with the literature where interbody devices and spinal instrumentation were reported to have less stabilizing effect in AR than in LB and FE [Lund et al. 1998, Harris et al. 2004]. With less stabilizing effect in AR without cement, no significant increase in ROM at adjacent segments was observed in this direction. However, the use of cement augmentation stabilized the surgical level but resulted in increased ROM at the adjacent level.

Previous studies using the stiffness protocol also found increased motion at adjacent non-instrumented levels as a result of decreased motion at the fusion level [Chow et al. 1996, Fuller et al. 1998, Eck et al. 2002]. Segmental motion at the non-instrumented level was previously observed to further increase with increase in fusion length from single level to double levels [Chow et al. 1996] and to triple levels [Fuller et al. 1998], and this observation was also consistent with our results. Higher applied moments were also necessary in order to achieve the same baseline ROM following spinal fixation [Fuller et al. 1998].

The yield strain of trabecular in the vertebra was found to be about 7700 microstrain in compression and 7000 microstrain in tension [Morgan and Keaveny 2001]. Microdamage to trabecular bone was found to occur with 4600 to 6300 microstrain in compression and only 1800 to 2400 microstrain in tension [Nagaraja et al. 2005]. The strains measured on the surface of the vertebral body in this study were below these known damaging ranges with a maximum mean strain of 1864 microstrain (s.d. = 580) with cement and rigid rod extension during LB, under the maximum applied moment of 5 Nm. The measured strain values were thus in the correct order of magnitude and were comparable to these previous studies.

The observations of increased stability at the destabilized level following cement augmentation and posterior rod extension, determined using the hybrid protocol, were similar to results obtained using the flexibility protocol (Chapter 6) (Figures 6.8 to 6.11 compared to Figures A.5 to Figures A.8). The hybrid protocol could however be used to determine effects at adjacent non-instrumented levels while the flexibility protocol could not. On the other hand, the flexibility protocol could be used to compare flexibility of different surgical constructs with a less cumbersome analysis procedure. Thus if the objective is to compare flexibility the flexibility protocol should be used, while the hybrid test protocol should be used to study adjacent level
Chapter 7  Adjacent Level Effects

effects. Data in previous studies that used the flexibility protocol [Rohlmann et al. 2001, Lindsey et al. 2003, Schmoelz et al. 2003] could be reanalysed using the hybrid protocol and the results at the adjacent segments could be compared to ascertain the absence or presence of adjacent level effects.

7.4.3 The Use of Cement Augmentation and Posterior Rod Extension

The detrimental effects of device loosening and adjacent level effects are two major issues faced by the surgeon when carrying out internal fixation in the osteoporotic patient.

This study clearly demonstrated that both extension of posterior rods and cement augmentation reduced motion at the destabilized level, and this could translate to better fixation and fewer cases of implant loosening in the osteoporotic patients. Smaller ROM at the destabilized level following cement augmentation using the flexibility test protocol (Chapter 6) also supported the use of cement to reduce device loosening.

This study also demonstrated decreased motion at the rod extension level following the use of posterior rod extension. In patients with observable early stage degeneration at the adjacent segment to the immediate surgical level, the use of posterior rod extension might prove useful in preventing accelerated adjacent segment disease. While posterior rod extension could alleviate the incidence of adjacent segment disease at the rod extension level, it will likely result in postponement of adjacent segment disease to other levels. In patients with healthy adjacent segments, the use of posterior rod extension has no further advantage in improving fixation at the immediate surgical level as compared to cement augmentation.

Furthermore, this study showed significant differences between flexible and rigid rod extension; in particular, a lesser degree of increased ROM and vertebra strains at the non-instrumented distal levels was observed with flexible rod extension. Flexible rod extension might thus result in less cases or delayed emergence of adjacent segment disease in the patients as compared to rigid rod extension.

Overall, cement augmentation resulted in more rigid fixation, while posterior rod extension reduced motion at the extension level and increased motion at other levels.

In an attempt to compare the different surgical configurations, a graphical presentation and an analytical technique were used and will be briefly described. The optimal device performance could be considered to be a function of 1) decreased ROM at the destabilized level, 2) normalized ROM at adjacent level close to or less than unity, and 3) normalised strain at adjacent level close to unity.
In the graphical presentation technique, mean ROM at adjacent levels was plotted against ROM at destabilized level for each surgical configuration and across the different levels (Figure 7.21). Data points closer to the left have better fixation at the destabilized level, while data points close to or less than the horizontal value of 1 have similar adjacent level ROM as the intact state. An ideal region that corresponds to these criteria could be drawn and the reader should note that the boundary of this ideal region is arbitrary. Cemented configurations resulted in better fixation at the destabilized level in general, as seen earlier. In AR (Figure 7.21a), all data points were on the right of the ideal region, indicating that ROM at the destabilized level were not greatly reduced. In LB and FE (Figures 7.21b and 7.21c), while some surgical conditions resulted in ROM at the destabilized level to fall within the ideal region, there were wide vertical spread of the data points. From the plots, it could be seen that a decrease in ROM at the rod extension level (level below destabilized) is generally associated with increases in ROM at other levels. Among the cemented configurations, surgical intervention with no extension rods resulted in a less vertical spread and more data points closer to the ideal region, and might be the best surgical configuration.
Figure 7.21 Normalized ROM at all levels plotted against normalized ROM at the destabilized level. Data points that lie to the left have better fixation at the destabilized level. Data points that lie close to the horizontal value of 1 have similar ROM as the intact state and are considered optimum, while data points above 1 indicates increased ROM. The shaded box represents an ideal zone for all the data points. A decrease in ROM at the rod extension level is generally associated with increases in ROM at other levels, which appears as wider vertical spread (longer vertical lines).
In the analytical technique, a score system was utilized (Table 7.27). Equal weighting was allocated to the immediate surgical level (50 points) and the adjacent level (50 points). Points for the immediate surgical level were higher if the surgical configuration resulted in smaller ROM as compared to the intact. All scores were calculated based on comparison to the intact values. For the adjacent level factor, the 50 points were further allocated to ROM at adjacent levels (25 points) and strains (25 points). ROM at the rod extension level and level below were considered. Higher points were given for normalized ROM at the adjacent level closer to unity. For the strain values factor, the points were further allocated to FE strains (12.5 points) and LB strains (12.5 points). Higher points were again given for normalized strains closer to unity. The final score was highest for cement augmentation with no rod extension, with 72 out of 100.

### Table 7.27 Score for different surgical configuration calculated based on comparison to corresponding intact values.

<table>
<thead>
<tr>
<th>Score (Max)</th>
<th>No Cement</th>
<th>Cemented</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No ext</td>
<td>Flex ext</td>
</tr>
<tr>
<td>Stabilization (50)</td>
<td>8</td>
<td>18</td>
</tr>
<tr>
<td>Adjacent ROM (25)</td>
<td>23</td>
<td>19</td>
</tr>
<tr>
<td>Strain in FE (12.5)</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Strain in LB (12.5)</td>
<td>12</td>
<td>9</td>
</tr>
<tr>
<td>Total (100)</td>
<td>54</td>
<td>57</td>
</tr>
</tbody>
</table>

where

\[
\text{Stabilization} = \frac{w}{3} \sum_{3 \text{directions}} \frac{|\text{ROM}_{\text{fixation}} - \text{ROM}_{\text{int act}}|}{\text{ROM}_{\text{int act}}}
\]

\[
\text{Adjacent ROM} = \frac{w}{3 \times 2} \sum_{2 \text{adj levels}} \sum_{3 \text{directions}} \begin{cases} \frac{\text{ROM}_{\text{adjacent}}}{\text{ROM}_{\text{int act}}}, & \text{if } \text{ROM}_{\text{int act}} > \text{ROM}_{\text{adjacent}} \\ 2 - \frac{\text{ROM}_{\text{adjacent}}}{\text{ROM}_{\text{int act}}}, & \text{otherwise} \end{cases}
\]

\[
\text{Strain in FE} = \frac{w}{6 \times 6 \text{gauges}} \begin{cases} \frac{\text{Strain}_{\text{adjacent}}}{\text{Strain}_{\text{int act}}}, & \text{if } \text{Strain}_{\text{int act}} > \text{Strain}_{\text{adjacent}} \\ 2 - \frac{\text{Strain}_{\text{adjacent}}}{\text{Strain}_{\text{int act}}}, & \text{otherwise} \end{cases}
\]
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\[
\text{Strain in LB} = \frac{w}{4} \sum_{\text{4 gauges}} \begin{cases} \frac{\text{Strain}_{\text{adjacent}}}{\text{Strain}_{\text{intact}}} , & \text{if } \frac{\text{Strain}_{\text{intact}}}{\text{Strain}_{\text{adjacent}}} > 1 \\ 2 - \frac{\text{Strain}_{\text{adjacent}}}{\text{Strain}_{\text{intact}}} , & \text{otherwise} \end{cases}
\]

, and \( w \) is the corresponding weighting allocated.

The result of this score system depends heavily on the weighting allocated to each factor. The highest score with cement augmentation and no rod extension does not mean that it will be the best technique in all clinical cases. It is not possible to come to a straightforward conclusion that any one surgical configuration is superior to others, and this score system is an overly simplified comparison. Overall, cement augmentation is recommended to improve device fixation. The pros and cons of the use of posterior rod extension need to be considered on a case by case basis by the surgeon.

7.4.4 Vertebra Strains

The higher strains at L1 in FE with cement augmentation and/or posterior extension were consistent with the higher ROM observed at both adjacent motion segments (2 and 3 levels below destabilized level) (Figures A.15 and A.19 in Appendix A). The non-significance in vertebral body strains at T12 (gauges 1 and 3) were possibly due to a combination of decreased ROM at the rod extension level (Figure A.11) and increased ROM at 2 levels below destabilized level (Figure A.14).

The higher strains in L2 in LB with cement augmentation and/or posterior extension were consistent with the higher ROM observed at both adjacent motion segments (Figures A.14 and A.18). The decreased ROM at rod extension level (Figure A.10) and increased ROM at 2 levels below destabilized level (Figure A.14) resulted in a general net increase in vertebral body strains at the measurement sites.

The magnitude of vertebral strain, increase in ROM or intradiscal pressures at adjacent levels that would result in adverse adjacent level effects in the osteoporotic patient has not been previously studied. One limitation of the current study was that the observed increase in strain at adjacent vertebrae following cement augmentation or posterior extension could not be ascertained to be 1) beneficial and promote bone growth or 2) detrimental and result in adverse adjacent level effect. It is commonly known that some degree of strain on the bone could stimulate bone growth. Indeed, a recent prospective study comparing instrumented
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lumbosacral fusion against discectomy and hemilaminotomy without fusion, found increased BMD in 3 cephalad adjacent vertebrae with use of instrumentation at 10 years follow-up [Singh et al. 2005]. In the osteoporotic spine however, increased loading at the adjacent vertebrae could cause localised failure of the trabeculae and could trigger accelerated vertebral fracture at adjacent levels. Further research is necessary in order to have a deeper understanding of the strain data.

7.5 Conclusion

In conclusion, posterior rod extension might prevent adjacent level disease at the extension level by reducing ROM, but on the other hand could cause accelerated adjacent level disease beyond the rod extension levels. Posterior rod extension should be used with caution and when its use is necessary, flexible rod extension would be a better choice than rigid rod extension. Cement augmentation resulted in improved fixation of device and the results in this study indicated increase in ROM and strains at the adjacent levels in some directions.

7.6 References

Chapter 7  Adjacent Level Effects


[29] Panjabi MM. Biomechanical testing to quantify adjacent-level effects. World Congress of Biomechanics 2002; Conference Abstract.


Chapter 8
General Discussion, Conclusions and Recommendations
Chapter 8  General Discussion and Conclusion

8. General Discussion, Conclusions and Recommendations

8.1 General Discussion

The number of patients with degenerative conditions requiring spinal care and surgery is expected to increase in the next few decades with our aging population (Chapter 1). Implant loosening and accelerated adjacent level degeneration are two major problems associated with internal fixation of the aging spine. This thesis addressed both of these surgical issues in separate studies, first on improving bone-implant interface strength posteriorly (Chapters 2 and 3) and anteriorly (Chapters 4 and 5) and next on improving overall construct strength (Chapter 6), and lastly on adjacent level effects (Chapter 7). These results tend to support the use of cement augmentation of pedicle screws, so as to improve both interface properties at the pedicle screw-bone interface (Chapter 3) and at the cage-vertebra interface (Chapter 5). Moreover, the extension of posterior fixation to the adjacent segment with flexible extension rods might reduce the incidence of accelerated adjacent level degeneration at the extension level (Chapter 7), but increase the risk at other levels beyond the extension.

Spinal instrumentation devices were not designed for use in the osteoporotic patient group. The US Food and Drug Administration (FDA), which gives approval before a new spinal device can be used in the US, requires pedicle screw manufacturers to carry out static and fatigue tests in accordance with ASTM F1717 [US FDA 2004]. The ASTM F1717 focuses on the static and fatigue lifespan of the devices and, as discussed in Chapter 2, does not consider the effect of the devices on adjacent bone. Since spinal fixation devices are usually metallic, they are generally stiffer than the bone with which they will be in contact. As a result, the high stress concentration at the bone-implant interface often causes localised trabecular failure, especially in the osteoporotic patients. Loosening of spinal devices in the osteoporotic patients is thus not unexpected. The importance of vertebral bone density in pedicle screw testing (Chapter 2) was highlighted at the ASTM meeting: “Spinal Implants: are we evaluating them appropriately?” and subsequently published [Tan et al. 2003], with the hope that implant companies, the ASTM committee and the FDA would be more aware of the issue. While it will take some time before any concrete action, if any, will be made by these different groups, a present solution using existing technologies to address the problems of spinal instrumentation in the osteoporotic patients is needed.

The use of instrumentation in the osteoporotic patient was recommended as not advisable almost a decade ago by an expert panel of spine surgeons [Andersson et al. 1997], except in cases of deformity or gross instability. It was agreed at the time that there is a need for development of instrumentation whose material properties would allow for rigid fixation and
bone healing without affecting adjacent levels. Advances in the last decade in this field of surgical intervention in the osteoporotic spine have focused mainly on biocompatible cement and motion preservation devices. While cement could prevent implant loosening in the osteoporotic spine, no studies according to my knowledge, have attempted to address both the problems of implant loosening and biomechanical effects at adjacent levels in the osteoporotic spine. The recently popular motion preservation devices claim to be able to restore motion at the surgical level and therefore eliminate adjacent level effects. These devices are currently used in clinical trials on younger age groups and may not be suitable in the elderly patients with spinal degeneration and osteoporosis.

The problem of loosened pedicle screws can be approached with different methods by the spine surgeon. To prevent potential loosening of pedicle screws, pedicle screws have been augmented with additional devices such as laminar hooks, sublaminar wires and more recently with cement. No direct biomechanical comparison with physiological applied loads between these techniques has been carried out prior to our recent study being published in *Spine*. Previous studies on pedicle screw fixation strength used the pull-out test which, in our opinion, is not representative of the *in vivo* loading conditions. In our paper [Tan et al. 2004], known *in vivo* loads were simulated with a test setup that applied both compressive and bending moment to the screw heads which allowed pedicle screws motion to be measured (Chapters 2 and 3). Compared to without augmentation, all 3 augmentation techniques resulted in reduced motion of the screws in a loosened screw model, with no significant difference in motion magnitudes between the techniques. Motion patterns of the screws were however different. The motion pattern of screws with calcium phosphate cement most closely restored the motion to those observed in normal bone, which suggested that it might provide enhanced fixation over the other two techniques. Cement augmentation was thus selected to be used in the studies in Chapters 6 and 7.

Surgeons are aware of the inherent clinical risks with each technique and take them into consideration when choosing the technique to use. The exothermic reaction during cement setting could affect the neighbouring cells, and migration of the cement into blood vessels and the spinal canal during injection of the cement could cause undesired complications. Sublaminar wires and laminar hooks are placed within the spinal canal and in direct contact with the dura mater, which might impinge during surgery or abrade in the long term. In spite of the risks, these 3 techniques could also be used in conjunction with each other to prevent implant loosening and with the extension of posterior rods (Chapters 6 and 7) to prevent adjacent level...
effects. The added cost could be justifiable if the surgery could result in no further revisions as a result of complications such as loosening or adjacent level effects.

The issue of interbody device subsidence was addressed in Chapters 4 and 5. In Chapter 4, it was found that larger interbody devices and shapes that engaged the stronger peripheral regions of the endplate resulted in better bone-implant interface properties. As pedicle screws or anterior screws were commonly used in conjunction with interbody devices, Chapter 5 addressed the issue of trabecular disruption at the cage-vertebra interface following vertebral body screw insertion. Pedicle screw insertion into the vertebral body was found to significantly reduce the strength of the cage-vertebra interface. Cement augmentation of pedicle screws however significantly improved the cage-vertebra interface properties. Selecting appropriate device size and shape and the use of cement with instrumentation are thus possible techniques for the spine surgeon to reduce interbody device subsidence.

Adjacent level effects following cement augmentation and posterior extension were addressed next. Using the flexibility protocol and the hybrid flexibility-stiffness protocol, the effects at the destabilized level and adjacent levels were studied in Chapters 6 and 7 respectively. Cement augmentation was found to consistently reduce intersegmental motion at the destabilized level, with and without concurrent usage of extension rods. Posterior extension with either rigid or flexible rods also reduced motion at the extension level, under the flexibility test protocol, but not to the degree with cement augmentation. Using the hybrid flexibility-stiffness protocol to determine adjacent level effects, the use of only cement augmentation resulted in decreased motion at the destabilized level but increased motion at adjacent levels. The use of posterior extension rods however decreased motion at both destabilized and extension levels, but increased motion at other non-instrumented levels. This result was expected with the hybrid protocol as the underlying basis was the same range of motion following surgery.

Comparing results from the flexibility and hybrid protocols, decreased motion at the destabilized level with cement augmentation and posterior extension was observed in both protocols. Similar results at the destabilized levels were in fact obtained using either protocol. The hybrid flexibility-stiffness protocol could thus replace the flexibility protocol as it can be used to analyse data on both the destabilized and adjacent levels. With posterior extension, both protocols demonstrated reduced ROM at the extension levels. At the adjacent level however, cement augmentation only did not result in significant difference in ROM using the flexibility protocol but was significantly increased using the hybrid protocol. At the next adjacent level (2 levels below destabilized level) no changes were observed with the flexibility protocol following
posterior extension while significantly increased ROM was again found using the hybrid protocol. Thus the flexibility protocol was not suitable for studying adjacent level effects, while the hybrid protocol was.

The hybrid flexibility-stiffness test protocol, first described by Panjabi in 2002, was described in one other study in a conference proceeding [Goertzen et al. 2003]. The specimen length used in Goertzen (2003) was from L2-S1 (4 motion segments), with rigid fixation across L5-S1 and extension system between L4-L5. The basic assumption that the patient will incur the same pre-injury ROM following surgery is the main point of scrutiny for the hybrid test protocol. While an unprecedented long specimen length was used in this study (T9-L3, 6 motion segments) to address adjacent level effects, it still falls short of the recommended length (T1-S1) [Panjabi and Goel 2005]. Nonetheless, the hybrid flexibility-stiffness test protocol was successfully carried out in Chapter 7 with exciting results and implications for future biomechanical tests on adjacent level effects.

Adjacent level effects would most likely surface in the elderly patient with degenerative conditions following a rigid fixation. For example, while cement augmentation of pedicle screws could prevent screw loosening (Chapter 3), reduce interbody device subsidence (Chapter 5), and decrease motion at the destabilized level (Chapters 6 and 7), it was found to result in significantly increased ROM and vertebral strains at adjacent levels (Chapter 7). These increased ROM and strain were evidence of biomechanical changes at adjacent levels following spinal fixation and are part of the cause of accelerated adjacent level degenerations. Extending posterior instrumentation to the adjacent level also reduced motion at the destabilized level (Chapter 6), and also has the added advantage of reducing motion at the extension level (Chapters 6 and 7). With increased rigidity and extent over a larger number of levels, the risk of adjacent level effects surfacing at the remaining non-instrumented levels is also increased. Thus posterior rod extension should only be used when absolutely necessary, and flexible rod extension should be considered.

While patients' DXA values could be compared against known population data to determine osteopenia and osteoporosis based on WHO's definition, no equivalent data set are available for scans on dissected specimens. The fact that in situ and ex situ DXA measurements could greatly differ after skin and soft tissue dissection [Svendsen et al. 1995, Burklein et al. 2001], clearly signals that population data and t-scores should not be used to define status (normal, osteopenic or osteoporotic) of dissected specimens. Thus we could only infer from the specimens' age and population charts, as shown in Figure 1.10, and from physical examination that they are most likely either osteopenic or osteoporotic and in some cases
normal. In any case, the loosened screw model was used in Chapters 2, 3, 6 and 7 to represent the worst case scenario of loosened pedicle screws in the osteoporotic spine. All specimens used in this thesis were in the older age ranges. The mean age of the specimens was 74.5 years (range from 48 to 90 years) in the study in Chapter 3, 77 years (58 to 93 years) in Chapter 4, 77 years (62 to 93 years) in Chapter 5 and 75 years (64 to 84 years) in Chapters 6 and 7. Mean lateral DXA aBMD in Chapter 3 was 0.7 g/cm\(^2\) while mean lateral DXA aBMD in Chapters 4 and 5 were 0.46g/cm\(^2\), and in Chapters 6 and 7 were 0.42 g/cm\(^2\). The higher aBMD values for specimens in Chapter 3 could be due to the use of a different DXA machine (Lunar Corp, Madison, WI) and different scan and analysis protocol [Grant et al. 2002]. Mean lateral aBMD for specimens in Chapters 4 to 7 were fairly similar as the same scanner, software and analysis protocol were used. As the studies in this thesis were carried out using cadaveric specimens to simulate the immediate post-operative condition before any biological healing occurred, all results should be interpreted in this light. The effects of different surgical techniques on bone healing and bony fusion were not within the current scope. Indeed, rigid implants could result in bone resorption of neighbouring bone due to stress shielding and in accordance with Wolff's law.

8.2 Conclusions

Both issues of implant loosening and adjacent level effects in the osteoporotic spine were addressed in this thesis. The following specific conclusions were made:

1) Vertebral bone density was an important factor in implant loosening and the assessment of spinal devices should consider this factor on the long term survivability of the bone-implant interface following implantation.

2) Pedicle screw loosening in the osteoporotic spine was reduced following augmentation with calcium phosphate cement, laminar hooks and sublaminar wires. Augmentation of pedicle screw with calcium phosphate cement resulted in screw motion most similar to those observed in normal bone.

3) Interbody device subsidence was reduced with larger sized devices and with devices that engaged the stronger regions of the vertebral endplate, particularly with the clover-leaf shaped device.

4) Inclusion of pedicle screw fixation increased interbody device subsidence while cement augmentation of anterior and posterior vertebral screws improved cage-vertebra interface strength.
5) In the corpectomy model, cement augmentation of pedicle screws consistently reduced motion at the primary surgical level and improved fixation of loosened devices, while posterior rod extension improved fixation in the absence of cement.

6) Posterior rod extension could prevent adjacent level effects at the extension level but might postpone the problem to the remaining non-instrumented levels. The least changes at the remaining non-instrumented levels were observed when no extension rods were used. When the use of extension rods are necessary, flexible extension rods resulted in less changes at the remaining non-instrumented levels than rigid extension rods.

8.3 Contributions
The following novel contributions to the field were made:

1) A new test setup was used to apply physiological loads onto pedicle screws and to measure screw motion in vitro. The use of pedicle screw motion to define screw loosening is new.

2) Comparison between cement augmentation, laminar hook and sublaminar wires was not previously carried out. Knowledge of pedicle screw motion in vitro, with and without augmentation, gave researchers a better understanding of screw loosening and how the different augmentation techniques achieve better screw fixation in the osteoporotic spine.

3) Knowledge that larger interbody cages and cage shapes which could engage the peripheral regions of the endplates improved cage-vertebra interface properties, provided surgeons with a guideline on the use of interbody devices in the osteoporotic patients.

4) The use of pQCT to identify densification of trabeculae in interbody device subsidence is new. Bone quality within this densification zone is important to prevent subsidence of interbody devices.

5) The effects of pedicle screws and cement augmentation on the bone-interbody device interface properties had not been previously studied. This study provided biomechanical evidence that cement augmentation could prevent interbody device subsidence in the osteoporotic patients.

6) The comparison between cement augmentation and posterior rod extension to improve fixation at the fusion level in the osteoporotic spine had not been previously carried out. This study provided biomechanical evidence that cement augmentation results in better
fixation and surgeons could avoid extensive surgical procedures with posterior rod extension.

7) The hybrid test protocol was not previously applied in practice and this study validated the technique. The hybrid test protocol could become the standard biomechanical test technique for determining adjacent level effects.

8) The effect of posterior rod extension to adjacent non-instrumented levels was not previously studied and this study cautions on its impact on accelerated adjacent level disease at the remaining non-instrumented levels.

9) The use of flexible rod extension was demonstrated to reduce adverse effects at the remaining non-instrumented levels as compared with the use of rigid extension. This knowledge provides a direction for future development of devices that specifically address adjacent level effects.

8.4 Recommendations

1) The current commonplace use of cement injection into vertebra with compression fracture could pose a problem if these patients require future spinal fixation. Further directions of research should address the issue of drilling and tapping into cement-augmented vertebrae to prepare for the insertion of pedicle screws, and compare against other forms of spinal fixation such as the use of laminar hooks or sublaminar wires.

2) Long term side effects, if any, of cement in patients are still not clear. The use of cement should be further investigated.

3) Determining the number of extension levels and optimal flexibility of the flexible rod at each extension level, based on patient factors, surgical level, number of rigid fixation levels, could be future directions of research.

4) A functionally graded flexible posterior rod could be developed, so that the number of connection pieces could be reduced.

5) Future development and research should be geared towards the feasibility of using motion preservation devices in the elderly.

6) Cross links were not used to connect the posterior rods in this study. The effects of cross-links on adjacent level biomechanics, especially in AR, could be future direction for research.

7) Helical axes of motion could be used to further determine kinematic changes following rigid fixation and posterior rod extension.
8) The balance weight system of the spine machine could do with a feedback control system which could track and translate the balance weight to follow the motion of the "cheese block".

8.5 References


Appendix A

2-way ANOVA comparison on intersegmental ROM
at each level,
between cement and rod extension
using the hybrid test protocol
Appendix A

A.1 Level Above Destabilized Level

Figure A.1  effect of cement, $p = 0.009$; effect of rod extension, $p < 0.001$; interactions, $p = 0.5$.

Figure A.2  effect of cement, $p < 0.001$; effect of rod extension, $p < 0.001$; interactions, $p = 0.3$. 
Figure A.3  effect of cement, $p = 0.001$; effect of rod extension, $p = 0.005$; interactions, $p = 0.2$.

Figure A.4  effect of cement, $p = 0.006$; effect of rod extension, $p = 0.001$; interactions, $p = 0.5$. 
A.2 Destabilized Level

**Axial Rotation**

- Not Cemented
- Cemented

Figure A.5  effect of cement, $p = 0.003$; effect of rod extension, $p = 0.008$; interactions, $p = 0.04$.

**Lateral Bending**

Figure A.6  effect of cement, $p < 0.001$; effect of rod extension, $p < 0.001$; interactions, $p < 0.001$. 

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Figure A.7  effect of cement, $p < 0.001$; effect of rod extension, $p < 0.001$; interactions, $p < 0.001$.

Figure A.8  effect of cement, $p = 0.009$; effect of rod extension, $p < 0.001$; interactions, $p = 0.001$. 
A.3 Rod Extension Level

Figure A.9 effect of cement, \( p = 0.3 \); effect of rod extension, \( p < 0.001 \); interactions, \( p < 0.001 \).

Figure A.10 effect of cement, \( p = 0.1 \); effect of rod extension, \( p < 0.001 \); interactions, \( p < 0.001 \).
Figure A.11 effect of cement, $p = 0.002$; effect of rod extension, $p < 0.001$; interactions, $p = 0.006$.

Figure A.12 effect of cement, $p = 0.008$; effect of rod extension, $p < 0.001$; interactions, $p = 0.006$. 
A.4 2 Levels Below Destabilized Level

Figure A.13  effect of cement, \( p = 0.06 \); effect of rod extension, \( p < 0.001 \); interactions, \( p = 0.2 \).

Figure A.14  effect of cement, \( p = 0.01 \); effect of rod extension, \( p < 0.001 \); interactions, \( p = 0.5 \).
Appendix A

**Figure A.15** Effect of cement, $p = 0.02$; effect of rod extension, $p < 0.001$; interactions, $p = 0.02$.

**Figure A.16** Effect of cement, $p = 0.09$; effect of rod extension, $p < 0.001$; interactions, $p = 0.06$. 
A.5 3 Levels Below Destabilized Level

**Axial Rotation**

- Cemented
- Not Cemented

<table>
<thead>
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<th>ROM Normalized to Intact</th>
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<th>Flexible extension</th>
<th>Rigid extension</th>
</tr>
</thead>
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<td></td>
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<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td></td>
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<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
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<tr>
<td></td>
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<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
</tbody>
</table>

*Figure A.17* effect of cement, $p < 0.001$; effect of rod extension, $p < 0.001$; interactions, $p = 0.2$.

**Lateral Bending**

- Cemented
- Not Cemented

<table>
<thead>
<tr>
<th>ROM Normalized to Intact</th>
<th>No extension</th>
<th>Flexible extension</th>
<th>Rigid extension</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>p &gt; 0.001</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td></td>
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</tbody>
</table>

*Figure A.18* effect of cement, $p < 0.001$; effect of rod extension, $p < 0.001$; interactions, $p = 0.3$. 
Appendix A

Figure A.19  effect of cement, \( p = 0.03 \); effect of rod extension, \( p < 0.001 \); interactions, \( p = 0.2 \).

Figure A.20  effect of cement, \( p = 0.02 \); effect of rod extension, \( p = 0.001 \); interactions, \( p = 0.7 \).
Appendix B

2-way ANOVA comparison on vertebra strain at L1 and L2, in FE and LB, between cement and rod extension using the hybrid test protocol.
Appendix B

B.1 Flexion Extension

**Figure B.1**  Effect of cement, $p = 0.05$; effect of rod extension, $p = 0.01$; interactions, $p = 1.0$.

**Figure B.2**  Effect of cement, $p = 0.04$; effect of rod extension, $p < 0.001$; interactions, $p = 0.2$. 
Figure B.3  effect of cement, \( p = 0.3 \); effect of rod extension, \( p = 0.1 \); interactions, \( p = 0.3 \).

Figure B.4  effect of cement, \( p = 0.001 \); effect of rod extension, \( p = 0.001 \); interactions, \( p = 0.2 \).
Figure B.5  effect of cement, $p = 0.3$; effect of rod extension, $p < 0.001$; interactions, $p = 0.1$.

Figure B.6  effect of cement, $p = 0.1$; effect of rod extension, $p = 0.003$; interactions, $p = 0.1$. 
B.2 Lateral Bending

Figure B.7 effect of cement, $p = 0.06$; effect of rod extension, $p < 0.001$; interactions, $p = 0.2$.

Figure B.8 effect of cement, $p = 0.003$; effect of rod extension, $p < 0.001$; interactions, $p = 0.4$. 
Figure B.9  effect of cement, $p = 0.002$; effect of rod extension, $p = 0.001$; interactions, $p = 0.4$.

Figure B.10  effect of cement, $p < 0.001$; effect of rod extension, $p < 0.001$; interactions, $p = 0.3$. 