Biomechanical and finite element analyses of alternative cements for use in vertebral kyphoplasty

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A Thesis

entitled

Biomechanical and Finite Element Analyses of Alternative Cements for use in Vertebral Kyphoplasty

by

Andrew Donald Jones

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

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May 2013
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Biomechanical and Finite Element Analyses of Alternative Cements for use in Vertebral Kyphoplasty

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The University of Toledo
May 2013

A vertebral compression fracture occurs when the vertebral body of the spine collapses due to osteoporosis or trauma. Depending on the degree of osteoporosis, the forces required to induce vertebral compression fracture can vary while the forces required to induce fractures via trauma are large. However, the vast majority of vertebral compression fractures occur in elderly people or in individuals with osteoporotic disorders. These fractures, which tend to cause a collapse of the anterior wall of the vertebral body, result in the vertebra forming a wedge shape causing pain and altering the biomechanics of the spine. Vertebroplasty and kyphoplasty are two minimally invasive surgical procedures that inject cement into the fractured vertebra to relieve pain and provide stability. While highly successful, there are a few limitations that can alter the long term outcome of the patient.

Kyphoplasty/vertebroplasty procedures traditionally use PMMA to treat the fractured vertebrae due to its mechanical properties. However, with time the bone erodes around the cement due to osteoporosis and inhibited bone remodeling due to the cytotoxicity of PMMA [1, 2]. Acrylic monomers left over from the polymerization of PMMA are responsible for the foreign body reactions observed in augmented vertebrae
The exothermic reaction of PMMA is also responsible for thermal necrosis and can cause complications in cases of extravasation [4, 5]. Severe complications due to extravasation can include paraplegia from cement in the spinal canal and pulmonary embolisms due to cement migration [6, 7]. Lastly, PMMA is not bioactive and will not be reabsorbed, causing the cyotoxic cement to remain in the body permanently.

Thus, alternative cements with similar mechanical strengths are being explored. Calcium phosphate cements (CaP) have been a material of high interest due to their bioactive and thermal properties. They have a similar chemical composition as that of the mineral components of natural bone [8]. As such, they promote bone growth into the cement and with time are completely replaced by natural bone [9]. CaP cements also cure via crystallization and have been shown to have reduced curing temperatures, removing the risk for thermal necrosis [1, 10]. Despite these advantages, there are reservations of traditional CaP cements due to deficiencies in mechanical properties. As CaP cements are ceramics instead of polymers, such as PMMA, they have different fracture mechanisms and tend to be very brittle.

The purpose of this study was to evaluate two different CaP cements, one of which is polymerized, and compare their biomechanical compression properties to PMMA via cadaveric experimentation and finite element modeling. Cadaveric experiments were carried out to investigate the failure loads of individual osteoporotic thoracolumbar vertebrae. Fractures were artificially created and specimens were restored with one of the cements of interest via Osseoplasty. Restored samples were tested for static and cyclic loading failure.
A three dimensional, non-linear osteoporotic L1-S1 finite element model that had been previously validated was used to study the effects of cement on adjacent vertebrae. A compression fracture was simulated in the L3 vertebral body by using a modulus reduction criterion. Vertebral augmentation was then simulated using the material properties of CaP, polymerized CaP (pCaP), and PMMA bone cements to compare with the unaltered osteoporotic model. Mechanical properties of the bone were altered to reflect various combinations of level specific osteoporotic degeneration. All motion was conducted via load control protocols. Maximum von Mises stresses were recorded for the endplates of the augmented and adjacent vertebrae. Stress profiles were also captured for the same endplates.

Cadaveric testing results showed that PMMA significantly increased the maximum compression strength of the osteoporotic bone. CaP and pCaP restored the strength to its intact condition. Further cadaveric testing is needed with simulated physiological loads on a motion segment augmented with pCaP. It is also recommend that animal testing be done in further studies to compare bone remodeling and integration between cement types.

Finite element modeling of the three cements showed that osteoporosis was the driving force behind increased endplate stresses. There were no significant differences between the three cements modeled. All three cements changed the biomechanical loading placed on L3, the augmented vertebra, which became apparent under certain physiological loading conditions. While the stress contours of the endplates did change for L3 due to cement, this change in loading was not evident on the adjacent vertebral endplates.
The FE results suggest that cement augmentation does alter spine biomechanics but osteoporosis and spinal deformities are the main factors behind increased adjacent vertebral endplate loads. This model does not account for deformities or degenerated discs. This is important to note as a healthy disc may be able to account for the altered loading of the augmented vertebra whereas a degenerated disc may not. As vertebroplasty does not correct for deformities and kyphoplasty does not fully restore vertebral height, the deformity created by the initial VCF still influences the biomechanics of the spine. It is unclear how significant of an influence osteoporosis, spinal deformities, and cement augmentation are in increasing the rate of adjacent vertebral fractures.
I would like to dedicate this work to my family and friends - without you I would not be where I am today. Thank you.
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# Table of Contents

Abstract iii
Acknowledgements viii
Table of Contents ix
List of Tables xii
List of Figures xiii
List of Abbreviations xxi
List of Symbols xxii

1. Introduction 1
   1.1. Overview 1
   1.2. Anatomy of the Spine 1
   1.3. Osteoporosis and Vertebral Compression Fractures 4
   1.4. Vertebroplasty and Kyphoplasty 6
   1.5. Biocompatible and Bioactive Materials 7
   1.6. Purpose of Study 8

2. Literature Review 10
   2.1. Overview 10
   2.2. Osteoporosis 10
   2.3. Vertebral Compression Fractures 11
   2.4. Treatment Methods for Pain Reduction 12
2.4.1. Posterior Fixation
2.4.2. Vertebroplasty
2.4.3. Kyphoplasty

2.5. Clinical Limitations and Complications
2.5.1. Vertebroplasty and Kyphoplasty
2.5.2. Calcium Phosphate and PMMA

2.6. Biomechanics of Vertebroplasty and Kyphoplasty Augmented Vertebra

3. Materials and Methods
3.1. Introduction
3.2. Biomechanical Evaluation
3.2.1. Sample Preparation
3.2.2. Fracture Creation
3.2.3. Specimen Augmentation
3.2.4. Testing
3.3. Finite Element Analysis
3.3.1. Lumbar Finite Element Model
3.3.2. Osteoporotic Finite Element Ligamentous Lumbar Model
3.3.3. Fracture and Cement Creation in L3 of Ligamentous Lumbar Model
3.3.4. Loading Conditions
3.3.5. Analysis Criteria

4. Results
4.1. Biomechanical Testing Results
4.2. Finite Element Modeling Results

4.2.1. Osteoporotic Flexion

4.2.2. Osteoporotic Extension

4.2.3. Osteoporotic Lateral Bending

4.2.4. Osteoporotic Rotation

4.2.5. Osteoporotic Compression via Follower Load

4.2.6. Maximum von Mises Stress for Normal Bone under Flexion, Extension, Lateral Bending, and Rotation

4.2.7. Specific Osteoporotic Vertebral Levels

4.2.8. Maximum Shear Stress of Cement

5. Discussion

5.1. Biomechanical Results

5.2. Finite Element Analysis of Discussion

5.3. Limitations of Cadaveric Study

5.4. Limitations of Finite Element Analysis

5.5. Recommendations for Future Studies

References

A Biomechanical Testing Data
List of Tables

3-1 Material Properties and Quantities of Elements Found in Finite Element Model...... 32
3-2 Material Properties of Osteoporotic Vertebral Levels........................................... 33
3-3 Cement Material Properties Used in Finite Element Analysis of Kyphoplasty
    Procedure..................................................................................................................... 33
3-4 Material Properties of Ligaments Used in Finite Element Model of Lumbar Spine.. 34
4-1 Two-way ANOVA statistics comparing cement types with intact or augmented
    specimens ....................................................................................................................... 41
4-2 Sample description for augmented specimen static compression results.............. 42
A-1 Osteoporotic specimen DEXA results and height measurements while intact, after
    fracture, and after restoration pCaP............................................................................ 100
A-2 Osteoporotic specimen DEXA results and height measurements while intact, after
    fracture, and after restoration CaP............................................................................. 101
A-3 Osteoporotic specimen DEXA results and height measurements while intact, after
    fracture, and after restoration PMMA......................................................................... 102
A-4 Dynamic testing specimen height measurements using potted superior and inferior
    endplates as references. ............................................................................................ 103
List of Figures

1–1 Anatomy of the Spine with Regions of Interest Labeled. Source:
  http://www.neurospineinstitute.org/assets/images/spinal_curves_regions.jpg .......... 2

1–2 Anatomy of the invertebral disc showing annulus fibrosis and nucleus pulposus.
  Source: http://ittcs.files.wordpress.com/2010/05/img_0179.jpg................................. 3

1–3 X-ray image of coronal and sagittal section of T11 vertebrae showing the trabeculae
  array fanning out of the base of the pedicle [11]..................................................... 4

1–4 Micro-CT scans of healthy vertebral bone and osteoporotic vertebral bone how the
  difference of trabecular bone structure as a result of osteoporosis. ...................... 5

2–1 Radiograph of Vertebral Compression Fracture....................................................... 12

2–2 Diagram of collapsed vertebra (left) and the collapsed vertebra being injected with
  cement via vertebroplasty (right) [37]................................................................. 14

2–3 Anteroposterior fluoroscopic image of bipedicular kyphoplasty with the tamps
  inflated inside the fractured vertebra [45]............................................................. 15

3–1 Measurements taken on vertebral samples from cranial and lateral view ............. 24

3–2 Prepared pre-fractured sample potted in bondo showing transverse slit, intact pedicle,
  and center marked on superior end plate.............................................................. 24

3–3 Static loading set-up showing aligned and leveled sample properly secured with MTS
  actuator in place......................................................................................................... 25
3–4 Fractured sample showing results of 50% strain. ................................................................. 25

3–5 Fluoroscopic images of inflated balloon showing restoration of vertebral height (top) and cement filled augmented specimen (bottom)............................................................. 27

3–6 Dynamic testing set-up with superior and inferior potted endplates. MTS load is placed 10mm anterior from the Distance: ML line. ................................................................. 28

3–7 Image of pCaP integrated with normal bone. Image taken after sample failed during static testing and was sawed in half with a hand saw.............................. 29

3–8 L1-S1 Finite Element Model .............................................................................................. 32

3–9 Elements Selected for Fracture in L3 are Highlighted....................................................... 35

3–10 Application of Bending and Torsional Moments and Follower Load Placed on Finite Element Model ........................................................................................................ 36

4–1 Initial fracture and static loading profiles for the first pCaP augmented specimen... 39

4–2 Initial fracture and static loading profiles for the first PMMA augmented specimen.......................................................... 39

4–3 Initial fracture and static loading profiles for the first CaP augmented specimen..... 40

4–4 Average static loading failure measurements with standard deviation bars for all static testing conditions. ............................................................................................... 40

4–5 Maximum von Mises Stress of Vertebral Endplates of Osteoporotic Bone with Augmented L3 when 10Nm Flexion Moment is Applied ............................................. 43

4–6 Endplate von Mises Stresses of L2 Endplate after 10Nm Flexion Moment is Applied ......................................................................................................................... 44

4–7 Endplate von Mises Stresses of L3 Superior Endplate after 10Nm Flexion Moment is Applied ......................................................................................................................... 44
4–8 Endplate von Mises Stresses of L3 Inferior Endplate after 10Nm Flexion Moment is
Applied ............................................................................................................. 45
4–9 Endplate von Mises Stresses of L4 Endplate after 10Nm Flexion Moment is
Applied ............................................................................................................. 45
4–10 Maximum von Mises Stress of Vertebral Endplates of Osteoporotic Bone with
Augmented L3 when 10Nm Extension Moment is Applied ............................. 47
4–11 Endplate von Mises Stresses of L2 Endplate after 10Nm Extension Moment is
Applied ............................................................................................................. 47
4–12 Endplate von Mises Stresses of L3 Superior Endplate after 10Nm Extension
Moment is Applied ......................................................................................... 48
4–13 Endplate von Mises Stresses of L3 Inferior Endplate after 10Nm Extension
Moment is Applied ......................................................................................... 48
4–14 Endplate von Mises Stresses of L4 Endplate after 10Nm Extension Moment is
Applied ............................................................................................................. 49
4–15 Maximum von Mises Stress of Vertebral Endplates of Osteoporotic Bone with
Augmented L3 when 7.5Nm Lateral Bending Moment is Applied .................. 50
4–16 Endplate von Mises Stresses of L2 Endplate after 7.5Nm Lateral Bending Moment
is Applied ......................................................................................................... 51
4–17 Endplate von Mises Stresses of L3 Superior Endplate after 7.5Nm Lateral Bending
Moment is Applied ......................................................................................... 51
4–18 Endplate von Mises Stresses of L3 Inferior Endplate after 7.5Nm Lateral Bending
Moment is Applied ......................................................................................... 52
4–19 Endplate von Mises Stresses of L4 Endplate after 7.5Nm Lateral Bending Moment is Applied .......................................................... 52

4–20 Maximum von Mises Stress of Vertebral Endplates of Osteoporotic Bone with Augmented L3 when 7.5Nm Rotation Moment is Applied ....................................... 54

4–21 Endplate von Mises Stresses of L2 Endplate after 7.5Nm Rotation Moment is Applied .................................................................................................................. 54

4–22 Endplate von Mises Stresses of L3 Superior Endplate after 7.5Nm Rotation Moment is Applied ........................................................................................................... 55

4–23 Endplate von Mises Stresses of L3 Inferior Endplate after 7.5Nm Rotation Moment is Applied ........................................................................................................... 55

4–24 Endplate von Mises Stresses of L4 Endplate after 7.5Nm Rotation Moment is Applied .................................................................................................................. 56

4–25 Maximum von Mises Stress of Vertebral Endplates of Osteoporotic Bone with Augmented L3 Compared to a Non-augmented and Fractured L3 and the Original Control Model when 1175N Follower Load is Applied.............................................. 57

4–26 Endplate von Mises Stresses of L2 Endplate after 1175N Follower Load is Applied .................................................................................................................. 58

4–27 Endplate von Mises Stresses of L3 Superior Endplate after 1175N Follower Load is Applied .................................................................................................................. 58

4–28 Endplate von Mises Stresses of L3 Inferior Endplate after 1175N Follower Load is Applied .................................................................................................................. 59

4–29 Endplate von Mises Stresses of L4 Endplate after 1175N Follower Load is Applied .................................................................................................................. 59
4–30 Maximum von Mises Stress of Vertebral Endplates of Normal Bone with Augmented L3 when 10Nm Flexion Moment is Applied ........................................ 61

4–31 Maximum von Mises Stress of Vertebral Endplates of Normal Bone with Augmented L3 when 10Nm Extension Moment is Applied ......................... 61

4–32 Maximum von Mises Stress of Vertebral Endplates of Normal Bone with Augmented L3 when 7.5Nm Lateral Bending Moment is Applied .................. 62

4–33 Maximum von Mises Stress of Vertebral Endplates of Normal Bone with Augmented L3 when 7.5Nm Rotation Moment is Applied .......................... 62

4–34 Maximum von Mises Stress of L2 Vertebral Endplate in Flexion as Different Combinations of Osteoporotic Vertebral Levels are Defined ..................... 64

4–35 Maximum von Mises Stress of L2 Vertebral Endplate in Extension as Different Combinations of Osteoporotic Vertebral Levels are Defined ..................... 64

4–36 Maximum von Mises Stress of L2 Vertebral Endplate in Lateral Bending as Different Combinations of Osteoporotic Vertebral Levels are Defined ................. 65

4–37 Maximum von Mises Stress of L2 Vertebral Endplate in Rotation as Different Combinations of Osteoporotic Vertebral Levels are Defined ......................... 65

4–38 Maximum von Mises Stress of L3 Superior Vertebral Endplate in Flexion as Different Combinations of Osteoporotic Vertebral Levels are Defined ................. 66

4–39 Maximum von Mises Stress of L3 Superior Vertebral Endplate in Extension as Different Combinations of Osteoporotic Vertebral Levels are Defined ................. 66

4–40 Maximum von Mises Stress of L3 Superior Vertebral Endplate in Lateral Bending as Different Combinations of Osteoporotic Vertebral Levels are Defined .......... 67
4–41 Maximum von Mises Stress of L3 Superior Vertebral Endplate in Rotation as Different Combinations of Osteoporotic Vertebral Levels are Defined.................. 67
4–42 Maximum von Mises Stress of L3 Inferior Vertebral Endplate in Flexion as Different Combinations of Osteoporotic Vertebral Levels are Defined.................. 68
4–43 Maximum von Mises Stress of L3 Inferior Vertebral Endplate in Extension as Different Combinations of Osteoporotic Vertebral Levels are Defined.................. 68
4–44 Maximum von Mises Stress of L3 Inferior Vertebral Endplate in Lateral Bending as Different Combinations of Osteoporotic Vertebral Levels are Defined.................. 69
4–45 Maximum von Mises Stress of L3 Inferior Vertebral Endplate in Rotation as Different Combinations of Osteoporotic Vertebral Levels are Defined.................. 69
4–46 Maximum von Mises Stress of L4 Vertebral Endplate in Flexion as Different Combinations of Osteoporotic Vertebral Levels are Defined.................. 70
4–47 Maximum von Mises Stress of L4 Vertebral Endplate in Extension as Different Combinations of Osteoporotic Vertebral Levels are Defined.................. 71
4–48 Maximum von Mises Stress of L4 Vertebral Endplate in Lateral Bending as Different Combinations of Osteoporotic Vertebral Levels are Defined.................. 71
4–49 Maximum von Mises Stress of L4 Vertebral Endplate in Rotation as Different Combinations of Osteoporotic Vertebral Levels are Defined.................. 72
4–50 Maximum shear stresses of the cements under various loading conditions. ........ 73
A–1 Initial fracture and static loading profiles for the second pCaP augmented specimen ........................................................................................................ 92
A–2 Initial fracture and static loading profiles for the third pCaP augmented specimen ........................................................................................................ 93
A–3 Initial fracture and static loading profiles for the fourth pCaP augmented specimen. ................................................................. 93
A–4 Initial fracture and static loading profiles for the fifth pCaP augmented specimen. ........................................................................ 94
A–5 Initial fracture and static loading profiles for the second PMMA augmented specimen. .................................................................... 94
A–6: Initial fracture and static loading profiles for the third PMMA augmented specimen. .................................................................... 95
A–7 Initial fracture and static loading profiles for the fourth PMMA augmented specimen. .................................................................... 95
A–8: Initial fracture and static loading profiles for the fifth PMMA augmented specimen. .................................................................... 96
A–9: Initial fracture and static loading profiles for the second CaP augmented specimen. .................................................................... 96
A–10: Initial fracture and static loading profiles for the third CaP augmented specimen. ...................................................................... 97
A–11: Initial fracture and static loading profiles for the fourth CaP augmented specimen. ...................................................................... 97
A–12: Initial fracture and static loading profiles for the fifth CaP augmented specimen. ...................................................................... 98
A–13 Dynamic testing with maximum dynamic load of 25% of mean static failure load for 100K cycles at 5Hz. ................................................................. 98
A–14 Dynamic testing with maximum dynamic load of 50% of mean static failure load for 100K cycles at 5Hz. ............................................................ 99

A–15 Dynamic testing with maximum dynamic load of 75% of mean static failure load for 100K cycles at 5Hz. ............................................................ 99
List of Abbreviations

BMD .........................Bone Mineral Density
CaP .........................Calcium Phosphate
CT ............................Computer Tomography
DEXA ........................Dual-Energy X-ray Absorptiometry
FDA .........................Food and Drug Administration
FE ............................Finite Element
FEA ............................Finite Element Analysis
FSU ............................Functional Spinal Unit
NIH ............................National Institute of Health
pCaP ...........................Polymerized Calcium Phosphate
PMMA ........................Polymethyl Methacrylate
VCF ............................Vertebral Compression Fracture
WHO ............................World Health Organization
List of Symbols

Hz.......Hertz
kN......Kilonewton
m .......Meter
mm .....Milimeter
N.........Newton
Chapter 1

Introduction

1.1 Overview

This chapter will discuss the anatomy of the human spine and osteoporosis which is a non-trivial affliction that is extremely common in older age. Complications from osteoporosis include vertebral compression fractures which can significantly reduce the quality of life in individuals. It is therefore necessary to understand current surgical techniques to repair the fractured vertebra which include the injection of biocompatible cements into the bone. Despite the success of these techniques, there are limitations, mostly related to the material chosen to cement the vertebra. It is therefore our goal to evaluate the mechanical properties of two new cements, one of calcium phosphate and the other being a polymerized calcium phosphate, and compare them with industry standard PMMA in order to offer a more mechanically compatible solution.

1.2 Anatomy of the Spine

The human spine is one of the most important parts of the body. It is responsible for protecting nerves stretching from the brain to the lower limbs while providing motion and flexibility to the body. It supports the entire weight of the truck and serves as an attachment point for muscles, ligaments, and tendons. Consisting of 33 separate
vertebrae, or bones of the spine, it is divided into 4 regions of interest coined cervical, thoracic, lumbar, and sacrum (Figure 1–1). The cervical vertebrae consist of the 7 vertebrae connecting the skull to the thoracic region, which contains 12 vertebrae. The thoracic vertebrae transition into the lumbar vertebral region which contains 5 vertebrae. The last region, the sacrum, contains 9 vertebrae which are typically fused together and connect to the hips.

In between the vertebra are inter-vertebral discs. They allow motion to occur without the bones grinding against each other and act as shock absorbers. Each disc is composed of a ring of fibers known as the annulus fibrosis. These fibers contain the soft, gel like center known as the nucleus pulposus.
On the posterior portion of each vertebra, there are bony extrusions known as facet joints. They connect each vertebra to the one directly above and below it. There are two joints between each pair of vertebrae with one of the left and right side each. These allow the vertebra to rotate as well as restrict the range of motion of the spine to prevent damage to the nerves and bones.

The vertebral body is composed of trabeculae, or small strands of bone and connective tissue, that forms the porous structure of the cancellous bone. High resolution x-ray images obtained by Heggeness and Douherty [11] show that the trabeculae form a fan shaped array originating from the medial corner of the base of the pedicles as shown in Figure 1–3. This is significant to note as trabeculae density decreases as the distance
from the point of origin increases, leaving the anterior portion of the vertebral body less dense than the posterior portion.

Figure 1–3: X-ray image of coronal and sagittal section of T11 vertebrae showing the trabeculae array fanning out of the base of the pedicle [11].

1.3 Osteoporosis and Vertebral Compression Fractures

Osteoporosis is a disease which results in bone decalcification and loss of bone density. X-ray computer tomography (CT) scans of vertebral trabecular structure of healthy and osteoporotic bone are shown in Figure 1–4. As evident from the figure, the porosity of the bone increases and the strength of the trabeculae decrease. This results in an increase in risk of fracture. As the condition is painless until fracture occurs, it is not uncommon for it to develop unnoticed up to the point of fracture. Out of all bone diseases, osteoporosis is the most common.
Figure 1–4: Micro-CT scans of healthy vertebral bone (left) and osteoporotic vertebral bone (right) show the difference of trabecular bone structure as a result of osteoporosis [12].

Causes of osteoporosis include: drop in estrogen in women and testosterone in men, lack of exercise, genetic history, excessive amounts of alcohol, low body weight, and smoking. To diagnose osteoporosis prior to fracture, it is necessary to be screened on a regular basis via dual-energy x-ray absorptiometry (DEXA) which measures bone mineral density. If osteoporosis is diagnosed early, it can be treated with mineral supplements and various medications such as bisphosphonates, estrogens, raloxifene, and calcitonin. A doctor may also recommend a change in diet and exercise as a preventative for osteoporosis.

In the spine, osteoporosis can result in vertebral compression fractures (VCF). This type of fracture results when the vertebrae collapses and is compressed, predominantly in the anterior portion of the vertebrae. Usually, this produces a wedge shape between the inferior and superior endplates, resulting in immediate localized pain and the spinal deformity kyphosis. Kyphosis results in abnormal posture and shifts the center of gravity of the upper body, causing an increase in loading of the vertebrae and an
increased risk for subsequent VCFs. It also causes pain in the fractured vertebrae. Along with increased loads on vertebrae, complications resulting from kyphosis include decreased lung capacity, back pain, and neurological symptoms such as leg weakness.

1.4 Vertebroplasty and Kyphoplasty

Two treatment options for VCFs include vertebroplasty and kyphoplasty. Both are minimally invasive procedures that seek to stabilize fractured vertebrae by injecting cement into the bone to reduce motion.

Vertebroplasty is the process of injecting cement, most usually PMMA, into the collapsed vertebrae. While the mechanisms of pain relief are not immediately known, it is proposed that the reduction of motion in the fracture is a contributing factor. As PMMA hardening is an exothermic reaction, it has been suggested that the thermal reaction kills the nerve endings inside the vertebrae, also providing pain relief. Despite the success of this procedure for immediate, there are a few complications that result.

First, vertebroplasty does not restore the height of the vertebrae, leaving the spinal deformity intact. Kyphosis of the spine remains and resulting complications are still a health concern for the patient. It has been shown that adjacent level vertebral fractures are not uncommon after vertebroplasty. This is due in part to abnormal loading conditions of the kyphotic deformity and in part to the mismatch of material properties between the PMMA and fractured bone. In cases of extravasation, where the cement leaks or bursts through the fracture, thermal necrosis can cause complications to the surrounding tissue. This is especially a concern if the extravasation occurs and PMMA leaks into the spinal canal. Even if there is no extravasation, thermal necrosis can lead to high subsidence and poor bonding between PMMA and the surrounding bone. PMMA is
also cytotoxic, which helps promote bone resorption, contributing to the subsidence and cement loosening.

To reduce instances of extravasation and restore spine biomechanics, kyphoplasty was developed. This procedure using a balloon, or bone tamp, to restore vertebral height and to create a cavity for cement injection. The restoration of height reduces the kyphotic deformity. The cavity creation allows cement to be injected at a lower pressure compared to vertebroplasty, reducing the instances of extravasation. Despite these advantages, the complications that result from using PMMA still exist.

1.5 Biocompatible and Bioactive Materials

There are many complications that result from using PMMA. PMMA is not bioabsorptive so it will not break down and be absorbed by the bone. This is an issue as bone will never grow into or replace the PMMA, resulting in the eventually loosening of the cement in the vertebrae as the fixation mechanisms weaken [13, 14]. A contributing factor to implant loosening is the cytotoxicity of PMMA, which has been shown to inhibit bone remodeling and induce foreign body reactions at the site of the implant [1, 2, 4]. Along with implant loosening, PMMA has been found to increase the stiffness of the augmented vertebra as much as 12 fold [15]. It has been hypothesized that this increase in stiffness and altered biomechanics is responsible for the increased rate of adjacent level vertebral fractures observed post-operatively [14].

In cases of extravasation, where the cement leaks from the vertebral body, PMMA can cause many more issues. The polymerization process of PMMA is an exothermic reaction that can reach temperatures of 100°C which is more than high enough to cause thermal necrosis of the surrounding tissue [16]. Even without thermal necrosis,
extravasation can cause serious complications such as paraplegia and pulmonary embolisms [6, 7].

Therefore, it is desirable to replace PMMA with a substitute material that is both mechanically and chemically compatible with the osteoporotic spine. Calcium phosphate (CaP) cements are the most ideal candidate for replacing PMMA. Chemically, they are very similar to the minerals found in bone, making them biocompatible and bioabsorptive [8]. The crystallization temperature for them is also much lower, insuring that thermal necrosis does not occur in patients [1, 10]. They also have a lower modulus of elasticity compared to PMMA, reducing the increase in stiffness of augmented vertebrae suggesting a decrease in adjacent vertebral fractures [17]. As they degrade, no toxic metabolites are released. With time, the CaP will be reabsorbed completely, leaving the patient with restored, natural bone.

Despite so many benefits, there is one crippling attribute to CaP as a replacement for PMMA; its mechanical properties. CaP, unlike PMMA, is a very brittle, ceramic material. As such, it performs poorly when placed under large shear loads which can happen in an unstable vertebra before the fracture heals. Depending on the severity of the VCF and the stability of the spine, CaP may not be a suitable candidate material [18]. Even with this limitation, research is going into developing different CaP formulations that may address the mechanical limits.

1.6 Purpose of Study

To address the concern of mechanically insufficient CaP alternatives, two new CaP formulations were evaluated. The first is a novel polymerized calcium phosphate (pCaP) cement and the second is a novel traditional CaP cement. Both materials have
stiffness values that more closely match cancellous bone compared to the high stiffness PMMA. It is proposed that these two cements will be able to provide the mechanical durability needed to replace PMMA while restoring the biomechanical properties of the vertebra to their pre-fractured state.

To test this, we determined their *in vitro* mechanical compression strength through static and cyclic loading until the point of failure. The second component of the study was to predict *in vivo* changes in loading as the result of these cements using finite element models. A full ligamentous model of a L1-S1 spine segment was used with L3 being the augmented vertebra. Cements were compared as to how they altered the stress magnitude and distribution on the endplates of the augmented vertebra as well as the adjacent vertebrae which can be an indication of increased risk for adjacent vertebral fractures.
Chapter 2

Literature Review

2.1 Overview

This chapter provides a review of vertebral augmentation with the primary focus being on PMMA and CaP cements. This review will include subsections on osteoporosis, vertebral compression fractures, vertebroplasty, kyphoplasty, PMMA, CaP, and lastly how all of the above alter the biomechanics of the spine. Vertebroplasty and Kyphoplasty will focus on their respective clinical approach to treating vertebral compression fractures as well as provide a brief history into the development of each method. PMMA and CaP sections will address the biological and mechanical limitations and advantages of each. The biomechanical discussion will address the limitations of each method and what can be done to improve vertebroplasty/kyphoplasty to restore conditions to the pre-fracture state.

2.2 Osteoporosis

Osteoporosis is the most common type of bone disease in the world [19]. The disease results in loss of bone minerals and the bone becomes more porous, decreasing the overall strength of the bone. This leads to an increase in the risk of bone fracture and is one of the major contributors for vertebral compression fractures. In 1994, the World
Health Organization (WHO) clinically defined osteoporosis as “a bone mineral density (BMD) that is 2.5 standard deviations or more below the average value for young healthy women” [20]. The most valid technique to measure BMD is dual energy x-ray absorptionmetry, or DEXA [21].

Low BMD is a widespread issue in postmenopausal women where it is estimated that 25% of women above the age of 50 will develop a vertebral compression fracture (VCF) [22]. The American Academy of Orthopaedic Surgeons has stated that nearly 700,000 patients each year in the United States will suffer a VCF due to osteoporosis [23]. The cost to treat all of these patients is not trivial and is only becoming larger. In fact, the annual cost exceeds $17 billion which closely rivals the annual cost of heart disease of $19 billion [24].

2.3 Vertebral Compression Fractures

Compression fractures occur in the spine when the body of the vertebra collapses or cracks as shown in Figure 2–1. Roughly 85% of all VCFs are due to primary osteoporosis, or osteoporosis directly as the result of menopause and/or aging. The rest of VCFs are caused by secondary osteoporosis or malignancies [25]. Up to 3 out of 4 instances of vertebral fractures do not result in immediate clinical attention [26]. It is apparent from the high percentage of VCFs that are not immediately diagnosed, if at all, that the fracture does not always cause immediate pain or trauma until other complications arise with time [26]. Approximately 1 out of 3 instances of VCF will develop into chronic pain, which is sometimes dismissed by patients as arthritis or aches that come with age [25]. In instances of severe fracture, the pain can be overwhelming and reduce the ability of individuals to conduct activities of daily living. Fractures also
pose health risks and can cause life threatening complications. Along with a loss of height, VCFs and the resulting kyphosis can lead to a decrease in pulmonary capacity, malnutrition, decreased mobility and depression due to the inability to perform daily duties and chronic pain [27].

If left untreated, the risk of a second VCF within one year increases by 5-fold [28]. This is due to misalignment of the spine as the result of the deformity, known as kyphosis, from the VCF [29, 30]. This deformity becomes permanent if the fracture is not treated and the bone heals at its reduced height. As more levels become weakened and fracture, the kyphosis becomes much more pronounced. Severe kyphosis can greatly impair internal organs and limit the ability of the individual to complete daily tasks such as getting out of bed and walking [31-33].

2.4 Treatment Methods For Pain Reduction

2.4.1 Posterior Fixation

The focus of any treatment should be the elimination of pain with a secondary goal of reducing risk factors for future complications. Unfortunately, surgery is the only
option for patients who have both chronic pain and moderate to severe kyphosis. Traditional methods such as rods, screws, hooks, and implants are less than ideal for elderly patients as surgery takes time to recover and can cause damage to the surrounding tissue. Complications can also result after the surgery as screws, hooks, implants may not remain fixed in the already osteoporotic bone resulting in a loss of correction. Lastly, these methods can alter the biomechanics of the motion segment. This alteration can create future problems in the adjacent vertebrae due to increased loads, especially if the adjacent levels are osteoporotic.

2.4.2 Vertebroplasty

Galibert et al. developed the idea of injecting PMMA into vertebrae to reduce the mechanical instability due to hemangiomas in 1987 [34]. It wasn't until 1990 that Galibert and Deramond used PMMA injections to counteract the damage done by osteoporosis to vertebrae [35]. The operative procedure developed in 2000 allows for four individual vertebra to be augmented with cement via unipedicle injection or two vertebra via bipedicle injection during one operation [36]. In Heini’s specified procedure, patients were to lie prone on a radiolucent operating table. This provides for anteroposterior and lateral projection fluoroscopic guidance to the surgeon during the operation. Local anesthesia is to be given in the skin and soft tissue around the vertebra to be augmented. Penetrating the skin with a stab incision, a 2mm K-wire is embedded into the pedicle or pedicles of the vertebra to be augmented. These are later advanced to the center of the vertebral body. A biopsy needle can then be inserted into the body of the vertebra using the k-wire as guidance. The wire is removed once the needle is satisfactorily positioned. A mixture of PMMA and non-ionic contrast dye is mixed and
injected. The injection stops immediately if there are signs of extravasation in the spinal canal or through the anterior cortical shell. If there are no signs of leakage, injection stops when the vertebra is full, or more specifically, when the entire vertebral frame is filled with cement.

![Diagram of collapsed vertebra (left) and the collapsed vertebra being injected with cement via vertebroplasty (right)](image)

**Figure 2–2:** Diagram of collapsed vertebra (left) and the collapsed vertebra being injected with cement via vertebroplasty (right) [37]

While this procedure does restore the strength of the bone, it does not restore the height of the vertebra, leaving the spinal deformity intact. Despite the spinal deformity, ranges of 86% to 97% of patients have reported pain relief shortly after the procedure [15, 38]. This suggests that in most cases, the cause of pain is not from kyphosis, but rather the fractured vertebra. Originally, pain relief mechanisms from PMMA were thought to be due to added stability of the fracture and due to thermal necrosis of neural tissue due to the polymerization of PMMA [39-41]. While it is apparent that thermal necrosis is a consequence of using PMMA, it has more recently been concluded that damage to the neural tissue is not the mechanism for pain relief [42]. This evidence is further strengthened by studies which have shown that vertebroplasty performed with CaP cements instead of PMMA have shown comparable results in terms of pain relief in patients, despite CaP curing at low temperatures, avoiding issues due to thermal necrosis.
As the source of pain in VCFs has been difficult to determine, the most reasonable assumption as to the pain relief mechanics behind vertebroplasty seem to be the stability of the fracture, by preventing further collapse and reducing micro-motion of the bone.

### 2.4.3 Kyphoplasty

Kyphoplasty is a procedure which improves upon the limitations of vertebroplasty. In order to reduce the injection pressure required to insert cement into the fractured vertebrae as well as to restore physiological height of the bone, a balloon, or bone tamp, is inserted into the collapsed vertebra and inflated (Figure 2–3). Once a cavity is created and the vertebral height restored, the tamp(s) are deflated and removed. Cement is then injected in much the same as in vertebroplasty.

![Image](image.png)

**Figure 2–3:** Anteroposterio fluoroscopic image of bipedicular kyphoplasty with the tamps inflated inside the fractured vertebra [45]

It is assumed that since this is derived from vertebroplasty, that the pain relief mechanics are the same for both procedures. As a result, kyphoplasty has a high percentage of success in terms of significant pain reduction in patients [25, 45, 46]. As
well as providing pain relief, kyphoplasty has the added benefit of restoring correcting deformities, restoring the natural alignment and biomechanics of the spine [24].

2.5 Clinical Limitations and Complications

2.5.1 Vertebroplasty and Kyphoplasty

As vertebroplasty and kyphoplasty are extremely similar operations, it makes sense that both have similar complications. Complications during and after these two procedures include cement leakage, adjacent level fractures, and infection [6, 47-49]. A study of 4456 vertebroplasty and 1624 kyphoplasty procedures found that cement leakage occurs in 41% and in 9% of vertebrae treated by vertebroplasty and kyphoplasty respectively [50]. While more than 97% of cement leakage cases are asymptomatic, the complications than can result from leakage are severe [50]. Side effects from cement leakage include paraplegia and radiculopathy due to cement in the spinal canal [6, 51-53], pulmonary embolisms due to venous cement migration [7], and increased mechanical loads on adjacent vertebra from cement leakage into the disc [54].

Cement leakage in vertebroplasty is more prominent due to the required pressure needed to successfully inject and fill the vertebral body [55, 56]. The pressure required to inject the cement can often exceed the limits of the bone, requiring for the injection to be aborted, leaving the vertebrae only partially filled and impacting the outcome of the surgery. Other factors that impact injection pressure include cement viscosity. PMMA, compared to CaP, has a much lower viscosity which makes it desirable to use among surgeons [52]. Viscosity itself also contributes to cement leakage, with lower viscosity cements more likely to cause issues [57].
2.5.2 **Calcium Phosphate and PMMA**

PMMA is currently the material of choice for use in vertebroplasty and kyphoplasty. It has desirable mechanical properties that limit failure inside the bone and has been shown to increase the compressive strength and stiffness of the osteoporotic vertebrae [17, 58]. Also, compared to mineral based cements such as CaP, PMMA has a lower viscosity which reduces the pressure required to inject the cement and the pressure in the vertebra [59].

Unfortunately, there are many complications as the result of using PMMA. As previously mentioned, PMMA is exothermic during its curing process, producing temperatures higher than 40°C and have been recorded as high as 100°C [16, 60, 61]. While a 100°C is extreme for a curing temperature for PMMA, the temperatures are more than high enough to induce thermal necrosis [42].

Along with necrosis, the biocompatibility of PMMA has come into question. Multiple studies have published data concluding that the rate of bone resorption is significantly greater with PMMA [13, 62]. It has also been shown that bone growth is suppressed as well in the presence of PMMA [63]. In retrieved human vertebrae after PMMA augmentation, cystic fiber formation at the PMMA and bone interface has been found as well as foreign body reactions in the tissue [2]. Lastly, as PMMA is not bioabsorbable, it will remain in the body, releasing acrylic monomers that did not react during the polymerization process, contributing to the foreign body reactions [3]. PMMA’s cytotoxicity and thermal damage are both major factors that lead to cement loosening and subsidence of the bone with time.
As such, CaP cements have been proposed as a suitable replacement as they are of a similar chemical composition as natural mineral components of bone and teeth [8]. Due to their similar nature, CaP cements are not only biocompatible, but bioactive, promoting bone growth into the material as it is absorbed [9, 64]. Clinically, CaP has had mixed reports in literature. While there have been long and short term clinical studies citing CaP as an acceptable replacement for PMMA in both vertebroplasty and kyphoplasty [1, 43, 44, 65], there have also been clinical studies reporting full loss of augmentation benefits in as few as 3 months post-operatively [18, 66].

These discrepancies can be attributed to differences in brand of calcium phosphate cement used as mechanical properties vary widely as well as the types and locations of fractures in the spine. Blattert, Jestaedt [18] found CaP unsatisfactory after using it in Type A3 fractures which are osteoporotic burst fractures and are classified as having fractured endplates and posterior walls and while it did perform well with normal VCF, PMMA performed better for both types of fractures. Unlike PMMA, CaP cements are crystallized materials which are brittle, have lower ultimate compressive strengths, and fracture easily under shear forces which Blattert, Jestaedt [18] highlighted with CaP being unsuitable for unstable burst fractured vertebra. These mixed conclusions should illustrate that while successful in some applications, CaP cannot act as a complete replacement for PMMA. As a result, it is desirable to develop new CaP cements with improved mechanical properties to make them more suitable and reliable for use in vertebroplasty and kyphoplasty.
2.6 Biomechanics of Vertebroplasty and Kyphoplasty

Augmented Vertebra

Despite the wide success of PMMA and CaP in both vertebroplasty and kyphoplasty as a means of pain relief, there are still questions as to how both filler materials and operational methods alter the biomechanics of the spine. This question on biomechanics has arisen due to the noticeably high rates of subsequent vertebral fractures in adjacent vertebra after vertebroplasty and kyphoplasty [67-69]. Rates of secondary vertebral fractures post-operatively have been reported as low as 5% and as high as 52%. For kyphoplasty, it has been reported that rates as high as 10% of individuals have had an incidence of fracture in an untreated vertebrae within 90 days of surgery [69]. While these rates are high, it should be noted that it is not clear if the subsequent fracture is direct a result of the surgical procedure, mainly PMMA altering the biomechanics of the spine, or the patient’s already problematic osteoporosis. In all likelihood, it is a combination of factors.

To provide some insight into the altered biomechanics, many in vitro and finite element (FE) models have been developed to study this issue. The focus of cadaveric studies has been on intradiscal pressures and adjacent vertebral strains as endplate stresses have proven elusive to measure. In one study that measured the intradiscal pressure, it was found that vertebroplasty had no effect on the maximum stress found in the anterior annulus, anterior nucleus, and posterior nucleus but did see a significant increase in maximum stress of the posterior annulus [70]. In the same study, it was found that vertebroplasty also restored the stiffness of the segment to its pre-fracture conditions. Another study by Ananthakrishnan, Berven [71] revealed that vertebroplasty and
kyphoplasty do increase the intradiscal pressure compared to the pre-treatment levels, although the levels do not surpass values found in intact discs. Limitations on cadaveric studies measuring intradiscal pressure are numerous. Cadaveric discs do not have the same physiological properties of those found in vivo due to lower fluid and nutrition levels. It is also possible for the discs to become damaged and have altered mechanics due to the pressure sensors.

Other cadaveric studies have focused on how vertebral stiffness changes after augmentation. Baroud and Bohner [15] reported a 12-fold increase in vertebral stiffness when specimens were augmented with various PMMA cements in a vertebroplasty procedure. Heini, Berlemann [17] also reported an increase in vertebral stiffness with PMMA and vertebroplasty. While increased stiffness with PMMA may be true for vertebroplasty, in vitro biomechanical evaluations of kyphoplasty with PMMA and CaP have found the opposite to be true [27, 72]. Variations in these results may be attributed to the cement fill volume and brand of cement used [73, 74].

In order to better understand the results of cadaveric studies and to provide insight into endplate stress concentrations and distributions, FE modeling has proven an effective tool. Wilcox [75] produced a functional spinal unit (FSU) model of the L2-L3 lumbar segment and showed that when loaded, the intradiscal pressure decreased when the inferior vertebra was augmented with cement. Despite the decrease, there was a noticeably large increase in the endplate deformation [75]. Endplate deformation was found to be a consequence of cement augmentation as well in other studies [76, 77]. To determine which factors played a contributing role in altering endplate and cement stresses, Rohlmann, Boustani [78] conducted a probabilistic FEA study where cement
volume, cement symmetry, cement modulus, cancellous bone modulus, fracture shape, and fracture stiffness where all parameters which were studied. It was determined that fracture shape had the strongest effect on the maximum stresses [78]. While insightful, the model did not take into consideration cement contact with the endplate which has been shown to greatly increase the stiffness of the augmented vertebra [79]. In a separate study, it was found that the degree of kyphosis, and thus the shift in center of gravity, altered endplate loading much more significantly than cement [80].
Chapter 3

Materials and Methods

3.1 Introduction

This chapter describes the protocol used for the biomechanical evaluation and finite element analysis of three different cements for use in kyphoplasty. The biomechanical evaluation analyzed the restoration properties of the cements in vitro for static and cyclic loading conditions. The finite element analysis was performed to predict the performance of the cement under physiological loading conditions for a whole lumbar motion segment. The methods used for data collection and processing are also included.

3.2 Biomechanical Evaluation

3.2.1 Sample Preparation

7 spines were scanned with DEXA. 34 vertebral levels were classified as osteoporotic based on their T-scores. Spines were carefully dissected leaving the posterior elements intact and vertebrae were cleaned, making sure no damage was done to the endplates. Vertebral body height was measured as well as the mid sagittal plane distance and medial lateral distance of the superior and inferior endplates. The medial lateral distance was measured at the halfway point of the mid-sagittal plane distance of the superior and inferior endplates. A diagram for all measured dimensions is included in
Figure 3–1. The inferior endplate wrapped with plastic-wrap and then potted using bondo. The plastic-wrap prevented the bondo from infiltrating the vertebral body.

3.2.2 Fracture Creation

All specimens were fractured before being restored with PMMA, pCaP, or CaP. For fracture creation, a transverse slit was made with a hand saw with a blade width of 1.5mm in the middle of the vertebral body (Figure 3–1 and Figure 3–2). Samples were secured in a 3 axis vice on an MTS load cell. The vice was fixed to an XY table allowing the endplates to be leveled and aligned before compression (Figure 3–3). A fixture on the MTS machine applied a compressive force 10mm anterior to the geometric center of the superior endplate. The MTS was operated under displacement control and loads were applied at a rate of 5mm/min for a total displacement of 50% of intact sample height. This displacement was chosen to reflect worst clinically relevant loss of height to due VCF. Loads were recorded for each vertebral failure. These failure loads were used to calculate the maximum cyclic load for the dynamic testing.

Two-way ANOVA analysis was used to analyze all static loading results.
Figure 3–1a: Measurements taken on vertebral samples from cranial view (left) and lateral view (right). Mid sagittal plane measurements were taken along the Distance: AP line. Medial lateral measurements were taken at half the AP distance in the medial later direction. Loads were applied to the samples 10mm anterior to the Distance: ML line. Vertebral body heights were measured as shown. Transverse slits were made with a depth of half AP.

Figure 3–2: Prepared pre-fractured sample potted in bondo showing transverse slit, intact pedicle, and center marked on superior end plate.

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Figure 3–3: Static loading set-up showing aligned and leveled sample properly secured with MTS actuator in place. Displacement was controlled at a rate of 5mm/min for a total strain of 50%.

Figure 3–4: Fractured sample showing results of 50% strain.

3.2.3 Specimen Augmentation

Height restoration of the fractured samples was performed using Osseoplasty by Osseonballon. Access to the vertebrae was provided by hammering a pin, or in some cases, drilling a hole through one pedicle. A channel for the balloon was created using
the Osseoflex tool provided by Osseon. The balloon was inserted into the channel and adjusted so it would inflate in the desired location. Fluoroscopic images were taken during the procedure to ensure proper location of the balloon in the vertebrae (Figure 3–5). Once proper balloon position was obtained, the balloon was inflated with contrast solution until satisfactory height restoration was achieved. Cement was injected into the specimens until signs of extravasation were present (Figure 3–5). Samples were cured for 24 hours in a water bath at 37°C. Height measurements were made before and after restoration (Table A–1).
Figure 3–5: Fluoroscopic images of inflated balloon showing restoration of vertebral height (top) and cement filled augmented specimen (bottom).

3.2.4 Testing

Static testing was performed on 15 restored samples, 5 from each of the three cement types used for restoration. The procedure for the static testing was identical to the fracture creation protocol. Displacement and loads were recorded for all static loading tests. Two-way ANOVA analysis was used to compare all static compression data to determine any differences between groups. Tukey post-analysis test was used on a 95%
confidence to determine which cement groups significantly increased the fracture strength of the vertebral samples. Minitab 16 software was used for all analysis results.

Samples designated for dynamic testing had the superior endplate potted to provide a flat and uniform surface (Figure 3–6). Compressive loads of 25, 50, and 75% of the mean fracture load were applied at a rate of 5Hz for 100K cycles. 2 specimens were tested for each augmentation material used and each loading condition for a total of 18 samples. Displacement was recorded for the dynamic testing and potted superior and inferior endplate height was measured pre- and post-fatigue (Table A–4). As the data was collected at a frequency much different than the loading frequency, a 4th order Butterworth Filter with a cutoff frequency of 6Hz was used to analyze the displacement data.

Figure 3–6: Dynamic testing set-up with superior and inferior potted endplates. MTS load is placed 10mm anterior from the Distance: ML line.
3.3 Finite Element Analysis

3.3.1 Lumbar Finite Element Model

A finite element model of the intact ligamentous L1-S1 spine segment was used. The model had been created and validated in prior studies [81-85]. ABAQUS 6.11 was used to modify and analyze the model. A computed tomography (CT) scan of a cadaveric spine segment with 1.5mm thick transverse slices was used to obtain the geometric data for the model [86]. To insure proper geometric data, the spine chosen for model generation was free from abnormalities and defects. Material properties were chosen from literature or provided by the cement manufacturer.
The vertebrae, including their posterior elements, were modeled using C3D8 type elements. These FEA elements are hexagonal elements that have 8 nodes. For the body of the vertebra, a 0.5mm thick cortical shell encased the cancellous bone.

The intervertebral disc was modeled in two parts, one being the nucleus pulposus and the other being the annulus fibrosis. The nucleus pulposus, much like the bone, was modeled with C3D8 hexagonal elements. To simulate the hydrostatic characteristics of the nucleus pulposus, the elements were definite as having a Poisson’s ratio of $\nu = 0.4999$. A composite solid was used to model the annulus fibrosis with the matrix being 3-D solid hexagonal elements with neo-hooke hyperelastic material properties. The fibers in the matrix were modeled using REBAR elements with each layer having the fibers alternate orientation angle of $\pm 30^\circ$ to the horizontal. The fibers were defined to only transmit forces in tension with the thickness and stiffness of the fibers increasing as the distance from the nucleus increased.

Facet joints were composed of 3-D GAPUNI elements. The material properties of these elements are defined by contact behavior. The elements were spaced apart at 0.5mm from each other. As the gap between the elements closes, the force of the contact exponentially increases until it reaches the maximum defined stiffness of the posterior bone.

T3D2 elements, which are 3-D 2-node truss elements, were used to model the major ligaments of the spine. Seven ligaments were included in the model and consisted of the interspinous, supraspinous, intertranservse, capsular, posterior longitudinal, anterior longitudinal, and ligamentum flavum ligament. The material properties of these elements were defined as hypoelastic where the mechanical properties varied along with
the strain magnitude for a pre-determined strain rate. For simplification, it was assumed that all the ligaments were not under any pre-tension at rest, even though that is physiologically not the case.

Overall, the model contains 43602 elements and 61527 nodes. Material properties for the vertebrae and intervertebral discs are found in Table 3–1 and Table 3–2 for healthy and osteoporotic bone respectively. Table 3–3 and Table 3–4 contain the material properties of the ligaments used in the model and the material properties of the various cements used during kyphoplasty.
### Table 3–1: Material Properties and Quantities of Elements Found in Finite Element Model

<table>
<thead>
<tr>
<th>Element Set</th>
<th>Number of Elements</th>
<th>Element Type</th>
<th>Modulus of Elasticity (MPa)</th>
<th>Poissons Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortical Bone</td>
<td>4926</td>
<td>C3D8</td>
<td>12000</td>
<td>0.3</td>
</tr>
<tr>
<td>Cancellous Bone</td>
<td>15885</td>
<td>C3D8</td>
<td>100</td>
<td>0.2</td>
</tr>
<tr>
<td>Posterior Bone</td>
<td>4762</td>
<td>C3D8</td>
<td>3500</td>
<td>0.25</td>
</tr>
<tr>
<td>Nucleus Pulposus</td>
<td>4480</td>
<td>C3D8</td>
<td>9</td>
<td>0.4999</td>
</tr>
<tr>
<td>Annulus (Matrix)</td>
<td>5376</td>
<td>C3D8</td>
<td>0.3448 (hyperelastic)</td>
<td>0.3</td>
</tr>
<tr>
<td>Annulus (Fiber)</td>
<td>10608</td>
<td>REBAR</td>
<td>357-550</td>
<td>0.3</td>
</tr>
<tr>
<td>Cement</td>
<td>623</td>
<td>C3D8</td>
<td>See Table 3–3</td>
<td></td>
</tr>
<tr>
<td>Fracture</td>
<td>166</td>
<td>C3D8</td>
<td>15</td>
<td>0.3</td>
</tr>
</tbody>
</table>

![Figure 3–8: L1-S1 Finite Element Model](image_url)
3.3.2 **Osteoporotic Finite Element Ligamentous Lumbar Model**

The degree of osteoporosis and levels afflicted was parametrically evaluated to understand the influence of degeneration on cement stress distribution on the endplates of the augmented and adjacent vertebrae. The material properties used for the osteoporotic vertebral levels are found in Table 3–2. The conditions of osteoporosis used include full lumbar osteoporosis, osteoporosis in augmented level only, osteoporosis in augmented level and superior level, osteoporosis in augmented level and inferior level, and osteoporosis in augmented level and both superior and inferior levels. L3 was chosen to be the augmented level in order to have both of the adjacent levels as unconstrained.

Table 3–2: Material Properties of Osteoporotic Vertebral Levels

<table>
<thead>
<tr>
<th>Element Set</th>
<th>Number of Elements</th>
<th>Element Type</th>
<th>Modulus of Elasticity (MPa)</th>
<th>Poisson’s Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortical Bone</td>
<td>4926</td>
<td>C3D8</td>
<td>8040</td>
<td>0.3</td>
</tr>
<tr>
<td>Cancellous Bone</td>
<td>15885</td>
<td>C3D8</td>
<td>34</td>
<td>0.2</td>
</tr>
<tr>
<td>Posterior Bone</td>
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<td>C3D8</td>
<td>2345</td>
<td>0.25</td>
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<tr>
<td>Nucleus Pulposus</td>
<td>4480</td>
<td>C3D8</td>
<td>9</td>
<td>0.4999</td>
</tr>
<tr>
<td>Annulus (Matrix)</td>
<td>5376</td>
<td>C3D8</td>
<td>0.3448 (hyperelastic)</td>
<td>0.3</td>
</tr>
<tr>
<td>Annulus (Fiber)</td>
<td>10608</td>
<td>REBAR</td>
<td>357-550</td>
<td>0.3</td>
</tr>
<tr>
<td>Cement</td>
<td>623</td>
<td>C3D8</td>
<td>See Table 3–3</td>
<td></td>
</tr>
<tr>
<td>Fracture</td>
<td>166</td>
<td>C3D8</td>
<td>15</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Table 3–3: Cement Material Properties Used in Finite Element Analysis of Kyphoplasty Procedure

<table>
<thead>
<tr>
<th>Cement</th>
<th>Modulus of Elasticity (MPa)</th>
<th>Poisson’s Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMMA</td>
<td>2200</td>
<td>0.41</td>
</tr>
<tr>
<td>CaP</td>
<td>691</td>
<td>0.15</td>
</tr>
<tr>
<td>pCaP</td>
<td>540</td>
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</tr>
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</table>
Table 3–4: Material Properties of Ligaments Used in Finite Element Model of Lumbar Spine

<table>
<thead>
<tr>
<th>Element Set</th>
<th>Number of Elements</th>
<th>Element Type</th>
<th>Modulus of Elasticity (MPa)</th>
<th>Poisson’s Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior Longitudinal</td>
<td>240</td>
<td>T3D2</td>
<td>7.8 (&lt;12%) 20.0 (Else)</td>
<td>0.3</td>
</tr>
<tr>
<td>Posterior Longitudinal</td>
<td>144</td>
<td>T3D2</td>
<td>10.0 (&lt;11%) 20.0 (Else)</td>
<td>0.3</td>
</tr>
<tr>
<td>Ligamentum Flavum</td>
<td>21</td>
<td>T3D2</td>
<td>15.0 (&lt;6.2%) 19.5 (Else)</td>
<td>0.3</td>
</tr>
<tr>
<td>Intertransverse</td>
<td>30</td>
<td>T3D2</td>
<td>10.0 (&lt;18%) 58.7 (Else)</td>
<td>0.3</td>
</tr>
<tr>
<td>Interspinous</td>
<td>42</td>
<td>T3D2</td>
<td>10.0 (&lt;14%) 11.6 (Else)</td>
<td>0.3</td>
</tr>
<tr>
<td>Superspinous</td>
<td>12</td>
<td>T3D2</td>
<td>8.0 (&lt;20%) 15.0 (Else)</td>
<td>0.3</td>
</tr>
<tr>
<td>Capsular</td>
<td>84</td>
<td>T3D2</td>
<td>7.5 (&lt;25%) 32.9 (Else)</td>
<td>0.3</td>
</tr>
</tbody>
</table>

3.3.3 Fracture and Cement Creation in L3 of Ligamentous Lumbar Model

Elements in the anterior region of the cortical and cancellous bone were chosen for fracture creation. The elements, shown in Figure 3–9, were given weakened material properties used by Rohlmann, Boustani [78]. Fracture continued through the cortical and cancellous bone until reaching the cement. Only one type of fracture condition was used for this study.
Elements in the center of the cancellous portion of L3 were selected and reassigned material properties to that of the chosen cement. Perfect contact and bonding between the cement and cancellous bone was assumed. The cement was not in direct contact with the inferior or superior endplate of the augmented vertebrae. Cement was assumed to be at the geometric center of the vertebrae and assumed to be from a unipedicular procedure, creating only one plug.

3.3.4 Loading Conditions

The inferior S1 endplate was fixed in all six degrees of freedom as a boundary condition. A follower load of 400N was applied between each vertebral level in the model. For flexion and extension, a moment of ±10N·m was applied to a point on the
superior endplate of L1. For lateral bending and rotation a moment of ±7.5N·m was applied to the same point on the endplate of L1 that was used for flexion and extension. For a compression load case, the follower load was increased to 1175N and no moment was applied.

Figure 3–10: Application of Bending and Torsional Moments and Follower Load Placed on Finite Element Model

3.3.5 Analysis Criteria

For the finite element model analysis, the maximum von Mises stress was determined at the superior and inferior endplates of L3 as well as the adjacent endplates of L2 and L4. These endplates are of interest as they can indicate an increased risk for subsequent vertebral fracture post-augmentation. It is therefore necessary to understand what effects the stiffness of the cements studied have on the endplates of the augmented
and adjacent vertebrae. Stress contours of the endplates will also be recorded in order to see any shift in loading on the vertebra due to altered biomechanics.

The maximum shear stress was found for the cement elements for flexion, extension, lateral bending, and rotation. This was necessary as calcium phosphate cements are weaker under shear loads compared to compressive loads.
Chapter 4

Results

4.1 Biomechanical Testing Results

The load vs displacement curve for each of the 15 specimens is provided before and after augmentation. The load vs displacement curves for the first specimen for each cement are provided in Figures 4-1 through 4-3. No observable trends are present in the load vs displacement curves for the pCaP and PMMA cement groups as there is large variation between the osteoporotic specimens. For the CaP group, there appears to be a reduction in stiffness of the vertebral body. The appendix contains the rest of the load vs displacement curves not found in this section.

Osteoporotic intact samples had a mean failure load of 2699 ± 1734N for the pCaP group and that cement increased the failure load to 5042 ± 2710N. The osteoporotic intact samples for the PMMA group had a mean failure load of 2934 ± 1303N and PMMA increased the limit to 7274 ± 3878N. For CaP, the intact samples had a mean failure load of 1471 ± 143N and the cement restored the failure load to 2024 ± 463N.
Figure 4–1: Initial fracture and static loading profiles for the first pCaP augmented specimen.

Figure 4–2: Initial fracture and static loading profiles for the first PMMA augmented specimen.
Figure 4–3: Initial fracture and static loading profiles for the first CaP augmented specimen.

Figure 4–4: Average static loading failure measurements with standard deviation bars for all static testing conditions. Range of loads applied to T12-L5 vertebrae during flexion highlighted in grey [87].
Two-way ANOVA analysis using Minitab 16 software was used to compare between the three intact groups and the three augmented groups. Results from the Two-way ANOVA analysis can be found in Figure 4–1. As shown, there is no statistical difference between the three intact groups. Tukey HSD test analysis has shown that after augmentation, there is a significant difference in strength between specimens restored with CaP (M=2024, SD=464) and PMMA (M=7275, SD=3879). There is no significant difference between PMMA (M=7275, SD=3879) and pCaP (M=5043, SD=2710) and between pCaP (M=5043, SD=2710) and CaP (M=2024, SD=464). It should be noted that pCaP and CaP did not significantly increased the maximum failure load of the restored specimens compared to their original intact conditions. PMMA is the only cement which significantly increased the strength of the vertebral specimen. Sample group descriptions for augmented specimens are found in Table 4–2.

Table 4–1: Two-way ANOVA statistics comparing cement types with intact or augmented specimens

<table>
<thead>
<tr>
<th>Source</th>
<th>DF</th>
<th>SS</th>
<th>MS</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fracture</td>
<td>1</td>
<td>43654549</td>
<td>43654549</td>
<td>9.58</td>
<td>0.005</td>
</tr>
<tr>
<td>Cement</td>
<td>2</td>
<td>57648569</td>
<td>28824285</td>
<td>6.33</td>
<td>0.006</td>
</tr>
<tr>
<td>Interaction</td>
<td>2</td>
<td>17955099</td>
<td>8977550</td>
<td>1.97</td>
<td>0.161</td>
</tr>
<tr>
<td>Error</td>
<td>24</td>
<td>109327192</td>
<td>4555300</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>29</td>
<td>228585410</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Dynamic test results measuring the displacement under loading revealed that for the 25% mean failure loading condition, osteoporotic PMMA and pCaP samples performed similarly with a mean displacement of 6.86mm and 7.62mm respectively \((p=0.739)\). For the 50% loading condition, PMMA had a mean displacement of 8.60mm compared to the pCaP group that had a mean displacement of 16.46mm \((p=0.070)\). For the 75% loading condition, the PMMA group had a mean displacement of 13.81mm compared to the pCaP group mean displacement of 17.12mm. Statistical comparison between the two osteoporotic groups for the 75% loading condition could not be obtained due to premature failure of one of the PMMA augmented samples. Figure A–13 shows the displacement as a function of load cycle number for the three cements.

### 4.2 Finite Element Modeling Results

#### 4.2.1 Osteoporotic Flexion

The lumbar finite element model was defined as having osteoporotic bone for all levels (L1-S1). It was augmented with CaP, PMMA, and pCaP. As a control, the fracture was created in a full osteoporotic lumbar model and used as a sample. The data for the original healthy lumbar spine was included for comparison to show the effects of osteoporosis and cement augmentation. The lumbar spine was loaded with a 10Nm
moment to produce flexion. Maximum von Mises stresses were recorded for the endplates of interest and stress contours were generated and included in this section.

Figure 4–5: Maximum von Mises Stress of Vertebral Endplates of Osteoporotic Bone with Augmented L3 Compared to a Non-augmented and Fractured L3 and the Original Control Model when 10Nm Flexion Moment is Applied
L2 Endplate von Mises
Flexion 10Nm

Figure 4–6: Endplate von Mises Stresses of L2 Endplate after 10Nm Flexion Moment is Applied

L3 Superior Endplate von Mises
Flexion 10Nm

Figure 4–7: Endplate von Mises Stresses of L3 Superior Endplate after 10Nm Flexion Moment is Applied
L3 Inferior Endplate von Mises
Flexion 10Nm

Figure 4–8: Endplate von Mises Stresses of L3 Inferior Endplate after 10Nm Flexion Moment is Applied

L4 Endplate von Mises
Flexion 10Nm

Figure 4–9: Endplate von Mises Stresses of L4 Endplate after 10Nm Flexion Moment is Applied
As shown in the figures, there is no significant difference between the three cements under flexion loading. It should be noted that augmentation does play a role in lowering the maximum endplate stresses of the superior and inferior L3 endplates to the predicted levels of a healthy and intact lumbar. While the maximum load may be reduced, there is a slight but noticeable shift in loading on L3 once it is augmented as shown in Figure 4–7. Cement augmentation does not reduce the stress placed on L2 and L4 endplates created by the fracture and osteoporosis.

4.2.2 Osteoporotic Extension

For this analysis condition, the lumbar finite element model was defined as having osteoporotic bone for all levels (L1-S1). It was augmented with CaP, PMMA, and pCaP along with a non-augmented model of a full osteoporotic lumbar segment with a fracture in L3. Again, the data for the original healthy lumbar spine was included for comparison to show the effects of osteoporosis and cement augmentation. The lumbar spine was loaded with a 10Nm moment to produce extension. Maximum von Mises stresses were recorded for the endplates of interest and stress contours were generated and included in this section.
Figure 4–10: Maximum von Mises Stress of Vertebral Endplates of Osteoporotic Bone with Augmented L3 Compared to a Non-augmented and Fractured L3 and the Original Control Model when 10Nm Extension Moment is Applied

L2 Endplate von Mises Extension 10Nm

Figure 4–11: Endplate von Mises Stresses of L2 Endplate after 10Nm Extension Moment is Applied
L3 Superior Endplate von Mises
Extension 10Nm

Figure 4–12: Endplate von Mises Stresses of L3 Superior Endplate after 10Nm Extension Moment is Applied

L3 Inferior Endplate von Mises
Extension 10Nm

Figure 4–13: Endplate von Mises Stresses of L3 Inferior Endplate after 10Nm Extension Moment is Applied
As with flexion, there is no significant difference between the three cements under extension loading. Cement augmentation does not reduce the stress magnitude of the endplates of interest to pre-fracture and pre-osteoporotic conditions for any vertebral level under extension. Unlike the flexion loading condition, osteoporosis and a fracture caused a shift in endplate stress in L4 shown in Figure 4–14. Cement augmentation does cause a shift in endplate stress distribution for the superior and inferior endplates of L3 compared to the osteoporotic and fractured model.

4.2.3 **Osteoporotic Lateral Bending**

As with the prior sections, the lumbar finite element model was defined as having osteoporotic bone for all levels (L1-S1). It was augmented with CaP, PMMA, and pCaP
along with a non-augmented model of a full osteoporotic lumbar segment with a fracture in L3. Also, the data for the original healthy lumbar spine was included for comparison to show the effects of osteoporosis and cement augmentation. The lumbar spine was loaded with a 7.5Nm moment to produce right lateral bending. Maximum von Mises stresses were recorded for the endplates of interest and stress contours were generated and included in this section.

![Osteoporotic Endplate von Mises Stress Lateral Bending](image)

Figure 4–15: Maximum von Mises Stress of Vertebral Endplates of Osteoporotic Bone with Augmented L3 Compared to a Non-augmented and Fractured L3 and the Original Control Model when 7.5Nm Lateral Bending Moment is Applied
L2 Endplate von Mises
Lateral Bending 7.5Nm

Figure 4–16: Endplate von Mises Stresses of L2 Endplate after 7.5Nm Lateral Bending Moment is Applied

L3 Superior Endplate von Mises
Lateral Bending 7.5Nm

Figure 4–17: Endplate von Mises Stresses of L3 Superior Endplate after 7.5Nm Lateral Bending Moment is Applied
Figure 4–18: Endplate von Mises Stresses of L3 Inferior Endplate after 7.5Nm Lateral Bending Moment is Applied

Figure 4–19: Endplate von Mises Stresses of L4 Endplate after 7.5Nm Lateral Bending Moment is Applied
Once again, there is no significant difference between the three cements in terms of maximum von Mises stresses produced on the endplates. Cement augmentation does not reduce the stress magnitude of the endplates of interest to pre-fracture and pre-osteoporotic conditions for any vertebral level under extension. There is no noticeable difference in stress contours for the adjacent endplates of L2 and L4 outside of the change between the healthy, intact model and the fractured and osteoporotic model. Cement augmentation does change the stress distribution for both L3 endplates compared to pre-surgical conditions, but this change is not transferred to L2 and L4.

4.2.4 Osteoporotic Rotation

A 7.5Nm moment was applied to the osteoporotic lumbar spine model to produce right rotation. L3 was augmented with CaP, PMMA, and pCaP along with a non-augmented model of a full osteoporotic lumbar segment with a fracture. For comparison to an intact and non-augmented lumbar, the data from the original model was included. Maximum von Mises stresses were recorded for the endplates of interest and stress contours were generated and included in this section.
Figure 4–20: Maximum von Mises Stress of Vertebral Endplates of Osteoporotic Bone with Augmented L3 Compared to a Non-augmented and Fractured L3 and the Original Control Model when 7.5Nm Rotation Moment is Applied

L2 Endplate von Mises
Rotation 7.5Nm

Figure 4–21: Endplate von Mises Stresses of L2 Endplate after 7.5Nm Rotation Moment is Applied
L3 Superior Endplate von Mises  
Rotation 7.5Nm  

Figure 4–22: Endplate von Mises Stresses of L3 Superior Endplate after 7.5Nm Rotation Moment is Applied  

L3 Inferior Endplate von Mises  
Rotation 7.5Nm  

Figure 4–23: Endplate von Mises Stresses of L3 Inferior Endplate after 7.5Nm Rotation Moment is Applied
Figure 4–24: Endplate von Mises Stresses of L4 Endplate after 7.5Nm Rotation Moment is Applied

No obvious differences between the endplate stresses or the stress contours of the augmented lumbar models present themselves as a result of rotation. The endplates of the augmented L3 vertebra do have different loading distributions than the osteoporotic and fractured vertebra (Figure 4–22 and Figure 4–23). These differences do not present themselves on the L2 and L4 endplates (Figure 4–21 and Figure 4–24). It appears that osteoporosis and the fracture are responsible for the increase in maximum stress of the vertebral endplates compared to the control model.

4.2.5 Osteoporotic Compression via Follower Load

A 1175N follower load was applied to compress the lumbar spinal segment. The bone was given osteoporotic material properties and L3 had a simulated fracture. CaP, PMMA, and pCaP were used for cement augmentation. One model was analyzed
without any cement augmentation as a control. The original model was analyzed as well to show the effects of osteoporosis and fracture on the endplate stresses. Maximum von Mises stresses were recorded for the endplates of interest and stress contours were generated and included in this section.

Figure 4–25: Maximum von Mises Stress of Vertebral Endplates of Osteoporotic Bone with Augmented L3 Compared to a Non-augmented and Fractured L3 and the Original Control Model when 1175N Follower Load is Applied
L2 Endplate von Mises
Follower Load 1175N

Figure 4–26: Endplate von Mises Stresses of L2 Endplate after 1175N Follower Load is Applied

L3 Superior Endplate von Mises
Follower Load 1175N

Figure 4–27: Endplate von Mises Stresses of L3 Superior Endplate after 1175N Follower Load is Applied
L3 Inferior Endplate von Mises
Follower Load 1175N

Figure 4–28: Endplate von Mises Stresses of L3 Inferior Endplate after 1175N Follower Load is Applied

L4 Endplate von Mises
Follower Load 1175N

Figure 4–29: Endplate von Mises Stresses of L4 Endplate after 1175N Follower Load is Applied
No obvious differences between the endplate stresses or the stress contours of the augmented lumbar models present themselves as a result of rotation. The endplates of the augmented L3 vertebra do have different loading distributions than the osteoporotic and fractured vertebra (Figure 4–27 and Figure 4–28). These differences do not present themselves on the L2 and L4 endplates. Osteoporosis is responsible for the increase in maximum stress of the endplates as well as the load shift shown on the superior and inferior L3 endplates.

4.2.6 Maximum von Mises Stress for Normal Bone under Flexion, Extension, Lateral Bending, and Rotation

To illustrate the effects of cement on the lumbar spine without osteoporosis, the lumbar spine model was defined with the entire model having normal bone material properties. A fracture was simulated in L3 and cement replaced some of the cancellous bone inside the vertebra. The original model without the fracture and cement augmentation was used as a control for comparison. Maximum von Mises stress for the inferior L2, inferior and superior L3, and superior L4 endplates.
Figure 4–30: Maximum von Mises Stress of Vertebral Endplates of Normal Bone with Augmented L3 Compared to a Non-augmented and Fractured L3 and the Original Control Model when 10Nm Flexion Moment is Applied

Figure 4–31: Maximum von Mises Stress of Vertebral Endplates of Normal Bone with Augmented L3 Compared to a Non-augmented and Fractured L3 and the Original Control Model when 10Nm Extension Moment is Applied
There are no significant differences of the maximum stresses observed in the endplates of L2 and L4 between the cement augmented models and the original intact
lumbar model. When placed in flexion, the cement augmented models reduced the maximum stress of both L3 endplates (Figure 4–30). This decrease is also present in the L3 superior endplate when rotation occurs (Figure 4–33). In extension, there is a slight increase in the superior L3 endplate maximum von Mises stress as well as the inferior endplate of L3 for lateral bending (Figure 4–31 and Figure 4–32). This shows that cement augmentation does play a role in altering lumbar biomechanics as the loading of L3 has changed.

4.2.7 Specific Osteoporotic Vertebreal Levels

To determine the effect of osteoporosis on other adjacent vertebra, the lumbar model was modified where only specific vertebral levels were defined as osteoporotic and the rest of the levels were given normal bone mechanical properties. This sought to address whether a weakened and augmented vertebra had any effect on an adjacent healthy vertebra. It also took into consideration the possibility of what multiple osteoporotic vertebrae had on a healthy vertebra. These different combinations of healthy and osteoporotic vertebrae were placed under flexion, extension, lateral bending, and rotational moments and maximum von Mises stresses were recorded for the regions of interest. For comparison, a bar was placed for the maximum von Mises stress found in the original model for that endplate and loading condition.
Figure 4–34: Maximum von Mises Stress of L2 Vertebral Endplate in Flexion as Different Combinations of Osteoporotic Vertebral Levels are Defined

Figure 4–35: Maximum von Mises Stress of L2 Vertebral Endplate in Extension as Different Combinations of Osteoporotic Vertebral Levels are Defined
The maximum endplate von Mises stress of the inferior L2 endplate when L3 is augmented only increases from the original intact state when L2 itself is given material properties matching that of osteoporosis. Defining L3 or L3 and L4 as having
osteoporosis does not result in an increase of stress on the L2 inferior endplate. These observations are valid for all four loading conditions applied.

Figure 4–38: Maximum von Mises Stress of L3 Superior Vertebral Endplate in Flexion as Different Combinations of Osteoporotic Vertebral Levels are Defined

Figure 4–39: Maximum von Mises Stress of L3 Superior Vertebral Endplate in Extension as Different Combinations of Osteoporotic Vertebral Levels are Defined
Figure 4-40: Maximum von Mises Stress of L3 Superior Vertebral Endplate in Lateral Bending as Different Combinations of Osteoporotic Vertebral Levels are Defined

Figure 4-41: Maximum von Mises Stress of L3 Superior Vertebral Endplate in Rotation as Different Combinations of Osteoporotic Vertebral Levels are Defined
Figure 4–42: Maximum von Mises Stress of L3 Inferior Vertebral Endplate in Flexion as Different Combinations of Osteoporotic Vertebral Levels are Defined

Figure 4–43: Maximum von Mises Stress of L3 Inferior Vertebral Endplate in Extension as Different Combinations of Osteoporotic Vertebral Levels are Defined
As L3 is the augmented vertebra, there are fluctuations of the maximum endplate stresses as a result of the cement. For flexion and osteoporotic L3 bone, the cement manages to restore the maximum stress values to the healthy, intact condition (Figure 4–
38 and Figure 4–42). With healthy bone and this loading condition, cement augmentation lowers the maximum stress evaluated in the endplate. Having L2 or L4 as osteoporotic does little to change the observations made of the L3 endplate stress for flexion. Whether or not L3 is osteoporotic, which it should be in a clinical case as there is no need to augment a healthy vertebra, does play a role in changing the maximum endplate stress observed for both the inferior and superior endplate. Whether or not L2 and L4 are osteoporotic or healthy seems to have negligible effect on endplate stresses for all loading conditions.

Figure 4–46: Maximum von Mises Stress of L4 Vertebral Endplate in Flexion as Different Combinations of Osteoporotic Vertebral Levels are Defined
Figure 4–47: Maximum von Mises Stress of L4 Vertebral Endplate in Extension as Different Combinations of Osteoporotic Vertebral Levels are Defined

Figure 4–48: Maximum von Mises Stress of L4 Vertebral Endplate in Lateral Bending as Different Combinations of Osteoporotic Vertebral Levels are Defined
4.2.8 Maximum Shear Stress of Cement

The maximum shear stress of the cement was recorded. Figure 4–50 contains the maximum shear stresses of pCaP, CaP, and PMMA under flexion, extension, lateral bending, and rotation. As presented in the figure, pCaP was found to have the lowest maximum shear stress for all loading conditions with CaP having very similar, but slightly larger shear stress values. PMMA was found to have a larger shear stress applied to the cement body. This is interesting to note as from all of the previous results, there has been no difference between the three cements in terms of their effect on the endplates of the augmented and adjacent vertebral bodies.
Figure 4–50: Maximum shear stresses of the cements under various loading conditions.
Chapter 5

Discussion

5.1 Biomechanical Results

Two-way ANOVA analysis of the three osteoporotic intact specimen groups revealed no statistical difference, indicating that the osteoporotic vertebral fracture strength was comparable between donors.

The two-way ANOVA analysis with Tukey’s multiple comparison revealed that PMMA statistically improved the mechanical compressive strength of the osteoporotic vertebral specimens. CaP and pCaP were able to restore the vertebral samples to pre-fracture condition with no statistical improvement. The results for PMMA and CaP match the trends presented in a study conducted by Lim, Brebach [52] despite the use of a different CaP formulation. Tukey’s multiple comparison post analysis showed that there was no statistical difference between the vertebral strength of PMMA and pCaP augmented vertebrae and between pCaP and CaP augmented vertebrae. PMMA statistically had a greater failure load than CaP augmented specimens.

Dynamic testing showed that there was no significant difference between osteoporotic specimens augmented with either PMMA or pCaP after 100K loading cycles.
up to 50% of intact failure load. Statistical significant could not be determined for the 75% of intact failure load case.

It should be noted that for the 50% and 75% pCaP and 75% PMMA test groups, displacements as large as 7 mm occurred within the first 200 cycles before data collection began. It is believed that this is due to the already weakened tissue and bone failing around the cement. One specimen, shown in Figure 3–7, was sawed in half after a 50% displacement load was placed on it revealing no signs of failure in the cement body.

Quasi-static strength and cyclic loading data suggests that pCaP could be a replacement for PMMA for use in kyphoplasty. Further testing should be done for pCaP to evaluate fatigue under physiological loading conditions.

5.2 Finite Element Analysis Discussion

Adjacent vertebral fractures have been thought to be the result of abnormal loading conditions as the result of vertebral augmentation [48, 67, 88]. Many studies have shown that when high modulus cement is used in the vertebral body, such as PMMA, that there is a significant increase in vertebral stiffness [15, 17]. Along with increased stiffness of the vertebral body, there have been reported increases of intradiscal pressure as the result of vertebral augmentation [71].

Along with the study of the single vertebra level mechanical testing, a finite element study of the full lumbar spine was used to further explore the mechanics of CaP and pCaP as replacement materials for PMMA in vertebroplasty and kyphoplasty. The results of the finite analysis show that the major contributor to increased endplate stresses is not cement augmentation but bone degradation. Along with this, there is no significant
difference in the results between the three cements themselves, suggesting that all three are equally valid for use in kyphoplasty.

It should be noted that the lack of an increase in endplate stress due to cement does not mean that cement augmentation does not alter the biomechanics of the lumbar spine. A good example of this is found in Figure 4–27 where the stress concentration shifts from the far posterior edge to a more central and slightly posterior point. While the altered biomechanics sometimes present themselves when analyzing the endplates of the augmented vertebra itself, there were no instances where the stress contours of adjacent vertebral endplates significantly changed as a result of cement augmentation. Osteoporosis and a fracture were responsible for all changes in loading on the adjacent vertebral endplates from their healthy, intact conditions.

While this result is counter intuitive to what has been found clinically, the results do confirm with those presented by Rohlmann, Boustani [78]. In that study, a full lumbar motion segment was used and L3 was the chosen augmented level. Much like the results presented here, it was found that the material properties and shape chosen for the fracture and the properties chosen for the bone were the significant contributors to changes in endplate stresses. Baroud, Nemes [77], who used bone properties similar to the normal intact bone models used in this study, found that the augmented vertebra resulted in a 93% reduction in the endplate bulge, resulting in an 11% increase in stiffness for the entire motion segment. Despite this high deformation of the endplate of the augmented vertebra, Baroud, Nemes [77] noted that the stresses and strains of the adjacent vertebra did not substantially change from the pre-augmented model.
While this study did not look at endplate strain, others have shown large strains in adjacent vertebral endplates. Two such models include those presented by Polikeit, Nolte [76] and Wilcox [75]. Differences between the model used for this study and the model used by Polikeit and Wilcox may explain some of the results. For the model used by Polikeit et al. (2003), there are two major differences that may have affected the results. The first is that the modulus of elasticity chosen for the endplate elements were 670 MPa, where as the current study assumed that the osteoporotic endplates had a modulus of 8040 MPa. The second major difference is that Polikeit et al. (2003) assumed that all of the cancellous bone was replaced by cement which is not clinically realistic. The combination of those two factors may have attributed to the adjacent level increase in stress witnessed in Polikeit’s study.

Wilcox [75] used a different method to conduct his analysis. The author used a damaged based approach where an osteoporotic but intact L2-L3 motion segment was compressed and elements that were plastically deformed beyond a certain criterion were replaced with weaker material properties or cement, depending on the severity of deformation. The model was compressed a second time after augmentation. Like Baroud, Nemes [77], Wilcox (2006) showed that augmentation increased stiffness, shifted vertebral loading, and caused deformation of the vertebral endplate. Wilcox (2006) did show an increase in strain of the adjacent vertebral endplate. This increase in strain may be attributable to the damage done to the adjacent vertebra during the initial loading which created the failure of the augmented vertebra which is not addressed in the current model. Wilcox (2006) also used significantly lower modulus of elasticity values
for both cortical and cancellous bone, suggesting that the influence of cement stiffness may only be applicable after a certain degree of osteoporosis.

5.3 Limitations of Cadaveric Study

There are a few limitations of the cadaveric study that should be mentioned. The first limitation is the method used to create the initial fracture in the specimens. While this method did create a compressive fracture, it unfortunately fractured the superior endplate in every specimen as well. It is unclear how cement would have affected the stiffness and strength of the vertebral body had the endplate remained in tact. As the superior endplate was fractured, the vertebral body did not compress into the wedge shape found in vivo, rather it produced a flat horizontal surface (Figure 3–4).

Another limitation was the sawing of the anterior wall. While it was necessary to promote wedging and to simulate the collapse of the anterior wall that occurs in an in vivo VCF, it removed the tissue outside the fracture. This is significant because as cement was injected into the vertebral body, there was no tissue to prevent extravasation. This may have resulted in more cement in the anterior region of the vertebral body than what would be found in vivo.

5.4 Limitations of Finite Element Analysis

The first limitation of the FE lumbar model used in this study did not account for kyphosis. Kyphoplasty can restore as much as 90% of the height of the vertebral body, but the deformity still remains. This deformity has been shown to shift the center of gravity for the lumbar and cause an increase in endplate stress [80]. While this increased loading may have resulted in a significant differentiation between the cement augmented vertebral models from the untreated osteoporotic fracture model, it is unlikely that the
increased loading would have resulted in different endplate stresses between cement types.

The second limitation of the model was the material properties chosen for osteoporosis. While the material properties for osteoporosis have been published previously, these values will vary among patients [76]. The severity of osteoporosis may also result in cement having a more pronounced impact on the augmented and adjacent vertebra as shown by Wilcox [75]. This is important to note as the results presented have shown that osteoporosis is a major contributor to increased endplate stresses and shifts in load distribution in lumbar endplates. Although the material properties for the bone were changed for osteoporosis, the material properties for the intervertebral disc did not change. This is opposite of what has been witness in vivo as discs do degenerate. A healthy disc may be enough to shield the adjacent vertebra from the changes in loading of an augmented vertebra.

5.5 Recommendations for Future Studies

For future studies, it is recommended that the biomechanical analysis of a cadaveric lumbar motion segment be conducted. While the finite element model was insightful in how the strength of each of the three cements tested will perform in a lumbar spine, there are assumptions made that may cause the cements to perform differently in vitro. Some of these assumptions include perfect bonding between cement and bone as well as lack of failure modeling of the cement. A cadaveric study will address issues that were assumed not to exist in the finite element model will help identify any physiological loading conditions, static or otherwise, that may cause failure of the cement.
The other option, instead of a cadaveric motion segment, would be to test the cements in osteoporotic animal models. One of the main attractions to CaP cements is their osteoconductivity. It is therefore recommended that a comparison study be done with pCaP and PMMA to determine the rate of bone resorption of the cement in an osteoporotic \textit{in vivo} model. The animal test can also highlight any loading weaknesses of pCaP if it is susceptible to unusual shear loading.

For future finite element modeling, better vertebral fracture and cement augmentation modeling needs to be investigated. In this study, cement was perfectly bonded to bone which is not realistic. It is also not a uniform blob in the center of the vertebra, rather the cement snakes out from the central cavity into voids in the cancellous bone. Fracture patterns have been shown to have significant influence in altering spine biomechanics of the lumbar region and this needs to be addressed in future models [78]. Clinical issues such as subsidence and cement loosening where also not investigated with this model which may play a role in the biomechanics of the augmented vertebra.
References


19. *Osteoporosis - overview*. 2012 November 15, 2012; Available from: 


Appendix A Biomechanical Testing Data

Figure A–1: Initial fracture and static loading profiles for the second pCaP augmented specimen.
Figure A–2: Initial fracture and static loading profiles for the third pCaP augmented specimen.

Figure A–3: Initial fracture and static loading profiles for the fourth pCaP augmented specimen.
Figure A–4: Initial fracture and static loading profiles for the fifth pCaP augmented specimen.

Figure A–5: Initial fracture and static loading profiles for the second PMMA augmented specimen.
Figure A–6: Initial fracture and static loading profiles for the third PMMA augmented specimen.

Figure A–7: Initial fracture and static loading profiles for the fourth PMMA augmented specimen.
Figure A–8: Initial fracture and static loading profiles for the fifth PMMA augmented specimen.

Figure A–9: Initial fracture and static loading profiles for the second CaP augmented specimen.
Figure A–10: Initial fracture and static loading profiles for the third CaP augmented specimen.

Figure A–11: Initial fracture and static loading profiles for the fourth CaP augmented specimen.
Figure A–12: Initial fracture and static loading profiles for the fifth CaP augmented specimen.

Figure A–13: Dynamic testing with maximum dynamic load of 25% of mean static failure load for 100K cycles at 5Hz.
Figure A–14: Dynamic testing with maximum dynamic load of 50% of mean static failure load for 100K cycles at 5Hz.

Figure A–15: Dynamic testing with maximum dynamic load of 75% of mean static failure load for 100K cycles at 5Hz.
Table A–1: Osteoporotic specimen DEXA results and height measurements while intact, after fracture, and after restoration pCaP

<table>
<thead>
<tr>
<th>Specimen</th>
<th>T-Scores</th>
<th>Level</th>
<th>Height (mm)</th>
<th>Height w/ Bondo (mm)</th>
<th>Fracture Height w/ Bondo (mm)</th>
<th>Height Augmented w/ Bondo (mm)</th>
<th>Percent Restoration</th>
</tr>
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<tbody>
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<td>-4.3</td>
<td>T10</td>
<td>28.50</td>
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<td>21.38</td>
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<td></td>
<td></td>
<td>T11</td>
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<td>33.40</td>
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<td>32.16</td>
<td>22.78</td>
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<td></td>
<td>L1</td>
<td>28.48</td>
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<td>26.80</td>
<td>27.33</td>
<td>10.8%</td>
</tr>
<tr>
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<td></td>
<td>L2</td>
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<td>35.81</td>
<td>26.19</td>
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<td>T11</td>
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<td></td>
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<td>Std. Dev.</td>
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Table A-2: Osteoporotic specimen DEXA results and height measurements while intact, after fracture, and after restoration CaP

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<th>Height w/ Bondo (mm)</th>
<th>Fracture Height w/ Bondo (mm)</th>
<th>Height Augmented w/ Bondo (mm)</th>
<th>Percent Restoration</th>
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<td>Height w/ Bondo (mm)</td>
<td>Fracture Height w/ Bondo (mm)</td>
<td>Height Augmented w/ Bondo (mm)</td>
<td>Percent Restoration</td>
</tr>
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<td>25.90</td>
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Average 84.6%
Std. Dev. 16.0%
Table A–4: Dynamic testing specimen height measurements using potted superior and inferior endplates as references.

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<th>Specimen</th>
<th>Level</th>
<th>Pre-Fatigue Height (mm)</th>
<th>Post-Fatigue Height (mm)</th>
<th>Displacement (mm)</th>
<th>Avg.</th>
<th>Std. Dev.</th>
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<td>37.51</td>
<td>32.13</td>
<td>5.38</td>
<td>4.06</td>
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<td>44.10</td>
<td>41.37</td>
<td>2.73</td>
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</tr>
<tr>
<td></td>
<td>50%</td>
<td>55903 T10</td>
<td>38.72</td>
<td>26.90</td>
<td>11.82</td>
<td>12.21</td>
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<td>27.15</td>
<td>12.59</td>
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<tr>
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<td>75%</td>
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<td>38.34</td>
<td>25.34</td>
<td>13.00</td>
<td>12.24</td>
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<td>38.80</td>
<td>27.32</td>
<td>11.48</td>
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<td>37.28</td>
<td>30.96</td>
<td>6.32</td>
<td>3.82</td>
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<td>37.18</td>
<td>35.87</td>
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<tr>
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<td>50%</td>
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<td>30.31</td>
<td>5.60</td>
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<td>5.31</td>
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<td>75%</td>
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<td>30.41</td>
<td>6.37</td>
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Note: Heights were measured with potted inferior and superior endplates.