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Technical Review

Biomechanical evaluation of kyphoplasty with calcium phosphate cement in a 2-functional spinal unit vertebral compression fracture model

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Abstract

BACKGROUND CONTEXT: Kyphoplasty is used to treat vertebral compression fractures (VCFs) by inflating a balloon within the vertebral body (VB) to create a void, thereby reducing the fracture, and then depositing polymethylmethacrylate (PMMA) into that void to augment the VB. Calcium phosphate (CaP) may be preferable to PMMA because it is resorbable and nontoxic, although there are concerns about its compressive strength during the setting process.

PURPOSE: To evaluate the ability of a particular self-setting CaP cement to restore the structural integrity of a VCF in a 2-functional spinal unit (2FSU) cadaver model under physiologically relevant loading.

STUDY DESIGN/SETTING: Repeated-measures compressive testing on a cadaver thoracolumbar 2FSU VCF model.

METHODS: Ten 2FSU thoracolumbar specimens were tested to evaluate structural integrity under compressive loading during initial anterior VCF creation (in the central VB), after fracture, and after kyphoplasty treatment. Bipedicular kyphoplasty treatment was performed in a 37°C chamber to reduce the fracture and create a void, which was filled with CaP (n=5) or PMMA (n=5) and allowed to cure for at least 15 minutes. Using fluoroscopic imaging, the sagittal area of the VB (SAVB), the minimum central VB height (MCVBH), and the wedge angle were measured on the central VB for each condition at a 1,000-N compressive load. A repeated-measures linear model was used to determine if the differences in these parameters among the various experimental conditions were statistically significant ($p < .05$).

RESULTS: Compared with the fractured condition, there was a significant improvement in the SAVB, MCVBH, and wedge angle under a physiologically relevant 1,000-N compressive load applied after kyphoplasty. There was no statistically significant difference between treatment with CaP or PMMA.

CONCLUSIONS: The structural properties of CaP-augmented VBs are similar to those of PMMA-augmented VBs. Our study indicated that, after at least 15 minutes of setting, a fractured 2FSU specimen treated with kyphoplasty with PMMA or CaP could withstand physiologically relevant loading.

Keywords: Biomechanics; Kyphoplasty; Vertebral augmentation; Calcium phosphate; PMMA; Vertebral compression fractures; 2FSU

FDA device/drug status: approved for this indication (KyphX Inflatable Bone Tamp, KyphX HV-R Bone Cement); investigation/not approved (KyphOS FS Calcium Phosphate Bone Substitute).

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Introduction

Balloon kyphoplasty (hereinafter termed kyphoplasty) is a treatment for vertebral compression fractures (VCFs) designed to reduce the fracture and augment the vertebral body (VB) with bone cement. The biomechanical results [1–7] and clinical outcomes [8–15] of VB augmentation with polymethylmethacrylate (PMMA) are good. The benefits of PMMA include good biocompatibility, bioinertness, ease of handling, good mechanical strength, low cost, and familiarity to spine surgeons and interventional radiologists [16]. However, PMMA does not allow for direct apposition of new bone, lacks the potential to remodel and/or integrate into adjacent bone, and usually is encapsulated by a thin fibrous layer after implantation. Other possible drawbacks of PMMA are the known high polymerization temperature and the potential for monomer toxicity [16].

To help compensate for some of the actual or perceived drawbacks of PMMA, several other filler materials, such as composite materials (acrylic cements in combination with ceramics) and ceramic bone cements (calcium phosphate [CaP] and calcium sulfate), are being used clinically in patients undergoing vertebral augmentation procedures, but mostly outside the United States [16–18]. CaP has been proposed as an alternative augmentation material because it is nontoxic, has a low exotherm, and has the potential to resorb gradually and be replaced by new host bone via creeping substitution [19–23]. Several animal studies have shown that CaP cements are highly osteoconductive and undergo gradual remodeling [24–28]. In addition, CaP exhibits a much lower exotherm than does PMMA [29] and does not cause tissue necrosis and/or neural injury secondary to high curing temperatures. However, the biomechanical properties of CaP in a load-bearing situation are of concern [30] because, compared with PMMA, it achieves a different ultimate compressive strength at a different rate [31] and via a different mechanism. Other possible shortcomings of CaP include its lower viscosity, higher cost, and its handling and setting characteristics, which differ from those of the more familiar PMMA [16].

One of the critical factors in any kyphoplasty procedure for VCFs is the immediate restoration of structural integrity to allow for the safe transfer of the patient from the procedure table within a reasonable time period without disrupting the mechanical integrity of the treated VB. With PMMA as a positive control, we evaluated the ability of a self-setting CaP cement to restore the structural integrity of a VCF in a 2-functional spinal unit (2FSU) cadaver model under physiologically relevant loading. Our hypothesis was that augmentation via kyphoplasty with CaP would provide similar structural integrity to that of kyphoplasty with PMMA when evaluated at least 15 minutes after implantation.

Materials and methods

Specimens

Eight cadaver spines (two men, six women; age at time of death, 34–92 years; mean age±SD, 71±17 years) from established donor foundations were screened fluoroscopically (GE, OEC 6600 Mini C-Arm Fluoroscope; Salt Lake City, UT) for preexisting fractures or obvious deformities, and evaluated with a dual-energy X-ray absorptiometry scanner (Delphi C; Hologic, Bedford, MA) to verify they were osteopenic (T-score: less than −1.00 and greater than −2.50) [32]. Ten thoracolumbar 2FSU specimens (levels of interest: T6–T8, T9–T11, T12–L2, and L3–L5) were harvested and randomized into two treatment groups: CaP (n=5) and PMMA (n=5). The superior and inferior vertebrae of each 2FSU specimen were augmented with PMMA bone cement (Simplex; Stryker, Mahwah, NJ) under fluoroscopic guidance and anchored in aluminum potting dishes filled with dental-grade PMMA (Accurate Set, Inc., Newark, NJ); this was done to ensure that the central VB would be the level to fracture. Small stainless-steel ball bearings (1.6-mm diameter) were placed on the anterior surface of the central VB end plates for fluoroscopic visualization. A 10-mm radiopaque bar was placed adjacent to the central VB for image calibration. Radiopaque rods were inserted into the potting cement near the inferior VB to facilitate fluoroscope alignment. Specimens were stored frozen at −40°C until testing, whereupon each was thawed at −4°C for 12 hours and then in open air at room temperature for 2 hours; they then were immersed in a 37°C water bath for 1.5 hours to reach body temperature.

Mechanical testing

A servohydraulic test system (MTS Test Star IIm; MTS Corp., Eden Prairie, MN) was used, incorporating an environmental chamber capable of maintaining 37°C and high humidity, a load frame equipped with a 15-kN load cell, and fixtures designed to facilitate creation of an anterior wedge fracture in the central VB of the 2FSU specimen (Fig. 1). The loading regimen was based on previously published studies [17,33–36]. Each specimen was compression-loaded in three experimental conditions: intact, fractured, and treated. Each intact specimen was preloaded with 200 N, preconditioned from 200 to 500 N at 10 N/s for 10 cycles, and compressed at 3.0 mm/min until an anterior VCF was created (25% anterior height reduction) in the central VB. Each fractured specimen then was reset in the test setup, subjected to the same preloading and preconditioning, and compressed until the lesser of 2,000 N or 80% of the intact yield load was reached. After kyphoplasty treatment of the fractured VB with CaP or PMMA (see Treatment), each treated specimen was subjected to the same preloading and preconditioning, and compressed at