**VERTEBROPLASTY USING INJECTABLE CALCIUM PHOSPHATE CEMENT COMPARED TO POLYMETHYL METHACRYLATE IN A UNIQUE CANINE VERTEBRAL BODY LARGE DEFECT MODEL**

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**Introduction:** Vertebroplasty was developed to mechanically reinforce and restore height of weakened or fractured vertebral bodies. Clinically, polymethylmethacrylate bone cement (PMMA) has been used but carries risks of thermal injury to the spinal cord and may allow continued collapse. Use of calcium phosphate (CaP) cement offers the potential for resorption of the cement over time and replacement with new bone as a biological method to restore vertebral body mass and avoid potential thermal cord injury. A previous study from our laboratory in human cadaveric spine specimens showed that CaP cement was effective at increasing the compressive strength of vertebral bodies [1]. In the present study, the mechanical vertebral strength and histological assessment of the bone response to these two materials are compared using a canine vertebral body large defect model.

**Methods and Materials:** Two level vertebroplasties were performed at L1 and L3 in 20 skeletally mature large hounds weighing 30 to 41 kg and studied for 1 mo. (N=10) and 6 mos. (N=10) under an IACUC protocol. In each dog, one vertebral defect was injected with the test material, CaP cement (BoneSource), and the other defect with PMMA containing 30% BaSO$_4$ as a control with material location randomized. Both materials were supplied sterile by the manufacturer, Stryker Howmedica Osteonics, Rutherford, NJ. The canine model vertebroplasty was performed through a dorsal spinal approach with the defect created through the lateral vertebral body wall extending into and across the width of the central body. Defects of reproducible size were created using custom instrumentation. Accessible cancellous bone was excavated without perforation of the end plates or spinal canal resulting in a central rectangular vertebral defect nominally 18x5x22 mm, representing loss of approximately 3/5 the length, 1/2 the height, and ¾ of the width of the body. The materials were injected using a syringe until the defects were filled and the volumes were recorded (mean, 1.5cc of CaP cement and 5.6cc of PMMA). Animals were euthanized clinically for neurological changes and radiographs were obtained preoperatively, postoperative and at 1, 3, 4 and 6 mos. After euthanasia with a super saturated solution of pentobarbital, 5 dogs from each group were used for mechanical tests and the remaining 5 per group processed for undecalcified, plastic -embedded histology. Basic fuchsin and toluidine blue-stained sections were studied by light microscopy to evaluate the remaining cement, the cement-bone interface, new bone formation, foreign body reaction, and the surrounding vertebral bone. 

**Results:** All dogs amputated within 5 days without neurological deficits, or fractures, and no infections occurred throughout the study. Radiographically, postoperative views revealed that the implant materials were consistently placed well within the vertebral bodies. There was no extrusion through any endplate. A density difference was apparent between PMMA and CaP in postoperative radiographs and persisted throughout the study with PMMA appearing denser than CaP. Compared to the immediate postoperative films, there was a decrease in density of the CaP cement sites of 50% in 1 of 10 dogs at 1 mo. and of 25% in 4 of 10 at 6 mos., but no change over time in the PMMA sites. Material extrusion was evident postoperatively into the spinal canal area however this was actually intrusion into the ventral vertebral sinus vessels with a greater frequency in PMMA 7/20 than CaP 1/20. Cement intrusion of the central vertebral body vessels was seen in 5/20 CaP and 8/20 PMMA injected vertebrae. Grossly, at examination of the explanted vertebrae from the 10 dogs in the histological group, extrusion of cement into the vertebral sinus on the spinal canal floor was confirmed in 3/10 CaP vertebrae and 6/10 PMMA vertebrae. Examination of the cut surface of the discs of the motion segment revealed a low incidence of degenerated discs.

CT scan analysis indicated that the average % volume fill with cement was not statistically different between CaP at 1 mo. (31.27%) versus 6 mos. (27.13%) and between PMMA at 1 mo. (42.74%) versus 6 mos. (39.43%). However, at both 1 and 6 mos. PMMA had a significantly larger percentage fill than CaP (p =0.005 and p =0.002) respectively. Mechanical tests of compression strength revealed no significant difference in vertebral body height and compressive strength among the groups. There was a trend for CaP treated vertebrae to increase in compressive strength from 1mo. to 6 mos. (4900+ 372 N v. 7211+ 963 N) and for PMMA to decrease (8305+1674 N v. 6502+1916 N) compared to adjacent non-treated vertebrae (5771+927 v. 5866+971). Motion segment testing found no statistical differences among groups for elastic modulus or hysteresis, dynamic moduli from cyclic loading, and for decrease in disc stresses (stress relaxation). These suggest that injection of CaP or PMMA did not cause significant changes in the biomechanical behavior of the adjacent discs up to 6 months.

Histology showed both materials were well integrated into the vertebral body bone. Some differences were evident in bone response. Vertebral sites containing PMMA were characterized by new bone present on cement surfaces and new bone forming on the surrounding trabecular surfaces. Often a thin fibrous membrane incompletely surrounded the residual PMMA bolus centrally and cement intruded into trabecular spaces, vascular channels and the canal. Comparison of 1month and 6 months sections was characterized by an increase in the amount and extent of fibrous tissue surrounding the PMMA cement. PMMA was frequently intruded into the vessels on the canal floor while this occurred infrequently with CaP.

A majority of the material residual in the central vertebral body and surrounding trabecular spaces but infrequently in the canal or vessels. Unlike PMMA, the CaP was undergoing resorption and remodeling, which was apparent as fragmentation with vascular invasion and bone ingrowth into the material bolus and encompassing smaller fragments dispersed into the trabecular spaces. Abundant woven and lamellar bone was found on the CaP cement surfaces but the remaining defect was filled. Of the material intruded into the spinal canal or vessels. Unlike PMMA, the injectable CaP set in situ and restored height of weaken or fractured vertebrae. Clinically, vertebroplasty using injectable CaP cement offers the biomechanical advantage of the adjacent discs up to 6 months.

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