Polymerized Biodegradable Cement to Replace Poly(Methyl Methacrylate) in Vertebral Compression Fracture Augmentation – a Biomechanical Evaluation

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Statement of purpose: Kyphoplasty and vertebroplasty procedures traditionally have used poly(methyl methacrylate) (PMMA) to treat the fractured vertebrae due to its mechanical properties and ease of use. Clinical research has revealed that bone erodes around the cement over time due to effects of stress shielding caused by a difference in the material properties of the implant and peri-implant tissues. PMMA is not osteoconductive or resorbable, so the implant cannot be remodeled and replaced with host tissue. Alternative biomaterials with comparable mechanical strengths but biomimetic mechanical properties are being explored. The present study evaluated a novel injectable polymerized calcium phosphate cement (pCaP) biomaterial whose elastic modulus is comparable to cancellous bone, which had previously demonstrated osteoconduction and resorption in a rabbit tibial defect model. The mechanical properties of vertebral bodies (normal and osteoporotic) augmented with both PMMA or pCaP were determined.

Methods: 33 human vertebral bodies were harvested from 7 cadaveric spines (11 normal and 22 osteoporotic), and were DEXA scanned and dissected with the posterior elements and endplates intact. Measurements of all samples were taken in the saggital and cranial planes. A transverse osteotomy was created in the anterior cortex of each sample to facilitate a uniform failure pattern. Samples were then potted and fractured with an MTS load frame at 5mm/min to 50% strain. All fractures were reduced via uni-pedicular technique using a steerable balloon (Osseoflex®,Osseon Therapeutics), and then augmented with either PMMA or pCaP and cured for 24 hours at 37ºC (Figure 1). Augmented samples were loaded to failure in static uniaxial compression. Paired T-Test was used to assess differences in strength.

Figure 1: Reduction of vertebral compression fracture (left) and stabilization of reduced fracture using injectable cement (right).

Results: Average percentage height restoration for normal samples was found to be 74.1±26.1% compared to 82.3±28.3% for osteoporotic samples. Static testing results demonstrated that pCaP can restore normal vertebrae to intact (pre-fracture) strength (Figure 2). Normal vertebral samples had a mean failure load of 8999 ± 2046N and pCaP augmented normal specimens had a mean failure load of 9277 ± 1876N (p=0.853). Osteoporotic samples had a greatly reduced intact load limit of 2816 ± 1451N, which was increased by a factor of 1.8 to 5042±2710N following augmentation with pCAP, which was statistically significant (p=0.008). Paired T-Test revealed no statistical difference between pCaP augmented and intact vertebral bodies for normal specimens. PMMA and pCaP both statistically improved the mechanical compressive strength of osteoporotic bodies with no significant difference between pCaP and PMMA augmentation (p=0.327).

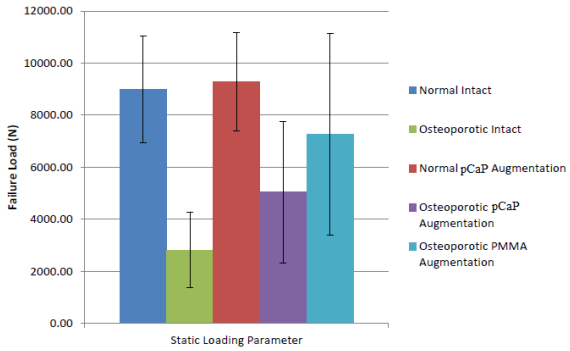

Figure 2: Average static failure loading measurements for all conditions.

Conclusions: Uniaxial compression data suggests that pCaP could be a suitable replacement for PMMA in the treatment of vertebral compression fractures in both normal and osteoporotic tissues. Additional biomechanical evaluation of traditional calcium-phospate cements in this model may provide valuable control data for a clinically used resorbable biomaterial in kyphoplasty and vertebroplasty. Further in-vivo research may be required to understand the effects of pCaP resorption and remodeling on the mechanical properties of augmented vertebral bodies.