MECHANICAL EVALUATION OF A BIOACTIVE CALCIUM ALUMINATE CEMENT FOR PERCUTANEOUS CEMENT AUGMENTATION OF VERTEBRAL FRACTURES

INTRODUCTION: Over 700,000 new osteoporotic vertebral compression fractures are reported in the U.S. each year, outnumbering fractures of the hip and ankle combined.1 Vertebroplasty and kyphoplasty are minimally invasive procedures in which cement is percutaneously injected into the fractured vertebra to stabilize the fracture, provide pain relief and in some instances correct kyphotic deformity. The vast majority of procedures are performed using polymethylmethacrylate (PMMA). However, PMMA is not an optimal material. PMMA lacks osseous integration, has high exothermic curing temperatures and there is the possibility of toxicological effects.2,3 Bioactive cements offer the advantage of providing integration between the material and the bone, lower curing temperatures and no toxicological effects. The injection characteristics and the ability to restore vertebral strength and stiffness of PMMA (Vertebroplastic, DePuy, England) and a bioactive calcium aluminate cement (CAC, Doxa AB, Sweden) were compared.4

METHODS: Determination of Injection Characteristics: Cement was filled into 2ml syringes. Cement was injected through standard 11G cannulae at a constant rate of 0.2 ml/s by applying pressure to the syringe plunger via the hydraulic actuator of an MTS materials testing machine (858 Bionix, MTS, Eden Prairie, MN, USA). When the cement had been fully expressed from a syringe, the next full syringe was inserted in the loading machine and testing continued. Load data (±0.1N) and displacement data (±0.001mm) were recorded continuously. Cement injection continued until cement had been fully expressed from all syringes, or failure of a syringe occurred.

Mechanical Compression Testing: Twenty human thoracolumbar vertebral bodies (VB) were disarticulated (six donor specimens), the discs excised, and posterior elements removed to facilitate mechanical testing. Volumetric bone density and deformation data were recorded at 10 Hz from which strength and stiffness of the VB were calculated. Strength was defined as the maximum load recorded up to 6 mm of compressive deformation.5 Stiffness was defined as the slope of the force-deformation curve between 500 N and half the initial VB strength6 assessed by linear regression using a linear least squares approach.

Vertebrae were floated in plastic bags in a 37°C water bath at all times, except for when performing compression tests (MTS) or cement injection. Mechanical testing, to determine the strength and stiffness of the VBs was performed in three stages: 1) intact, 2) fractured and 3) augmented with cement (performed 24hours after cement injection to allow curing). The superior endplate was compressed at a rate of 5 mm/min until the average initial VB height was reduced by 25%. Force and deformation data were recorded at 10 Hz from which strength and stiffness of the VB were calculated. Strength was defined as the maximum load recorded up to 6 mm of compressive deformation.5 Stiffness was defined as the slope of the force-deformation curve between 500 N and half the initial VB strength6 assessed by linear regression using a linear least squares approach.

Cement was injected into the fractured VB using an 11G cannula inserted unipедicularly and advanced to the anterior third of the vertebral body. Cement was injected by hand using standard 2 ml and 1 ml syringes under fluoroscopic observation.

Statistical Analysis: Differences in outcome parameters between groups were evaluated using a matched-pairs Student's t-test (Stastica Version 7.1, StatSoft Inc., Tulsa, OK) with a significance level defined as p≤0.05.

RESULTS: Injection characteristics for the two cements were distinctly different. CAC demonstrated a prolonged plateau in injection force, followed by a rapid increase as cement setting progressed, while Vertebroplastic viscosity constantly increased with time (Figure 1). Strength was restored to fractured vertebra, 139±67 and 176±88 of initial values (Figure 2) for both CAC and Vertebroplastic augmented vertebrae respectively (p<0.06). Stiffness could not be restored to initial values (Figure 2). Stiffness values were, on average, 37%±18 and 60%±47 of the intact values for CAC and Vertebroplastic specimens respectively (p<0.25).

DISCUSSION: Our current tests focused on the mechanical aspects of the cement behaviour. The CAC demonstrated a more constant injection force, possibly allowing a surgeon to better determine filling response (leak or obstruction) through tactile force feedback. The strength and stiffness of vertebrae augmented with CAC and Doxa cements were similar. Strength was restored for both cement types, the greatest percentage increases were noted in highly osteoporotic specimen (Pearson’s correlation coefficient R=0.68). The advantages of the tested bioactive cement, combined with its consistent injection characteristics, enhanced radio-opacity and similar mechanical properties to PMMA, may make it an attractive option for VB cement augmentation.


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Figure 1: Injection force versus time from initial mixing. Each data set represents the injection of cement from a syringe. The initial steep slope represents static friction, compliance in the plunger/barrel system and possibly cement inertia, followed by cement flow (constant or reduced injection force) and finally an increase in force when the plunger reached the end of the syringe. Also shown is a representative CAC and Vertebroplastic AP fluoroscopic image. Qualitatively, the cement border appeared more distinct for CAC injected VBs.

Figure 2: Strength and stiffness of CAC and Vertebroplastic cement augmented VBs were similar. Injected cement volume had a minor effect on the percentage of initial strength restored (Pearson’s correlation coefficient R=0.14 and 0.7 for CAC and Vertebroplastic respectively).