BIOMECHANICAL EVALUATION OF VERTEBRAL AUGMENTATION WITH CALCIUM SULFATE CEMENT IN CADAVERIC OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURES

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INTRODUCTION

Vertebral compression fractures cause pain, disability and deformity. Treatment with kyphoplasty utilizes an inflatable balloon tamp followed by the percutaneous injection of polymethylmethacrylate (PMMA) cement into the fractured vertebral body (Figures 1-4, from www.kyphon.com).

This procedure restores vertebral body height and may spontaneously resolve debilitating pain. However, PMMA kyphoplasty has disadvantages such as thermal necrosis, lack of biocompatibility and potentially fatal toxicity. Calcium sulfate cement is less toxic, biocompatible, osteoconductive and bioabsorbable. The purpose of this study was to evaluate the biomechanical performance of calcium sulfate for kyphoplasty compared to the clinical standard.

METHODS

Thirty-three vertebral bodies (T9 to L4) were harvested from cadaveric spines without tumors or deformity. After obtaining T-scores to determine the level of osteoporosis/osteopenia, the vertebral bodies were disarticulated, stripped of soft tissue and measured for height and volume. The posterior elements were then removed. Each vertebral body was compressed at 0.5 mm/sec using a hinged plating system on a materials testing machine (MTS, Eden Prairie, MN) to create an anterior wedge fracture and reduce anterior height by 25%. (Figure 5)

Failure strength (N) and stiffness (N/mm) were measured. Two KyphX inflatable balloon tamps were used to expand each vertebral body to within 10% of original vertebral height. After randomization three

Figures 1-4: (fracture, insert, expand, fill).

Figure 5: Test setup.
groups were created: Group A - no cement; Group B - Calcium Sulfate; Group C - PMMA. Groups B and C were filled to 25% of intact vertebral volume. All vertebral bodies were then retested to obtain post-treatment stiffness and failure load. Data between treatments and across repairs were compared using a two-way ANOVA (p<0.05) using a Tukey’s post-hoc correction test for multiple comparisons.

RESULTS

Treatment with PMMA restored vertebral strength to 127% of intact (4168N±2288) and stiffness to 70% of intact (810N/mm±380). Treatment with calcium sulfate restored strength to 108% of intact (3429N±2440) and stiffness to 46% of intact (598N/mm±318). For strength (Figure 6), PMMA and calcium sulfate were not significantly different (p=0.3). Calcium sulfate approached, but did not achieve, statistical significance when compared to control (p=0.06). PMMA had significantly greater strength than control (p=0.007).

For stiffness (Figure 7), there was no difference between PMMA and calcium sulfate (p=0.2) while both were statistically greater than control (p<0.05). No statistically significant difference in T-scores or pre-treatment strength and stiffness values were found among the three groups.

DISCUSSION

Use of calcium sulfate for kyphoplasty yields lower vertebral body strength and stiffness than PMMA kyphoplasty. This was not surprising given the much higher ex-vivo strength and stiffness profile of PMMA cement. The degree of restoration of strength with calcium sulfate was greater than expected, being slightly above pre-treatment intact bone which may reflect other properties of the cements such as filling differences. After kyphoplasty, high cement stiffness may be associated with increased adjacent level fractures in patients. The lower stiffness of calcium sulfate may potentially decrease this complication. Furthermore, calcium sulfate is non toxic, bio-absorbable, osteoconductive and euthermic. These properties may lessen the likelihood of adverse tissue reactions and may make it a suitable agent for the incorporation of growth factors that increase bone density. Further studies are required to assess in-vivo degradation of calcium sulfate after kyphoplasty prior to clinical use.

ACKNOWLEDGEMENTS

The study was funded in part by Wright Medical, Inc.