EVALUATION OF A CALCIUM PHOSPHATE BONE CEMENT WITH CARBOXYMETHYL CELLULOSE IN A SHEEP VERTEBRAL BONE-VOID MODEL

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<Introduction>
Poly(methylmethacrylate) (PMMA) is a commonly used cement for vertebroplasty, but an osteoconductive cement that slowly remodels has some theoretical advantages over PMMA. One such calcium phosphate cement, BoneSource® calcium phosphate cement (CPC; Stryker Orthopaedics) has been proposed for use in vertebroplasty. Little information exists about the long term in vivo properties of calcium phosphate cements for such an application. The aim of the current study is to evaluate the histological and mechanical properties of BoneSource CPC cement up to 3 years in a sheep vertebroplasty model.

<Materials and Methods>
Cement: The properties of BoneSource CPC have been previously described. For this study, 3 g of CPC was mixed with 100 mg of carboxymethyl cellulose to improve handling properties.

Study Design: This IACUC-approved study used 40 skeletally mature sheep. The animals were randomly assigned to one of six time groups and sacrificed at either 0, 3, 6, 12, 24, or 36 months postoperatively. An 8 mm drill hole was made in the lateral cortex of L3 and L5. The drill bit had a stop which permitted the drill to create no more than a 1 cm deep hole, creating a defect of known volume. One vertebral body injected with CPC and its adjacent levels (control) were used for mechanical testing; the other vertebral body treated with CPC was used for histological evaluation.

Specimens handling: CAT scans and radiographs were obtained to confirm the location of bone cement and to measure the radiodensity of each vertebra. Each vertebral body was sectioned perpendicular to the long axis of the cylinder of cement. Half of each vertebral body was embedded in plastic, without decalcification, and hand-ground sections were stained with Giemsa. The opposite half of each vertebral body was decalcified, dehydrated, embedded in paraffin, and thin sections were stained with hematoxylin and eosin. Undecalcified sections were digitized and the areas of the original defect, new bone formation, empty space or fibrous tissue, and residual cement were manually quantified with the use of histomorphometry technique. Results were expressed as percent area (n=6 / 0, 3, 6, and 12 month groups, n=8 / 24 and 36 month groups). Comparisons were made using the Kruskal-Wallis, Mann-Whitney U, and chi-square tests.

Compressive testing: Three vertebral bodies from each sheep: the augmented level and two adjacent levels, were harvested. The compressive stiffness and strength of control vertebral bodies and those augmented with CPC were measured.

<Results>
Radiographic and CT evaluation: With the number of samples available for evaluation, there was no significant postoperative time effect. The postoperative CT scans demonstrated adequately positioned and sized segmental defects in all sheep.

Histologic analysis: Figure 1 shows macrophotographs of undecalcified sections of each time group. The specimen harvested at time 0 shows the cement filling the cylindrical defect (Figure 1a). Portions of the cement show extensive bone apposition at 3 months (Figure 1b). The cortex has healed with new bone formation, bone apposition is established by 3 months and continues through 36 months. There is a gradual increase in bone and decrease in residual cement in cancellous bone area, which accelerates in the cortical bone (Figure 2). Histomorphometry results showing the percent of new bone formation and residual cement in cancellous (a, c) and cortical (b, d) bone areas.

Compressive testing: There were no differences in the stiffness and peak load strength between the vertebral body levels treated with CPC and the adjacent control levels, irrespective of the postoperative time.

<Discussion>
BoneSource calcium phosphate cement mixed with CMC had excellent osteoconductivity, biocompatibility, and adequate mechanical properties, and was found to be well-tolerated in the vertebra of mature sheep in this relatively long-term study. The cement had adequate compressive strength at time 0, and maintained that strength as it became a cement/bone composite during the 3-years in vivo. There was variability among animals, but histology suggests that considerable cement was still present in most samples after 3 years.

References:

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