HISTOLOGIC AND MECHANICAL EVALUATION OF A CALCIUM PHOSPHATE BONE CEMENT IN A SHEEP VERTEBROPLASTY MODEL

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<Introduction>

Polymethylmethacrylate (PMMA) is a cement used commonly for vertebral augmentation. However, an osteoconductive cement that remodels slowly 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. An injectable material similar to BoneSource®, CPC was recently used in a clinical trial of vertebroplasty and resulted in pain relief with no side effects. However, little information exists about the long term *in-vivo* properties of CPC 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 and to investigate the long-term *in-vivo* properties of BoneSource® CPC.

<Materials and Methods>

Cement: 5 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 female sheep. The animals were randomly assigned to one of six time groups and sacrificed at either 0, 3, 6, 12, 24, or 36 months (n=6 / 0, 3, 6, and 12 month groups, n=8 / 24 and 36 month groups) postoperatively. An 8 mm drill hole was made in the lateral cortex of L3 and L5. 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. Half of each vertebral body was stained with Giemsa. The opposite half of each vertebral body was stained with hematoxylin and eosin.

Compressive testing: The augmented level and two adjacent levels were harvested from each sheep. The adjacent levels were not treated and served as internal controls. Each vertebral body was cleaned of its intervertebral disc, and each endplate was potted in acrylic cement (Fastray, Bosworth, Skokie, IL). Each potted vertebral body was placed between platens on a servo-hydraulic materials testing machine (MTS, Eden Prairie, MN) and compressed axially along the central axis of the spine at a rate of 5mm/min. The resulting load versus displacement data were recorded at 10 Hz. The compressive stiffness and strength of the control vertebral bodies and those augmented with BoneSource CPC were measured. Comparisons were made using a multiple linear regression. Significance was defined as $p<0.05$.

<Results>

Radiographic and CT evaluation: There was no significant postoperative time effect. The postoperative CT scans demonstrated adequately positioned and sized segmental defects in all sheep.

Histologic analysis: In microphotographs of undecalcified sections of each time group, bone apposition was established by 3 months and continued to remain so through 36 months. No fibrous tissue, foreign body reaction, or inflammation was present at the cement-bone interface throughout the duration of this study. Macro photographs showed extensive replacement of the cement by Haversian systems. Osteoclasts and osteoblasts forming new bone within the cement were also evident.

Compressive testing: There were no significant differences in the stiffness and peak load strength between the vertebral body levels treated with CPC and the adjacent control levels. There was no significant effect of time on either strength or stiffness, nor was there any significant interaction between vertebral level and time for either strength or stiffness (Tables 1, 2).

Table.1 Stiffness

Time	n	Level Above	BoneSource	Level Below
0M	6	5544± 1721	5811± 1719	4718± 1564
3M	5	5522± 1743	3437± 1021	3367± 812
6M	6	4928± 1258	4002± 1694	5108±1617
12M	6	5445± 1988	7064± 1754	5506± 2131
24M	7	4667± 2107	4858± 1679	5024± 3421
36M	5	No data	4831± 2005	No data

Values are reported as mean and SD N/mm.

Table.2 Peak Load

Time	n	Level Above	BoneSource	Level Below
0M	6	9741 ± 1588	9895± 1686	10570± 2154
3M	5	10986 ± 2967	10808 ± 2649	8521± 1802
6M	6	9804 ± 1013	9155 ± 1901	8750±1339
12M	6	11633 ± 1116	11537 ± 2947	12730± 2831
24M	7	8972 ± 3027	9126 ± 2454	8279± 3778
36M	5	No data	12585 ± 4341	No data

Values are reported as mean and SD N/mm.

<Discussion>

In this 3-year study BoneSource® CPC mixed with CMC had excellent osteoconductivity, biocompatibility, and adequate mechanical properties, and was found to be well-tolerated in the vertebral body of mature sheep. The augmented vertebral bodies had adequate compressive strength at time 0, and maintained that strength as the injected cement became a cement/bone composite during the 3-year period *in vivo*. Histology suggests that a considerable amount of cement was still present in most samples at 3 years.

<Acknowledgement>

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