THE EFFICACY OF THREE DIFFERENT COMMERCIALY AVAILABLE DEMINERALIZED BONE MATRICES FOR INDUCING AN INTERTRANSVERSE SPINAL FUSION IN AN ATHYMIC RAT MODEL

*Peterson, B; *Whang, PG; *Iglesias, R; *Wang, JC; *+Lieberman, JR
*Dept. of Orthopedic Surgery, University of California, Los Angeles

Introduction
Although autogenous bone graft is the most widely used graft material for spinal fusion, demineralized bone matrix (DBM) preparations are now available for use as alternatives or supplements to autograft material. Demineralized bone matrices are prepared by the acid extraction of allograft bone, resulting in the loss of the mineralized component while retaining collagen and noncollagenous proteins, including growth factors. Because of differences in their processing, these substances possess variable osteoinductive activity. The purpose of this study was to directly compare the efficacy of three different commercially available DBM products for inducing spinal fusion in an athymic rat model.

Materials and Methods
DBMs Tested: 60 male athymic rats underwent surgery in this study. 18 animals were implanted with Allomatrix (Wright Medical), 18 with DBX (Synthes), and 18 with Grafton (Osteotech). 6 animals served as controls; these underwent decortication only and were sacrificed at the 8 week timepoint only.

Arthrodesis in Athymic Nude Rats: Approval was obtained from the Institutional Animal Care and Use Committee prior to beginning animal surgeries. This spine fusion model has been reported previously1. A midline incision was made in the skin, and the transverse processes of L4 and L5 were exposed. The transverse processes of L4 and L5 were decorticated bilaterally and 0.3 cc of graft was implanted on each side (0.6 cc total). For each group of 18 animals, 6 animals were sacrificed at 2 weeks, 6 were sacrificed at 4 weeks, and 6 were sacrificed at 8 weeks. A control group of 6 animals underwent decortication alone. These animals were sacrificed at 8 weeks.

Radiographic and Biomechanical Analysis: At each of the time points, radiographic analysis and manual biomechanical testing of the explanted spines was performed. Explanted spines were evaluated for radiographic evidence of fusion using a graded scoring system (0-no bone formation, 4-solid fusion). The radiographic findings were assessed with a nonparametric Kruskal-Wallis test comparing the distribution of ranked data in the various groups. Manual palpation has been determined to be the most sensitive and specific method of assessing fusion in this model. Spines were assessed by manual palpation by three different blinded observers. All spines were scored as either fused or unfused. The results of the scoring were subjected to statistical analysis.

Histologic Techniques: After sacrifice, spines were dissected out and sections were fixed in 40% ethanol, dehydrated, and embedded in polymethylmethacrylate (PMMA). Serial sagittal sections near the transverse processes were cut from the PMMA blocks. Sections were mounted on plastic slides, milled, polished, and surface stained with trichrome stain.

Results
None of the 6 spines which underwent decortication alone fused at the 8 week timepoint. At the 2 week timepoint, none of the spines implanted with any of the DBMs had fused (Figure 1). By radiographic analysis, Grafton demonstrated the most solid fusion masses at 4 week and 8 week timepoints. However, this difference was only significant with respect to Allomatrix and the control group that underwent decortication alone (p<.05) (Figure 2 and Figure 3).

Based on manual palpation of spines harvested at 2 weeks, none of the spines were scored as fused. At 4 weeks, Grafton was superior to DBX and Allomatrix. (5/6 fused, 2/6 fused, and 0/6 fused, respectively). At 8 wks, all 6 of the spines treated with Grafton had fused while 3 of 6 spines treated with DBX had fused. None of the spines treated with Allomatrix or those in the control group (decortication only) had fused. The increased fusion rate assessed by manual palpation in the Grafton treated groups was statistically significant compared to the DBX and Allomatrix treated groups.

Histologic analysis of Allomatrix, DBX, and Grafton treated spines demonstrated varying amounts of residual DBM. Histologic sections from the spines treated with Grafton and DBX demonstrated new bone formation at the 4 week and 8 week timepoints.

Discussion
All of the DBMs which were tested in this study are commercially available. This study demonstrates that there are differences in the osteoinductive potentials of commercially available DBMs. Clinicians need to carefully review the clinical indications for any DBM which they implant. Further comparative clinical testing of DBMs is indicated in order to determine which preparations are best suited for promoting successful spinal fusion in humans.

References
1 Boden SD et al. Spine 1995;20:412-20
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