Reduced Dose of rhBMP-2 with Demineralized Bone Matrix-based Product for Spinal Fusion
L. Zhao¹, L. Kanim¹, X. Zhang¹, Y. Safai¹, J. Houman¹, H. Bae¹, M. Kropf¹, R. Delamarter¹
¹Cedars-Sinai Medical Center, Surgery, Los Angeles, CA, United States

Each year there are more demineralized bone matrix-based products (DBMs) commercially available as allograft bone graft extenders for fusion procedures. DBM-based products are most commonly used with autograft, allografts, and possibly BMPs. Very few of these DBM-based products have been systematically evaluated in vivo. Even fewer of these DBM-based products have been evaluated when combined with, autografts, allografts, or BMPs. Previously we have reported fusion variability across different production lots of these DBM-based products. Recent studies have shown both intra product variability (lot-to-lot variability due to production lots) and inter product variability (product formulations). The purpose of this study was to assess the benefit of a subefficacious dose of rhBMP-2, or autogeneous bone added to a DBM-based product.

Methods. A L4-5 posterolateral lumbar spinal fusion was performed on athymic rats with implantation of 3 unique Lots of DBM-based product [EquivaBone™, Etex Co., Cambridge, MA] with and without subeffercient dose of 0.006 mg/ml rhBMP2 + DBM-based product. Each combination was tested on 4 rats total. Fusion success was determined at eight weeks (short-term endpoint) and 6 months (long-term endpoint) with use of radiographs and manual palpation of the vertebral segments. Fisher’s exact tests and Logistic regression were used to determine the differences and predictive abilities of assayed and added BMPs.

Results. All segments implanted with 0.006 mg/ml rhBMP2/ACS only were not fused; however, all segments implanted with the same dose of 0.006 mg/ml rhBMP2/ACS combined with DBM-based product were fused. Also, when 25% DBM and 25%CP was used with 50% ICBG fusion was also seen in all the animals after 6 months.

Discussion and Conclusion. Fusion was not observed with the low dose of rhBMP-2/ACS only. The higher the quantity of DBM to CP base in the product, the more rapid the bone formation. The optimal ratio between DBM and CP was 75% DBM to 25% CP. Very low doses of rhBMP-2 added to DBM-based product enhanced remodeling and rapid bone formation at all ratios of DBM to base. As is clinically practiced, autogeneous bone added to the DBM-based product also enhanced rapid bone formation.