Examination of the Role of Cells in Commercially Available Cellular Allografts in Spine Fusion. An in Vivo Animal Study

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Key Points:

- Despite the use of cellular bone matrices (CBMs) in spine surgery, there is little evidence to support the contribution of allogeneic cells within CBMs to bone formation.
- Study objective to determine the contribution of cells to spinal fusion by direct comparisons among viable CBMs, devitalized CBMs, and cell-free demineralized bone matrix (DBM).
- Study demonstrated allogeneic cellular component of 2 commercially available CBMs yielded no additional benefits in terms of spinal fusion.

Abstract

Background:
Despite the extensive use of cellular bone matrices (CBMs) in spine surgery, there is little evidence to support the contribution of cells within CBMs to bone formation. The objective of this study was to determine the contribution of cells to spinal fusion by direct comparisons among viable CBMs, devitalized CBMs, and cell-free demineralized bone matrix (DBM).

Methods:
Three commercially available grafts were tested: a CBM containing particulate DBM (CBM-particulate), a CBM containing DBM fibers (CBM-fiber), and a cell-free product with DBM fibers only (DBM-fiber). CBMs were used in viable states (CBM-particulate$_v$ and CBM-fiber$_v$) and devitalized (lyophilized) states (CBM-particulate$_d$ and CBM-fiber$_d$), resulting in 5 groups. Viable cell counts and bone morphogenetic protein-2 (BMP-2) content on enzyme-linked immunosorbent assay (ELISA) within each graft material were measured. A single-level posterolateral lumbar fusion was performed on 45 athymic rats with 3 lots of each product implanted into 9 animals per group. After 6 weeks, fusion was assessed using manual palpation, micro-computed tomography (μ-CT), and histological analysis.

Results:
The 2 groups with viable cells were comparable with respect to cell counts, and pairwise comparisons showed no significant differences in BMP-2 content across the 5 groups. Manual palpation demonstrated fusion rates of 9 of 9 in the DBM-fiber specimens, 9 of 9 in the CBM-fiber$_d$specimens, 8 of 9 in the CBM-fiber$_v$ specimens, and 0 of 9 in both CBM-particulate groups. The μ-CT maturity grade was significantly higher in the DBM-fiber group (2.78 ± 0.55) compared with the other groups ($p < 0.0001$), while none of the CBM-particulate samples demonstrated intertransverse fusion in qualitative assessments. The viable and devitalized samples in each CBM group were comparable with regard to fusion rates, bone volume fraction, μ-CT maturity grade, and histological features.

Conclusions:
The cellular component of 2 commercially available CBMs yielded no additional benefits in terms of spinal fusion. Meanwhile, the groups with a fiber-based DBM demonstrated significantly higher fusion outcomes compared with the CBM groups with particulate DBM, indicating that the DBM component is probably the key determinant of fusion.

Clinical Relevance:
Data from the current study demonstrate that allogeneic cells yielded no additional benefit in spinal fusion and emphasize the need for well-designed clinical studies on cellular graft materials.

NanoBone® Rapid Osteogenesis

Artoss, Inc.
425 E Saint Germain St, Ste 106
St. Cloud, MN 56304-0752

T: +1 320.259.4321
F: +1 320.961.2160
info@nanobone.us
www.nanobone.us