Evaluation of "AFT" Bone Void Filler in a Sheep Vertebral Bone Defect

Takaaki Fujishiro*, Thomas W. Bauer*, Naomi Kobayashi*, Howard B. Seim III**, A. Simon Turner**
*The Cleveland Clinic Foundation, **Colorado State University

Purpose: Vertebral augmentation has been widely used to treat vertebral compression fractures due to osteoporosis, osteolytic metastasis, or myeloma, and pain relief afforded by vertebral augmentation has been well documented. The ability to reconstruct the vertebral body with an osteoconductive material would be an attractive improvement over intravertebral injection of polymethyl methacrylate cement. Bone graft materials, if properly contained to permit load bearing, could offer an opportunity for biologic vertebral augmentation.

The purpose of this study is to evaluate the histological appearance of a bone graft substitute composed of a mixture of demineralized bone granules: 212 - 850 microns (12%); non-demineralized cortical and cancellous chips (44%); and a 2% sodium hyaluronate solution (44%) (AFT Bone Void Filler™, Musculoskeletal Transplant Foundation, Edison, NJ), with several other materials in a sheep vertebral bone void model.

Materials & Methods

Surgery: Twelve skeletally mature sheep of approximate equal size were utilized in this Institutional Animal Care and Use Committee approved study. A lateral retroperitoneal approach through the oblique abdominal muscles to the plane ventral to the transverse processes was made. The ventral spinal muscles were cleared from the lateral aspects of vertebral bodies, and a drill was used to create an 8mm by 15 mm cavity in the L3, L4, and L5 vertebral bodies.

Some defects were left empty; others were filled with one of three different materials:

a) AFT(Allograft Filler tube) Bone Void Filler™ (Musculoskeletal Transplant Foundation, Edison, NJ)
b) Calcium sulfate (OsteoSet™ Pellets, Wright Medical Technology, Arlington, Tenn.)
c) Empty Defect
d) Autograft (harvested from the left iliac crest)

At 6 weeks (four animals) and 12 weeks (eight animals) after surgery, the sheep were killed, and the lumbar vertebral bodies were harvested, fixed in 70% ethanol, and evaluated histologically.

Histologic preparation: The specimens were sectioned transversely through the graft area, and transferred to 10% neutral buffered formalin. Half of each specimen was dehydrated in alcohols, and embedded in Spurr's plastic (Polysciences, Inc., Warrington, PA) without decalcification. The remainder of each specimen was dehydrated in a graded series of alcohols, decalcified, and embedded in paraffin. Sections were stained with Giemsa (undecalcified) or hematoxylin and eosin (decalcified).

Histologic analysis: Microscope slides were reviewed with special reference to evidence of new bone formation, residual graft material, foreign-body reaction, and inflammation.

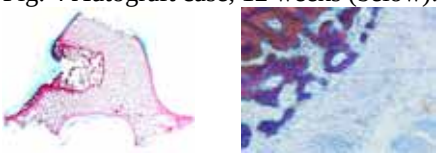
Results: All AFT cases showed good new bone formation, with variable amounts of residual DBM and mineralized bone graft (Fig 1). Some OsteoSet cases showed relatively good new bone formation, but some of them showed little new bone formation and more fibrous tissue. Residual mineral material consistent with OsteoSet was present in nearly all specimens in that group (Fig. 2). Most of the defects that had been left empty showed no new bone formation and were filled with fibrous tissue and fat (Fig. 3). Some of the Autograft cases showed relatively good new bone formation, but some of them showed little new bone formation (Fig. 4). Defects treated with either AFT, OsteoSet or autograft had more bone than untreated defects. Among the treatment groups, the most bone was seen in defects treated with AFT.

Fig. 1 Representative AFT case at 12 weeks (below):

Fig. 2 Representative OsteoSet case at 12 weeks (below):

Fig. 3 Empty defect, 12 weeks (below):

Fig. 4 Autograft case, 12 weeks (below):



Discussion: Bone graft substitute or extender materials have different biologic activity and mechanical properties, based on composition, methods of processing, carrier materials and other variables. Although it does not offer significant immediate mechanical strength when used without adjunctive support, a preparation composed of a mixture of DBM and mineralized bone graft may have osteoconductive and osteoinductive properties that would be desirable for filling voids in bone. The AFT material tested in this study was associated with more new bone formation than either untreated defects, voids treated with calcium sulfate, or autograft.

Conclusions: In conclusion, this study demonstrated differences in the amount of new bone formation associated with three different bone graft materials: AFT, OsteoSet and autograft in a sheep vertebral bone void model. No adverse inflammatory reactions were associated with any of the graft materials.

Acknowledgement: The study was funded by the Musculoskeletal Transplant Foundation (Edison, NJ)