Based Upon the Published Source:


Fibers made of demineralized allograft bone offer an additional osteoconductive effect to an osteoinductive material.
DEMINERALIZED BONE
AND BONE HEALING

Grafting materials heal bone by interacting with cells at the surgical site in one or more ways:

- Providing Bone Forming Cells (e.g. autograft)
- Signaling and recruiting cells that will become bone forming cells (Osteoinduction)
- Providing a scaffold for use by cells in making new bone (Osteoconduction)

Demineralized bone is made of allograft bone which has been prepared by acid treatment to remove the mineral component of the bone material. Demineralized bone has the potential to be osteoinductive – generating de novo bone in a muscle site, as demonstrated in the 1960’s and later.¹ The proteins responsible for osteoinduction – the BMP’s and growth factors—are embedded in the extracellular matrix of the demineralized bone matrix. When processed in a way that respects the potential of the embedded proteins,² ³ ⁴ these materials can assist in bone healing by recruiting cells and influencing them to transform to osteoblastic cells, then to make new bone.

FIBERS AND PARTICLES

The great majority of formulated demineralized bone products use demineralized particles in their formulation. The objective of this work was to determine whether demineralized bone fibers would perform equivalently or better than particles.
NON-CLINICAL EVALUATION OF INDUCTIVITY AND CONDUCTIVITY IN FIBERS AND PARTICLES

The rabbit posterolateral fusion model had been developed to provide a challenging healing site for comparative evaluation of grafting materials. The model utilized autograft, as well as commercial grafting materials as extenders or replacements for the graft, and then evaluated them in the model against autograft performance. In earlier studies, autograft had been shown to heal 73% of the time. This became a benchmark for material performance comparison.

Allograft formulations, all using rabbit allograft to avoid cross-species incompatibility, were compared amongst:

- A particle-based formulation of demineralized bone (a glycerol-based gel, made of rabbit bone) and
- Two fiber-based formulations (a moldable putty and a flexible sheet, both with entangled demineralized fibers of rabbit bone)

All materials were evaluated in three configurations:

- As extenders (50% autograft: 50% demineralized bone),
- As replacements (100% demineralized bone, no autograft), and
- As extracted forms (100% demineralized bone, form which growth factors had been extracted using guanidine hydrochloride).

Note that animal data may not predict clinical results, and in particular, performance as an autograft replacement in rabbits is unlikely to simulate performance in human clinical conditions. The model does, however, provide a standardized, challenging environment for the comparative evaluation of grafting materials.

The methods of the study included:

- Demineralized bone made from rabbit allograft and formulated with glycerol carrier
- 3cc graft material for all DBM and DBM/allograft groups
- 108 rabbits underwent L5-L6 single level posterolateral fusion
- Assessment by X-ray, manual palpation and histology at 6 weeks
- Plastic-embedded, stained and sectioned implant sites evaluated in both sagittal and coronal planes

SUMMARY OF RESULTS

Radiographic

Inspection indicated that none of the fusion masses extended beyond the intended level. When used as an extender, the demineralized bone fiber-containing grafts fused all of the animals. When the equivalent amount of unextended autograft was used (representing the condition of limited autograft availability), the fusion masses were less robust and less consistent (33% fusion).

Radiographic fusion was achieved at 6 weeks in 100% of the animals receiving the flexible sheet form. Animal data embodies a test model, and may not be representative of human clinical results.
Fusion Rate – Manual Palpation
Spines were assessed for fusion by manual palpation. Results indicated higher rates of fusion in forms that incorporated fiber-based demineralized bone, whether autograft was also used or not.

To remove the influence of the inductive proteins, one group of samples was treated to remove the inductive proteins, creating grafts that were osteoconductive only. The results showed improved fusion performance in the fiber-based demineralized bone materials, even without their inductive proteins.

Histology
Among the extender and 100% DBM groups, histologic sections confirmed the improved performance of the fiber forms. Histology showed that Flexible sheet DBM/Autograft fusion masses were larger than those of the Putty DBM/Autograft fusion masses, and appeared more mature (more osteoblastic activity and less cartilage at higher magnification). Gel (Particle) DBM/Autograft healed and remodeled in the regions adjacent to the transverse processes, but was slower to heal or resorbed (in non-unions) in the central span between the transverse processes.

Bone formation in graft comprising 50% autograft/50% fiber-based flexible DBM. 33 × original magnification.

Osteoblasts make tissue from the surfaces of the demineralized bone. When gaps separate the substrate particles, the cell cannot easily bridge to the next particle. Fibers offer connected pathways that provide avenues for cells to achieve deep penetration of the grafting site.
KEY TAKEAWAYS

- The rabbit posterolateral defect is a site that challenges grafting materials, allowing performance differentiation.
- Graft volume is an important contributor to fusion success.
- When processed well, both fibers and particles of demineralized bone are osteoinductive.
- Additionally, fibers of demineralized bone were shown to offer improved osteoconductive effects relative to particles (p<0.05).
- Fiber effects, in both moldable putty form and flexible sheet form, improved healing performance when used with autogenous bone, as an extender than autograft alone (p<0.01).

REFERENCES
