

Packing Behavior of Calcium Phosphate Bone Graft Substitutes

T.D. Clineff, J.P. Murphy, J.G. Marx.

Orthovita, Inc., Malvern, PA

Statement of Purpose: Synthetic, calcium phosphate (CaP) bone graft substitutes are biocompatible and have documented usage throughout the body (1, 2, 3). Orthopedic biomaterial manufacturers have progressed from processing coral to using nanotechnology as a basis for their bone graft substitutes. This study evaluated the ability of commercially available calcium phosphate bone graft substitutes to fill a contained defect and its potential clinical implications.

Methods: Representative bone defects were created in the distal femoral condyle of synthetic femurs (Sawbones®, Pacific Research Laboratories Inc., Vashon, WA). A load cell was clamped in an inverted position in order to measure a downwardly applied force. The Sawbone was fixtured to the load cell. The bone graft substitutes were immersed in animal blood and packed into the defects.

The time and loading responses were measured during the packing. Filled defects were analyzed with back-scatter electron imaging and image analysis. Four bone graft substitutes (ultraporous β -tricalcium phosphate in cylinder and morsel form, conventional porous β -tricalcium phosphate cylinders and coralline hydroxyapatite morsels) were tested using these methods.

Results / Discussion: The results of the packing study indicate that morsels and blocks of ultraporous β -TCP pack into a bone defect with the same maximum applied forces and similar time response to applied force as coralline hydroxyapatite. Additionally, image analyses of the packed sites illustrate that ultraporous β -TCP deforms into the defect and fills it uniformly and completely (Table 1). The packing forces did not reduce its material structure, porosity (nominally 90%) and pore distribution to a significant degree. Denser calcium phosphates were unable to deform and left gaps for potential fibrous tissue formation (Figure 1).

while hydroxyapatite and conventional β -TCP allowed significant gaps to remain.

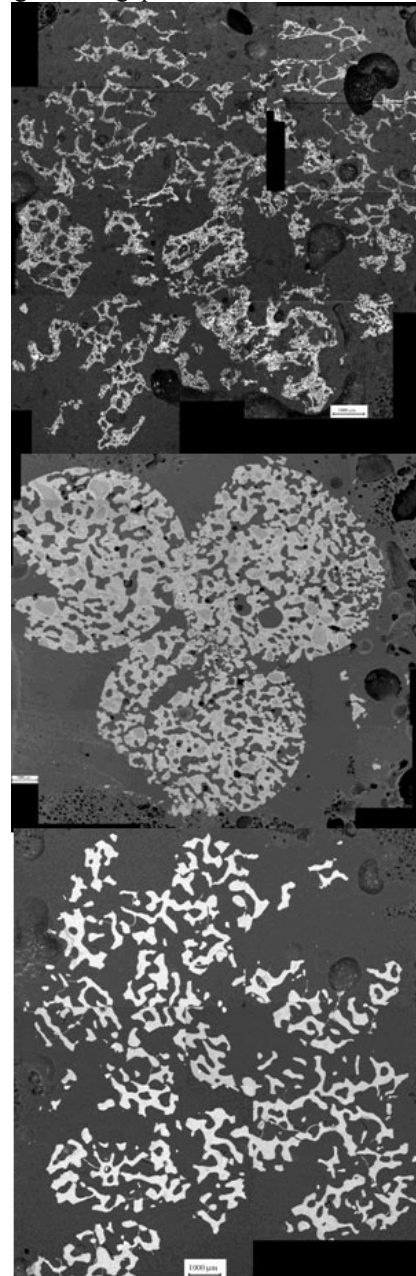


Figure 1. Backscatter electron imaging of contained defects filled with (top) ultraporous β -TCP, (center) conventional β -TCP cylinder, and (bottom) coralline hydroxyapatite morsels.

References: 1. Bucholz, 1987, Orthop Clin North Am, 18(2), 323-34. 2. Damien 1991, J Appl Biomat, 2(3), 187-208. 3. Gazdag 1995, J Am Acad Orthop Surg, 3(1), 1-8.

Table 1. Image analysis demonstrates that ultraporous β -TCP homogeneously filled a contained defect in Sawbone.

Obs	Coralline HA % Packed Material	Ultraporous β -TCP
1	33.8	10.6
2	25.9	11.6
3	35.9	12.5
4	21.9	8.9
5	21.3	14
Mean	27.8	11.5
StDev	6.8	1.9

Conclusions: The results indicate that the packing forces were equivalent between ultraporous β -TCP and coralline hydroxyapatite. Image analysis demonstrated that the structure of the materials studied were not affected by the packing. The ultraporous β -TCP packed the entire defect,