

In vivo assessment of Callos®/OsteoVation® Calcium Phosphate Cement Containing Autologous Bone

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STATEMENT OF PURPOSE

The current standard of care for depressed tibial plateau fractures is reduction of the articular surface and filling of the resulting cancellous defect with autograft or allograft bone. Due to the low mechanical stability after fixation with autograft and allograft bone chips, the use of synthetic bone void fillers within the cancellous defect is increasing. The ideal material would possess both the mechanical strength needed to support the depressed fragment(s) and the appropriate biological properties to match and support native healing and remodeling.

Callos®/OsteoVation® Bone Void Filler is the next generation of bioactive calcium phosphate (CaP) cements with improved physical and mechanical properties. The cement's biological properties may be enhanced by the addition of autologous bone at time of surgery, thereby providing a faster remodeling rate. The objective of this study was to evaluate and understand *mechanical* (setting, compressive, and tensile properties) and *biological* (in vivo healing and remodeling rate) effects on the cement by addition of autologous bone.

METHODS

Callos®/OsteoVation® Bone Void Filler was used as directed and supplied by the manufacturer (Skeletal Kinetics, Cupertino, CA.). A mixture of cortical and cancellous bone was harvested from intact fresh frozen sheep femora using an Osteoharvester device (Osteomed, Addison Texas) or the Bone Graft Harvester (Acumed, Hillsboro Oregon) and added unmodified to Callos/OsteoVation following one minute of mixing.

Mechanical analyses

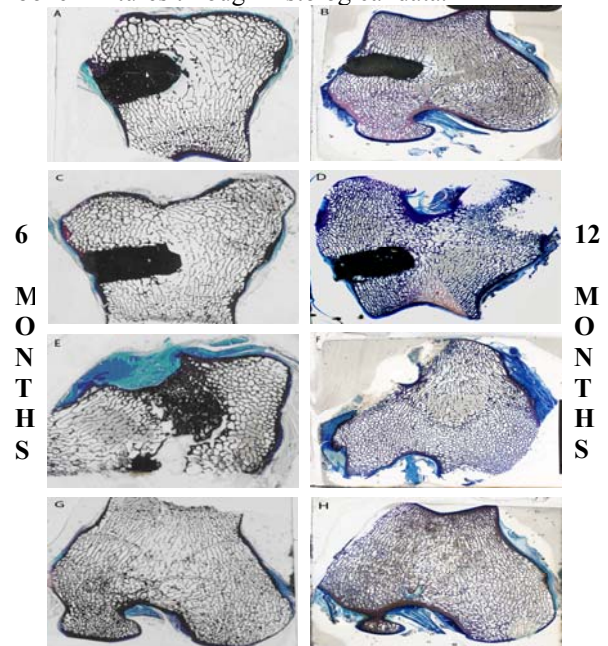
Callos®/OsteoVation® has a setting strength of 1200N at 11 minutes, tensile strength of 4.5 MPa and compressive strength of 50 MPa. Bench top tests were conducted to evaluate the mechanical properties (setting, tensile and compressive strengths) of the Callos/bone composite cements. In these tests, morselized bone in concentrations 5%, 10%, 20%, 35%, and 50% (w/w) was incorporated into the Callos/OsteoVation.

Animal study

A total of 9 skeletally mature ewes were used in the study. A total of four metaphyseal defects were evaluated in each animal – two (2) defects located in the proximal tibial metaphysis and two (2) in the distofemoral metaphysis. Each defect had a diameter of 10 mm and depth of 20 mm and were filled with Callos/OsteoVation, 5% Autografted Callos/OsteoVation, 50% Autografted Callos/OsteoVation, and Autograft. Three (3) ewes each were sacrificed at the implantation periods of 1, 6 and 12 months and then histological analysis was performed to provide morphometric measurements.

RESULTS

- There was a bone dose-dependent effect on the properties of the cement, wherein progressive addition of autologous bone increased Callos cements' setting time (that is, decreased setting strength at 11 minutes) and decreased its tensile and compressive strength. Although autografted-cements' strengths were low in comparison to the control, they still demonstrated sufficient *in vitro* strengths for implantation *in vivo*.
- The 1 month histology results showed no significant difference in the remodeling rate. Considerable remodeling was observed at the 12-month time point. Figure below shows the differences in the remodeling rate at 6 months and 12 months between the cement-bone mixtures through histological data.



A,B: Callos/OsteoVation; C,D: 5% Autografted Callos/OsteoVation; E,F: 50% Autografted Callos/OsteoVation; G,H: Autograft.

CONCLUSIONS

- Pure Callos/OsteoVation shows as an excellent osteoconductive material, perfect bone apposition and some remodeling on the periphery of the cement
- Callos/OsteoVation mixed with 5% by weight bone shows slightly reduced mechanical strength while the remodeling rate was close to pure Callos/OsteoVation.
- Callos/OsteoVation mixed with 50% by weight autologous bone retains setting strength and other properties (5 MPa compressive strength) sufficient for use in most bone graft filler applications. This mixture remodels to new bone in this animal model much more rapidly than the pure Callos/OsteoVation.
- Autograft alone shows complete remodeling in 6 months but does not provide any mechanical strength (< 1 MPa) to the defect site.