In vivo assessment of SKaffold Calcium Phosphate Cement Containing Autologous Bone

Sahil Jalota, Michael J. Jeastra, David G. Delaney, and Duran N. Yetkinler – Skeletal Kinetics, Cupertino, CA

The standard of care for depressed tibia fractures is elevation of the articular surface and filling of the resulting cancellous defect with autograft or allograft bone. Due to inherent morbidity and limited availability of bone grafts, alternatives to this procedure are under evaluation. The ideal material would possess both the mechanical strength needed to support the depressed fragments and biological properties to match and support native healing. To date, no synthetic biomaterial has provided this combination of properties.

BACKGROUND

- Evaluate the changes observed on the mechanics (setting, tensile and compressive properties) and biological response (in vivo remodeling rate) of the cement by adding autologous bone.
- Evaluate the changes observed in these properties by using two bone harvesting systems – Acumed™ Bone Graft System (Acumed®, Hillsboro, OR) and OsteoHarvester™ (Osteomed®, Addison, TX).

OBJECTIVE

- Evaluate the changes observed on the mechanics (setting, tensile and compressive properties) and biological response (in vivo remodeling rate) of the cement by adding autologous bone.
- Evaluate the changes observed in these properties by using two bone harvesting systems – Acumed™ Bone Graft System (Acumed®, Hillsboro, OR) and OsteoHarvester™ (Osteomed®, Addison, TX).

MATERIALS AND METHODS

- SKaffold™ Impress™ (Skeletal Kinetics®, Cupertino, CA) is an apatitic calcium phosphate (CaP) cements.
- Autologous bone was extracted using Acumed® and Osteomed® bone graft harvesting systems.
- Ovine metaphyseal defect model - 4 defects per animal:
  - 2 disto-femoral defects (medial aspect),
  - 2 proximo-tibial defects (medial aspect).
- Implantation duration: 1, 6, 12 month.
- Four CaP/Bone compositions
  - A: 100 wt.% CaP,
  - B: 95 wt.% CaP, 5 wt.% Bone (structural without activity),
  - C: 50 wt.% CaP, 50 wt.% Bone (autograft extender),
  - D: 100 wt.% Bone.
- Undecalcified histology was performed on the implanted samples.

RESULTS

- There was a bone dose-dependent effect on the mechanical properties of the cement, wherein progressive addition of autologous bone increased CaP cements’ setting time (that is, decreased setting strength at 11 minutes) and decreased its tensile and compressive strength. Similar results were observed for both bone graft harvesting systems.
- Although autografted-cements’ strengths were low in comparison to the control, they still demonstrated sufficient in vitro strengths for implantation in vivo.
- Extensive bone apposition and remodeling around the periphery of the cement was observed in each CaP-bone composition at 1, 6 and 12 months time point.
- There was a little or no difference in the remodeling rate of pure CaP cement and 5% Autografted CaP cement at both time points (6 and 12 months) as seen in Figure 3 a through d, wherein the block of cement is still visible in the radiographs.
- The 50% Autografted CaP cement (Fig. 3e) shows partial remodeling at 6 months whereas full remodeling is observed in the Autograft samples (Fig. 3f) at this time point.
- Specimens with 50% Autografted CaP cement (Fig. 3f) show complete remodeling at 12 months, demonstrating significant enhancement in replacement of the implanted material by new bone.

DISCUSSION

- CaP cement remodels in vivo through a cell mediated activity. Such a cement offers a simple autograft extending option, and may find increase usage in skeletal surgeries.
- CaP cement use as autograft extender may enhance both phagocytotic and osteogenic processes, resulting in an earlier acceptance and improved osseointegration of cement.

CONCLUSION

- Pure CaP cement shows nearly complete bone apposition and some remodeling on the periphery of the cement.
- CaP cement with 5 wt.% bone shows slightly reduced mechanical strength while the remodeling rate was similar to pure CaP cement.
- CaP cement with 50 wt.% 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 faster than the pure CaP cement and may be of great clinical value in situations where a rapid return of bone architecture is desired.
- Autograft completely remodels in 6 months but does not provide any mechanical strength (< 1 MPa) to the defect site.