BACKGROUND

- 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.

OBJECTIVE

- Evaluate the changes observed on the Mechanics (setting, and tensile properties) and Biological response (in vivo remodeling rate and in vitro viability) 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™ (Skeletal Kinetics®, Addison, TX).

MATERIALS AND METHODS

- SKaffold™ Impress™ (Skeletal Kinetics®, Cupertino, CA) is an apatitic calcium phosphate (CaP) cement.
- Autologous bone was extracted using Acumed® and OsteoHarvester® 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 with bio-activity),
  - C: 50 wt.% CaP, 50 wt.% Bone (autograft extender),
  - D: 100 wt.% Bone.
- Typical histology was performed on the implanted samples.
- Short-term (0-48 h) in vitro cell viability and function within the CaP cement/bone composite material was evaluated using Promega Celltiter-Blue® cell viability assay.

RESULTS

- Acumed’s bone graft harvester system resulted in coarser bone than OsteoHarvester.
- Setting strength showed a bone dose-dependent effect with strength decreasing considerably with addition of 50% bone into CaP cement (Figs. 1 and 2).
- Both bone harvesting systems showed similar effect on the setting strength (Figs. 1 and 2). When 20 wt.% bone was added, CaP cement retained approximately 60% of its setting strength at 10 minutes.
- Tensile strength of CaP cement at 24 hours with 30 wt.% cortical bone inclusions, decreased by 75% (Figure not shown).
- Figure 3 demonstrates in vivo histology of native cement implanted for 1 month. Bone apposition to this injected cement is apparent.
- Figure 4 demonstrates a 50% bone-loaded cement implanted for 1 month. Histology shows bone apposition; bone particles and cement are also visible in this micrograph.
- Figure 5 shows the in vitro cell viability data. The pristine bone showed the strongest signal. Five-times higher cell viability on the 50% bone-loaded CaP cement was observed in comparison to cement alone. Pristine cement shows background absorbance levels.

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 better osseointegration of cement.

CONCLUSIONS

- Cortical/cancellous bone added to CaP bone void filler adversely affects the curing and tensile strengths of the material when added above 35% by weight.
- Additions of up to 20% bone showed reduced, but acceptable tensile and setting strengths.
- 1-month in vivo histological results were inconclusive, 6- and 12-month histology will be evaluated in order to evaluate remodeling rate differences.
- In vitro cell viability testing results show that the cells remain alive after mixing with CaP cement, thereby bone-incorporated cement may provide enhanced remodeling properties than native cement.

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