In vivo results of a polylactide – ceramic composite in sheep at 3 years

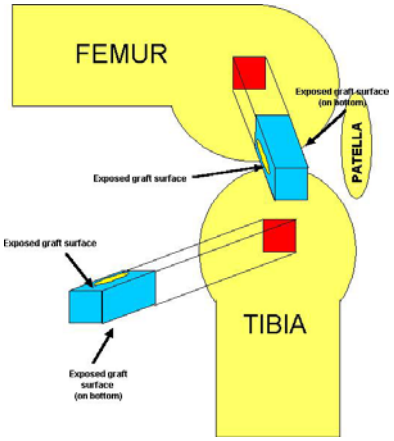
Purpose

Ceramic bone graft substitutes derived from coral species provide a 3 dimensional structure similar to native cancellous bone and have been clinically successful for many years. However, their brittle nature limits their use to non-load bearing applications unless augmented in some manner. The mechanical properties of porous ceramics can be substantially improved by filling the porosity with polymers such as polylactides. This results in a high strength, solid composite that can be machined into various implants. Reports on the long-term *in vivo* performance of this class of implants remains scares. This study examined the *in vivo* response of a novel, ceramic-polylactide composite in bilateral ovine cancellous defects in the long bones at 3 years following implantation.

Methods

Following institutional ethical approval, bilateral defects were made in the medial distal femur and proximal tibia (*figure 1*) of 4 adult wethers (18 months old). Defects with dimensions of 11 mm x 11 mm x 25 mm were created in a step-wise fashion to allow a press fit manner. Ceramic-polylactide (ProOsteon 500R and 70-30 PLLA) devices (CPD) were fabricated with an open, internal slot designed to hold graft materials. Defects were randomly allocated to following: 1) Empty, 2) Autograft, 3) CPD filled with autograft, 4) CPD filled with a block of ProOsteon 500R, and 5) ProOsteon 500R block alone. The slots were oriented along the long-axis of the femur or tibia. Marker pins were placed into the bone above and below the surgical site to identify the surgical site. Animals were sacrificed at 3 years following surgery. The right and left femur and tibia were harvested and carefully dissected to assess any adverse soft tissue reactions. High resolution radiographs were taken in the anteroposterior and lateral planes using a Faxitron machine and mammography film. Computed tomography scans (2 mm) were and 3 dimensional models created using AMIRA to visualise the in vivo response at the surgical sites.

Figure 1



Results

All animals recovered well following surgery and were load bearing within 2 days following surgery. No adverse events occurred for any animals during the 3 year. Macroscopic dissections at sacrifice revealed no adverse reactions in the soft tissues or at the level of the periosteum. The wounds were well healed and the surgical sites were only identifiable by the marker pins placed at surgery. Radiographs did not reveal any adverse reactions and a well healed surgical site. Computed tomography revealed the empty defects to remain empty at 3 years (figure 2) while the autograft sites were completely healed. Evidence of the block of 500 R was observed on CT at 3 years with signs of bone infiltration and resorption (figure 2). The CPD devices were resorbed at 3 years with bone present in the slot (figure 3). No adverse reactions to the adjacent bone were observed with the CPD devices. The 500R portion of the CPD device was noted to be integrated with the adjacent bone or resorbed.

Figure 2: Empty defect and block of 500R at 3 years

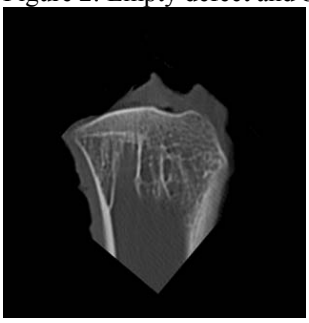


Figure 3: CPD device at 3 years in the proximal tibia

Conclusion

The 11x11x25 mm defect remained a critical size even at 3 years in this ovine model while the autograft sites undetectable The long term results of this polylactide-ceramic device when placed in cancellous bone did not demonstrate any adverse reactions at 3 years. Computed tomography revealed the implants to be resorbed with a well healed interface to the adjacent cancellous bone bed. Bone was present in the slot of the CPD along with resorption of the 500R component.