ABSTRACT INTRODUCTION

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® Bone Void Filler is the next generation of bioactive calcium phosphate (CaP) cements, which is easy to mix, has better intraoperative handling properties, develops early mechanical strength (fast-setting), resists wash-out in a wet environment and has enhanced mechanical properties (increased tensile strength, flexural strength and fracture toughness). 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 effects on the material’s functional properties by adding different concentration of bone have not been studied. The primary objective of this study was to evaluate and understand the changes observed on the Mechanics (setting, compressive, and tensile properties) and Biologics (in vivo healing and remodeling rate) of the cement by addition of autologous bone. The secondary objective was to evaluate the changes observed in these properties when using two bone harvesting systems – Acumed’s and Osteomed’s.

METHODS

Callos® 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 following one minute of mixing. Setting strength was evaluated at open body temperature (32°C) using a modified Gilmore needle indentation test at time periods of 4, 6 and 10 minutes post mix. The cements were kept submerged in phosphate buffered saline (PBS) until tested. Diametral tensile testing was used to determine the tensile strength following 24 hours of curing at 37°C in PBS. Compressive strength was measured after 24 hours and 72 hours of curing in PBS at 37°C.

In vivo model

For the in vivo study, a total of 18 skeletally mature ewes were used in this study. A total of four metaphyseal defects were created, two defects were located in the proximotibial metaphysis and two in the distofemoral metaphysis. Defects each having a diameter of 10 mm and a depth of 20 mm were created in each animal, but a single harvesting system was used in any one animal. The Acumed harvester creates 10-mm diameter defects during harvesting, while the OsteoHarvester creates 4.5-mm diameter defects. Therefore, after harvesting autologous bone with the OsteoHarvester, the defects were expanded to 10-mm diameter with the Acumed system. Standard operating procedures were followed in treating the sheeps prior to and after surgery. The defects were filled with the following compositions (one group per defect):

- Group A: 100% Callos® cement
- Group B: 95% Callos® cement, 5% autologous bone
- Group C: 50% Callos® cement, 50% autologous bone
- Group D: 100% autologous bone

Ewes are implanted with the above-mentioned groups using both Acumed’s and Osteomed’s harvesters. Histologies of implanted areas were performed after 1 month, 6 month and 12 months.

Post-implantation procedure

To evaluate bone formation after implantation, Calcium-binding dyes will be administered subcutaneously. Xylenol orange (90 mg/cc at 1 cc/kg) will be administered the day after surgery to label both new bone formation sites and morselized bone surfaces immediately after surgery. To label new bone formation surfaces at sacrifice, calcein green (30 mg/cc at 0.33 cc/kg) will be administered two weeks prior to sacrifice. Following implantation intervals of 1, 6, and 12 months, animals will be humanely euthanized according to the guidelines of the AVMA Panel on Euthanasia. Histological analysis, Micro-CT imaging and mechanical testing will be performed after implantation.

RESULTS SECTION

- Setting (Fig. 1) and tensile (Fig. 2) strengths of Callos were reduced in a bone dose dependent manner. Callos retained approximately 60% of its setting strength at 10 minutes and 40% of its tensile strength at 24 hours with cortical bone inclusions of 20% by weight. Setting and tensile strengths dropped by 75% at 35% bone inclusion.

- Compression strengths (Fig. 3) were reduced to 45% of their control values with 20% included bone.

- Injected volumes of cement were significantly lower following addition of as little a 5% bone. Complete injection failures resulted for samples with 20% included bone.

DISCUSSION

Cortical/cancellous bone added to Callos 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. Addition of autogenous bone is feasible up to approximately 20 weight percent bone and may have significant benefits for more rapid bone healing and cement replacement in vivo. In vivo histology results will be presented at the time of the meeting.