Introduction:
Thermal insult and monomer toxicity associated with the use of polymethyl methacrylate (PMMA) bone cement remains a concern for arthroplasty surgeons in cemented fixation and defect filling. Curing of bone cement is an exothermic reaction generating heat energy which is absorbed and dissipated by the implant, adjacent bone and soft tissues. Whilst there is no definitive evidence regarding critical values or their durations, an increase in temperature of the cortical bone to above 50°C has been implicated with a reduced regenerative capacity [1] and above 56°C with osteonecrosis [2]. Bone necrosis can result in premature failure of the prosthetic fixation and subsequent aseptic implant loosening.

We conducted this study to test the null hypothesis that temperatures associated with curing of PMMA bone cement are not sufficiently high enough to result in thermally-induced necrosis of cancellous bone and soft tissues in an ovine model. The elevation in temperature of the surrounding cancellous bone and cement associated with curing was measured in vivo and tissue status examined at 3 and 12 weeks postoperatively.

Materials and Methods:
Six (n=6) male sheep (18 months) were used in this study. Animals underwent a procedure in which fully-contained bilateral defects were created in the cancellous bone of the distal femur and proximal tibia using a Midas Rex burr (Medtronic, Fort Worth, TX) (Figure 1a). Irrigation was applied during burring.

Defects were flushed out with sterile physiological saline and a 2mm diameter Kirschner wire (k-wire) used to create three pilot holes (n=3) at locations proximal, central and distal to each defect for the insertion of type-k thermocouples (Figure 1b) (n=3 per defect). All thermocouples were connected to a dt80 Datalogger (Datatakerlogger Inc, OH) multiple-channel data acquisition system (Figure 1c) and were used to measure the elevation in temperature of cement and surrounding cancellous whilst cement cured. The terminus of each of the holes were intended to be located at a depth of approximately 5mm from the outer cortex and between 1-3mm from the boundary of the surgically-created defect. Tourniquets were not applied to the operated hindlimbs during the procedure.

Defects were filled with Surgical Simplex P (Stryker-Howmedica-Osteonics, Kalamazoo, MI) which was mixed for 2 minutes using an open-bowl technique. Temperature profiles were recorded for 20 minutes following injection. Upon temperature equilibration thermocouples were extracted and 2mm diameter k-wire dowels inserted to preserve the spatial location of the probe tips. Maximum temperatures and dwell times [3] for each thermocouple were computed.

Animals were euthanised at 3 (n=3) and 12 week (n=3) weeks postoperatively. A fluorochrome label (Oxytetracycline) was administered intramuscularly to each animal 1 week prior.

Harvested hindlimbs were radiographed and CT-scanned (250µm x 250µm x 500µm voxel resolution) and fixed in phosphate-buffered formalin. Cement volumes and probe-cement distances were computed from the CT data (Mimics 12.0, Materialise, Belgium).

The defects were isolated and processed for paraffin and PMMA histology according to the protocol shown in Fig 2a. Sections were stained in H&E and tetrachrome. The aim of the histological analysis was to evaluate the cellular response to the PMMA cement in the cancellous bone encompassing the defect 3 and 12 weeks postoperatively, concentrating specifically on areas of bone formation and calcification, fibrous tissue infiltration, tissue necrosis and bone resorption.

Results:
Animals tolerated the surgery well and no postoperative complications were encountered. Radiographic data revealed tips of the temperature probes to reside in either the bone adjacent to or within the cement mass. Mean defect volume was 0.585±0.251mL.

Mean distance from the probe to the cement was 1.9±2.0mm (Mean±SD) and mean maximum temperature measured in the cancellous bone was 49.3±10.2°C (range: 40.9°C – 82.2°C), which did not correlate with cement volume (r = -0.110, P=0.563) or probe distance (r = -0.112, P = 0.555). 8/30 probes which were not embedded within or in contact with the cement measured maximum temperatures in excess of 50°C (mean 62.2°C), having an average dwell time of 57 sec.

Histological analysis of the 3 week specimens revealed the presence of an intervening fibrous layer at the bone-cement interface (Fig 2a) and intimate contact between cement and cancellous bone was not a common feature. There was a marked reduction in the amount of fibrous tissue at this interface from 3 to 12 weeks postoperatively. Thermal damage/necrosis was not found to be a common feature at either 3 or 12 weeks postoperatively and was detected in 1/12 sites at 3 weeks only (Fig 2b). The maximum temperature reached in the vicinity of this area of necrosis was 73.3°C and had an associated dwell time of 124 seconds.

Discussion:
Despite mean maximum temperatures in the surrounding bone of 49.3±10.2°C (range: 40.9°C – 82.2°C) thermal damage/necrosis was not a common feature at 3 or 12 weeks following surgery. The exposure of bone to high temperatures in this animal model has not led to incidences of bone necrosis and soft tissue damage.

References: