BONE SUBSTITUTES CAN REPLACE MORCELLISED ALLOGRAFT FOR IMPACTION GRAFTING.

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Introduction
The effectiveness of allogenic bone graft for impaction grafting during revision hip replacement is determined by a number of factors that include the sterilisation method, the consistency of the graft, and by the immunogenic reaction. Supply of sufficient graft material may also be limited. The amount of graft used may be reduced by using increased amounts of synthetic materials such as hydroxyapatite (HA) and this may alleviate these problems. This study evaluated using mixtures of porous HA (ApaPore™) with allograft for cemented impaction allografting of the femoral stem in an ovine model. The aim was to test the hypothesis that increased quantities of porous HA (up to 90%), will be stable and induce similar bone remodelling to a 50:50 mixture with allograft.

Method
Twelve hemi-arthroplasty femoral components were inserted into the right hip of skeletally mature female commercially cross-bred sheep weighing between 65 and 80kg. Collarless femoral components were manufactured from Cobalt Chromium alloy and cemented in place following impaction of the femoral canal. Animals were randomly placed into one of two groups according to the allograft-ApaPore mixture used.

Group 1: ApaPore:allograft mixed 50:50.
Group 2: ApaPore:allograft mixed 90:10

There were six animals in each group and implants remained in vivo for 6 months. To quantify bone formation rates, oxytetracycline injections were given 2 months post-surgery and 3 weeks later, followed by a third administration in the fifth month post-surgery and a fourth injection 3 weeks later. In order to measure how well animals used there operated legs they were walked over a force plate pre-operatively and at 8, 16 and 24 weeks post-operatively. Twelve readings of maximum force (Fmax, N/m²) were taken and average values of right over left were calculated as a percentage (%AR/AL) where 100% represents full weight-bearing. After sacrifice, thin sections (~7μm thick) were prepared through four regions of the femur.

The proximal, mid and tip of the femoral component region and one distal to the implant tip were analysed (Fig 1) where bone area, ApaPore area, ApaPore-bone contact and cement mantle thickness were quantified and compared using image analysis techniques and backscattered Scanning Electron Microscopy (SEM).

Results
Ground Reaction Force (GRF) results demonstrated no significant differences between the two experimental groups at 8, 16 and 24 weeks post-operatively. In both groups, a significant decline in function was demonstrated 8 weeks post-op when compared with pre-operative values. In both groups, function gradually improved over time until at 24 weeks the percentage of the force going through the operated leg was over 90%. In both groups, the use of graft resulted in the formation of a cancellous network of bone on the endosteal surface which incorporated the ApaPore granules (Fig 3). No significant differences in bone apposition rates were identified when the proximal, mid and tip regions in the two groups were compared, however, significantly increased turnover was identified in the distal region in group 1 (0.0027 mm day⁻¹) when compared with group 2 (0.0013 mm day⁻¹) (p<0.05). In both groups increased turnover was observed in the proximal, tip and distal regions with least in the mid region of the stem. Results for new bone area (Fig 2) demonstrated no significant differences in any of the regions when group 1 and 2 were compared. In terms of location down the stem there was increased new bone in the proximal and distal regions in both groups (proximal =7.94mm² and 7.13mm²; distal =7.03mm² and 8.17mm²; group 1 and 2 respectively) with least new bone in the mid region of the stem (4.53mm² and 4.79mm²). In both groups, significantly increased amounts of ApaPore was observed in the proximal and distal regions of the femoral stem with least in the mid and tip region. No significant differences in cement mantle thickness and %Bone-ApaPore contact were identified when the two groups were compared.

Discussion
This ovine hemiarthroplasty model is a good model for revision hip arthroplasty as the femur is tubular with very little cancellous bone and is poorly vascularised which is similar to the sclerotic shell seen around failed hip replacements. Results demonstrated that hips maintained functional stability when a higher amount of ApaPore mixture was used. Results for bone turnover rates and the amount of new bone formation in the 90:10 mixture demonstrated ApaPore to be a comparable and suitable alternative to replace allograft in impaction grafting of a femoral component.

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