INTRODUCTION Aseptic loosening of cemented fixation is the chief cause of failure in young patients and revision cases with massive prostheses used for bone tumours. This study investigated the concept of extra-cortical plates as a cementless method of fixation for massive segmental bone tumour replacements. The hypothesis was that fixation of massive implants could be enhanced by using extra-cortical plates which alter local stresses, combined with coatings which encourage bone integration leading to beneficial bone remodelling resulting in integration of the implant with cortical bone. This hypothesis was examined by inserting experimental prostheses into the goat animal model and by developing a finite element analysis model which replicated the conditions of extra-cortical plate fixation in the human femur.

METHODS Twenty-six tibial mid shaft prostheses were inserted into the right tibia of goats under the animal scientific procedure act 1986. Two, three or six extra-cortical plates were anchored to the bone using transcortical bone screws. All of the plates were coated with hydroxyapatite (HA). Animals were sacrificed at 15 days to 6 months post surgery and thin sections were prepared. The bone remodelling rate was determined using fluorescein bone markers and bone was investigated histologically and radiographically. A finite element model reproducing a massive distal femoral replacement fixed to the left femur by three extra-cortical plates was developed. Ten-noded tetrahedral elements were used to produce a model which mimics the attachment of titanium 318 extra-cortical plates to bone. The three extra-cortical plates lay in the medio-lateral, medio-posterior and lateral planes of the femur. The length and thickness of the plates were varied and the results for Von Mises and strain energy density were analysed. FEA was also used to calculate second moments of area from cross sectional slices taken from the retrieved operated and unoperated goat tibiae. Bone was taken as a linear elastic and isotropic material with an elastic modulus of 20GPa and a Poisson’s ratio of 0.36. The properties of Ti6Al4V were used with an elastic modulus of 106GPa and a Poisson’s ratio of 0.36. The students unpaired t-test was used for statistical analysis where values <0.05 were classified as significant.

RESULTS All of the plated prostheses used in the animal study were securely fixed by new bone formation. Bone was in contact with the HA coated plates and apposition onto the external surface of the plate occurred through a combination of periosteal bone formation, invasion of bone through slots in the plate and bone growth over the ends of the plate. Fluorescein bone markers demonstrated significantly increased bone growth rates into the slots of the plates when compared with bone growth around the unslotted plate(p<0.05). Results of second moment of area demonstrated the 6-plated implant design as the stiffest design(p<0.05) and the 2-plated as the most flexible(p<0.05). Significantly more cortical porosis was observed around the 6-plated implant design when compared with the 2-plated implant design(p<0.05). Plate incorporation into the cortex as measured by bone attachment onto the plate surface was significantly increased at the tips of the plates in all designs when compared with the mid and distal regions(p<0.05). In the FEA model results obtained from the Von Mises failure criterion demonstrated stresses in the implant lower than the fatigue limit of titanium (220mpa). The stain energy density of bone was measured and compared with normal physiological values (Huiskes et al; 1997). Results demonstrated that SED levels in the bone adjacent to most regions along all three extra-cortical plates were too low to stimulate bone formation but predicted bone formation at the more flexible tips of the plates. The model also predicted increased SED’s when thinner plates were attached to bone. The length of the plates had no effect on SED values (fig 3).

DISCUSSION The animal study showed that the highest rates of bone ingrowth and reduced cortical porosis were present in regions surrounding the slots. The extra-cortical plates used in the animal study were HA coated and direct bone apposition was observed. In some cases the plates were surrounded by bone. Both the animal and FE studies concluded that the stiffer implant designs were least favourable with decreased bone formation and increased cortical porosis. The FEA model predicted bone formation at the ends of plates and this was observed in the animal model. Slots in the plates increased the flexibility, aided revascularisation and increased the surface area for the HA coating which increased bone formation. It was concluded that HA coated flexible extra-cortical plates provided a promising method for the long-term fixation of these implants.

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