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# A novel sheep model for evaluating biomaterials in cancellous bone

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**INTRODUCTION:** The use of sheep cancellous bone models is now well established for the assessment of new orthopaedic biomaterials and implants during either in vivo biocompatibility or corrosion studies. However, sheep have a limited availability of cancellous bone for implantation of biomaterials or surgical implants making it difficult to find multiple comparable sites within a same animal. Currently, one recommendation is to use the proximal and distal humerus and the proximal and distal femur for the implantation of a maximum of 8 different sites. These sites have different amounts of overlying soft tissue, and loading pattern which may effect the evaluation of implants.

The objective of this study was to develop a novel sheep model in which multiple implants can be tested in cancellous bone within the same animal. It was hypothesized 1)that the ovine distal femur and proximal tibia contain enough cancellous bone to allow multiple implants testing within the same animal and 2)that in vivo multiple implants application in the distal femur and proximal tibia within the same sheep is associated with minimal complications.

## Materials & Methods

*Cadaver studies:* Studies were performed to both characterize ex vivo the cancellous bone tissue contained in the ovine distal femur and the proximal tibia and to develop ex vivo new surgical instrumentation for multiple implants application in the ovine distal femur and proximal tibia cancellous bone.

*In vivo studies:* Implants - Cylinders (5mm x 15mm) of bioresorbable polymer-ceramic composite, based on poly (L-lactic acid) (PLA) and β-tricalcium phosphate (β-TCP) were implanted in the distal femur and proximal tibia during a bioperformance in vivo study and 316L stainless steel cannulated screws in combination with guide wires of different material were implanted during an in vivo corrosion study. Animals - Mature, female, Swiss alpine sheep were obtained from a flock maintained for orthopaedic research, such that size, shape and age were standardized, and the health status known.

*Surgical technique for the in vivo bioperformance study:* Operated animals were placed under general anesthesia in lateral recumbency with the medial aspect of the most dependent hind limb clipped and prepared for aseptic surgery. The collateral ligament of the medial femoro-tibial joint was identified and two 20G, 1 inch hypodermic needles were placed in the femoro-tibial joint on both side of the collateral ligament. A 10-cm incision was made over this ligament, extending through the medial femoral fascia and splitting the distal head of the gracilis muscle. Three-hole and 2-hole jigs were positioned; 1 cm from the joint space, on the distal femur and the proximal tibia respectively after surgical exposure was obtained (Fig1). A 5.1 mm depth-regulating drill bit was used to drill five 15 mm deep holes in the cancellous bone. The tested bioresorbable polymer-ceramic composite implants were inserted in these holes. Positional screws were placed to guide a jig made for harvesting implants following euthanasia. The surgical incisions were closed routinely in 3-layers. The sheep were changed to the opposite lateral recumbency and the second hind limb was operated in a similar way.

*Surgical technique for the in vivo corrosion study*: Positioning, preparation and surgical exposure was performed as described above. A K-wire was inserted in the middle of the medial femoral condyle and the proximal tibia, cranial to the medial collateral ligament and 1 cm distal to the joint space. Their placement was verified with fluoroscopy. Three-hole and 2-hole jigs were slid over the K-wires (Figure 1). Stab incisions were made and bone holes drilled to insert the tested implants. The wound was closed in two layers. The sheep were changed to the opposite lateral recumbency and the second hind limb was operated in a similar way.

Analgesia protocol and postoperative management: Systemic and local analgesia consisted of nerve blocks and pre-, intra- and postoperative administration of NSAIDs and opioids. The sheep were maintained in single pens until shortly after suture removal to avoid damage to the incision, and were then group housed.

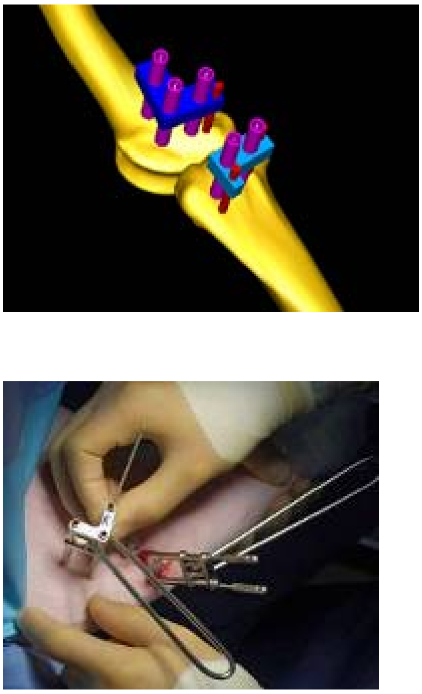
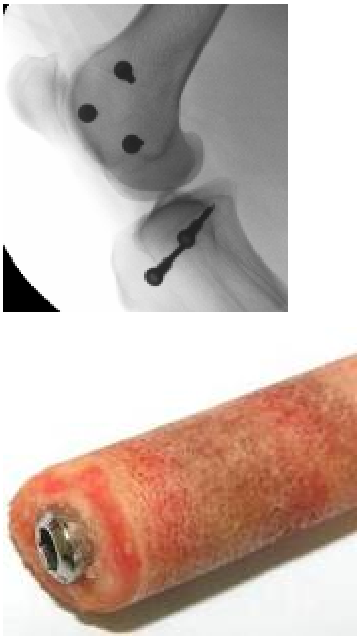


*Figure 1. Jigs positioning for the biocompatibility study (above) and corrosion study (below).*

**Results & Discussion:** Twelve sheep were included in the biocompatibility study and 18 in the corrosion study. No postoperative complications were recorded in 28 sheep. Two sheep were euthanized within 2 weeks of surgery: one with unresponsive pleuropneumonia and one with septic femoro-tibial arthritis. The described techniques allowed the insertion of 10 implants per animal. The designed jigs allowed accurate and reliable placement of all the implants in cancellous bone (Fig 2).



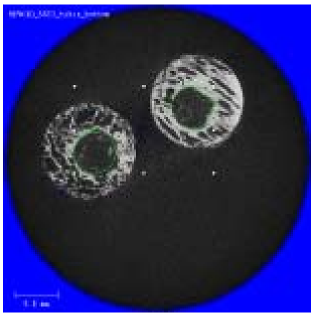


*Figure 2. Radiographs confirming placement of the implants in cancellous bone, the harvested core and CT images of the cores.*

**Conclusion:** This abstract describes a useful, low-morbidity, animal model for testing multiple biomaterials in cancellous bone in the same animal. Differences exist in the trabecular structure of the proximal tibia compared with the distal femur which should be considered in the experimental design. The size of implants tested is also limited. However the condensed spatial assignment of samples ensures shorter surgery times, the opportunity for effective local anaesthesia, and more similar loading patterns and amounts of overlying soft tissue compared with other models. Care is required to ensure that implants located in the distal most position of the femur do not penetrate the intercondylar notch. Images taken in two orthogonal planes are recommended. The technique also allows accurate harvest of implants, performed by coring out a bone plug surrounding the implant for detailed imaging and histological analysis (Figure 2).