Introduction: Fracture of the tibial and femoral diaphysis constitutes approximately 7% of fractures occurring in children. Such fractures are commonly repaired by intra-medullary nailing. While removal of implanted nails is often routinely performed after fracture healing it is not always without complication, often due to difficulty or inability to remove the nail. Currently intra-medullary nails are available in either stainless steel or Titanium-Aluminium-Niobium (TAN). TAN is known to have excellent biocompatibility, however, the excellent ability of TAN to promote bone on-growth has been suggested as a cause of the difficulty in removing nails made of this material. Stainless steel nails of a similar design are seldom associated with removal problems from bony integration. Numerous in vitro studies have shown that surface morphology of materials influences osteoblast proliferation, differentiation, and phenotype. Work in our group has shown on smooth surfaces such as that of clinically used stainless steel, there is a loss of osteoblastic phenotype like behavior with an increase in proliferation and spreading of the cells (typical of fibroblast like behavior). On microrough surfaces the osteoblastic phenotype behavior is maintained and an increase in expression of genetic markers associated with bone formation has been found. We hypothesise that a smooth surface, similar to that found with stainless steel, created by polishing of standard micro-rough TAN nails will help to eliminate the nail removal problems associated with excessive bone on-growth. This study aims to assess the effect of surface topography of TAN (Titanium-6% Aluminium-7% Niobium) intra-medullary nails on nail removal after a 12 month implantation in the sheep tibia.

Materials and Methods: Prior to its commencement, approval to perform this study was granted by an internal, institutional review board and the Cantonal animal ethics committee. Commercially available 9.5mm Universal Humeral Nails (UHN) made of standard micro-rough TAN (average surface roughness: SRa: 0.98 μm), shot-peened stainless steel (Sra: 0.58 μm) and pastepolished TAN (Sra: 0.18 μm) were used. Implant surface characterization of each nail used was assessed by non-contact profilometry. Fourteen female, Swiss Alpine sheep were divided into 2 groups of 7 sheep each (no fracture was created in this model). Seven sheep were implanted with a standard microrough TAN nail in one tibia and a standard smooth stainless steel nail in the opposite tibia. The remaining 7 sheep were implanted with a standard microrough TAN nail in one tibia and a smooth paste polished TAN nail in the opposite tibia. The nails were left in place for 12 months. There were no complications with the sheep. After euthanasia a pullout test was performed on the nails from 6 sheep from each group. The nails from one sheep from both groups were kept in situ for histomorphometric evaluation. A statistical evaluation of the data was performed by a paired T-test.

Results: The pullout tests demonstrated that the stainless steel nails had a significantly lower pullout force than the standard TAN nails implanted in the same sheep (p=0.028) (Figure 1). Removal of the pastepolished nails is currently in progress, however, the first nail to be removed has demonstrated a markedly lower pullout force for the pastepolished nail in comparison with the standard TAN nail implanted in the same individual (Figure 2). The histological specimens are currently in preparation and the remaining pastepolished nails will be removed shortly.

Discussion: The results of this study successfully demonstrate the effect of implant surface polishing on reducing pullout force for intra-medullary nails. The preliminary results of the pullout test of the pastepolished nail shows less force is required for loosening of the nail compared to the stainless steel results here. We are currently evaluating whether the polishing will affect the resistance to infection. Our previous work of examining the effect of polishing of cortical screw type implants also reduced the removal torque required, but to a lesser degree, which we believe is due to the smaller 3D shape of the 3.5mm screws. The simple 3D nature of the nails responds well to polishing (as observed with the profilometry measurements). We believe that the results of this study may be used to modify surface design of TAN intra-medullary nails and thereby reduce the complications experienced during nail removal, especially in paediatric patients.

2. Richards RG, Pearce AI, Pearce SG, Mile S, Schneider E, Archer CW. In Vivo Evaluation of Titanium And Titanium Alloy Screws With Modified Surfaces to Minimize Bone Adhesion Transactions of the 53rd annual meeting of the orthopaedic research society.