

In vivo evaluation of cpTi and TAN screws with modified surfaces to reduce bony integration.

A.I. Pearce¹, S.G. Pearce¹, S. Milz¹, C.W. Archer², R.G. Richards¹

¹AO Research Institute, Davos, Switzerland. ²School of Biosciences, Cardiff University, Wales.

Introduction: Approximately 10% of paediatric patients undergoing surgery to remove implants experience complications¹ including increased operative time, increased blood loss, trauma to surrounding tissues, longer hospital stay and implant particulate debris contamination. *In vitro* studies show that surface topography of materials influences osteoblast proliferation, differentiation and phenotype. On smooth surfaces such as that of clinically used stainless steel, there is a loss of osteoblastic phenotype and an increase in proliferation and spreading of the cells. On microrough surfaces the osteoblastic phenotype is maintained and an increase in expression of genetic markers associated with bone formation has been found. We deduce that increased bone adhesion to implants is the major cause of the implant removal difficulties. We hypothesise that very smooth (polished) surfaces have less bone adhesion (strength and amount) than microrough implant surfaces. This study aims to assess the effect of surface topography of TAN (Titanium-6%Aluminium-7%Niobium) and commercially pure titanium (cpTi) screws on bone-implant adhesion in a new sheep cortical (tibia) and cancellous (rib) bone model.

Methods: Synthes cortical bone screws were used with a diameter of 3.5mm and a length of 10mm. The material types included stainless steel (SS) with an average surface roughness (SRA): 0.09 μ m (negative control), cpTi (TS), SRA: 0.82 μ m (as machined, positive control), TAN (NS) (as machined, positive control), SRA: 0.96 μ m, cpTi electropolished (TE), SRA: 0.09 μ m and TAN electropolished (NE), SRA: 0.30 μ m. Surface topography was assessed by non-contact white light profilometry and scanning electron microscopy (SEM) on a subset of screws. 18 female Swiss Alpine sheep were divided into 3 groups of 6 sheep each. One of each screw variant was implanted into the medial aspect of both tibial diaphyses (unicortical) and into the proximal 1/3 of ribs 8 and 9 (left side), each sheep having a total of 20 implants. The implants were left in place for 6 (group 1), 12 (group 2) and 18 weeks (group 3). The bones were then harvested and the peak removal torque was measured for screws from rib

9 and the right tibia from each sheep. The screws from rib 8 and the left tibia were left in situ and embedded in MMA before being stained with Giemsa and Eosin. The percentage of direct bone-implant contact was measured for each screw from the left tibia and the 8th rib.

Results: No surgical complications were detected in any of the groups. Measurements of the peak removal torque required to loosen the implants at 6 weeks, showed that polishing of screws made of both cpTi and TAN results in significantly lower torque for removal than standard microrough (as machined) screws when placed into cancellous bone (rib, $p < 0.02$; Fig.1). There was also a significant decrease in peak removal torque of polished compared with standard cpTi screws when placed into the cortical bone of the tibia (Fig.2). At 12 weeks the difference between the standard microrough screws and their polished variants was even more apparent ($p < 0.001$). A difference in the time course of response was found between the two bone types with regard to removal torque. In the rib, implants showed an increase in removal torque between 6 and 12 weeks followed by a decrease at 18 weeks. In the tibia, the implants demonstrated a continual decrease in removal torque over the 18 weeks. Histologically, the polished implants demonstrated a lower percentage bone contact than their standard micro-rough counterparts (Fig.4 & 5). In both bone types there was an increase in the mean percentage bone contact between 6 and 12 weeks (Fig.3).

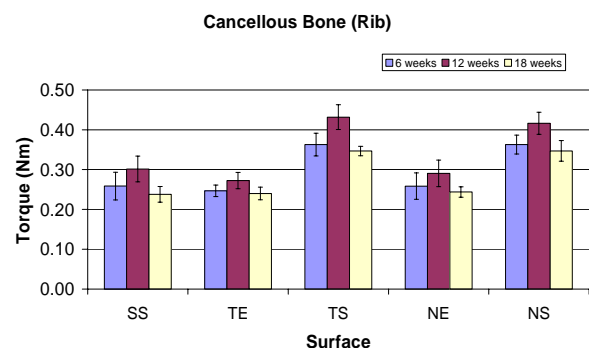


Fig1. Peak removal torque for implants placed into rib cancellous bone for 6, 12 and 18 weeks.

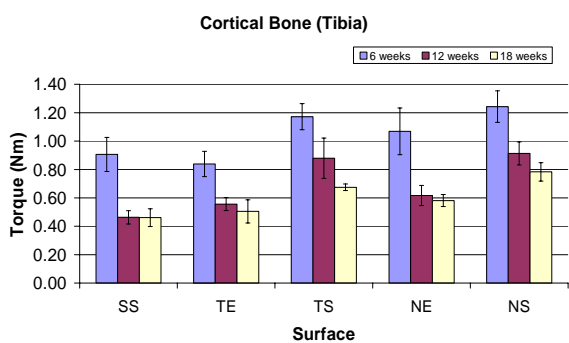


Fig2. Peak removal torque for implants placed into tibial cortical bone for 6, 12 and 18 weeks.

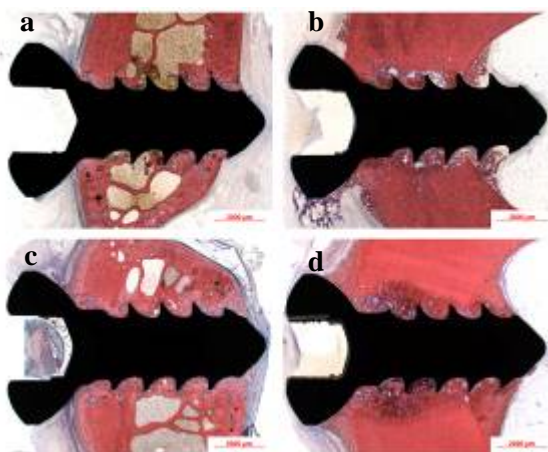


Fig3. Standard TAN screw a). Rib 6 weeks, b). tibia 6 weeks, c). Rib 12 weeks, d). Tibia 12 weeks (Giemsa-Eosin).

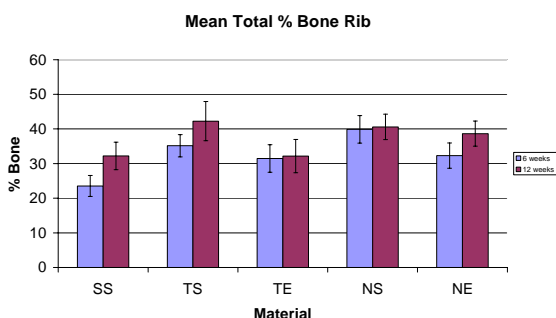


Fig4. Mean total % bone contact in rib implants at 6 and 12 weeks

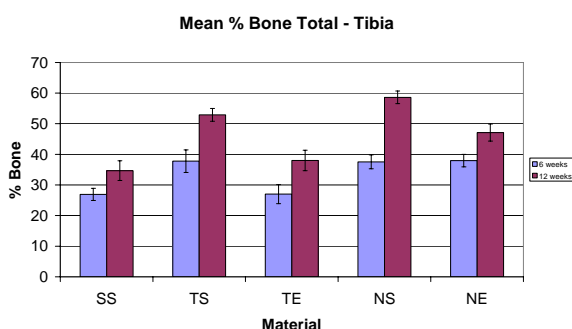


Fig5. Mean total % bone contact in tibial implants at 6 and 12 weeks

Discussion and Conclusion: This sheep model study successfully demonstrates the effect of implant polishing on both the strength and amount of bone-implant adhesion. The difference in the time course of response in removal torque between the rib and tibia may be due to a difference in the rate of bone turnover and remodelling between the ribs and tibia. Polig & Jee² have shown that in young adult beagles rib cortical bone has an annual turnover rate of approximately 18% while in the mid diaphysis of long bones it is less than 1%. In our study polishing of TAN resulted in a smaller decrease in removal torque compared to that of cpTi. This is probably due to the different effect of the polishing process on cpTi (pure α phase) to TAN (mix of α and β phase) leaving numerous protruding hard inclusion particles of TAN within the surface after polishing, resulting in a greater surface roughness than in cpTi.

The histological results demonstrate that surface polishing can reduce the amount of direct bone-implant contact. The results would suggest that the removal torque should increase in the tibia between 6 and 12 weeks, however this is not demonstrated in the measurements of removal torque. The histological measurements do not give a quantifiable assessment of the bone quality at the bone-implant interface. A more accurate estimation of this is given by the removal torque measurements. Our results would suggest that while there is an increase in the percentage bone contact in the tibial implants, the quality of the bone at the implant interface and hence the strength of bone attachment is reduced over the first 18 weeks in the tibia.

We can demonstrate a good correlation between surface roughness and torque removal as well as percentage of direct bone contact independent of the implant material (for the materials tested). Therefore polishing implant surfaces has the potential to reduce the torque required for their removal. We believe that the results of this study may be used to modify surface design of implants destined for removal, especially in younger patients and thereby reduce implant removal complications.

References: 1. T.P. Schmalzried et al. (1991) Metal removal in a pediatric population: Benign procedure or necessary evil? *J Pediatr Orthop* 11:72-76.
 2. E. Polig, et al. (1989) Bone structural parameters, dosimetry, and relative radiation risk in the beagle skeleton. *Radiat.Res.* 120.1: 83-101.