

Short term observations on Bonit[®] coated surfaces in self cutting implants

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INTRODUCTION: The stabilization of fractures in osteoporotic bone remains a challenging problem. A new type of implant for spinal fixation was developed to enlarge implant/bone interface and improve the osseointegration in osteoporotic bone. The implant is a perforated hollow cylinder, coated with a resorbable brushite coating (Bonit[®], Calcium / Phosphor 1/1.1, DOT GmbH, Germany). In an osteoporotic sheep model these implants were used for the stabilization of a spinal fusion¹. The implant showed bone ingrowth as expected, but a thin cell layer surrounding the cylinder surface was also visible after 16 weeks in situ. This observation led to the question whether the coating might have provoked these cellular reactions.

METHODS: Each implant was inserted after pre-drilling with a biopsy drill (7.35/6.45 outer/inner diameter) into the distal part of vertebra L3 or into the proximal part of vertebra L5¹. This was done in two animals and one of them was sacrificed immediately after the insertion of the first implant, the other two weeks after operation. From each animal an implant was collected and the bone removed. The implants were carefully washed, cleaned in an ultrasound bath and dried. Finally they were coated with a 10 nanometer Carbon layer and investigated in a light microscope (Axiotech, Zeiss, Germany) and in a scanning electron microscope (SEM, Hitachi S4100, Japan). The SEM was equipped with a secondary electron (SE) and a backscattered electron (BSE) detector. An energy dispersive X-ray analysis (EDX, Isis300, Oxford, UK) was also performed.

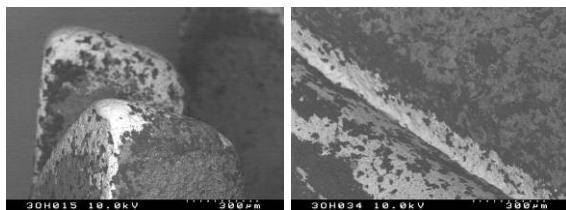


Fig. 1: BSE images of areas with worn off Bonit[®] coating on the outside of two teeth (left) and on a thread (right).

RESULTS: On both implants regions without Bonit[®] coating were found. The cutting edges of the implant (i.e. teeth, thread) exhibited

region where the coating was almost completely worn off (Fig. 1) independently of the time in situ. In regions not involved in the cutting process (i.e. small cross-holes, Fig. 2) the resorption of the Bonit[®] was clearly detectable after two weeks. Here approximately 30% of the surface was devoid of any coating. The cylindrical part between the teeth and the thread had lost the coating only in a few places. The EDX analysis confirmed Calcium and Phosphor in the coating and Titanium in the substrate.

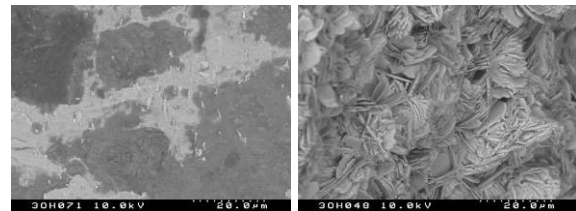


Fig. 2: Cross hole of an implant. After 2 weeks (left) most of the coating is resorbed (bright areas) compare to the original surface (right).

DISCUSSION & CONCLUSIONS: The present results suggest that the Bonit[®] coating is worn off in regions subjected to significant amounts of shear forces during implantation and possibly also during explantation. This especially includes the edges of the self cutting tread and the outer edges of the teeth. Here the implant obviously does not provide a design suitable for coating with Bonit[®]. According to Capello et al.³ such critical parts of an implant need to be optimized for the type of coating used here.

The amount of resorption observed in regions shielded from shear forces is comparable to that reported by Szmuckler et al.² after 6 weeks in non osteoporotic pig jaw.

REFERENCES: ¹Kossmann T et al.(1999) *Orthopäde* 28:432-40. ²Szmuckler et al.(2000) *Proc. 13th Int. Symp. on Ceramics in Medicine*, Milan, 395-8. ³Capello et al. (1998) *Clin. Orthop.* 355:200-11.