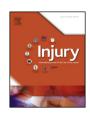
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Titanium and steel fracture fixation plates with different surface topographies: Influence on infection rate in a rabbit fracture model



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ABSTRACT

Introduction: Implant-related infection is a challenging complication in musculoskeletal trauma surgery. In the present study, we examined the role of implant material and surface topography as influencing factors on the development of infection in an experimental model of plating osteosynthesis in the rabbit. *Methods*: The implants included in this experimental study were composed of: standard Electropolished Stainless Steel (EPSS), standard titanium (Ti-S), roughened stainless steel (RSS) and surface polished titanium (Ti-P). Construct stability and load-to-failure of Ti-P implants was compared to that of Ti-S implants in a rabbit cadaveric model. In an *in vivo* study, a rabbit humeral fracture model was used. Each rabbit received one of three *Staphylococcus aureus* inocula, aimed at determining the infection rate at a low, medium and high dose of bacteria. Outcome measures were quantification of bacteria on the implant and in the surrounding tissues, and determination of the infectious dose 50 (ID₅₀).

Results: No significant differences were observed between Ti-S and Ti-P regarding stiffness or failure load in the cadaver study. Of the 72 rabbits eventually included in the *in vivo* study, 50 developed an infection. The ID₅₀ was found to be: EPSS 3.89×10^3 colony forming units (CFU); RSS 8.23×10^3 CFU; Ti-S 5.66×10^3 CFU; Ti-P 3.41×10^3 CFU. Significantly lower bacterial counts were found on the Ti-S implants samples compared with RSS implants (p < 0.001) at the high inoculum. Similarly, lower bacterial counts were found in the bone samples of animals in the Ti-S group in comparison with both RSS and EPSS groups, again at the high inoculation dose (p < 0.005).

Conclusion: No significant differences were seen in susceptibility to infection when comparing titanium and steel implants with conventional or modified topographies. Ti-P implants, which have previously been shown in preclinical studies to reduce complications associated with tissue adherence, do not affect infection rate in this preclinical fracture model. Therefore, Ti-P implants are not expected to affect the infection rate, or influence implant stability in the clinical situation.

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Introduction

One of the major complications in musculoskeletal trauma surgery is implant-related-infection. These infections are difficult to treat and have a significant socio-economic impact [1,2]. In spite of improvements in implant design, improvements in surgical technique, and the routine use of prophylactic antibiotics, implant-related infection remains an ever-present problem [3]. In terms of the role played by the implant itself, various implant-specific design or application features may influence infection

susceptibility. Such features include the type of metal (e.g. stainless steel, titanium), the surface topography (e.g. microrough, polished), and the type of plate (e.g. locking compression plate (LCP), dynamic compression plate (DCP)) [4–6].

Stainless steel, titanium and titanium alloys (e.g. titanium–6% aluminium–7% niobium, TAN) are the most common materials used in the manufacture of fracture fixation implants [7,8]. The difference in infection susceptibility between these metals has been a topic of research for over 20 years [9]. Experimental data in animal studies have indicated that titanium is superior to Electropolished Stainless Steel (EPSS) with regard to infection susceptibility [4,6,10] and this has generally been attributed to superior biocompatibility of titanium and the observation that fibrous capsules tend to form around EPSS implants. A small number of clinical studies [11–14] have seemed to corroborate

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these preclinical findings to a degree, although the effect appears to be marginal and limited to studies with relatively small patient numbers. In an attempt to define the infection susceptibility of common implant materials and topographies in a controlled manner, the infection susceptibility of titanium, TAN and EPSS LCP implants was previously assessed in an experimental setting using a non-fracture rabbit model [15]. However, no statistically significant differences were found between these materials as standard, or when the surfaces of the titanium implants were polished. It is likely that the fracture may be a critical component in the risk of infection since previous studies have shown that fracture stability is of paramount importance with respect to infection prevention and treatment [2].

The aim of this study was to define the role of implant material and surface topography in a preclinical *in vivo* model incorporating appropriate fracture biomechanics and bone healing. Such information would provide definitive preclinical proof as to whether the material, or surface topography, of fracture fixation devices plays a significant role in infection susceptibility with locking plates.

Materials and methods

Implant manufacturing

The LCPs used in this study were commercially available implants for human medicine (52 mm long, straight, 7-hole, 2.0 mm LCPs, DepuySynthes, New Jersey, USA). In total, four implant variants were included in this study: standard commercially available Electropolished Stainless Steel (EPSS); standard commercially available titanium (Ti-S); surface-roughened Stainless Steel (RSS); and surface polished Titanium (Ti-P) (Fig. 1).

The RSS plates were created from what were originally standard EPSS plates. The plates were roughened with a water jet, operating with an injector diameter of 0.3 mm, water pressure of 3800 bar and a speed of 250 mm/min. The entire upper and lower surface of the plate was treated, except a small circular margin along the most proximal and distal screw holes, where the plate was held under the waterjet (Fig. 1). The Ti-P plates were created from what were originally Ti-S plates by KKS Ultraschall AG, Switzerland. The polished screws are hereafter named TAN-P, and unpolished standard equivalents TAN-S. All implants were finally intensively rinsed with deionised water and dried. Prior to implantation, all LCPs and screws were rinsed with deionised water and steam autoclayed.

Surface characterisation

The surface topography of the standard and modified LCPs was quantitatively measured by non-contact, white light profilometry (FRT MicroProf 200 Profilometer, Fries Research & Technology, Germany). The surface topography was imaged with a Hitachi S-4700 field emission scanning electron microscope (SEM) operated in secondary electron (SE) detection mode at an accelerating voltage of 5 kV, emission current of 40 μA and a working distance of 12 mm.

Mechanical testing

Construct stability and load until failure of the Ti-P implants was compared to that of the Ti-S implants. Sixteen cadaveric rabbit humeri (n = 8 rabbits) were subjected to the same surgical procedure for the Ti-S and Ti-P groups as described for the in

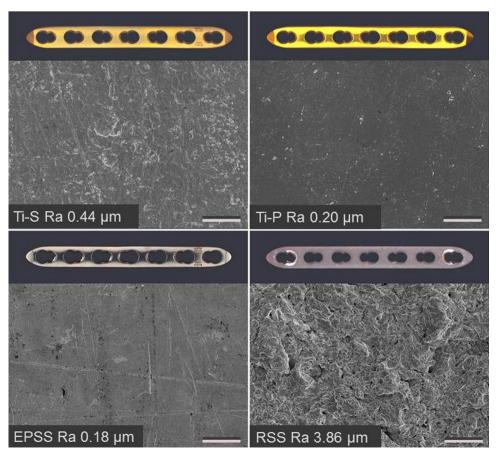


Fig. 1. The four LCP implants used in this study are shown as a SE micrograph and regular light microscopic image. Implants included were (upper left) Ti-S; (upper right) Ti-P; (lower left) EPSS; (lower right) R-SS (scale bar 50 μm).

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