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In vivo degradation of a new concept of magnesium-based rivet-screws in the minipig mandibular bone

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ABSTRACT

Self-tapping of magnesium screws in hard bone may be a challenge due to the limited torsional strength of magnesium alloys in comparison with titanium. To avoid screw failure upon implantation, the new concept of a rivet-screw was applied to a WE43 magnesium alloy. Hollow cylinders with threads on the outside were expanded inside drill holes of minipig mandibles. During the expansion with a hexagonal mandrel, the threads engaged the surrounding bone and the inside of the screw transformed into a hexagonal screw drive to allow further screwing in or out of the implant. The in vivo degradation of the magnesium implants and the performance of the used coating were studied in a human standard-sized animal model. Four magnesium alloy rivet-screws were implanted in each mandible of 12 minipigs. Six animals received the plasmaelectrolytically coated magnesium alloy implants; another six received the uncoated magnesium alloy rivet-screws. Two further animals received one titanium rivet-screw each as control. In vivo radiologic examination was performed at one, four, and eight weeks. Euthanasia was performed for one group of seven animals (three animals with coated, three with uncoated magnesium alloy implants and one with titanium implant) at 12 weeks and for the remaining seven animals at 24 weeks. After euthanasia, micro-computed tomography and histological examination with histomorphometry were performed. Significantly less void formation as well as higher bone volume density (BV/TV) and bone-implant contact area (BIC) were measured around the coated implants compared to the uncoated ones. The surface coating was effective in delaying degradation despite plastic deformation. The results showed potential for further development of magnesium hollow coated screws for bone fixation.

1. Introduction

In orthopaedic surgery, metallic implants may be left inside the body permanently beyond fulfilling their purpose of providing stability to the human skeleton.

In craniomaxillofacial surgery, many of these implants require removal after bone healing [1–3] as they incommode patients. A second surgery, however, increases patients' morbidity as well as surgical costs. Hence, the research and clinical community is interested in developing bioresorbable materials with biocompatibility, strength, radiovisibility, and osseointegration properties comparable to titanium.

Magnesium is an essential element for the metabolism and nutritional intake is 300–400 mg per day. Magnesium is also the lightest engineering metal and plays an important role in a broad variety of structural applications in transport and consumer goods industries [4,5]. Given its biodegradable capacity, biocompatibility, mechanical strength and ability for visualisation on radiographs [6,7], magnesium is a promising candidate for development [8–10]. Magnesium has already been clinically tested and successfully implanted as a biodegradable stent for cardiovascular procedures [11]. In orthopaedic surgery, first results of a prospective randomised study show similar good bone fixation after hallux valgus operation with magnesium screws as compared to titanium screws [12].

Magnesium and magnesium alloys are known to degrade to hydrogen gas and magnesium hydroxide when in contact with body fluids due to their limited corrosion resistance [6,13–17]. There are various ways to control the corrosion rates and consequent gas formation. A slow corrosion process can be achieved by adding rare earth elements or by coating the implant surface with a corrosion resistant layer [4,18–22]. The total gas formation can be reduced when the amount of magnesium implanted is reduced [23,24]. Additionally, the corrosion rate varies with the contact surface size of the implanted magnesium and with the surrounding tissue ion composition, osmolality,

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temperature, pH, and cell response [6,25–30]. The type and structure of the bone may influence the biodegradation [31]. Henderson et al. [28] found variable degradation rates of screws in the rabbit mandible, depending on their location in the bone, whether the screws were in the cortical bone or in the marrow space. In fact, little is still known about the degradation process of human standard-sized magnesium screws in cortical bone and surrounding bone reaction, specifically when the implant is almost fully embedded in the bone. There is a limitation in the insertion of magnesium screws by self-tapping in hard bone due to the limited torsional strength of magnesium alloys in comparison with titanium or steel [32,33].

Based on these considerations, a new type of expandable magnesium cylindrical hollow screw has been developed. The surface of the screw has been plasmaelectrolytically coated to reduce the initial rate of corrosion. The aim of this study was to investigate the degradation process of this new screw type in the mandibular bone of minipigs. We assessed the specific hard tissue response to the coated and uncoated implants, and checked if the surface coating is effective in controlling the corrosion rate despite the plastic deformation during the withdrawal of the mandrel. To achieve these aims, we performed an in vivo study on miniature pigs in order to use same sized implant as in humans. To evaluate the efficacy of the coating after different degrees of expansion, rivet-screws with two different diameters were compared.

2. Material and methods

2.1. Implants

The rivet-screw used in this study was a tubular implant with threads on the outside (Patent number US 8974508B2, [34]) as shown in Fig. 1. Two different rivet- sizes with identical wall thickness were used, a small rivet "a" (outer diameter Ø = 2.43 mm, inner diameter Ø = 2.1 mm, length = 6.0 mm, thickness = 0.165 mm) and a slightly larger rivet "b" (outer diameter Ø = 2.53 mm, inner diameter Ø = 2.2 mm, length = 6.0 mm, thickness = 0.165 mm). The rivet was first inserted into a drill hole (drill hole outer diameter of 2.5 mm for the small rivet and 2.6 mm for the large rivet). The rivet was then expanded and pressed against the bone wall by pulling back a mandrel with a hexagonal shape (Fig. 2).

During the expansion with the hexagonal mandrel, the threads engaged the surrounding bone and the inside of the rivet were transformed into a hexagonal screw drive. This transformation from a rivet into a hollow screw allows further screwing in or out of the implant. The two rivets with different diameters but identical wall thickness were expanded using the same hexagonal mandrel. As the inner diameter of rivet-screw "a" (Ø = 2.1 mm) was smaller than for rivet-screw "b" (Ø = 2.2 mm), rivet-screw "a" was deformed to a higher degree than rivet-screw "b". For rivet-screw "a", the expansion was close to the limit of plastic deformation of the used magnesium alloy. Less ductile material would lead to implant failure during expansion. In addition, the shear forces during the pulling back of the mandrel required a high adherence and damage tolerance of the coating. Although the diameter increase of 0.1 mm of rivet-screw "b" is small, it could have a large influence on failure behaviour, residual stress and degradation.

Rivet-screw "b" required a bigger drill hole and was submitted to a lesser degree of plastic deformation and shearing. In addition, the pressure exerted by the two types of rivet-screws onto the bone was presumably different due to the strain hardening of the material.

The interest of using these two geometries was therefore to see if these different starting conditions and accordingly the different deformation degrees of the implants had an influence on the degradation rate.

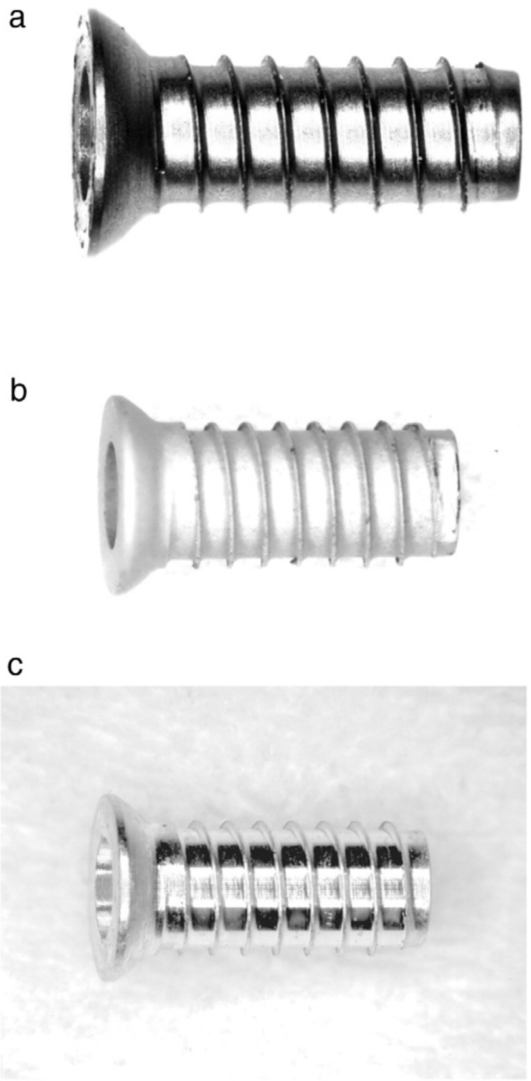

Fig. 1. Macroscopic image of the used titanium rivet-screw (a), macroscopic view of a magnesium rivet-screw with plasmaelectrolytic coating (a) and without coating (b).

All magnesium implants used in this study were made of a modified WE43 alloy based on the ASTM B80 standard for WE43 (chemical composition: Mg-Y-Nd-heavy rare earths). The Elektron SynerMag® alloy used was developed and manufactured by Magnesium Elektron (Swinton, UK). Half of the magnesium hollow screws received a 10 μm thick plasmaelectrolytic coating from AHC® (Kerpen, Germany) using a proprietary Magoxid® electrolyte (Fig. 1b & Fig. 3); the other half was used without a coating (Fig. 1c). X-ray photoelectron spectroscopy (XPS) measurements of rectangular plates with an angled polishing allowed a chemical analysis across the thickness of the coating. The coating was mainly composed of magnesium phosphate $Mg_3(PO_4)_2$ with some traces of Yttrium and Neodymium; no other rare earth could be identified inside the coating.

The magnesium implants were machined dry using hard metal tools, cleaned with ultrasound assistance in 90–100% ethanol, dried in air, packaged in vacuum pouches, and gamma-sterilised with a dose of 25–30 kGy.

For the control group, a drill hole of 2.25 mm in diameter and prototype rivet-screws made of pure titanium (cp Ti grade 2) were used (outer diameter Ø = 2.2 mm, inner diameter Ø = 2.1 mm, length = 6.0 mm, thickness = 0.05 mm).

2.2. Experimental animals and treatment groups

All animal experiments were conducted according to the Swiss federal animal welfare legislation and in accordance with the Swiss Animal