Bioresorbable RE-free Mg-Zn-Ca screws in a growing sheep model

J Eichler[1], SF Fischerauer[1], L Berger[3], E Martinelli[1], M Cihova[4], T Kraus[2], JF Löffler[4], AM Weinberg[1]

[1] Dept of Orthopaedics, Medical University Graz, Graz, AT. [2] Dept of Paediatric Orthopaedics, Medical University Graz, Graz, AT. [3] Institute of Building Construction and Technology, Vienna University of Technology, Vienna, AT. [4] Laboratory of Metal Physics and Technology, Dept of Materials, ETH Zurich, Zurich, CH.

INTRODUCTION: Screw osteosynthesis represents a gold standard method for the treatment of small and middle sized bone fragment fractures. Stabilization of corresponding fragments are surgically fixated by screw osteosynthesis with stainless steel or Titanium implants. However, unwanted side effects like loosening, inflammatory reactions and discomfort may be a consequence which makes screw removal by a second surgical intervention obligatory. Biodegradable Mg screws achieve adequate mechanical properties, render a removal intervention and might additionally be able to support the healing process. In the past, a huge drawback of Mg implants was their fast degradation rate, which can be retarded by alloying additional rare-earth (RE) elements. Nevertheless, they are considered to be noxious and not suitable for the human body, especially for a growing skeleton.

A first RE-free Mg-Zn-Ca alloy with 5 wt.% Zn (ZX50) developed huge amounts of gas inside the bone and was degrading too rapid [1]. Another Mg-Zn-Ca alloy, containing less Zn (ZX10) showed promising degradation characteristic hydrogen gas evolution in [2].

The aim of this study was to evaluate degradation, gas evolution and bone-implant interface reaction on Zn-poor Mg-Zn-Ca (ZX00) screws in an *in vivo* sheep model. An additional group with surface treatment (polishing) was evaluated towards the influence of expected surface impurities caused by the manufacturing process.

METHODS: n=7 RE-free Mg screws with d=3.5 mm and l=16 mm were manufactured using the alloy ZX00 (Mg–0.3Zn–0.4Ca) and divided into two groups. N=3 screws were surface treated (polishing with ethanol and phosphoric acid) and n=4 screws were used without this treatment. Implants received cleaning, packaging and gamma sterilization treatment and were implanted into diaphyseal right tibiae of two growing sheep (n=1 with polished screws and n=1 with unpolished screws). Animal trials were accredited by the Austrian Ministry of Science, Research and Economy, accreditation number BMWFW-66.010/0190-WF/V/3b/2014.

Screws were inserted after performing small incisions in the mid-diaphyseal region and the proximal and distal diaphysis. Tissue was mobilized carefully to avoid any harm. A monocortical drill-hole was made and a thread was cut in advance. After insertion, the wounds were closed in layers. Interventions were performed under sterile clinical conditions and general anaesthesia. Clinical CT imaging (Siemens Sensatom 64) was performed after 2 and 6 weeks. After week 6 both animals were euthanized and their tibiae were harvested and evaluated with Siemens Inveon micro CT for distinct bone incorporation and bone and tissue reactions. Implant volume, surface and gas volume was quantified with Materialise MIMICS, ver. 17.

RESULTS: All screws were well tolerated without adverse effects (redness, swelling) or osteolyses. New bone formation was found forming a tight bone-screw interface which differs in slightly lower bone contact for the polished screws. Moderate degradation and low amounts of gas were examined for polished and unpolished versions.

DISCUSSION & CONCLUSIONS: The slightly lower bone contact of polished ZX00 screws may be caused by changed surface condition or volume loss through polishing. However, further investigations are required to assess long term effects.

REFERENCES: [1] T. Kraus et al. (2012) *Acta Biomater* **8**:1230-8. [2] J. Hofstetter et al. (2014) *JOM* **66**: 566-72.

ACKNOWLEDGEMENTS: This work was financially supported by Laura Bassi BRIC, Austrian Promotion Agency.