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Degradable metallic implants - assessment of the current situation

Aging populations and a rise in osteoporosis-related fractures will sustain a need for orthopaedic intervention. In addition, juvenile patients and active adults exhibiting risky sporting activities also require perfect care. So far, these indications are treated mainly with non-degradable metal implants or in some cases also polymers. From the patient's point of view, degradable implants would clearly be preferred. Here degradable magnesium-based implants could become an alternative to permanent metallic implants which have to be removed after healing, or to replace degradable polymers which do not always show the required mechanical properties. Mg and its alloys degrade under physiological conditions. The great challenge here is to tailor the degradation in a manner that is suitable for a biological environment. Fast or uncontrolled corrosion is associated with strong hydrogen and ion release and severe pH changes, which can lead to a fast loss of mechanical stability and undesirable biological reactions. Since these processes are highly complex in a living system and sufficient data describing the degradation *in vivo* is missing, it is very difficult to produce knowledge based new alloys. Therefore, the development of new biodegradable Mg-based implants is strongly relying on the understanding of the degradation process in the living organism and the creation of an appropriate test system *in vitro*. Still, the endeavor is successful: one CE certified Mg-alloy compression screw (Magnezix, Syntellix AG, Germany) and a Mg-based drug-eluting stent (Magmaris, Biotronik AG, Germany) are in the market. In addition, in China and Korea patient trials (hip surgery and hand fracture) are reported. This presentation will outline the current status of Mg-implants and which perspectives Mg based implants could have.

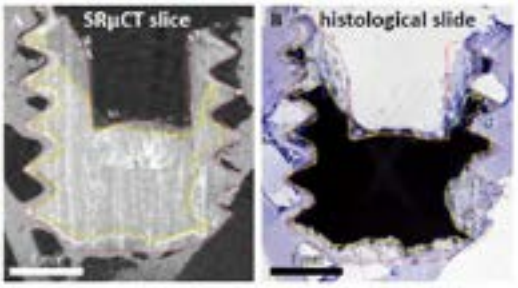

Figure 1: How much of the implant is left? Comparison between synchrotron radiation (SR) μCT (spatial resolution 2 μm) and histology shows the difficulty to quantify the actual remnants of the screw. This is even more true for patient images (image taken from [5]). Red line: contours of the degradation layers. Yellow line: contours of the residual metallic alloy.

Recent publications

1. L Wu, F Feyerabend A F Schilling, R Willumeit Römer, B J C Luthringer (2015) Effects of extracellular magnesium extract on the proliferation and differentiation of human osteoblasts and osteoclasts in coculture. Acta Biomat. 27:294-304.
2. B J C (2016) Luthringer, R Willumeit Römer (2016) Effect of magnesium degradation products on mesenchymal stem cell fate and osteoblastogenesis. Gene 575(1): 9-20.

3. K Jähn, H Saito, H Taipaleenmäki, A Gasser, N Hort et al. (2016) Intramedullary Mg2Ag nails augment callus formation during fracture healing in mice. Acta Biomater. 36:350-360.

4. Ahmad Agha, Nezha R, Willumeit Römer, Daniel Laipple, Berengere Luthringer, Frank Feyerabend et al. (2016) The degradation interface of magnesium-based alloys in direct contact with human primary osteoblasts cells. PLoS One. 11(6):e0157874.

5. S Galli, J U Hammel, J Herzen, T Damm, R Jimbo et al. (2016) Evaluation of the degradation behavior of resorbable metal implants for *in vivo* osteosynthesis by synchrotron radiation-based x-ray tomography and histology. Proc. SPIE 9967, Developments in X-Ray Tomography X, 996704 doi:10.1117/12.2237563.

Biography

Regine Willumeit Römer started as a Physicist studying structure and function of the ribosome. After her habilitation in biochemistry she worked on membrane active antimicrobial peptides and implant coatings (for permanent Titanium-based implants). In parallel she started working on biodegradable magnesium-based implant materials. In her division Metallic Biomaterials (Institute for Materials Research, Helmholtz-Center Geesthacht) the full value chain is covered: from fundamental materials design and production via different processing routes (cast and powder metallurgy), the study of degradation mechanisms towards the biological assessment of the material in cell culture and animal models.

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