Degradation behaviour of magnesium-alloy screws after distal metatarsal osteotomies in MRI

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Summary
Introduction: Magnesium (Mg) alloys have been introduced as a new material for biodegradable implants. Little is known about their behaviour in MRI and the appearance of the resorption process in humans.
Materials and Methods: Four patients were examined with MRI after distal metatarsal 1 osteotomy using a biodegradable Mg-screw. The examinations were carried out at 3, 6, 12 and 36 months after surgery.
Results: The Mg implants showed the expected degradation, but also a concomitant bone marrow oedema, not corresponding to the good clinical results. These were comparable to previous studies with standard steel or titanium implants.
Discussion: The implants proved to degrade in humans, nevertheless larger studies and comparative studies to standard screws are necessary for final conclusions.

Introduction

Implants of steel and titanium are, with regard to the quality of imaging using magnetic resonance imaging (MRI), a not inconsiderable source of artifacts and therefore make evaluation more difficult [8]. Due to the large difference in the magnetic properties between implants and surrounding tissue there are strong local magnetic field inhomogeneities. This results in typical susceptibility artifacts with signal loss, putative signal increases and geometric distortions [7].

New implants, such as that presented here of a resorbable magnesium alloy represent an alternative which due to the reduced magnetic susceptibility of magnesium, result in significantly fewer artifacts than from conventional implants of titanium or steel. As a result of which the evaluation of the imaging, above all in the area close to the implant, can be significantly improved [3, 5].
A further advantage when using resorbable implants is the lack of the need to remove any metal. In the case of conventional metal implants, a variety of factors may make removal of metal necessary. Thus in some implants bone degradation processes take place due to the relief and stress shielding of the bone by the implants (stress shielding) [3, 4]. The material, above all when there is only a thin soft tissue covering, is perceived as a nuisance by patients, sometimes even as painful [2]. In such cases a resorbable implant material waives the need to remove the metal.

Various magnesium alloys have demonstrated good biocompatibility in animal tests [10] and in first clinical applications on humans [9, 11]. The alternatively available resorbable implants made with polymers contrast by having more or less strong tissue reactions after implantation [12].

Innovative magnesium alloys are intended to avoid the disadvantage of previously available bioabsorbable and non-resorbable standard implants. In the first clinical study comparable results were demonstrated in the use of magnesium alloy with standard titanium implants [11].

In order to gain better knowledge of the behaviour of the material in humans, the reaction behaviour of the implant and the degradation process are to be investigated in MRI. The MRI is in this case a reliable imaging technique used in post-operative course assessment in the field of forefoot surgery [6].

Materials and Methods

Study execution

This is a case series. The patients were subjected respectively to MRI and a clinical examination with documentation of local status and collection of the AOFAS, FAAM scores, the VAS and patient satisfaction. Four patients, treated during and after the clinical study (OP period 2009 to 2014) were willing to take part in the study. The follow-up investigations took place 3, 6, 12 and 36 months post-operative (Table 2).

Table 1 Technical parameters of MRI examination

The participants were all female, average age was 53.5 years. The study was approved by the responsible ethics commission. All patients consented to the examination.

Operating technique and implant

The operation took place recumbent under regional anaesthesia. A lower leg tourniquet was placed. Via a separate dorsal incision the M. add. hallucis and the lateral sesamoid ligaments were separated. There then followed a strictly medial skin incision and presentation of the MTP-1 joint capsule. In the case of plantar advanced M. abd. hallucis there then followed the separation and subsequent anatomic refixation. The capsulotomy took place with an L-shape, this was followed by removal of the pseudoxostosis and a guide-wire was inserted to mark the direction of the osteotomy. There then followed a modified Chevron-osteotomy while maintaining a long plantar lower leg in order to avoid compromising circulation in the head. Then the metatarsal 1 head was moved into the desired position and temporarily fixed with a guide/wire; clinical and radiological position control followed by drilling using the wire with the drill bit and the reamer, whereby care is taken to ensure the reamer is fully immersed to enable countersinking of the screw head. The MAGNEZIX® screw (Syntellix AG, Hannover, Germany) is then inserted, length of screw 20 mm. There then followed the removal of the metatarsal excess, sealing of the joint capsule and refixation of the M. abd. hallucis. Based on
the clinical and radiological images it was then decided whether an Akin osteotomy was undertaken or not. All patients were mobilised post-operatively under full load with therapeutic shoes with a hard sole for six weeks. Physiotherapy was recommended after wounds were in a dry condition. Clinical and radiological controls took place after 6 and 12 weeks and approx. one year post-operative.

Radiological diagnostics

The examinations took place in a 3T-MRT unit (Magnetom Skyra, Siemens Healthcare, Erlangen, Germany), with a 16-channel ankle coil at time intervals of 3, 6, 12 and 36 months post-operative. A standardised examination protocol was used in the following sequence: T1 SE coronar and sagittal and TIRM coronar, sagittal and axial with a slice thickness of 2 mm (coronar and sagittal) and 5 mm (axial). The bandwidth (ARP) was adjusted to optimise artifact reduction. For exact details of examination parameters see Table 1.

Results

MRI

In the first post-operative control after three months the osteotomy gap was imaged with partial bone growth. This was accompanied by a reactive post-operative bone marrow oedema and an oedema of the host soft tissues. The screw contour is almost completely identifiable based on a restricted signal loss (Fig. 1).

After 6 and 12 months the osteotomy zone could only be delimited residually. In some cases there continued to be a non-specific oedema in the immediate neighbourhood of the osteotomy. The typical susceptibility artifacts of the magnesium screw (in particular "signal loss" and "signal pile up") reduced over time such that the screw canal was only incompletely imaged.

(Figure)

3 months 6 months 12 months 36 months

Figure 1: Selected patients with sample imaging of magnesium screw at various points in time. During the course the susceptibility artifacts are significantly regressive, matching the increasing implant resorption (white area). After 12 and 36 months there is evidence of a discrete joint effusion and subchondral cysts (arrow tips).

Over the long term course after 36 months with progressive implant degradation there is significant signal loss (Fig. 1).

It is possible to isolate a number of areas free of signals, the former length of the screw can no longer be identified. Accompanying this, the patient had a residual discrete bone marrow oedema in metatarsal 1 head and subchondral stony cysts and a slight joint effusion in the great toe base joint.

Discussion

The observed degradation behaviour in the MRI of the implant corresponds with the demands made of the implants. In all cases investigated there was a well observed growth of the osteotomy zone with concurrent resorption of the implant. Thus after 36 months there were only isolated susceptibility artifacts identifiable, which are most likely residues of the implant.
In the image morphology artifacts are also possibly caused by intra-operative metal abrasion. Throughout the entire period of the implant resorption bone marrow oedemas occurred differing widely per individual. The occurrence of the oedemas during the degradation process appears not to be related to the post-operative growth of the osteotomy. In the cases investigated there is also no apparent correlation to the clinical findings. Similarly the extent of signal loss and geometric distortion artifacts differ greatly case by case. This coincides with a diverse rate of degradation per individual.

In the study the Mg implants had a clear advantage with respect to MRI imaging. Even in vitro the MRI and CT investigation of magnesium implants have in general fewer artifacts than the standard implants of titanium and steel [1, 5]. The assessment of the osteotomy zone and the adjacent bone marrow reaction is much milder in the case of the magnesium screw in comparison with conventional titanium screws, due to the reduced susceptibility of magnesium and hence the much reduced artifacts. This is also seen in vitro and in cadaver examinations [1].

With respect to characterisation of the degradation processes in vivo further investigations are necessary with greater numbers of patients. In this MRI imaging would be the method of choice due to the advantages named for the magnesium implant and the absence of radiation doses.

Further investigations should also seek to investigate more closely the correlation of degradation rate and intensity with blood supply, physical stress, sporting activities, age, gender and complaints and other factors influencing the resorption rate.

Parallel investigations of a titanium comparative group also appears to be urgently required in order to arrive at a differentiated statement above all with respect to the comparability with the standard titanium implant. Furthermore this would enable the occurrence or persistence of marrow oedemas in the long-term resorption process to be better characterised. In clinical terms the patients investigated in this study treated with magnesium implants achieved good outcomes, as did the pre-study [11].

**Conflict of interest**

The execution of the study was supported by the Syntellix AG company. HWI is a member of the Syntellix AG supervisory board.

**References**


