Original article on the subject of
Short-term results after distal metatarsal osteotomies for hallux valgus, using a biodegradable Magnesium-implant

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Summary
Introduction: Biodegradable implants can help to minimize the risk for hardware removal after forefoot surgery. Magnesium-alloy implants are a new material for this indication.
Material and Method: 22 patients treated for symptomatic Hallux valgus deformity, by a distal metatarsal osteotomy, using a biodegradable Mg-Implant could be included in a prospective study.
Results: One patient had a traumatic dislocation of the osteotomy and had to be revised, all other showed a fast and uneventful bony healing. Clinical results were comparable to previous studies for distal metatarsal osteotomies.
Discussion: Implants made of Mg-alloys are a new alternative for biodegradable implants. Due to the short follow-up period and small patient collective, further studies have to be conducted for a final judgment.

Introduction

The necessity of removing implants after bone surgery in orthopaedics and maxillofacial surgery (OMF) represents a significant problem. Although there is no fundamental recommendation to remove orthopaedic implants, the necessity may arise due to a subjective nuisance or an actual irritation caused by the hardware. The interventions associated with this represent up to 5% of all orthopaedic interventions. In particular in the case of foot and ankle surgery, the proximity of anatomical structures and the thinness of the soft tissue cover result in more frequent indications for hardware removal [1]. These operations signify an in part considerable amount of effort and costs as well as a risk for the patients. For example studies indicate high complication rates caused by the removal of metalwork [2, 13, 15] and a lack of improvements to complaints and an increase in levels of complaint amongst some patients [1].

Therefore, the use of resorbable implants which degrade in a controlled fashion after healing of the bone structures makes sense. Whereas in the case of OMF surgery this has become a regular option in many cases, in the field of surgery on extremities only in a limited fashion.
Since biodegradable implants generally have lower biomechanical stability [4, 9] than non-resorbable implants, they are mainly used for indications in which the removal of metalwork is necessary or in which reduced biomechanical strength is acceptable [8, 11, 12, 14, 23].

The degradation of the polymers used to date results in various tissue reactions dependent upon the materials used, monomers, polymerisation degree, purity and mechanical stress [5]. The in part strong tissue reactions observed have limited the use of these materials [3, 4, 10, 16].

In order to avoid the disadvantages of the polymer-based resorbable implants used to date, an innovative magnesium alloy was developed. This alloy boasts higher strength than previous degradable materials and is said to be non-problematic in terms of absorption. The alloy demonstrated promising results in the animal model and in the first clinical study [22]. In the further course patients treated with this implant took part in a prospective follow-up study.

**Material and methods**

The study, in the period from August 2013 to February 2015, included all patients in which treatment of symptomatic hallux valgus (HV) was planned using a MAGNEZIX® screw (Syntellix AG, Hannover, Germany) by Chevron osteotomy. The surgical indication was symptomatic and conservative therapy of Hallux valgus (HV) with an intermetatarsal angle 1-2 (IMA) smaller than 15° and indication for Chevron osteotomy. Knock-out criteria were age below 18 years, relevant osteoporosis (existing or evaluated intraoperatively) or formation of cysts in the metatarsal-1 (MT1) head area. Treatment was offered to all patients during the pertinent period who satisfied the inclusion criteria.

The study was approved by the responsible ethics commission. All patients consented to the study.

For all patients, standardised clinical and radiological controls were planned pre-, 6, 12 weeks and one year post-operative. The clinical parameters were collected according to AOFAS forefoot scores, FAAM, SF-36 and subjectively for the state of swelling. In addition standardised radiographs under load were taken a.p. and laterally. Based on the x-rays the IMA, HV angle (HVA) and degenerative changes to the metatarsophalangeal joint (MTP) were analysed in accordance with Kellgren-Lawrence scores. Furthermore all resorption products occurring (gas) in the soft tissues and osteolyses were documented. These were then evaluated as “none”, “slight” (up to 1 mm), “medium” (up to 3 mm) or “serious”.

**Operating technique**

The operation followed a standard procedure. Initial lateral release through an intermetatarsal skin incision by tenotomy of the M. add. hallucis tendon and separation of the lateral sesamoid ligaments. This was followed by a medial skin incision over the MTP-1 joint. The M. abd. hallucis tendon was identified and separated from the capsule in pathological position, retracted and refixed in anatomical position at conclusion of the operation. After this the capsulotomy took place with exposure of the MTP-1 joint. Any medial pseudoxostosis was removed with the saw. The osteotomy took place after creating a long plantar lower leg for the purpose of improving support and ensuring flow in the vessels supplying the head. The dorsal bone cut was made almost vertically to create an osteotomy angle of minimum 90°. Afterwards the MT-1 head was displaced laterally by up to 50% of head width. In this position the head was then fixated with the K-wire (1.2 mm), part of the
The obligatory drilling of the hole then took place over the wire, because of the softer osteosynthesis material, and the screw head space reaming then took place using the depth markings on the instrument. This was then followed by insertion of the MAGNEZIX® screw (Syntellix AG, Hannover, Germany) of length previously determined and then removal of the metatarsal excess and thorough testing of osteotomy stability. In cases of insufficient primary strength implant was then replaced with a standard small fragment screw.

In the case of persistent Hallux valgus interphalangeus a standard Akin osteotomy was performed.

The intervention continued with sealing of capsule, refixation of the M. abd. hallucis and skin sutures.

Follow-up treatment took place under full load with therapeutic shoes with hard soles for a six-week period. Physiotherapy was recommended directly post-operative to ensure MTP-1 mobilisation.

**Implant**

The MAGNEZIX® screw used (Syntellix AG, Hannover, Germany) comprises a biodegradable magnesium (Mg) alloy which is fully degraded in the body and replaced by body-own tissue. The screw design corresponds with that of a standard Herbert screw (Fig. 1]. Screw diameter is 3.2 mm, available in lengths of 10 to 40 mm.

**Results**

In total 25 patients were included in the study. Average age was 45.9 (± 11.23) years. All patients were female with one exception.

In the initial phase of the study it was decided intraoperatively in the case of three patients to use a titanium screw instead of the MAGNEZIX® screw. This was due in one case to insufficient support for the osteosynthesis and in two cases due to breakage of the MAGNEZIX® screw during insertion. One patient withdrew her consent to the study and a further patient had to be excluded from the study following traumatic dislocation plus necessitated osteotomy revision, such that overall the data refers to 20 patients in the study.

No further intraoperative complications occurred.

In all cases, with the exception of one patient, an additional Akin osteotomy also took place.

Radiology showed a reduction of the IMA of 13.4° (± 2; 9.0 – 16.8) to 5.2° (± 2.8; 0.1 – 9.6) 12 weeks post-operative. The Hallux valgus angle reduced from 24.1° (± 6.1; 13.3 – 35.8) to 8.6° (± 6.3; 0.3 – 20).

All patients expectations were satisfied by the OP and would undergo the operation again.

**Figure 1.** MAGNEZIX® screw; one can see the different texture compared with other implants. The screw design is based on a proven double thread screw.

**Table 1** Clinical results of AOFAS, FAAM and SF36 scores and the sub-scores at times pre-, 6, 12 and 52 weeks post-operative. The average value and the standard deviation are stated.

<table>
<thead>
<tr>
<th>Score</th>
<th>Pre-operative</th>
<th>6 weeks</th>
<th>12 weeks</th>
<th>52 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>N = 20</td>
<td>N = 11</td>
<td>N = 9</td>
<td>N = 4</td>
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<tr>
<td>----------</td>
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</tr>
<tr>
<td>AOFAS</td>
<td>61.2 (±12.5)</td>
<td>69 (±12)</td>
<td>82.2 (±9.9)</td>
<td>86.2 (±6.9)</td>
</tr>
<tr>
<td>FAAM-ADL</td>
<td>61.2 (±17.5)</td>
<td>70.45 (±16.9)</td>
<td>83.8 (±11.9)</td>
<td>86.2 (±15.4)</td>
</tr>
<tr>
<td>FAAM-Sport</td>
<td>60.6 (±25.6)</td>
<td>20.5 (±33.1)</td>
<td>47.8 (±25.5)</td>
<td>73.8 (±38.9)</td>
</tr>
<tr>
<td>SF36-physical</td>
<td>68.8 (±20.1)</td>
<td>67.5 (±24.9)</td>
<td>85.5 (±10.4)</td>
<td>95 (±5.7)</td>
</tr>
<tr>
<td>SF-36 pain</td>
<td>53.8 (±19.4)</td>
<td>47.8 (±25.7)</td>
<td>64.9 (±18.4)</td>
<td>93 (±14)</td>
</tr>
<tr>
<td>SF-36 vitality</td>
<td>53.8 (±17.8)</td>
<td>52 (±26.9)</td>
<td>71.4 (±14.5)</td>
<td>73.8 (±13.1)</td>
</tr>
<tr>
<td>SF-36 health</td>
<td>77.9 (±16.2)</td>
<td>63.6 (±28.8)</td>
<td>62.3 (±37.1)</td>
<td>55.2 (±54.3)</td>
</tr>
<tr>
<td>SF-36 average</td>
<td>68.8 (±18.9)</td>
<td>56.6 (±17)</td>
<td>77.3 (±13.8)</td>
<td>86.5 (±9.1)</td>
</tr>
</tbody>
</table>

Pain when walking reduced from 4.4 (± 2.26; 0 – 8) pre-operative to 1.6 (± 1.6; 0 – 5) 12 weeks post-operative.

No patient underwent increasing degenerative changes of the MP1 during the course of the study compared with pre-operative findings. In the case of 17 of 20 patients x-rays at six weeks post-operative showed trabeculae bridging the osteotomy in the post-operative x-ray images (Fig. 2)

The a.p. images taken six weeks post-operatively show a light zone around the screw in the bone of 1.9 (± 1.4; 0 – 5.3) mm in the maximal extension. In the side position x-rays there is a parallel radiolucent anomaly of 2.5 (x 2.5; 0 – 7.8) mm in the sub-tissue. 12 weeks post-operative this is seen to have reduced to 1.7 (x 1.0; 0 – 3.4) mm or 0.7 (x 1.4; 0 – 4.5) mm in the a.p. and side images.

The AOFAS forefoot score, the FAAM and the SF36 score show in the relevant parameters a clear increase in value in post-operative development (see Table 1).

One patient had a prolonged painful swelling of the foot up until approx. six months after the operation. MTP-1 mobility was 93° pre-operative (x 16.8; 30 – 110) and 61.5° 12 weeks post-operative (x 24.4; 20 – 100).

**Discussion**

The use of bioresorbable implants could make the need to remove hardware from foot and ankle unnecessary. The use of a metallic magnesium-based alloy would overcome the previous limitations to such implants. The clinical study presented showed good clinical results for treating Hallux valgus deformities by a Chevron osteotomy using a bioabsorbable MAGNEZIX® screw.

The clinical and radiological results collected in this study are comparable with the previous series relating to treatment of Hallux valgus deformities by Chevron osteotomy [7].

Magnesium has been the subject of research for degradable implants for many tens of years. The use of different alloy materials and production processes allows the biological behaviour, in particular the rate of degradation, to be significantly influenced [6, 19]. A possible additive is that of “rare earths” elements, as used for the alloy in these screws.

**Fig. 2 a-f:** Imaging of healing course of 28-year-old patient after Chevron osteotomy and use of a MAGNEZIX® screw. Pre-operative there was a symptomatic hallus valgus deformity (a, b). In the x-ray control at 6 weeks post-operative the implanted screw is visible, which is less radio-opaque than conventional implants. A distal metatarsal corrective osteotomy took place using the Chevron procedure and additive Akin osteotomy fixed with a string cerclage. One can see a light radiolucent structure around the screw and in the dorsal soft tissue (b, c). 12 weeks post-operative one can see definitive consolidation and clear bone remodelling. The abnormalities seen in
the dorsal soft tissue are no longer present. Patient was quickly free of complications and very satisfied with development.

Thus the good resorption behaviour seen in the animal model could be verified here without any evidence of toxicity [20]. The approval study for the implant demonstrated the application's reliability in humans [22].

Compared to other, mainly organic, resorbable materials, e.g. poly-L-lactide (PLLA), which is degraded by macrophages, the degradation of magnesium takes place through corrosion and the formation of hydrogen. This (initially) gave rise to misgivings that the formation of gas would result in undesirable reactions. The slowing of the rate of degradation is intended to minimise this problem [21]. In the pre-studies, in animal model and in humans, no relevant gas formation or osteolyses were present. The histological examinations showed a direct bone-implant contact [18, 22]. Nonetheless, in this study, in particular at the 6-week control, there was a radiolucent zone around the screw in the bone and dorsal in the soft tissue. At the 12-week control the dorsal abnormality is diminishing in most cases, or is no longer detectable. The radiolucent areas, in particular in the dorsal structure, raise the question of gas formation, although this should be transported away. Further studies are necessary in order to understand the occurrence of this new phenomenon. In one case a prolonged swelling was observed which could possibly be related to the implant.

In the animal studies and in cell cultures, Mg has a certain osteo-anabolic effect as a positive side effect [7]. In our collective in most cases there was a noticeable early – as far as assessable using conventional radiology – consolidation of the osteotomy with crossing bone trabeculae after just six weeks. However, without any comparative group, this effect can only be referred to subjectively at present.

Mg alloy is softer than standard metal implants, such that despite the similar design to titanium screws it is necessary to undertake pre-drilling and in particular screw head countersinking using the pre-inserted Kirschner wire. Due to the slightly unfamiliar handling and the necessitated learning curve the surgeon decided intraoperatively in three cases in our collective to switch to a standard implant due to fracture or insufficient stability of the Mg screw. During the subsequent course of the study all treatments took place as planned.

The dislocation observed during the series of one osteotomy was sufficiently explained by the occurrence of a trauma (unprotected kicking of a bed leg three weeks postoperative) and is from our viewpoint not primarily due to the implant.

Despite the higher initial implant costs incurred through the use of a biodegradable implant it appears to make economic sense in those areas where hardware removal is frequently desired. By avoiding subsequent metal removal surgery it is possible to avoid the renewed surgery risks and costs as well as time lost at work. In the German DRG system, the additional costs due to inpatient intervention are however currently not reflected such that the extra costs are to the debt of the hospital. In a competitive health market, offering such a procedure could, however, represent a competitive advantage.

Limitations

The study has highlighted certain limitations such that the follow-up period is still too short to arrive at a final conclusion. Nonetheless in the case of all patients clinical and radiological healing is documented. Some of the patients in the study refused, due to the lack of clinical complications, to submit to the standard 12 month x-ray implant control at our hospital and
also refused to take further part in the study. This can be interpreted to the effect that the patients were so satisfied with the surgery that they did not wish any further consultation. Furthermore the complaints due to an implant generally result in renewed consultation after periods of greater than one year: this follow-up period has not yet expired in the present study. A further limitation is lack of a comparative group with which the results of the treatment could be compared.

Summary

The fixation of metatarsal corrective osteotomies using the Chevron procedure and a MAGNEZIX® screw appears to be a safe and reliable procedure. The origins of the radiolucent areas around the screw and in the soft tissue remain unclarified and require further observed but do not correlate with any clinical or radiological findings.

No direct implant-specific complications arose in this study collective, such as breakage of screws. However, during the initial phase it was decided intraoperatively in the case of three patients to switch to a standard implant and in the case of one patient there was a prolonged period of swelling. Due to the lack of long-term experience with the material the authors therefore advise that this implant be presently used above all as part of prospective data acquisition, that standardised follow-up control of the patients and documentation of any complications is ensured. In the recent past “innovations” in orthopaedics have shown in part considerable rates of complication which could possibly have been avoided by way of structured introduction of the devices. The manufacturer of the implant (Syntellix AG, Hannover, Germany) is responding to its responsibility and has developed a questionnaire system the scope of which includes a structured survey of surgeries performed on patients and possible complications.

Conflict of interest

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

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