Early Results Using a Biodegradable Magnesium Screw for Modified Chevron Osteotomies

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ABSTRACT: This is the first larger study analyzing the use of magnesium-based screws for fixation of modified Chevron osteotomies in hallux valgus surgery. Forty-four patients (45 feet) were included in this prospective study. A modified Chevron osteotomy was performed on every patient and a magnesium screw used for fixation. The mean clinical follow up was 21.4 weeks. The mean age of the patients was 45.5 years. Forty patients could be provided with the implant, in four patients the surgeon decided to change to a standard metallic implant. The AOFAS, FAAM and pain NRS-scale improved markedly. The hallux valgus angle, intermetatarsal angle and sesamoid position improved significantly. Seven patients showed dorsal subluxation, rotation or medial shifting of the metatarsal heads within the first 3 months. One of these patients was revised, in all others the findings were considered clinically not significant or the patients refused revision. This study shows the feasibility of using magnesium screws in hallux valgus-surgery. Surgeons starting with the use of these implants should be aware of the proper handling of these implants and should know about corrosion effects during healing and its radiographic appearance. © 2016 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. J Orthop Res

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Distal metatarsal osteotomies (DMO) are a standard treatment for mild to moderate hallux valgus (HV) deformities with good long term results.4 Initially it was introduced without fixation of the osteotomy,2 but for a more controlled correction and decrease the rate of head dislocations, various fixations, using K-wires, metal screws, or staples have been used.3–7 The need to remove these implants has been reported in up to 8% of the patients.8,9 Therefore, degradable implants have been introduced for DMO with good clinical results.10–12 Biodegradable implants have been in use for decades to overcome the disadvantages of standard metallic implants. These are associated with stress shielding,13–15 accumulation of metals in surrounding tissues,16–18 growth restriction, implant migration,19 hypersensitivity reactions, and allergic potential.20–22 Further on they can be associated with continuous pain23 and lead to interference in imaging.24 All these factors can lead to the necessity of implant removal, which is mentally stressful for the patients, expensive, consumes limited resources, can be complex, is associated with complications and often is of limited success.25–27

Most degradable implants used are made of polymers, like polyglycolid, poly-L-lactic acid, or poly-p-dioxanone.28 While some studies showed good results using these implants for distal metatarsal osteotomies,12,29,30 others found painful swelling, giant cell granuloma formation, osteolysis and sterile sinus formation.31–33 Recent research has focused on degradable metallic implants, made of iron (Fe), zinc (Zn), or magnesium (Mg). Magnesium has already been used as a biodegradable material for implants in the early 20th century, but was later abandoned. Hydrogen gas is produced during magnesium’s corrosion process; this is non toxic but can lead to local tissue displacement when produced too fast.34 While pure magnesium has an insufficient mechanical stability, the addition of specific alloying elements and the optimization of the production process significantly improves the mechanical characteristics and degradation properties of magnesium. Among others, the use of rare earth elements improves the corrosion resistance and does so without inappropriate effects if used in small quantities.35,36 Mechanically these magnesium alloys are close to those of natural bone.37 Additionally, magnesium shows an osteoanabolic effect and a good bone integration.38,39 Due to the high pH during degradation Mg also has short term anti-infectious properties.40

Due to their properties, Mg-based implants were successfully tested in animal models for the treatment of intraarticular fractures,41 in cranio-maxillofascial surgery42 or as interference screws for tendon to bone fixation.37 First studies in humans showed good short-term results and comparable results using a magnesium-alloy (based on MgYREZr) screw compared to a standard titanium-implant for DMO.43,44

Conflict of interest: HW is a member of the supervisory board of Syntellix AG. There has been no direct financial support for this study from this company.

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In this study, we present our early experience using a biodegradable magnesium screw for Chevron osteotomies.

MATERIALS AND METHODS

Study Design

We performed this study to analyze the feasibility of using an Mg-based screw for DMO. Between August 2013 and June 2015, 47 patients were included in this prospective case-series (Level of evidence: 4). The patients were treated for symptomatic HV with DMO. All complied for using a Mg-screw in their operation. Forty-four of these were included in this study and gave their written informed consent (Fig. 1). The responsible institutional review board approved the study (MHH Ethic Board Nr: 1919–2003). Inclusion criteria were symptomatic hallux valgus with indication for a Chevron-type osteotomy and majority. Exclusion criteria were osteoporosis noticed intraoperatively, hypersensitivity against implant ingredients and severe renal disease.

Operation

The operation was performed in a supine position, with a thigh tourniquet. Lateral release was done with an intermetatarsal incision, releasing the M. adductor hallucis and the lateral sesamoid ligaments. A standard medial approach was performed, the capsule incised and the exostoses removed. The center of the metatarsal head was marked with a 1.2 mm K-wire and an oscillating saw was used to perform a modified Chevron osteotomy. The head was shifted laterally and fixed with a temporary fixation-wire. Intraoperative X-rays were performed to verify the correct position. The screw was predrilled over the wire and another drill was used to make the countersink hole in the head. The length was measured and the appropriate screw was subsequently gently screwed in. The overriding bone of the proximal metatarsal was then removed. The capsule and skin were sutured and a standard dressing applied. Aftercare consisted of protected immediate full weight bearing with a stiff sole. Physiotherapy was recommended to mobilize the metatarso-phalangeal joint 1 (MTP1) after wound healing.

Implant

The MAGNEZIX® CS 3.2 (Syntellix AG, Hannover, Germany) is a standard Herbert-type screw (shaft Ø 2.4 mm, cannulation Ø 1.3 mm, head thread Ø 4.0 mm, shaft thread Ø 3.2 mm, different pitches for interfragmentary compression). The magnesium screw is made of an aluminum-free magnesium alloy (based on MgYREZr) that contains >90% magnesium. The screw weight is approximately 150 mg (20 mm length).

Follow-Up

Clinical and radiological follow-up (FU) examinations were scheduled preoperatively, 6, 12 weeks and 1 year postoperatively. The FU included range of motion (ROM) of the metatarsophalangeal joint-1 (MTP1), American Foot and Ankle Society Forefoot Score (AOFAS), Foot and Ankle Ability Measurement (FAAM), pain level according to a numeric rating scale (NRS), satisfaction rate and documentation of any complications.

All radiographs were performed a.p. and lateral weight bearing with a computed radiography system. All radiographic parameters were analyzed by two surgeons independently. All radiographic analysis were performed using a server-based imaging platform (Vue Pacs, Carestream, Stuttgart, Germany). The reader studies were performed using certified displays for diagnostic radiological review. The following parameters were accessed: Intermetatarsal 1–2 angle (IMA), hallux valgus angle (HVA), proximal and distal articular surfaces of the proximal phalanx angle (PDPAA), sesamoid position, and degenerative changes according to Kellgren and Lawrence classification. Bony healing was defined as the osteotomy crossing bone trabecular in one view. Radiolucencies around the implants were measured in a.p. and lateral view. The maximum radioluency-width was measured in the bone and in the soft-tissues using the PACS-Software.

![Figure 1. Patients under control: 47 (48 feet) patients complied for using the Mg-screw, two patients were immature and not included in the study, one patient refused participation. In five operations (four patients) the surgeon changed intraoperatively from the planned Mg-implant to a conventional implant. Thirty-nine patients had a 6 weeks control, 23 a 12 week and 8 a follow-up longer than 6 months. The reasons for not having a full follow-up were refusing participation in 1 at 6, 8 in 12 and 11 after 6-months. Seven patients were not 12 weeks postoperative and another 7 not >6 months postoperative during preparation of this paper.](image-url)
Statistical Analysis
All data were documented using Microsoft Excel 2016, statistical analysis was performed using GraphPad Prism 6.0. Data on interval scale (including scores, pain level and radiographic assessments) were analyzed using a paired Student’s t-test. In this study, \( p < 0.05 \) was considered statistically significant.

RESULTS

Patients
Forty-four patients (45 feet) were included in the study. All but two of the patients were female (95%), the mean age was 45.5 (±10.6; 19.6–68.2) years. For the exact number of patients see Fig. 1.

The mean last FU of the patients with a FU >6 month was 1.3 (±0.38; 0.47–1.65) years postoperatively.

Operation
In all patients the modified Chevron osteotomy was performed, in 90% an additional Akin osteotomy was added. In four patients (5 feet) it was decided to use a conventional implant intraoperatively. In one patient the implant was changed due to the failure of the Mg-screw during implantation and in three patients due to the inability to stabilize the osteotomy with the chosen Mg-screw. In these patients a sufficient stabilization could be achieved with a conventional implant.

Clinical Results
The AOFAS Score and the FAAM-ADL increased markedly, while the FAAM-Sport and the SF-36 sub-scores increased significantly (Table 1). The NRS for pain decreased from 3.7 to 0.3, but did not show significance. The mobility of the MTP1-joint decreased from 88.8 degrees to 65 degrees at the final FU, without significance.

All patients but one with a HV-relapse, were very or at least satisfied with the operation. All would undergo the operation again and recommend it to a family member.

There was one patient with a delayed wound healing, which finally healed without any surgical intervention. This and another patient reported a sensitive scar. In five patients an increased swelling was noticed during the first weeks, which vanished later on. One patient developed a hallux varus and was scheduled for revision, but refused to undergo the operation.

Radiology
The x-rays showed a significant improvement of all HV-parameters, including the HVA (\( p < 0.001 \)) and the IMA (\( p < 0.001 \)). Radiographic signs of bony healing could be seen in 79% after 6 and 90% of the feet after 12 weeks. The screws showed progressive degradation over time (Figs. 2 and 3).

Radiolucencies around the implant could be seen in the bone after 6 weeks in all but one and in 78% of the feet after 12 weeks. Dorsal to the screw a radiolucency

<table>
<thead>
<tr>
<th>Score</th>
<th>Pre-OP</th>
<th>6 weeks</th>
<th>12 weeks</th>
<th>Last FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>AOFAS</td>
<td>71.0 (±16.6; 53-85)</td>
<td>73.2 (±17.3; 49-100)</td>
<td>74.5 (±14.7; 49-99)</td>
<td>78.5 (±7.6; 68-85)</td>
</tr>
<tr>
<td>FAAM-ADL</td>
<td>68.5 (±13.3; 49-94)</td>
<td>72.2 (±17.2; 35-100)</td>
<td>75.4 (±13.1; 44-100)</td>
<td>77.5 (±7.6; 68-85)</td>
</tr>
<tr>
<td>FAAM-Sport</td>
<td>57.2 (±24.5; 40-100)</td>
<td>61.9 (±17.0; 28-90.5)</td>
<td>65.7 (±15.4; 35-89)</td>
<td>75.4 (±14.4; 42-93)</td>
</tr>
<tr>
<td>SF-36-general</td>
<td>66.3 (±18.6; 27-97.3)</td>
<td>58.9 (±25.0; 5-94)</td>
<td>77.4 (±15.4; 35-89)</td>
<td>78.5 (±7.6; 68-85)</td>
</tr>
<tr>
<td>SF-36-physical</td>
<td>70.8 (±18.2; 45-100)</td>
<td>61.9 (±25.0; 5-94)</td>
<td>65.7 (±15.4; 35-89)</td>
<td>78.5 (±7.6; 68-85)</td>
</tr>
<tr>
<td>SF-36-pain</td>
<td>47.9 (±22.5; 11-100)</td>
<td>41.9 (±25.0; 5-94)</td>
<td>65.7 (±15.4; 35-89)</td>
<td>78.5 (±7.6; 68-85)</td>
</tr>
<tr>
<td>SF-36-mental</td>
<td>57.3 (±18.2; 45-100)</td>
<td>47.9 (±22.5; 11-100)</td>
<td>65.7 (±15.4; 35-89)</td>
<td>78.5 (±7.6; 68-85)</td>
</tr>
<tr>
<td>MTP 1-mobility</td>
<td>88.8 (±19.6; 60-100)</td>
<td>75.3 (±27.3; 40-97)</td>
<td>62.9 (±25.1; 20-100)</td>
<td>65.7 (±15.4; 35-89)</td>
</tr>
</tbody>
</table>

Table 1. Clinical Scores and Findings Showed a Marked Improvement After the Operation
could be seen in the soft-tissue after 6 weeks in 59% and decreased to 30% of the feet after 12 weeks (for details see Table 2).

In five patients a CT-scan was performed, due to early implant disintegration, dislocation, radiolucencies, or pain (Fig. 3). After 6 weeks two of the implants showed signs of early disintegration. Radiologic findings in these two patients showed no axial alignment of the remaining fragments (Fig. 4) and another two showed signs of partial disintegration. After 12 weeks another screw showed signs of partial disintegration. Seven patients showed dorsal subluxation, rotation or medial shifting of the metatarsal heads within the first 3 months. The dislocation of the fragment was either judged clinically insignificant or the patient refused revision (Fig. 5) in all but one patient. In this patient the DMO was revised after 9 weeks and fixed with a standard metallic implant.

DISCUSSION

Using a biodegradable magnesium screw for distal metatarsal osteotomies yields good clinical results and helps to avoid the necessity of hardware removal. The procedure led to bony healing without need of revision surgery in 38 of 39 patients. All but one patient with a HV recurrence reported successful treatment and would recommend it to other patients.

To our knowledge, this study is the first report on a consecutive series of a fairly standardized procedure in clinical routine using innovative Mg-implant screws that corrode over time, leading to sufficient bone healing and subsequent implant integration. Therefore, no necessity developed to remove the implant which results in an advantage for the patient with a substantial risk reduction.

This study showed good clinical results after DMO for HV in the short-term and a high patient satisfaction rate. The findings after 6 and 12 weeks resemble the early postoperative discomfort expected after the operation. The final AOFAS Score is comparable to previously published series using biodegradable or standard implants. For a final conclusion a longer and complete FU is necessary.

Several issues concerning the specific use of these implants were found and need to be discussed: First, due to technical issues, not all patients with intended implantation of the Mg-screw could be suitably stabilized; second, although clinically judged not relevant in all but one, signs of early corrosion with subsequent disintegration in seven cases were found.

Table 2. Radiographic Hallux Valgus (HV) Parameters Improved Significantly After the Operation

<table>
<thead>
<tr>
<th>Measurement</th>
<th>preOP</th>
<th>6 weeks</th>
<th>12 weeks</th>
<th>Last FU</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 45</td>
<td>n = 39</td>
<td>n = 23</td>
<td>n = 8</td>
</tr>
<tr>
<td>IMA</td>
<td>12.8 ± 2.2; 8.1–16.8</td>
<td>5.2 ± 2.8; 0.3–10.8</td>
<td>5.1 ± 3.0; 0.1–9.5</td>
<td>7.4 ± 3.3; 1.3–11.4</td>
</tr>
<tr>
<td>HVA</td>
<td>25.1 ± 5.7; 14.4–36.3</td>
<td>8.3 ± 5.9; –6.3 to 19.8</td>
<td>7.4 ± 5.3; 0.3–20</td>
<td>10.3 ± 9.6; 0.3–26.2</td>
</tr>
<tr>
<td>PDPAA</td>
<td>7.9 ± 4.8; 0.6–19.5</td>
<td>2.7 ± 4.2; –4.7 to 12.1</td>
<td>2.5 ± 3.6; –5.6 to 7.5</td>
<td>–0.6 ± 4.6; –10.9 to 4.8</td>
</tr>
<tr>
<td>Sesamoid position</td>
<td>2.3 ± 0.6; 1–3</td>
<td>0.28 ± 0.5; 0–2</td>
<td>0.34 ± 0.6; 0–2</td>
<td>1 ± 0.53; 0–2</td>
</tr>
<tr>
<td>Kellgren-Lawrence score</td>
<td>0.1 ± 0.4; 0–2</td>
<td>0.2 ± 0.5; 0–2</td>
<td>0.2 ± 0.5; 0–2</td>
<td>0.9 ± 1.1; 0–3</td>
</tr>
<tr>
<td>Osseous healing</td>
<td>–</td>
<td>28/40</td>
<td>21/23</td>
<td>8/8</td>
</tr>
<tr>
<td>Radiolucency in bone</td>
<td>–</td>
<td>2.0 ± 1.3; 0–6</td>
<td>1.5 ± 0.9; 0–2.8</td>
<td>0</td>
</tr>
<tr>
<td>Radiolucency in soft-tissue</td>
<td>–</td>
<td>3.0 ± 3.0; 0–11</td>
<td>1.0 ± 1.8; 0–5.7</td>
<td>0</td>
</tr>
</tbody>
</table>

Osseous healing was defined by the osteotomy crossing bone trabecula. Any radiolucency areas around the screw were measured in mm. All numbers are given with standard deviation and mean. p-values were calculated for the preoperative scores and of the last FU. All significant p-values are printed in bold. IMA = first intermetatarsal angle, HVA = Hallux valgus angle, PDPAA = proximal to distal phalangeal articular angle.
In 5 feet an intraoperative decision was made to use a conventional implant. The reason for changing to a conventional implant was insufficient stabilization of the osteotomy in two patients, which might be due either to an improper screw length or position. The operating surgeon decided to change to a conventional implant and not try a second Mg-screw in these cases, due to the novelty of the implant.

In one patient a screw failure was noticed during insertion of the screw; as this patient was undergoing HV surgery on both feet simultaneously, no Mg-screw was used on the other side.

This finding can be explained with a different behavior of the metal in comparison to usually utilized titanium screws. Tests during implant development conducted in animal and cadaveric human bone studies showed the necessity to pre-drill including the contralateral cortical bone and the importance of completely countersinking the entry hole.

The more challenging screwing might also be the reason why, for the fourth patient, a standard titanium implant had to be used. As a teaching hospital the operations were performed by seven different surgeons and all of these incidents happened during the first cases of the individual surgeon. Therefore, implant failure during surgery can be explained by a learning-curve-effect with this implant. No intraoperative problems with the implants were seen after having gained experience.

The radiologic findings regarding the mean corrections of the IMA and HVA are in good agreement with previous studies. Within this study, an Akin osteotomy was conducted in 90% of the operations, which is higher than in most other previous studies but can be explained by the preoperative radiographic findings and probable regional differences. Another reason may be that all patients had an intraoperative radiographic control after shifting of the metatarsal head, which often demarks a HV interphalangeal position and leads to the decision to perform an additional Akin osteotomy. In most patients bridging bone trabecula could be seen within the first 6 weeks. This fast bony healing process might be due to the osteogenic potential of Mg-implants. As there was no control group, this finding can not be validated.

Close radiographic analysis showed different interindividual rates of corrosion between the treated patients. In some patients, corrosion effects, such as...
hypodense cavities were observed, in some cases radiolucency around the screws, corresponding to a retreating of the calcified bone. This process is not yet completely understood. While it has been hypothesized that this corresponds to Mg-hydroxide, degradation products, osteoblasts, and osteoid (non-mineralized bone matrix), it also seems possible that these cavities are due to hydrogen, which develops during the corrosion of Mg and displaces the bone. This hypothesis is supported by the radiolucencies found in the soft-tissues on the screw head and the CT-findings showing Hounsfield units conforming with gas. We found no risk factors corresponding with increased radiolucency, but an exact measurement of the volume of the concavities would only be possible with CT scans, which could not be done for all patients for radiation reasons.

We found signs of early corrosion with subsequent disintegration in seven of the 39 treated patients. This resulted in a radiographic shift of the metatarsal head, without leading to a clinically relevant failure in the short term in six of these patients.

Only few studies addressed the effect of stability of DMO with fixation. Lagaay et al. reported a dislocation and reoperation rate of 0.07%, but only analyzed the indications for reoperation not radiographs. Andrews et al. reported two dislocations in 60 patients and one reoperation after DMO with a long dorsal cut. Donnelly et al. reported about the actual used DMO with long plantar cut, showing a 0% dislocation rate. In a comparative study of K-wire fixation and biodegradable pin, Gill et al. showed a loss of fixation in 3 of 74 patients treated with K-wires and 1 of 70 treated with a biodegradable pin. The safety of slow-degrading implants for DMOs has been supported by other studies showing no dislocations. However, other studies on DMO fixed with biodegradable implants, showed a shift of the metatarsal head within the first weeks using biodegradable implants in 3–7%. It remains unclear, whether surgical problems or learning curve effects were related to the detected small dorsal shifts of the metatarsal head. However only one of the patients was revised due to the amount of dislocation, in all other cases the positional change was judged clinically insignificant or the patient refused revision due to absence of pain, which leads to a reoperation rate of 2.5%. This can be compared to the reoperation rate using a standard metallic implant for hardware removal, which can be as high as 8%. However, the relevance of the dislocations can finally only be concluded after a longer FU.

Signs of early corrosion in some patients of this study should be considered carefully, especially when trying to expand the application range to locations with different loading conditions than those of the forefoot. Although Austin’s initially introduced the V-type DMO without fixation due to its intrinsic stability, nowadays a fixation is generally recommended.

**Limitations**

A limitation of the study is the short-term follow up. Only four of the included patients had a follow-up of more than 6 months. Nevertheless, as the most relevant local findings occurred during the first 3 months after surgery and before bony union, we think that these results are already highly relevant for surgeons, who want to use these implants. Additional limitations of this study are the missing control group, and the incomplete follow-up.

**CONCLUSION**

Biodegradable screws possess advantages over non-absorbable implants due to their positive properties regarding stress-shielding, imaging and the necessity of implant removal. Magnesium based implants degrade without an implant directed inflammation reaction and possess higher strengths than degradable polymer implants. However, when using Mg-screws to stabilize bone osteotomies, one has to address proper training of implant handling up-front. Different inter-individual corrosion rates between patients can be
expected and loading conditions should be set with a safety margin to guarantee proper healing even in cases of early corrosion. Surgeons using these implants should know about corrosion effects during healing and radiographic appearance.

Within this study, we demonstrated the clinical application of degradable Mg-screws for hallux valgus surgery. This study demonstrates the clinical success using these screws. Surgeons starting to use this new degradable implant should carefully consider the reported aspects mentioned within this study.

AUTHORS’ CONTRIBUTIONS

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REFERENCES