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Internal fixation of three-dimensional distal metatarsal I osteotomies in the treatment of hallux valgus deformities using biodegradable magnesium screws in comparison to titanium screws

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ABSTRACT

Background: Various implants, for example K-wires, screws, plates or staples, have been introduced for the stabilisation of corrective osteotomies in hallux valgus surgery. To provide high initial stability and to avoid subsequent implant removal, a novel biodegradable magnesium screw (MAGNEZIX® CS, Syntellix AG, Hanover, Germany) has been developed and approved for clinical use.

Methods: Between October 2014 and June 2016, magnesium screws were used in 100 patients with a symptomatic hallux valgus deformity for the fixation of Chevron and Youngswick osteotomies. The results were compared to a retrospective cohort of 100 patients, in which titanium screws were applied to stabilize the osteotomies in a comparable manner. All follow-up data was collected retrospectively.

Results: Both cohorts showed no differences concerning the age of patients, comorbidities, number of corrected toes and duration of surgery. The median clinical follow up was 12.2 weeks (magnesium) and 11.7 weeks (titanium), respectively. No difference was found between the magnesium screws and the titanium screws in respect to prolonged wound healing or deep infection. One patient complained about a prominent screw head in the titanium group and one screw fracture was noticed in the magnesium group most probably due to early full weight bearing. All patients but four could start full weight bearing in normal shoes at six weeks.

Conclusions: Early results of 100 cases of biodegradable magnesium screws in hallux valgus surgery show non-inferior results concerning clinical outcome and complications compared to titanium alloy screws. To avoid implant removal, while keeping high initial stability, magnesium screws are an excellent option in hallux valgus surgery.

1. Introduction

Hallux valgus is the most common deformity of the forefoot. The global pooled prevalence of hallux valgus is estimated at up to 23 % in adults aged 18–65 years and 35.7 % in elderly people aged over 65 years [1]. Conservative treatment aims to reduce pain and symptoms, but is inefficient in correcting this deformity [2]. Therefore, up to 150 different surgical techniques have been developed for the correction of the deformity [3–6]. According to the guidelines published by the German Orthopaedic Foot and Ankle Society (DAF) in 2014, suitable surgical techniques for mild and moderate deformities are distal or proximal Metatarsal I (MT I) osteotomies [7].

Most of the modern osteotomy techniques for the correction of mild to moderate deformities have been described in the 1970s and 80s [8,9]. The Chevron osteotomy was presented as a modification of the Mitchell osteotomy with a high potential of correction, improved contact of the bone areas, and as a partially self-stabilizing osteotomy [10]. Initially, the Chevron osteotomy was introduced without additional internal fixation [9], but for a more controlled correction and a reduced rate of head dislocations, various fixations, e.g. Kirschner wires, metal screws or staples, have been used [11–13]. The need to remove these implants has been reported in up to 8% of the patients [14,15]. Therefore, degradable implants made of polymers, like poly-L-lactic acid (PLA) or polyglycolid acid (PGA) have been used with varying clinical results [16–19]. Some authors raised concerns like painful swelling, giant cell granuloma formation, osteolysis and sterile sinus formation [18,19].

To overcome these limitations, a biodegradable magnesium screw (MAGNEZIX® CS, Syntellix AG, Hanover, Germany) was

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developed [20]. MAGNEZIX® is an aluminium-free magnesium alloy that is classified as an MgYREZr alloy according to DIN EN 1753 (i.e. magnesium, yttrium, zirconium and other rare earth metals). Good biocompatibility, osteoconductive capacity and a degradation time of about one year were shown in animal studies [21]. Most clinical experience on MAGNEZIX® CS has been published so far on the correction of forefoot deformities [22,23], but not in larger series.

The aim of this evaluation was to describe the early clinical results of magnesium screws used in a consecutive series of 100 patients for the fixation of three dimensional distal MT I osteotomies. These results were compared to the early results of a second patient cohort, in which 100 titanium screws were used for the fixation of the osteotomies in a similar manner. We report on the experience of a single surgeon in a private practise.

2. Methods

2.1. Patients

The data of two patient cohorts was retrospectively evaluated. In total, 200 patients with a symptomatic hallux valgus deformity treated with a distal MT I osteotomy were analysed. Between October 2014 and June 2016 (20 months), a magnesium compression screw was used for or the fixation of the osteotomy in 100 consecutive patients. Between January 2013 and August 2014 (19 months), the osteotomy was stabilised by a titanium compression screw in 100 consecutive patients. The inclusion and exclusion criteria are shown in Table 1.

2.2. Surgical management

2.2.1. Implants

2.2.1.1. MAGNEZIX® CS 3.2 (magnesium alloy group [Mg group]). The MAGNEZIX® CS 3.2 (Syntellix AG, Hanover, Germany) is a double threaded compression screw (shaft ⌀2.4 mm, head thread ⌀4.0 mm, shaft thread ⌀ 3.2 mm, different pitches for interfragmentary compression). The magnesium screw is made of an aluminium-free magnesium alloy (based on MgYREZr) that contains >90% magnesium. The screw weight is approximately 150 mg (20 mm length).

2.2.1.2. Fixos CS 3.5 (titanium alloy group [Ti group]). Fixos screws are made of titanium alloy Ti 6Al-4V. They are indicated for fixing and stabilizing the elective osteotomies of the mid-foot bones and the metatarsal and phalanges of the foot only. The cannulated compression screw CS 3.5 mm was especially designed for the stabilisation of Chevron and Austin osteotomies (Head thread Ø4.2 mm, shank diameter thread base 2 mm, distal thread Ø3.5 mm, cancellous anchorage).

Table 1
Inclusion and exclusion criteria.

Inclusion criteria
• Symptomatic hallux valgus deformity • Otherwise normal function of the lower extremity • Age between 18 and 79 years • Patient is able to give consent to surgical treatment
Exclusion criteria
• Patient is not able to give consent to surgical treatment • Patients with neurological diseases of the musculoskeletal system • Allergies against the components of the screws • Participation in other studies 30 days before the start of this study and during the participation in this study

2.3. Surgical technique

All patients were operated in supine position and a tourniquet was used. After a longitudinal dorsal incision, the medial dorsal and plantar sensory nerves and the extensor hallucis longus (EHL) tendon were prepared and protected. For better visualization, surgical loupes were used. Lateral release was performed over the dorsal incision. The pseudo-exostosis was removed and a 90° chevron osteotomy was performed. In most of the cases, a second more proximal osteotomy was made parallel to the first dorsal cut. The interposing slice of bone was removed (Youngswick modification of the Austin osteotomy). Temporary fixation of the osteotomy with a K-wire was performed at the desired position of the screw. A two-step pilot drill bit was used to make the countersunk hole for the head. In the titanium group, the compression screw was inserted and the K-wire removed.

In case of the MAGNEZIX® CS 3.2, first the cannulated drill bit Ø 2.5/1.3 mm and then the cannulated countersink Ø 3.5/1.3 mm were use. Next, the magnesium screw was placed and the K-wire was removed. Overriding bone of the proximal metatarsal fragment was removed and the soft tissue closed.

In most patients, this osteotomy was combined with a medial closing wedge osteotomy of the proximal phalanx of the great toe (Akin) to correct the hallux valgus interphalangeous component. The Akin osteotomy was usually stabilized with a staple (StaFIX, Stryker, Mahwah, New Jersey, USA).

In 48 patients of the Ti group and in 50 patients of the Mg group the MT I osteotomy was combined with other surgical procedures like Mini-Chevron-osteotomies of MT V, arthrodesis of the proximal and/or distal interphalangeal joints (PIP and DIP joints), arthrolyses of the metatarsophalangeal joints (MTP joints) and lengthening of tendons.

2.4. Data collection and outcome parameters

Patient demographics, date, type and duration of surgery were collected from the surgical notes. Co-morbidities (Diabetes mellitus, rheumatoid arthritis, depression, conditions following tumour surgery and chemotherapy, high blood pressure and cardiovascular disease) and medications were extracted from the medical history file of each patient. Technical problems or complications during surgery or in the immediate postoperative period (e.g. allergic reactions or acute infection) were collected the same way. During follow-up visits, special attention was payed to delayed wound healing, signs of infection and any kind of implant failure. Radiographic reports were analysed for any failure or breakage of implants, dislocation of the osteotomy gap, delayed union and signs of degradation of the magnesium screws. If patients presented after the regular follow-up, signs of chronic infection and implant-related complications like prominent or painful screw heads or tips with irritation of the soft tissue envelope were of special interest.

2.5. Statistics

Student's t-test and Welch's t-test were used to compare the two treatment groups concerning patients age, duration of surgery, comorbidities and number of treated toes. For the four primary binary endpoints of the intra- and postoperative complications upper 95% confidence limits were calculated to evaluate the difference between the Mg and Ti group according to Agresti and Caffo [24] by using the function Prop.diff in the R package pairwiseCI [25]. Large down to small positive limits are considered as still tolerable (non-inferior) increase of complications in Mg interprets.

3. Results

3.1. Patients

The average age in the Mg cohort was 50.9 years and in the Ti group 52.3 years ($p > 0.05$) (Table 2). There were 95 female patients in the Mg group compared to 90 in the Ti group. No differences concerning comorbidities between the groups were found (all $p > 0.05$, Table 2).

The clinical follow up was 12.2 weeks in the Mg group and 11.7 weeks in the Ti group. Follow-up radiographs were taken at 6.0 weeks on average in the Mg group and at 4.7 weeks in the Ti group (Table 2). All but four patients (three deep wound infections, one screw fracture) could start full weight bearing in normal shoes at six weeks. Radiological and clinical examination revealed osseous union.

3.2. Surgical technique

Mostly Youngswick osteotomies have been performed (Mg group: 96 Youngswick and 4 Chevron-Osteotomies; Ti group: 98 Youngswick and 2 Chevron-osteotomies) (Table 2). In the Mg group 50 patients had the correction of the first ray only, while in 38 two toes, in 10 three toes and in 1 four toes and in 1 all toes were corrected. In the Ti group in 52 patients only the correction of the first ray was performed, while in 37 two toes, in 10 three toes and in 1 four toes were corrected. On average, 1.65 toes were corrected in the Mg group and 1.60 in the Ti group ($p > 0.05$).

The duration of surgery did not differ in both groups (60.6 min in the Mg group vs. 56.6 min in the Ti group, $p > 0.05$). Handling of the magnesium screws was comparable to the behaviour of titanium screws. No difference was noticed for tightening or unscrewing (if necessary) compared to titanium screws.

3.3. Complications

Delayed wound healing was defined as wound drainage, wound dehiscence or necrosis of the wound edges persisting longer than three weeks after surgery. No significant difference was seen in delayed wound healing, which was found in three patients of the Mg group and four patients of the Ti group ($p > 0.05$) (Tables 2 and 3). One patient complained about a prominent screw head in the Ti group, but did not agree to a revision surgery for screw removal. One screw fracture was recorded in the Mg group: four weeks after surgery the breakage of the screw and dehiscence of the osteotomy gap was noticed on a radiograph. One deep infection occurred in the Ti group and two in the Mg group (not significantly different, $p > 0.05$) (Tables 2 and 3).

Table 3
Upper 95% confidence levels for the differences between Mg and Ti.

Endpoint	Upper limit
Soft tissue irritation by implants	0.038
Delayed wound healing	0.057
Deep surgical site infections	0.026
Screw fracture	0.017

3.4. Radiographic results

In the Ti group, the radiographic reports of the follow-up X-rays at 6 weeks described the correct placement of the implants and early signs of union and bone healing without any abnormalities. Only in case of the deep infection the removal of the implant was documented. In the Mg group, the radiographic reports described the correct placement of the implants and bone healing without any abnormalities in 60% of the cases (Figs. 1 and 2). In the other 40 % of the Mg cases, descriptions for implant specific phenomena were found in the records. These radiographic paraphrases included terms like “radiolucency”, “lytic area”, “signs of loosening” or “osteolysis”, “area of resorption” or “demineralisation around the magnesium screw” (Fig. 3). In three cases, “gas formation” was described in the soft tissue adjacent to the magnesium screw (Fig. 4). However, these patients showed no clinical symptoms and were free of pain. In contrast to these descriptions, all osteotomy gaps were well reduced without any dislocation and showed early signs of union and bony consolidation within 6 weeks.

Table 2
Comorbidity of patients and clinical results.

	Ti6Al4V (Fixos CS 3.5, Stryker)	Magnezix® CS, Syntellix
Number of patients	100	100
Average age in years	52,34	50,87
Pat. with diabetes mellitus	4	3
Pat. with rheumatoid arthritis	5	2
Obese patients	0	0
Pat. with osteoporosis	1	1
Pat. with depression	3	3
Pat. with status after tumour treatment	4	3
Pat. with hypertension	23	23
Pat. with cardiovascular disease	7	4
Gout arthropathy	0	0
Duration of surgery in min	56,6	60,6
Number of corrected toes on averaged	1,60	1,65
Number of corrected toes in detail	1:52; 2:37; 3:10; 4:1; 5:0	1:50; 2:38; 3:10; 4:1; 5:1
Radiographic follow up in weeks	4,7	6,0
Clinical follow-up in weeks	11,7	12,2
Soft tissue irritation by implants (number of cases)	1	0
Delayed wound healing (number of cases)	4	3
Deep surgical site infection (number of cases)	1	2
Screw fracture (number of cases)	0	1

Fig. 1. Follow-up radiograph at 5 weeks. a) AP-view and b) lateral view.

Fig. 2. Enlargement of Fig. 1b): correct placement of the Mg screw and early signs of bone healing.

4. Discussion

In 2013 Windhagen et al. published the first clinical results of a biodegradable magnesium-based screw for the internal fixation of MT I osteotomies in twelve patients [22]. Our retrospective evaluation provides for the first time data of a large cohort of 100 patients, in which degradable magnesium-based screws were used for the similar indication. A cohort of 100 patients with a titanium alloy screw fixation of MT I osteotomies served as a control. No significant differences between both patient cohorts concerning patient age, duration of surgery, number of corrected toes and comorbidities were found. This allows the direct comparison of the intra- and post-operative outcomes or potential complications of both cohorts.

4.1. Stability of implants

Only one screw fracture was found in the Mg group, but no implant failure in the Ti group (difference not significant, $p > 0.05$). The breakage of the magnesium implant occurred in a 56-year-old female, obese patient with diabetes mellitus (NIDDM) at four weeks postoperatively. She was tripping over a stair and was most probably full weight bearing in that situation. The patient was admitted to an external hospital, where two revision surgeries were performed. In the first stage, a debridement was done and in the second stage the osteotomy was stabilised again with an internal fixation.

During the degradation process magnesium screws lose stability over time and disappear later on. In case of this event, while the patient was most probably full weight bearing such a screw is likely to break. Nevertheless, titanium implants are also prone to break in different situations [26,27]. In contrast to polymer-based implants, magnesium alloys show promising biomechanical results in vitro [28] and in vivo [29]. The failure rate of polymer-based implants was reported to be as high as 4% of patients in orthopaedic and traumatologic indications [30]. In contrast, the failure rate in this large series was just 1%, caused by a traumatic incident and not significant vs. titanium. Our clinical results confirm the positive mechanical properties of Mg screws, which were comparable to Ti screws concerning the clinical outcome in our cohort.

4.2. Prolonged wound healing

Two previous studies reported delayed wound healing in patients with Mg screw fixation of MT I osteotomies in two of twelve [22] and in one of 45 cases [23]. In our 100 patients, we did not find a significant difference concerning prolonged or delayed wound healing between both cohorts (Mg group 3% vs. Ti group 4%, $p > 0.05$).

Fig. 3. Follow-up radiograph at 5 weeks in ap view: small radiolucency around the MAGNEZIX® CS.

Fig. 4. Follow-up radiograph at 5 weeks in lateral view: radiolucency in the soft tissue above the screw head indicating slight gas formation.

4.3. Deep wound infections

We had to face one deep wound infection in the Ti group and two in the Mg group (not significant, $p > 0.05$). This corresponds to a post-operative infection rate of 1.5 %, which is generally tolerated and comparable to results summarized in current literature [2,31]. The patient from the Ti group was a 28 y.o. male with the surgical correction of two toes. Additionally, in the medical history an anxiety disorder was noticed, which is a relative contraindication for magnesium screws (MAGNEZIX® CS 3.2, Instructions for Use, Syntellix AG, Hanover). Concerning the Mg group, both patients were females, 67 and 68 y.o. and had corrective surgery of three or four toes. The intraoperative samples from revision surgery (debridement, irrigation, implant removal) showed growth of *Staphylococcus aureus* and *Enterococcus* spec., respectively. The number of patients in this study is too small for a risk factor assessment. However, number of corrected toes and duration of surgery might contribute to an increased risk of infection, as shown for other orthopaedic procedures [32].

4.4. Radiographic findings

Plaass et al. noticed in MT I osteotomies fixed with Mg screws radiolucencies in all but one of their patients around the implant at 6 weeks and in 78% at 12 weeks after surgery [23]. We can confirm these implant specific phenomena, but only in 40% of the radiographic reports of our patients. The physiologic mechanisms correlating to the above mentioned radiolucencies on radiographs are not fully understood yet [33]. In our patients, further evaluations using CT or MRI scans have not been performed. However, it seems to be possible that these findings are due to a hydrogen evolution, which is a natural phenomenon during the corrosion process of Mg [23]. Additionally, other factors might be responsible for such radiolucencies around the screw: loss of mass, cell migration (e.g. osteoblasts, osteoclasts) and non-mineralized bone formation (osteoid), respectively [34]. Figs. 5–7 show follow-up radiographs at 6 and 12 months and 1.6 years.

In other series [22,23], all cases (with or without these radiographic phenomena) resulted in a complete healing and bony fusion without any adverse events. Therefore, radiographic phenomena on their own cannot be considered as a reason for a revision surgery. Surgeons and radiologist have to be aware of the technology behind the implant, the biomaterial and its radiographic pattern of degradation. With this in mind, the radiographic findings can be correctly interpreted and explained.

4.5. Limitations

The primary limitation of this study was the relatively short follow-up time. Therefore, future studies should focus on long-term outcome in larger series. The treatment period for MT-I osteotomies in our institution lasts about 12 weeks with one follow-up radiograph 6 weeks after surgery (standard of care). Nevertheless, in our experience most complications occur during the first three months after surgery, especially with the start of full weight bearing at 6 weeks [31,34,35].

4.6. Economic analysis of magnesium-based implants in hallux valgus surgery

Overall hallux valgus patient data is not available. Therefore, we will initially focus on the reported in-patient cases in Germany. 40,064 patients with hallux valgus were treated in an in-patient setting (ICD-10: M20.1) in 2015 [36].

4.6.1. Computation of direct costs in an in-patient setting

Since the DRG reimbursement for the initial operation will be identical irrespective of the choice of the implant, the difference is only in the price of the implants. To our experience, magnesium-based implants cost up to 60€ more than conventional implants depending on diameter, length, and quality of the conventional implant. Thus, the additional costs for the usage of magnesium-based implants are up to 2,403,840€.

Fig. 5. Follow-up radiographs at 6 months. a) AP-view and b) lateral view.

Patients may need an implant removal of conventional implants. In the literature, the implant removal rate in hallux valgus surgery was reported up to 8% [14,15,37], which equals 3205 removals. In an in-patient setting, the mean costs of implant removal (I21Z, I23A, I23B) are 2653.89€ in 2015 [38]. Therefore, the avoidable costs for implant removal are 8,505,717.45€ in an in-patient setting leading, in total, to avoidable costs of 6,101,877.45€.

4.6.2. Computation of indirect costs in an in-patient setting

The implant removal also induces indirect costs. In 2015, the average hospital stay is 3.4 days for implant removal procedures (DRG: I21Z, I23A, I23B) [38]. However, the temporary disability may last two additional days more after hospital stay leading to 5 days absence from work. In 2015, the average indirect costs per day are 193€ [39]. Consequently, the avoidable indirect costs are 3,092,825€.

Fig. 6. Follow-up radiograph at 12 months lat. View.

Fig. 7. Follow-up radiograph at 1.6 years.

4.6.3. Number of hallux valgus in out-patient surgeries in Germany

Due to lack of public data we assumed that the number of out-patient patients is one to two times higher than the number of inpatient patients (i.e. 40,064 up to 80,128 out-patient patients) due to economic incentives (non-budgeted reimbursement). The same assumption applies for implant removals (i.e. 3205 up to 6410).

4.6.4. Computation of direct costs in an out-patient setting

The implant removal costs are 402.35€ per case ("Einheitlicher Bewertungsmaßstab" [codebook for out-patient treatment]; code no.: 31132 [205.02€], 31503 [54.02€], 31615 [10.95€], 31822 [132.36€]) [40]. Thus, the additional costs for magnesium-based implants range from 1,114,308.25€ to 2,228,616.50€.

4.6.5. Computation of indirect costs in an out-patient setting

In case of implant removal in an out-patient setting, we estimate the absence from work to be 4 days. Consequently, the avoided indirect costs range from 2,474,260€ to 4,948,520€.

4.6.6. Overall comparison of the costs between conventional and magnesium-based implants

Applying magnesium-based implants has a huge cost saving potential both in terms of direct and indirect costs. If conventional

Table 4
Comparison in costs of conventional vs. magnesium-based implants in hallux valgus surgery.

Target population in an in-patient setting (M20.1 hallux valgus)	40,064
Number of implant removals (in-patient)	3205
Direct costs (in-patient)	
Additional costs of magnesium-based implants (assuming 60€ more expensive)	2,403,840.00€
Avoided costs of implant removal (total)	8,505,717.45€
Avoided direct costs by using magnesium-based implants	***6,101,877.45€***
Indirect costs for implant removal (in-patient)	
In-patient stay (5 days-off, 193€ indirect costs)	3,092,825.00€
Avoided indirect costs by using magnesium-based implants	***3,092,825.00€***
Avoided societal costs by replacement (in-patient, in % market exploitation)	
100% market exploitation	***9,194,702.45€***
50% market exploitation	4,597,351.23€
10% market exploitation	*919,470.25€*
5% market exploitation	459,735.12€
Avoided societal costs by replacement (in-patient and out-patient, in % market exploitation)	
100% market exploitation	***11,914,605.95€***
50% market exploitation	5,957,302.98€
10% market exploitation	1,191,460.60€
5% market exploitation	595,730.30€

Bold and italic numbers are the total costs or the most important amounts.

implants are replaced by magnesium-based implants, the society could save up to 11.9 Mio € (Table 4).

5. Conclusion

This study demonstrated that the biodegradable magnesium-based screws were statistically non-inferior to the conventional titanium screws and clinically superior, since there is no need to remove Mg screws later on. We did not observe any significant differences in mechanical stability, wound healing or infection rate. In 40% of the patients, implant-specific phenomena were found in follow-up radiographs. Surgeons, radiologist and patients should not be irritated by these phenomena, since they are an inherent part of the magnesium alloy degradation process. Complete consolidation of the osteotomy was seen in all cases with these radiologic, implant-specific findings.

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Conflict of interest

The author is working as a consultant for Syntellix AG, Hanover, Germany.

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