



# Magnesium-based bioabsorbable screw fixation for hallux valgus surgery – A suitable alternative to metallic implants



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## ABSTRACT

**Background:** The primary aim of this pilot study was to prospectively evaluate outcomes of the MgYREZr bioabsorbable screw in the setting of hallux valgus corrective surgery. The secondary aim was to compare the outcomes against a control group treated with conventional titanium screws.

**Methods:** A consecutive series of patients with hallux valgus deformity (n = 24) underwent forefoot reconstruction surgery with a scarf osteotomy to the first metatarsal using MgYREZr screws. Functional scores, radiological outcomes, and complication profile were recorded over 12 months. Results were compared against a control group of patients (n = 69) using titanium alloy screws.

**Results:** At 1-year post-operative, both functional and radiological outcomes showed significant improvements. Compared to the control group, there was no significant difference in functional outcomes, yet radiological improvements were significantly better in the control group.

**Conclusions:** The MgYREZr bioabsorbable screw is a suitable alternative to titanium alloy screws for hallux valgus corrective surgery.

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## 1. Introduction

Hallux valgus corrective surgery typically involves an osteotomy to the first metatarsal to correct the deformity along with appropriate soft tissue procedures and additional adjunct osteotomies for adequate correction. Conventionally, stainless steel or titanium metallic implants have been used to fix the osteotomy. Stainless steel and titanium are favoured due to their good mechanical strength, biocompatibility and resistance to corrosion [1]. However, in recent years the use of bioabsorbable implants has been gaining popularity due to some advantages over the conventional metallic implants. These bioabsorbable implants do not interfere with postoperative radiographic imaging, especially in MRI, owing to the absence of a metal artefact [1–5]. They also reduce the level of stress shielding as their Young's modulus

approximates normal bone more closely than stainless steel or titanium [1–4,6]. Moreover, as the implant gradually degrades, there is no need for removal of the implant, eliminating the need for a potential second surgery [2–4,6,7]. Finally, in the more global travelling community, anxieties pertaining to metal detectors in airports and implants are allayed.

Bioabsorbable polymers such as poly-L-lactic acid (PLLA), poly-glycolic acid (PGA) and poly-L-lactide-co-glycolide (PLGA) have been used in various areas of surgery but have their disadvantages. Due to their mechanical weakness, they occasionally break during or just after the implant is inserted [5]. At times, they can stimulate a foreign body reaction [3,4,6,8–10] through the degradation process that involves hydrolysis, resulting in an acidic pH environment [8,10,11] promoting infection [10] and formation of osteoclasts [8]. Pure magnesium was once considered an option due to its mechanical properties being comparable to cortical bone, alkalisation of its surrounding environment and its osteoinductive properties that stimulate bone growth. However, the major concern with pure magnesium has been the uncontrollable hydrogen gas formation [12,13] secondary to degradation, leading to local tissue displacement and at times, decreased survival rates in rats [12].

To date, magnesium-based alloys have been found to control this degradation rate, with several animal studies demonstrating its excellent safety profile [14–16]. There is limited data on the use

*Abbreviations:* HVA, hallux valgus angle; IMA, intermetatarsal angle; SF-36, Short Form 36; AOFAS-HMI, American Orthopaedic Foot and Ankle Society Hallux Metatarsophalangeal Interphalangeal; VAS, visual analogue pain score; NA, equal variances not assumed.

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of this implant clinically, as seen by the only other study using this implant [6] where the Chevron osteotomy was performed.

The purpose of this single centre prospective case series was to evaluate the clinical and radiological outcomes of a magnesium-based (MgYREZr; MAGNEZIX) bioabsorbable compression screw in hallux valgus corrective surgery involving the scarf osteotomy. The secondary aim was to compare the radiological and patient-reported functional outcomes with a control group of patients who had the same procedure performed with conventional titanium screws.

## 2. Materials and methods

### 2.1. Ethical approval

This prospective case series was approved by our institution's review board (Approval number: 2016/00309).

### 2.2. Inclusion and exclusion criteria

A consecutive series of patients with symptomatic hallux valgus who had failed nonoperative treatment and gave their informed consent to operative correction were included in this study. With preoperative radiographic evaluation, all patients demonstrated a hallux valgus angle (HVA) of more than 15 (range, 21.5–50.7) degrees and an intermetatarsal angle (IMA) of more than 8 (range, 8.8–21.8) degrees.

Exclusion criteria included those patients deemed unsuitable for a scarf osteotomy correction of their hallux valgus deformity (first tarsometatarsal joint instability or first metatarsophalangeal joint arthrosis) and those with active signs of infection.

### 2.3. Subjects

From March 2015 to May 2016 at the Tan Tock Seng Hospital (Singapore), Orthopaedic Surgery Clinic, patients with symptomatic hallux valgus and radiological indications for operative intervention were nominated for this prospective case series.

26 feet in 25 consecutive patients were recruited in the study but one patient was lost to follow up after her 3-months follow up visit as she had return to her native country (Table 1).

### 2.4. Functional and radiological evaluation

Functional evaluation was carried out preoperatively and at 1-year postoperative using validated scores: Short Form 36 (SF-36), as well as American Orthopaedic Foot and Ankle Society Hallux Metatarsophalangeal Interphalangeal (AOFAS-HMI) score. In addition, the visual analogue pain score (VAS) was used. The preoperative functional evaluation was done during the preoperative clinic consultations whilst the postoperative scores were tabulated at the 1-year postoperative consultation visits.

**Table 1**  
Patient demographics.

Demographic	Value
Number of patients recruited	25
Number excluded	1
Number of feet/recessions	25 (1 case of bilateral surgery)
Age	Mean: 54.5 years $\pm$ 12.0 years Range: 21–71 years
Gender	Female: 23, male: 1
Side of operation	Left: 14 (56%), right: 11 (44%)
Follow up months	Mean 12 months Range: 12–16 months

Radiological evaluation was performed with weightbearing X-rays (preoperative, 3 and 12 months postoperative), and a limited field forefoot CT scan was performed at 12 months postoperative to evaluate osteotomy healing, bioabsorption and any alterations to the surrounding bone or soft tissue.

The HVA was calculated by measuring the angle between the straight lines that cut the proximal and distal metaphyseal midpoints of the first metatarsal and proximal phalanx. The IMA was calculated by measuring the angle between the straight lines that crossed from the centres of the first and second metatarsals [17]. The reliability of interobserver variability of 5° or less in the measuring of the HVA and IMA has been validated [18].

Selection bias was minimized by recruiting consecutive patients from the same clinic with the same inclusion and exclusion criteria. Both the MAGNEZIX and conventional titanium groups were recruited in the same way, and thus minimizing design bias. Data was collated prospectively in both groups, thereby minimising response bias.

### 2.5. Comparing outcomes

Functional and radiological outcomes were compared against a control group fixed with conventional titanium screws. This control group (n=69) had the same forefoot reconstruction procedure done with a scarf osteotomy to the first metatarsal in the same institution, with no difference to the intra- or postoperative protocol. Data for the patients in this control group were extracted from a prospective research database maintained in our hospital for the period December 2012 to March 2015, preceding the start of this study. Patients in this historical dataset were from the same demographics, that were recruited as well as followed up in the same fashion as this case series.

### 2.6. Implant

The MAGNEZIX screw (Syntellix AG, Hannover, Germany) is a Magnesium alloy MgYREZr (magnesium, yttrium, rare earth, zirconium) that is reported to have good biocompatibility, osteoconductive properties and an appropriate soft tissue inflammatory response [8]. This implant has been approved for use by several regulatory bodies globally (CE marked, Health Sciences Authority Singapore). It is indicated for use in intra- and extra-articular fractures, nonunions, bone fusion, bunionectomies, as well as osteotomies [19]. All consecutive patients in this study had their first metatarsal scarf osteotomy stabilised with two 3.2 mm MAGNEZIX compression screws.

### 2.7. Surgery

The scarf osteotomy is commonly used for operative correction of hallux valgus deformity [17,20–22]. In our institution, the scarf osteotomy is our procedure of choice as part of a forefoot reconstruction for patients with a bunion deformity and metatarsalgia. All first metatarsal scarf osteotomies are performed in conjunction with a modified McBride's procedure. Other adjunct procedures that may be performed concurrently include an Akin's osteotomy of the hallux proximal phalanx and a Weil's osteotomy of the lesser metatarsal.

### 2.8. Statistical analysis

IBM SPSS Statistics for Windows, Version 20 (IBM Corp, Armonk, NY) was used to perform statistical analysis and identify significant changes between the preoperative and 1-year postoperative scores, as well as comparing the 1-year postoperative scores between the MAGNEZIX and control groups. Paired sample

t-test was performed on the pre- and postoperative MAGNEZIX patient data sets, while Levene’s test for equality of variance was performed between the two implant groups. Hedges’ g was used to determine the effect size of statistically significant results when comparing between the MAGNEZIX and control groups. Results were expressed as mean with ranges. A p-value <0.05 was considered statistically significant. Descriptive statistics were used for the demographic variables.

2.9. Post-hoc power analysis

Post-hoc power analysis was done using G\*Power version 3.0.10 [23], utilising the means and standard deviations of the postoperative HVA of the MAGNEZIX and control groups. Post-hoc calculation was done as the a priori calculation was not completed due to this being a pilot study for the use of the MAGNEZIX screw in scarf osteotomies. Assuming the level of significance ( $\alpha=0.05$ ) and using the postoperative HVA of the MAGNEZIX group (n=24) and the titanium group (n=69), we determined the effect size (d=0.928) and power of the study ( $1 - \beta=0.97$ ).

3. Results

3.1. Functional outcomes

Preoperative and 1-year postoperative SF-36, AOFAS-HMI and VAS scores were obtained. Functional outcomes analysis was therefore performed on the remaining 24 patients (25 feet) and summarized in Table 2.

At 1-year postoperative, there were significant improvements in the AOFAS-HMI, VAS and all domains of the SF-36 questionnaire except for role limitation due to emotional problems.

3.2. Radiological outcomes

Preoperative and 1-year postoperative X-rays were taken for all cases (n=24). The mean 1-year postoperative HVA and IMA showed significant improvements (Table 2). Asymptomatic peri-implant soft tissue gas shadows were seen on some 3-month X-rays, all of which had resolved on the 12-month postoperative X-ray. In these patients, no symptomatic concerns were reported during this interval. Figs. 1–4 are preoperative and postoperative weightbearing X-rays of a 34-year-old female patient’s left foot who received the MAGNEZIX compression screw.

CT scans were performed in 18 out of the 24 patients who were analysed. The remaining 6 patients declined to have CT scans due to concerns with excessive radiation. CT evaluation confirmed

complete healing of the osteotomy in all 18 patients with no peri-implant gas shadows. In a few patients, almost full absorption of the MAGNEZIX screw had occurred at the 1-year mark with the residual tissue demonstrating Hounsfield units closely resembling that of normal bone. Figs. 5–7 are CT scans of the same 34-year-old female patient’s left foot 11 months postoperative.

3.3. Comparing against conventional titanium screws

The functional and radiological outcomes in the MAGNEZIX series were compared against the control group fixed with conventional titanium screws (Table 3). The outcomes of this comparison are summarized in Table 4. For the values that equal variances were not assumed (NA), it meant that the variability between the two compared outcomes were significantly different, such that it would not be accurate to compare that parameter for the two groups.

The 1-year postoperative outcomes between the two groups showed that the SF-36 general health domain for patients in the MAGNEZIX group was significantly better than in the control group. On the other hand, radiological improvements in HVA and IMA for patients in the control group were significantly better than the MAGNEZIX group.

3.4. Complications

There were 3 cases (12.5%) of superficial cellulitis and 1 case (4.2%) of neuropathic operative site pain. All the cases with cellulitis resolved after a 1-week course of oral antibiotics. The one patient who reported neuropathic operative site pain had evidence of lumbar spondylosis with radicular pain. This patient’s symptoms were adequately managed with regular physical therapy sessions and a reducing dose of neuropathic medications. Comparatively, there were 3 cases (4.3%) of cellulitis and 1 case (1.4%) of complex regional pain syndrome in the control group. Of note, there was 1 patient (1.4%) who had her implant electively removed due to prominence of the implant that caused discomfort.

4. Discussion

There is limited clinical data on magnesium-based implants, despite its inherent benefits.

There have been a few studies evaluating the use of the MAGNEZIX screw in chevron osteotomies for hallux valgus corrective surgery [6,24,25]. The longest study duration was at 1 year in two studies [24,25] with the largest of only four patients followed up by the end of the study [24]. These studies

**Table 2**  
Summary of MAGNEZIX group results (preoperative and 1-year postoperative) (n=24).

MAGNEZIX Parameter	Preoperative Mean ± SD	1-year postoperative Mean ± SD	Improvements Mean ± SD	p-value
SF-36				
Physical functioning	78.8 ± 21.7	93 ± 10	14.2 ± 20.8	0.002
Role limitations due to physical health	71 ± 40	90 ± 16.1	19 ± 30	0.004
Role limitation due to emotional problems	85.3 ± 32	94.7 ± 12.5	9.3 ± 26.4	0.090
Energy/fatigue	67.1 ± 14.4	84.5 ± 9.2	17.4 ± 12.5	<0.001
Emotional well-being	79.7 ± 14.2	90.2 ± 9.5	10.6 ± 18.3	0.008
Social functioning	87 ± 17.9	97.5 ± 7.2	10.5 ± 19.7	0.013
Pain	59.5 ± 20.4	80.8 ± 15.1	21.3 ± 21	<0.001
General health	72.8 ± 15.8	92.2 ± 11.6	19.4 ± 15.3	<0.001
AOFAS-HMI	65.8 ± 16	89.5 ± 11.6	23.7 ± 12.4	<0.001
VAS	4.3 ± 1.9	0.5 ± 0.6	-3.8 ± 1.9	<0.001
HVA	33 ± 8	17.7 ± 7.1	15.2 ± 7.9	<0.001
IMA	15.8 ± 3	10 ± 3.7	5.8 ± 3.9	<0.001

Fig.1



Fig.2



Fig.3



Fig.4



**Figures 1–4.** Weightbearing Xrays of a 34 year old female patient's right foot pre- and post-operative. 1: Antero-posterior (AP) view, pre-operative. 2: AP view, 13 months post-operative. 3: Lateral view, pre-operative. 4: Lateral view, 13 months post-operative.

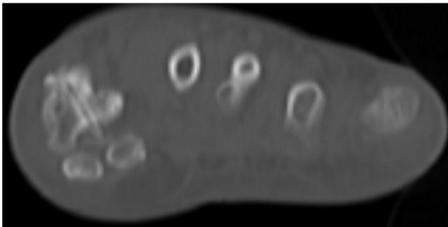


Fig. 5.

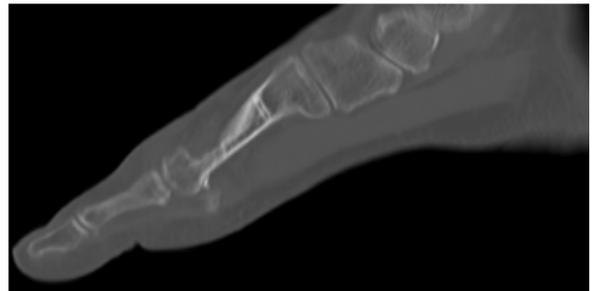


Fig. 7.

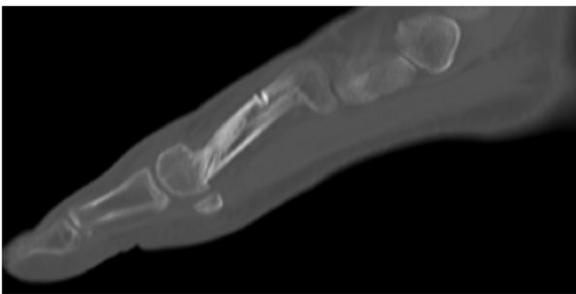


Fig. 6.

demonstrated significant functional outcomes and radiological correction maintained at least 3 to 6 months postoperative.

Most of the animal and clinical studies [6,13–16,19] found peri-implant gas lucencies through radiographic imaging but this did

not result in any complications. Our study also found similar lucencies that were clinically insignificant and appeared to mostly resolve by the third postoperative month.

The only published series comparing MAGNEZIX to titanium screws for chevron osteotomy found no significant difference in any of the outcome measures [6].

It has been reported that after 12 months, the MAGNEZIX implant will be completely absorbed and the residual material turned to a high-density apatite formation. This results in a radiographically visible but not fully intact metallic screw [14]. Only one long-term study of four patients with the MAGNEZIX implant for chevron osteotomy underwent MRI scans after 36 months, showing the former implant site to have significant signal loss, suggestive of implant resorption and bone deposition [26].

Several studies reported postoperative complications of scarf osteotomy for hallux valgus treatment using conventional screws. There were 2.8–14% of cases [27–31] who had symptomatic hardware requiring an additional procedure for removal of implant resulting in pain resolution. Furthermore, two studies [32,33]

**Table 3**  
Comparison of postoperative functional outcomes.

Comparison Parameter	MAGNEZIX group Mean ± SD	Control group Mean ± SD	Sig (2-tailed)	Hedges' g
SF-36				
Physical functioning	93 ± 10	89.1 ± 14.2	0.214	–
Role limitations due to physical health	90 ± 16.1	93.1 ± 20.1	0.487	–
Role limitation due to emotional problems	94.7 ± 12.5	95.2 ± 16.4	0.891	–
Energy/fatigue	84.5 ± 9.2	74.8 ± 16.6	0.001 (NA)	–
Emotional well-being	90.2 ± 9.5	84.8 ± 16	0.110	–
Social functioning	97.5 ± 7.2	94.1 ± 16.1	0.162 (NA)	–
Pain	80.8 ± 15.1	87.1 ± 18.6	0.137	–
General health	92.2 ± 11.6	78 ± 16.9	<0.001*	0.9
AOFAS-HMI	89.5 ± 11.6	83.6 ± 14.1	0.065	–
VAS	0.5 ± 0.6	1.3 ± 2.2	0.005 (NA)	–
HVA improvement	15.2 ± 7.9	24.1 ± 10.8	<0.001*	0.88
IMA improvement	5.8 ± 3.9	7.8 ± 4.1	0.031*	0.49

\* Denotes statistically significant findings (< 0.05).

**Table 4**  
Summary of control group results (preoperative and 1-year postoperative) (n = 69).

Titanium Parameter	Preoperative Mean ± SD	1-year postoperative Mean ± SD	Improvements Mean ± SD	p-value
SF-36				
Physical functioning	73.7 ± 21.4	89.1 ± 14.2	15.5 ± 22.8	<0.001*
Role limitations due to physical health	66.7 ± 39.5	93.1 ± 20.1	26.4 ± 36.6	<0.001*
Role limitation due to emotional problems	78.3 ± 37.4	95.2 ± 16.4	16.9 ± 34.1	<0.001*
Energy/fatigue	66.4 ± 16.6	74.8 ± 16.6	8.5 ± 19.4	0.001*
Emotional well-being	77.2 ± 13.2	84.8 ± 16	7.5 ± 14.9	<0.001*
Social functioning	82.4 ± 17.8	94.1 ± 16.1	11.7 ± 17.4	<0.001*
Pain	67.2 ± 18.3	87.1 ± 18.6	19.8 ± 22.1	<0.001*
General health	73 ± 17.6	78 ± 16.9	5 ± 20.2	0.043*
AOFAS-HMI	63.8 ± 14.8	83.6 ± 14.1	19.8 ± 16.7	<0.001*
VAS	5.8 ± 2.3	1.3 ± 2.2	–4.5 ± 2.6	<0.001*
HVA	35.7 ± 9.6	11.6 ± 6	24 ± 10.8	<0.001*
IMA	16.1 ± 3.6	8.3 ± 3	7.8 ± 4.1	<0.001*

\* = equal variances assumed, significant difference found.

reported peri-implant fractures in 2–3.8% of cases, even up to 7 months postoperative [32] suggestive of stress shielding contributing to these complications.

The only comparative study [6] reported delayed wound healing in 2 out of 13 (15.4%) patients for the MAGNEZIX group, and 1 out of 13 (7.7%) patients for the titanium group. That same study also reported 1 out of 13 patients (7.7%) in the titanium group removing her implant due to a symptomatic screw head.

**4.1. Limitations**

This study has a couple of limitations. First, the interventional group sample size is small when compared to the control group size. This was the direct result of the lack of an a priori sample size calculation, affecting the power of the study. However, we were able to perform post-hoc power analysis and determined the power of the study (1 – β = 0.97). Second, the minor variability in the combination of procedures performed in the study on top of the use of the MAGNEZIX screw in the scarf osteotomy for correction of the hallux valgus deformity in all cases. Given the variability between every forefoot deformity, the necessity to perform each forefoot reconstructive procedure slightly differently with a combination of adjunct procedures is clinically more relevant. Some of the patients did have lesser toe deformities or metatarsalgia apart from just bunion pain. Others with forefoot metatarsalgia with or without lesser toe deformities were typically dealt with a flexor to extensor lesser toe tendon transfer and a

Weil's osteotomy of the lesser metatarsal. A proportion of patients (n = 5) with a hallux valgus deformity also required an Akin's closing wedge osteotomy of the hallux proximal phalanx. Titanium screws were used for fixation in these other adjunct procedures (Akin's osteotomy and Weil's osteotomy) as the 3.2 mm MAGNEZIX screw, the only size available at the time of this study, was deemed too large for these smaller bones. Whilst it is possible this minor variability in the combination of procedures for each patient may have influenced the functional outcomes, there was no suggestion that these variations were any different between the MAGNEZIX group and the control group.

**5. Conclusion**

This study is the first of its kind evaluating the use of the MAGNEZIX compression screw in the scarf osteotomy for hallux valgus corrective surgery; improvements in almost all functional and radiological outcomes were significant. We also demonstrated non-inferiority of the MAGNEZIX implant when compared to titanium screws.

In addition, the MAGNEZIX implants are biocompatible, demonstrated no need for removal as observed by its absorption and resulted in no artefact when imaged with a CT scan There were no concerns with the strength of the implant, implant prominence, or peri-implant fractures. The osteotomy healed uneventfully in all cases with no loss of metatarsal alignment. Given the findings of our study and the inherent advantages of a bioabsorbable screw, it

is likely the MAGNEZIX implant has the potential for wider application across orthopaedic surgery such as in ligament reconstruction [9,16,27], trauma [19,28] and oral maxillofacial surgery [7,27]. Further studies with different implant sizes in different operative settings is required to fully establish the role of this new technology in our treatment armamentarium.

### Conflict of interest

We declare that the authors of this article: Dr Jianrong Tommie Choo, Dr Sean Wei Hong Lai, Dr Camelia Qian Ying Tang and Dr Gowreeson Thevendran did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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