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ORIGINAL ARTICLE

Comparison between bioabsorbable magnesium and titanium compression screws for hallux valgus treated with distal metatarsal osteotomies: A meta-analysis

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ABSTRACT

Objectives: In this review, we discuss the efficacy and safety of biodegradable magnesium screws compared to titanium screws in the treatment of hallux valgus (HV) in patients undergoing distal metatarsal osteotomy (DMO).

Materials and methods: Eligible scientific articles published prior to October 2022 were retrieved from the PubMed, Springer, ScienceDirect, and Cochrane Library databases. The terms used for searching included "hallux valgus", "distal metatarsal osteotomies", and "bioabsorbable magnesium screw" which were limited in the title or abstract through the text. The title and abstract were checked one by one to exclude the non-related studies. For primary identified studies and relevant systematic reviews, the full texts were accessed and browsed to finally include the eligible studies. No restriction was set on publication language and publication status.

Results: Two randomized-controlled trials (RCTs) and three non-RCTs that met the inclusion criteria were included. There was no significant difference in the American Orthopaedic Foot and Ankle Society (AOFAS) score, postoperative HV angle (HVA), intermetatarsal angle (IMA), Visual Analog Scale (VAS) score, soft tissue irritation, implant fracture, reoperation, and infection rates between two groups.

Conclusion: Bioabsorbable magnesium compression screws show comparable clinical or radiological results to titanium compression screws in the treatment of HV in patients undergoing DMO.

Keywords: Biodegradable screws, hallux valgus, meta-analysis, osteotomy.

Hallux valgus (HV) is one of common deformities of the forefoot and may result in severe pain, forefoot deformity, and impaired quality of life.[1] For mild cases, conservative treatment including physical therapy, insole or brace wearing can temporarily relieve pain and delay the progress of deformity.[2] In case of treatment failure, surgical treatment is commonly used to correct deformity, restore function, and relieve pain. Currently, distal metatarsal osteotomy (DMO) has been shown to be an effective technique for the correction of mild-to-moderate HV deformities with a congruent metatarsophalangeal joint.[3]

Metallic screw fixation after DMO allowing early rehabilitation and weight-bearing is commonly used to prevent postoperative loss of reduction.[4] However, adverse effects such as irritation of metallic screws or stress shielding are still inevitable. Elective implant removal due to irritation of metallic screws is seen in up to 26.9%

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of patients.[5] In addition, metallic screws result in artefact on computed tomography scans and have noise on magnetic resonance imaging.[6]

Biodegradable implants, such as polyglycolide, polydioxanone, and poly-L-lactic acid pins, have been developed to overcome the limitations of standard metallic implants.[7] However, some complications such as granuloma formation and foreign body reactions, sinus formation, and allergic reactions have been reported.[8] Recently, alternative bioabsorbable magnesium-based screws have been introduced in orthopedic surgery.[9] Several studies[10,11] have compared biodegradable magnesium screws with metal screws in patients undergoing DMO. However, whether biodegradable magnesium screws are effective and safe as metallic screws in DMO still remains controversial.

In this review, we discuss the efficacy and safety of biodegradable magnesium screws compared to titanium screws in the treatment of HV in patients undergoing DMO.

MATERIALS AND METHODS

Search strategy

This meta-analysis was prepared in accordance with the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). Two blinded authors independently conducted the searching strategy. The current study firstly searched electronic database for possible literatures in the following database: PubMed, Springer, Science Direct, and Cochrane Library databases from their respective inception dates to October 2022. The terms used for searching included "hallux valgus", "distal metatarsal osteotomies", and "bioabsorbable magnesium screw" which were limited in the title or abstract through the text. The duplications were firstly deleted. The title and abstract were checked one by one to exclude the non-related studies. For primary identified studies and relevant systematic reviews, the full texts were accessed and browsed to finally include the eligible studies. The bibliographies of the initial studies were additionally manually checked by turn for other relevant articles. No restriction was set on publication language and publication status.

Inclusion criteria

Eligibility criteria were defined using the Population, Intervention, Comparator, Outcomes and Study Design (PICOS) approach. Studies were selected for further quality evaluation and data extraction based on the following inclusion criteria: *(i)* HV patients treated with DMO; *(ii)* the test group were treated with bioabsorbable magnesium screws, the control group were treated with titanium compression screws; *(iii)* the clinical outcomes included postoperative American Orthopaedic Foot and Ankle Society (AOFAS) score, HV angle (HVA), intermetatarsal angle (IMA), distal metatarsal articular angle (DMAA), Visual Analog Scale (VAS), soft tissue irritation, implant fracture, loss of correction, reoperation, infection, and wound complications; *(iv)* studies were published comparative trials including randomized-controlled trials (RCTs) or non-RCTs.

Exclusion criteria

We excluded articles that were: *(i)* duplicate articles or articles including the same patients, content and results; *(ii)* theoretical research, case reports, meta-analyses, systematic reviews, expert comments, economic analyses and conference reports; and *(iii)* studies with non-relevant outcome.

Data extraction

Data extraction was independently performed by two researchers including the following aspects of the study population: authors, country, study design, publication year, sample size, age, sex, and outcome measures. The lack of clarity during the extraction was resolved by discussion between them. Multiple publications from the same studies were clustered.

Quality assessment

All eligible studies were independently evaluated by two reviewers. According to the Cochrane Handbook for Systematic Reviews of Interventions,[12] quality assessment of the included RCTs was conducted. For the non-RCTs, methodological quality was assessed using methodological index for non-randomized studies (MINORS).[13]

Statistical analysis

Statistical analysis was performed using the RevMan version 5.1 software (The Cochrane Collaboration, Oxford, UK). The mean differences (MDs) and 95% confidence intervals (CIs) were determined for continuous variables. The dichotomous data were expressed as the risk differences (RDs) with 95% CIs. The heterogeneity for each outcome was evaluated using the standard chi-square test. I^2<50% and p>0.05 was defined as no significant heterogeneity and the fixed-effect model was adopted. Otherwise, the random-effect model was selected, in case of I^2>50% and p<0.05. For heterogeneity, the random-effect model was used with reverse variance method. After excluding the obvious source of clinical heterogeneity, the random-effects model was used to

pool the data. When obvious clinical heterogeneity existed, the researchers performed subgroup or sensitivity analyses or only descriptive analyses.

RESULTS

Search results

A total of 52 studies were identified as potentially relevant literature reports. There were no additional studies identified through other sources. We obtained 28 articles, when the duplicate articles were removed. By scanning the title and abstract, 15 studies were excluded according to the eligibility criteria. Another eight articles were further excluded by reading the full text. Ultimately, two RCTs[10,15] and three non-RCTs[11,14,16] were eligible for data extraction and meta-analysis. The searching process is shown in Figure 1.

Characteristics of included studies

Demographic characteristics and other details of the included studies are presented in Table I. In each study, baseline characteristics of the two groups were found to be similar.

Risk of bias assessment

The methodological quality of RCTs was assessed according to the Cochrane Handbook for Systematic Reviews of Interventions (Figure 2). Inclusion and exclusion criteria were clearly stated in all RCTs. None of two included RCTs reported methodology for randomization, concealment of allocation, and blinding. Unclear bias was not reported due to incomplete outcome data or selective outcomes. The MINORS scores of the non-RCTs range from 17 to 20. The methodological quality assessment of the non-RCTs is presented in Table II.

Outcomes of the meta-analysis

Postoperative HVA

Postoperative HVAs were assessed in three studies. The pooled results demonstrated that postoperative HVA in the bioabsorbable screw groups was similar to that in the metal screw groups (MD= 2.56, 95% CI: -0.00 to 5.13; p=0.05) (Table III) (Supplementary 1).

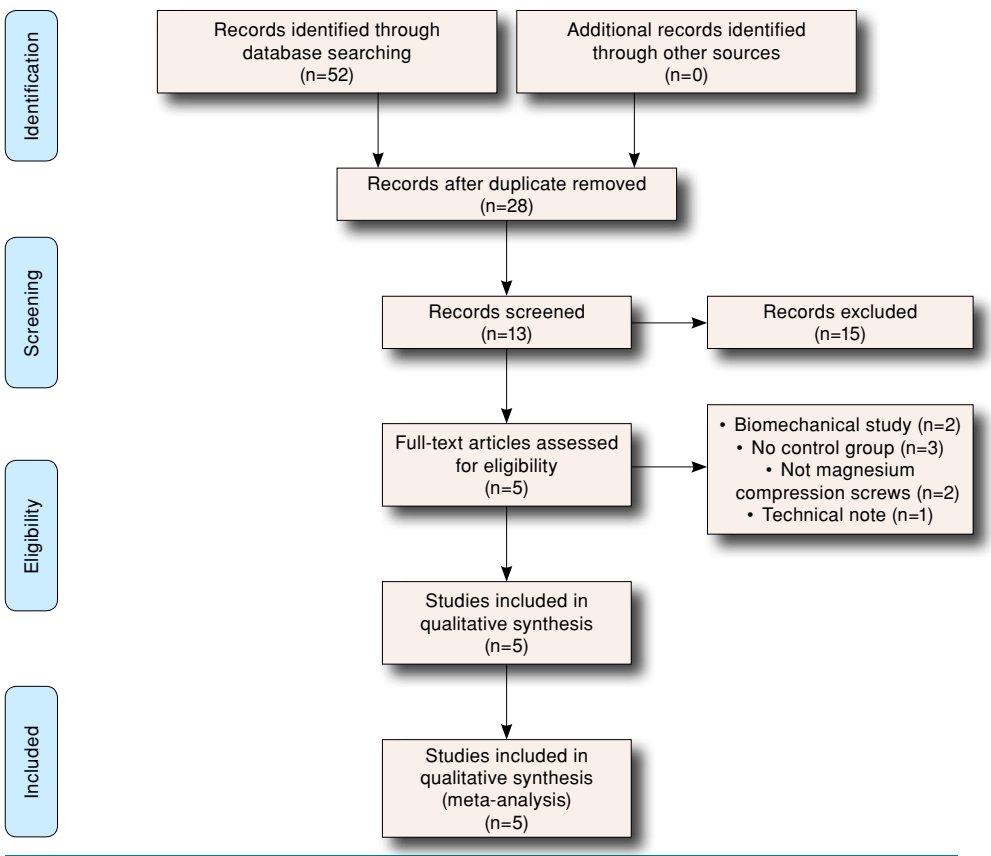


FIGURE 1. Flowchart of the study selection process.

TABLE I
Characteristics of included studies

Study	Date	Design	Type of screw	Cases	Mean±SD (age year)	Female	Osteotomy	Follow-up
Acar et al.[14]	2018	RCS	Mg	17	49.9±15.1	14	Chevron	19 months
			Ti	17	48.5±14.6	13		16.2 months
Klauser[11]	2018	RCS	Mg	100	50.9	95	Youngswick/Chevron	3 months
			Ti	100	52.3	90		3 months
Plaass et al.[10]	2018	RCT	Mg	8	56±8.9	NS	Chevron	3.18 years
			Ti	6	52±9.0	NS		3.1 years
Wendelstein et al.[16]	2021	RCS	Mg	16	60.6±12.1	16	Chevron	13 months
			Ti	16	60.2±11.5	16		14.34 months
Windhagen et al.[15]	2013	RCT	Mg	13	57.2±7.2	11	Chevron	6 months
			Ti	13	49.9±16.5	13		6 months

SD: Standard deviation; RCS: Retrospective controlled trial, RCT: Randomized-controlled trial, Mg: Magnesium, Ti: Titanium, NS: Not stated.

Postoperative IMA

Postoperative IMAs were assessed in three studies. The pooled results demonstrated that postoperative IMA in the bioabsorbable screw groups was similar to that in the metal screw groups (MD=0.14, 95% CI: -0.86 to 1.13; p=0.79) (Table III) (Supplementary 2).

Postoperative VAS

Postoperative VAS scores were reported in three studies. The pooled results demonstrated that postoperative VAS in the bioabsorbable screw groups was similar to that in the metal screw groups (MD=-0.12, 95% CI: -0.78 to 0.53; p=0.71) (Table III) (Supplementary 3).

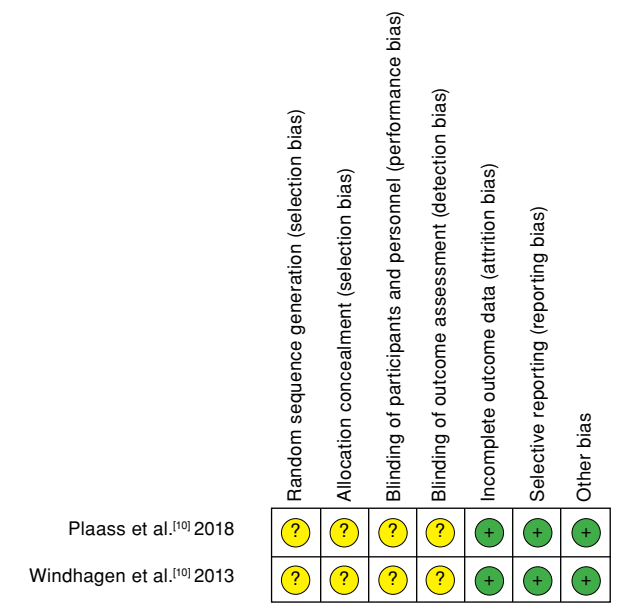


FIGURE 2. The summary of bias risk of randomized-controlled trials.

Postoperative AOFAS score

Postoperative AOFAS scores were available in three studies. The pooled results demonstrated that postoperative AOFAS score in the bioabsorbable screw groups was similar to that in the metal screw groups (MD=2.65, 95% CI: -2.05 to 7.34; p=0.27) (Table III) (Supplementary 4).

Soft tissue irritation

Soft tissue irritation was assessed in four studies. The pooled results demonstrated that the incidence of soft tissue irritation in the bioabsorbable screw groups was similar to that in the metal screw groups (RD=-0.03; 95% CI: -0.07, 0.01; p=0.13) (Table III) (Supplementary 5).

Implant fracture

Implant fracture was reported in two studies. The pooled results demonstrated that the incidence of implant fracture in the bioabsorbable screw groups was similar to that in the metal screw groups (RD=0.04; 95% CI: -0.09, 0.18; p=0.51 (Table III) (Supplementary 6).

Reoperation

Reoperation was performed in four studies. The pooled results demonstrated that the incidence of reoperation in the bioabsorbable screw groups was similar to that in the metal screw groups (RD=-0.06; 95% CI: -0.15, 0.04; p=0.22) (Table III) (Supplementary 7).

TABLE II
Quality assessment for non-randomized trials

Quality assessment for non-randomized trials	Acar et al.[14]	Klauser[11]	Wendelstein et al.[16]
A clearly stated aim	2	2	2
Inclusion of consecutive patients	1	2	2
Prospective data collection	0	0	0
Endpoints appropriate to the aim of the study	2	2	2
Unbiased assessment of the study endpoint	2	2	2
A follow-up period appropriate to the aims of study	2	2	2
Less than 5% loss to follow-up	0	2	2
Prospective calculation of the sample size	0	0	0
An adequate control group	2	2	2
Contemporary groups	2	2	2
Baseline equivalence of groups	2	2	2
Adequate statistical analyses	2	2	2
Total score	17	20	20

TABLE III
Meta-analysis results

				Overall effect		Heterogeneity	
Outcome	Studies	Groups (Mg/Ti)	Effect estimate	95% CI	*p*	I^2 (%)	*p*
Hallux valgus angle	3	46/46	2.56	-0.00-5.13	0.05	0	0.79
Intermetatarsal angle	3	46/46	0.14	-0.86-1.13	0.79	51	0.13
Visual Analog Scale	3	41/39	-0.12	-0.78-0.53	0.71	0	0.86
AOFAS score	3	41/39	2.65	-2.05-7.34	0.27	0	0.77
Soft tissue irritation	4	138/136	-0.03	-0.07-0.01	0.13	4	0.37
Implant fracture	2	116/116	0.04	-0.09-0.18	0.51	58	0.12
Reoperation	4	54/52	-0.06	-0.15-0.04	0.22	0	0.78
Infection	3	133/133	0.00	-0.04-0.04	1.00	0	0.62

Mg: Magnesium; Ti: Titanium; CI: Confidence interval; AOFAS: American Orthopaedic Foot and Ankle Society.

Infection

Infection was reported in three studies. The pooled results demonstrated that the incidence of infection in the bioabsorbable screw groups was similar to that in the metal screw groups (RD=0.00; 95% CI: -0.04, 0.04; p=1.00) (Table III) (Supplementary 8).

DISCUSSION

Our meta-analysis included five studies. The aim of our meta-analysis was to compare the efficacy and safety of bioabsorbable and metallic screws for HV treated with DMO. In the analysis of studies, we found that bioabsorbable magnesium compression screws showed comparable clinical or radiological results to metallic screws.[17]

Distal metatarsal osteotomy is an effective intervention for relieving pain and restoring function associated with mild-to-moderate HV deformities.[4] Postoperative VAS is a patient-reported score and is used extensively in many studies to assess patient pain following HV correction surgery.[18] The pooled data showed that postoperative VAS scores in the bioabsorbable magnesium screw groups were similar to that in the metallic screw groups. Our results are consistent with recent studies. Postoperative function determines the overall efficacy of HV correction surgery.[18] The present meta-analysis showed that postoperative AOFAS scores in the bioabsorbable magnesium screw groups were similar to that in the metallic screw groups. Based on these findings, we conclude that the bioabsorbable magnesium screws

have a similar therapeutic efficacy to titanium screw fixation in terms of function for DMO.

The requirement of removing metal implants is not uncommon in HV surgery due to metallic screws irritating the skin and cause pain and discomfort while wearing shoes. Jentzsch et al.[4] reported that elective implant removal due to irritation of metallic screws was up to 26.9% of the patients in the treatment of HV. Our results showed that there was no significant difference between two groups in terms of the incidence of soft tissue irritation. However, four patients in the metallic screws groups required removal of the screws (none in bioabsorbable magnesium screw groups), which corresponds to a 2.9% implant removal rate.

Complete bone union without correction loss is an important factor for determining patient satisfaction and overall outcome after DMO.[19] Sahin et al.[20] compared the fixation of distal chevron osteotomy (DCO) with bioabsorbable magnesium or titanium screws biomechanically. They found that the headless titanium screw and the magnesium screw provided equal stabilization for DCO fixation. Plaass et al.[10] also reported the presence of a radiolucent zone around the implant in all, but one of a patient series at six weeks and in 78% of cases at 12 weeks after surgery. Acar et al.[14] showed that a radiolucent zone was observed around the screws in all their patients on the early postoperative radiographs and this radiolucency continued long after six months even until 12 months with a decrease in size. As the osteotomy was already united, the presence of this radiolucent zone did not cause any displacement of the osteotomy. The current meta-analysis showed that postoperative implant fracture was not significantly different between the two groups, suggesting that the use of bioabsorbable magnesium screws is comparable for fixation of the osteotomy site.

When bioabsorbable magnesium screws implanted in the human body, a degradation or corrosion process takes place within a certain period of time, possibly leading to infection and inflammatory/allergic responses.[21] Acar et al.[14] found that gas evolution started immediately after implantation of magnesium screws. They reported that variable amounts of gas could be observed in soft tissues during the first two months and this gas was quickly absorbed and was not observed later than the third month. In the current meta-analysis, two of 133 patients in the bioabsorbable magnesium screw groups and two of 133 patients in the metallic screw groups had infection. The infection and reoperation rates in the bioabsorbable magnesium screw groups are similar to that in the metallic screw groups, consistent with previous studies.

Nevertheless, several limitations to this meta-analysis should be noted. First, only two RCTs and three non-RCTs were included, and the sample size of all the studies was relatively small. Second, the suboptimal methodological quality of the included studies and insufficient outcomes may weaken our analysis. Third, we were unable to perform subgroup analysis and determine the source of heterogeneity for the limited number of studies that were included. Further large-scale studies and meta-analyses are needed to confirm these findings.

In conclusion, bioabsorbable magnesium compression screws show comparable clinical or radiological results to titanium compression screws in the treatment of HV in patients undergoing DMO.

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Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Contributed to conception and design of this study: X.F., G.X.W., C.G.W., Z.J.L.; Study selection and data extraction of the finally included studies were done independently assessed the methodological quality of each included study: by X.F., G.X.W., C.G.W.; Contributed to preparation of the manuscript: X.F., G.X.W., Z.J.L.; The final version of the article was approved by all the authors. Thank you very much.

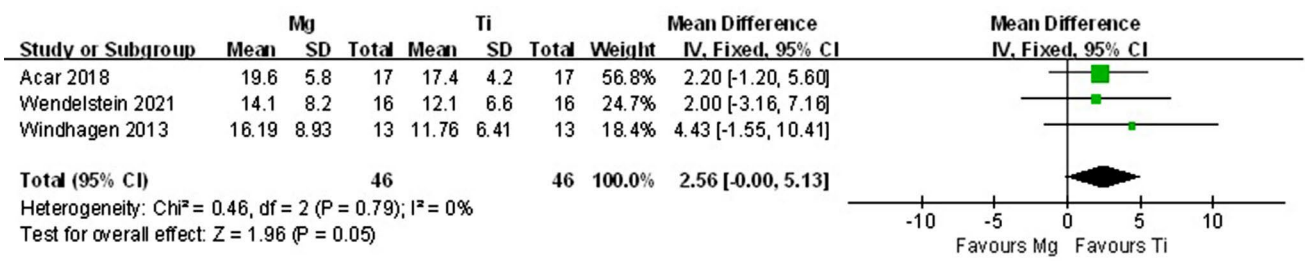
Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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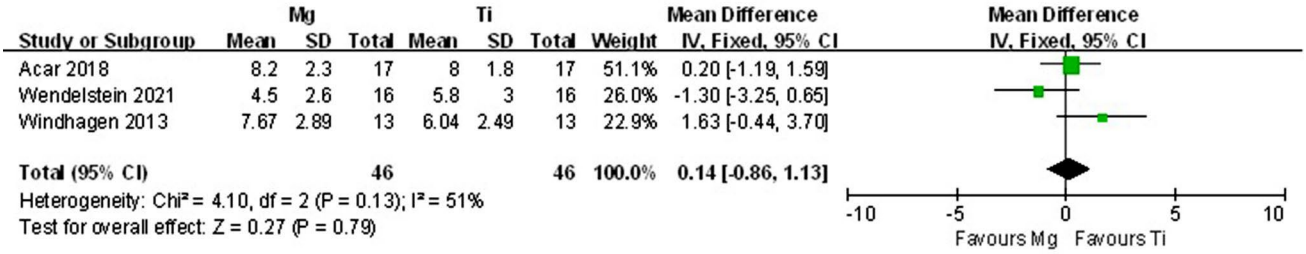
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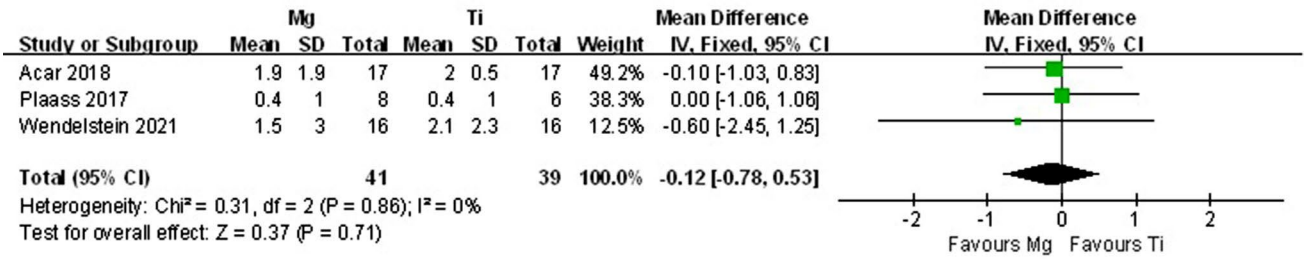
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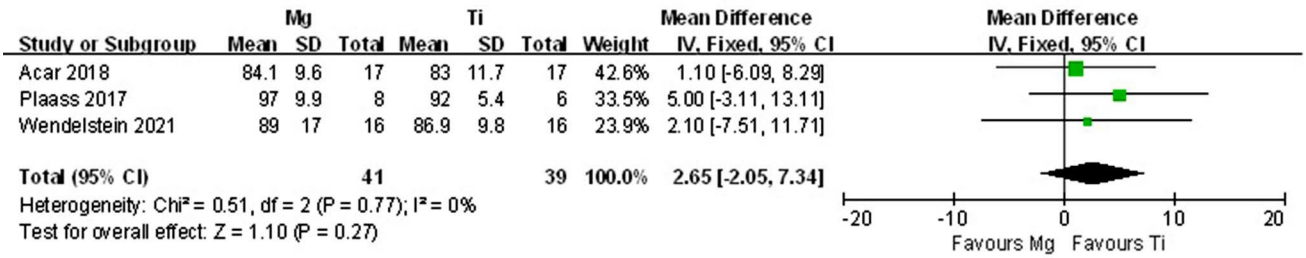
SUPPLEMENTARY 1. Supplementary information-postoperative HVA (Forest plot).
HVA: Hallux valgus angle; CI: Confidence interval.



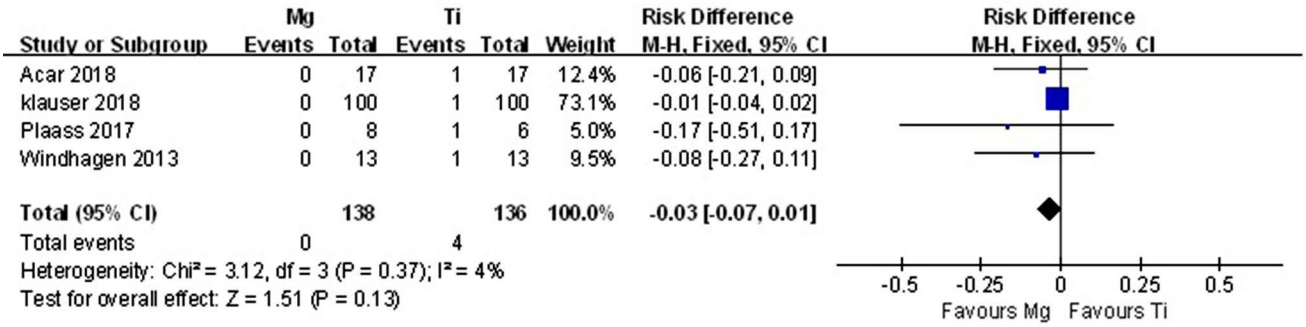
SUPPLEMENTARY 2. Supplementary information-postoperative IMA (Forest plot).
IMA: Intermetatarsal angle; CI: Confidence interval.



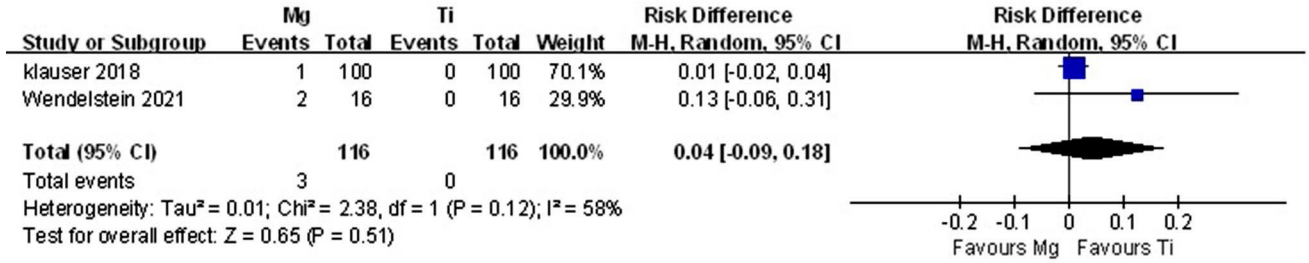
SUPPLEMENTARY 3. Supplementary information-postoperative VAS (Forest plot).
VAS: Visual Analog Scale; CI: Confidence interval.



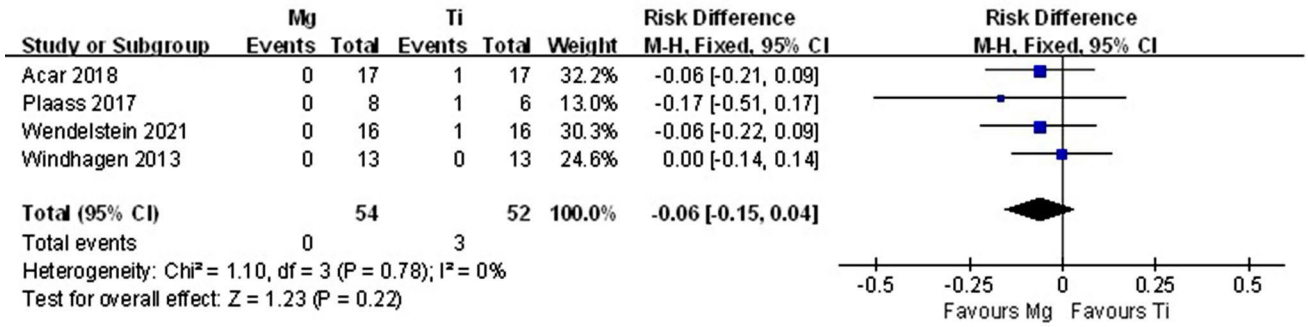
SUPPLEMENTARY 4. Supplementary information-postoperative AOFAS (Forest plot).
AOFAS: American Orthopaedic Foot and Ankle Society; CI: Confidence interval.



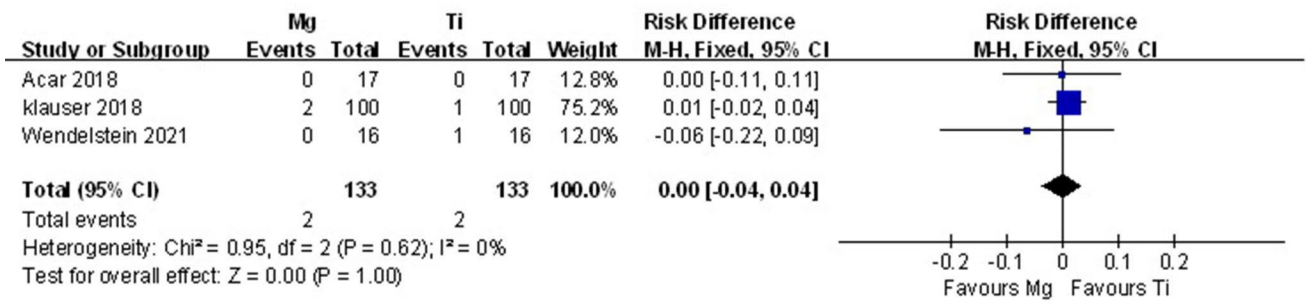
SUPPLEMENTARY 5. Supplementary information-soft tissue irritation (Forest plot).
CI: Confidence interval.



SUPPLEMENTARY 6. Supplementary information (Forest plot).
CI: Confidence interval.



SUPPLEMENTARY 7. Supplementary information-reoperation (Forest plot).
CI: Confidence interval.



SUPPLEMENTARY 8. Supplementary information-infection (Forest plot).
CI: Confidence interval.