



LITERATURE REVIEW

RESORBABLE WE43 VERSUS TITANIUM FIXATION DEVICES- EVALUATION OF TREATMENT OUTCOMES: A SYSTEMATIC REVIEW

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Abstract

Background: Internal fixation of mandibular fractures with Titanium (Ti) plates has become the gold standard for treatment in the adult population. Unfortunately, Ti plates had a tendency to undergo corrosion causing inflammation of surrounding bone that often led to failure of treatment. Magnesium (Mg) based newer materials such as WE43 alloy have been studied extensively for its ability to resorb in the presence of living tissue. Mg based WE43 alloy has demonstrated superior corrosion resistance and mechanical properties comparable to standard Titanium devices. The aim of this systematic review was to know whether WE43 based fixation devices can be used as an alternative to Ti based fixation devices for osteosynthesis.

Materials and Methods: PubMed, Cochrane, Google Scholar, Web of Science, were searched to find the studies comparing the WE43 fixation devices and Ti based fixation devices for osteosynthesis. No filters were applied. Search terms related to WE43, titanium, fixation, osteosynthesis, corrosion resistance, fracture fixation, complications of treatment, etc, were used to search relevant studies.

Data extraction, quality assessment, and summary synthesis for treatment outcomes including corrosion resistance, stability, osteosynthesis, adverse effects were carried out.

Results: 5 studies consisting of 3 in-vivo animal studies and 2 clinical trials were included after the screening of search results. In the animal studies, i)16 rabbit specimens were divided into 2 groups -Group I received Ti based implants, while Group II received Mg based WE43 implants. ii)10 beagle dogs were divided into 2 groups and evaluated at 4, 12, and 24 weeks after implant placement. iii)18 hemi mandibles of sheep were tested to check the outcome of fracture fixation between Mg and Ti based fixation devices. Group I used Ti1.0, Group II used Mg 1.75, and Group III used Mg 1.5. In the clinical trials, i) fixation of mandibular head fracture was done in 31 using WE43 screws and 29 patients using Mg screws and ii) 11 patients treated with Mg compression screws and 10 patients with Ti compression screws.

Conclusions: Comparison of properties of WE43 with Ti in the animal models has shown a non-inferiority of the Mg based material. Biomechanically, the human studies revealed promising results concerning the use of WE43 as a potential alternative to Ti in fracture fixation. Further evaluation is warranted under biomechanical loading conditions to verify the clinical performance of the material.

Keywords: WE43 alloy, resorbable plates, Titanium plates, mandibular fracture fixation.

INTRODUCTION

Titanium (Ti) based screws and miniplates have been used as conventional fracture fixation devices in the maxillofacial region for several years.^{1,2,3} Internal fixation of mandibular fractures with Ti plates has become the gold standard for treatment in the adult population. While their popularity is attributed to their superior mechanical properties and excellent biocompatibility with the facial structures, Ti devices have a few limitations.⁴⁻⁷ The need for an additional invasive procedure for removal of these metallic structures when indicated is one of the key drawbacks of their clinical application. In addition, Ti has shown the tendency for stress-shielding on bone due to mismatch in the load distribution between surrounding bone and metal. Post treatment radiographs have also demonstrated higher incidence of artifacts due to radiopaque Titanium.⁸⁻²⁵

Magnesium (Mg) has been studied extensively for its ability to resorb in the presence of living tissue. Since Mg exhibits an elastic modulus similar to cortical bone, it has a lower tendency for stress shielding of the fracture segments (26). Several Mg based alloys have been tested for their bioresorbable activity, namely AZ31, AZ91, WE43, LAE442, etc.²⁷ Mg has demonstrated the potential to induce osteogenesis,²⁸ with anti-inflammatory,²⁹ antimicrobial,³⁰ and antitumor properties.³¹⁻³⁶ Of these alloys, MgYREZr (i.e., WE43) has demonstrated superior corrosion resistance and mechanical properties,³⁷ and hence, has been chosen as the Mg alloy of interest in this study.

AIM

The aim of this systematic review was to know whether WE43 based fixation devices can be used as

an alternative to Ti based fixation devices for osteosynthesis.

RESEARCH QUESTION

Can WE43 fixation devices be used as an alternative to conventional Titanium fixation devices for osteosynthesis?

PICOS ANALYSIS

The search terms for the eligibility criteria using PICOS acronym are summarized below:

Population: patients requiring mandibular osteosynthesis, osteosynthesis, fracture fixation, mandibular fracture internal fixation.

Intervention: WE43 plates, resorbable plates, WE43 screws, WE43 alloy miniplates, WE43 resorbable screws, WE43 fixation devices.

Control: Titanium plates, Titanium fixation devices, Titanium screws, Titanium miniplates.

Outcome: treatment stability, local bone formation, complications, adverse effects of fracture fixation, hydrogen gas formation, local inflammation.

Study design: All clinical trials conducted from 2014-2024.

MATERIALS AND METHODS

Protocol: This systematic review was reported according to the Preferred Reporting Items for Systematic reviews and Meta Analyses (PRISMA) statement.³⁸

Eligibility criteria: In order to be included in this Systematic Review, the studies that have: 1) evaluated osteosynthesis or fracture fixation using WE43

miniplates or screws and compared with conventional Titanium based fixation device; 2) evaluated and reported following outcomes: plate stability, local bone formation around the material, mechanical properties of the material, potential complications such as gas formation or local inflammation. Studies conducted in vitro, case reports, case reviews, opinion, reviews were excluded.

Search strategy: An electronic search of available literature was conducted through the following databases: PubMed, Cochrane, Google Scholar, and Web of Science. The following search terms were used: Mandibular osteosynthesis, osteosynthesis,

fracture fixation, mandibular fracture internal fixation; WE43 plates, resorbable plates, WE43 alloy miniplates, WE43 screws, WE43 resorbable screws, WE43 fixation devices; Titanium plates, Titanium fixation devices, Titanium screws, Titanium miniplates; plate stability, local bone formation, potential complications, gas formation, local inflammation. These search terms were combined using Boolean operators ‘OR’ and ‘AND’ to produce a broad-spectrum survey of the available literature. The search strategy used in each of the databases is summarized below in Table 1.

Table 1. Search strategy for each database and individual results

DATABASE	SEARCH STRATEGY	RESULTS
PubMed	(Mandibular osteosynthesis) OR (osteosynthesis) OR (fracture fixation) OR (mandibular fracture internal fixation) AND (WE 43 plates) OR (resorbable plates) OR (WE43 alloy mini plates) OR (WE43 screws) OR (WE43 resorbable screws) OR (WE43 fixation devices) AND (Titanium plates) OR (Titanium fixation devices) OR (Titanium screws) OR (Titanium miniplates) AND (plate stability) OR (local bone formation) OR (potential complications) OR (gas formation) OR (local inflammation)	31
Cochrane Database	Mandibular osteosynthesis OR osteosynthesis OR fracture fixation OR mandibular fracture internal fixation AND WE 43 plates OR resorbable plates OR WE43 alloy mini plates OR WE43 screws OR WE43 resorbable screws OR WE43 fixation devices AND Titanium plates OR Titanium fixation devices OR Titanium screws OR Titanium miniplates AND plate stability OR local bone formation OR potential complications OR gas formation OR local inflammation	12
Google Scholar	Mandibular osteosynthesis OR osteosynthesis OR fracture fixation OR mandibular fracture internal fixation AND WE 43 plates OR resorbable plates OR WE43 alloy mini plates OR WE43 screws OR WE43 resorbable screws OR WE43 fixation devices AND Titanium plates OR Titanium fixation devices OR Titanium screws OR Titanium miniplates AND plate stability OR local bone formation OR potential complications OR gas formation OR local inflammation	166
Web of Science	Mandibular osteosynthesis OR osteosynthesis OR fracture fixation OR mandibular fracture internal fixation AND WE 43 plates OR resorbable plates OR WE43 alloy mini plates OR WE43 screws OR WE43 resorbable screws OR WE43 fixation devices AND Titanium plates OR Titanium fixation devices OR Titanium screws OR Titanium miniplates AND plate stability OR local bone formation OR potential complications OR gas formation OR local inflammation	97

Data extraction

The following parameters were extracted: author, year, study design, population, sample size, site, type of procedure, method of intervention (type of fixation used), duration of assessment, method of outcome assessment, potential complications.

Summary Synthesis

Statistical analysis of the data by performing a meta-analysis was not possible because the articles had very different objectives. Thus, the results were based on a descriptive analysis of the mechanical

properties, bone density and quality at the site of placement, adverse effects of the material used such as inflammation or hydrogen gas formation, and any failure of the device used.

Quality assessment and Level of Evidence

Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) tool was used to evaluate the quality of evidence in the included studies 39. Table 2a and 2b summarize the findings below.

Table 2a. GRADE assessment of quality of evidence for the animal studies

S.NO	STUDY DESIGN	QUALITY OF EVIDENCE
1.	Levorova et al., 2017- Animal study	Moderate quality of evidence
2.	Byun et al., 2019- Animal study	Low quality of evidence
3.	Fischer et al., 2023- Animal study	Low quality of evidence

Table 2b. GRADE assessment for quality of evidence of human trials

S.NO	STUDY DESIGN	QUALITY OF EVIDENCE
1.	Kozakiewicz et al., 2022- RCT	Moderate quality of evidence
2.	Kozakiewicz et al., 2022- RCT	Moderate quality of evidence

Risk of Bias assessment

SYSystematic Review Centre for Laboratory animal Experimentation (SYRCLE) Risk of Bias assessment tool was developed based on the Cochrane Collaboration RoB tool.⁴⁰ In this present review,

SYRCLE RoB was used to evaluate the 3 animal studies. Figure 2a, 2b and 2c summarize the findings below. The Cochrane RoB2.0 tool was used for evaluating the bias in the clinical studies.⁴¹ Figure 2a and 2b summarize the findings.

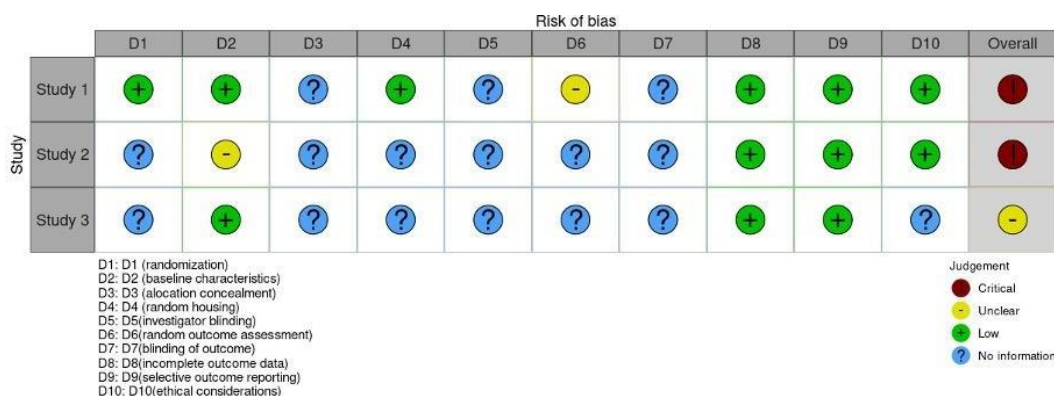


Figure 2a. Traffic plot for Risk of Bias of animal studies using SYRCLE tool

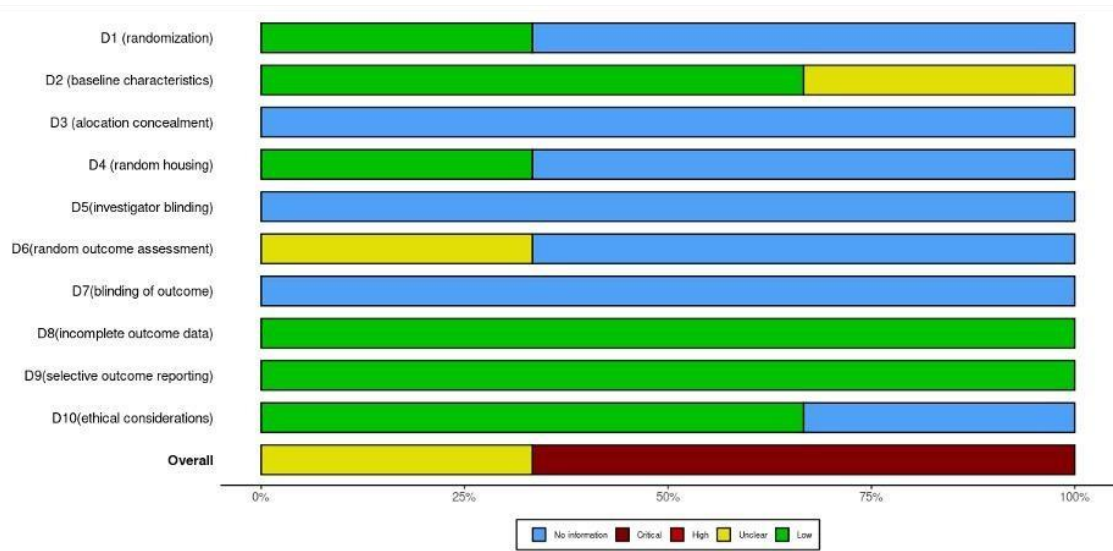


Figure 2b. Summary plot for SYRCLE assessment criteria of animal studies

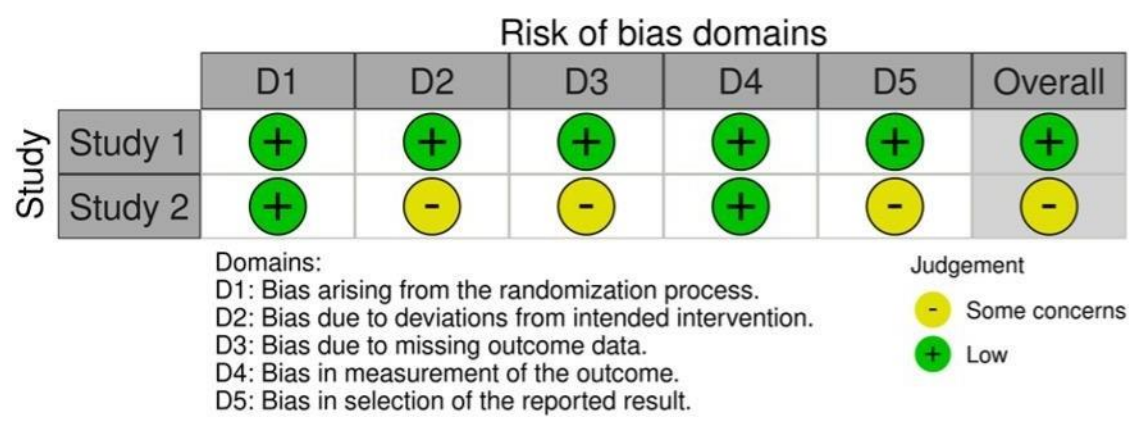


Figure 2c. Traffic plot for Risk of Bias using Cochrane's Collaboration RoB2.0 tool for Randomized Controlled Trials

RESULTS

Study selection flowchart A flowchart of article selection is presented in Figure 1. Preliminary survey of the databases using Boolean Operators 'AND' and 'OR' produced the following results. From the items retrieved by the keyword-based search of databases, duplicates were eliminated. Following this, titles were screened, and full text articles were assessed for

eligibility. Only 5 of these studies were included in this systematic review. Of these, 3 studies were conducted in animal specimens and 2 studies were conducted as clinical trials in human subjects.

Characteristic table.

The characteristics of the animal studies included in this review are tabulated below in Table 3. Table 4 summarizes the characteristics of the in vivo studies included in this review.³⁸

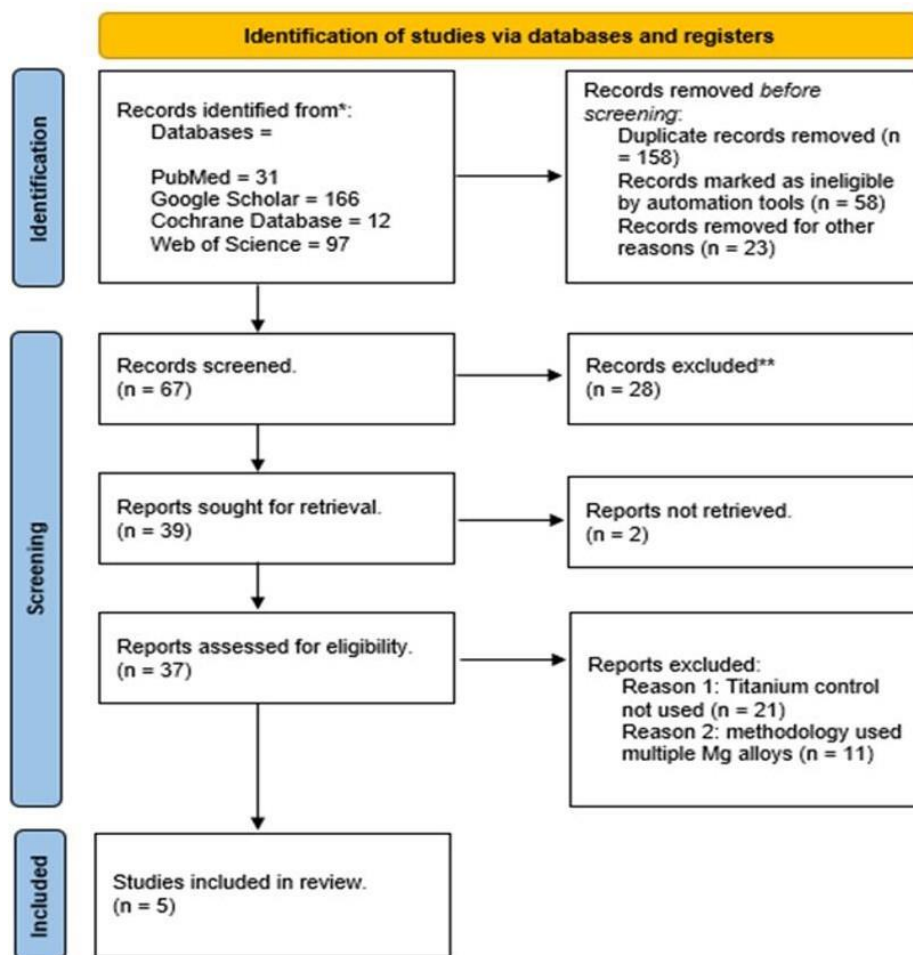


Figure 1. PRISMA flowchart of selected studies

Table 3. Characteristics of the animal studies included in this systematic review

	Levorova <i>et al.</i> , 2017 (42)	Fischer <i>et al.</i> , 2023 (43)	Byun SH <i>et al.</i> , 2019 (44)
Study design	Animal study-rabbits	Animal study-sheep heads	Animal study-beagle dogs
Sample	16 samples Group I - implants of Ti Group II - implants of WE43	18 samples (6 per group)	10 beagle dogs
Type of fixation (intervention)	Group I - Pure Ti screws (control) Group II - WE43 screws	Group I - Ti 1.0: 1mm thickness plate Group II - Mg 1.75: 1.75mm thickness plate Group III - Mg 1.5: 1.5mm thickness plate	Group I - Ti plates and screws (control) Group II - WE43 plates and screws (experiment)
Duration of intervention	Implants were evaluated at 4, 8, 12, and 16 weeks after placement.		Examined at 4, 12, and 24 weeks. At the end of 24 weeks, all animals were sacrificed.
Potential complications	Fragmentation of implant,	In all cases, failure of the	Wound dehiscence, plate

	Bone-interface contact, Changes in implant volume with time, Material fractures, threads thinning.	upper plate was observed.	exposure, gas formation, stability of fixation
Statistical tests		Mann-Whitney U test	
Conclusions	WE43 implants retain size and shape till 12 weeks. Bone healing is satisfactory in the WE43 group when compared to Ti control.	Higher stiffness observed in Ti plates.	Mechanical strength of extruded WE43 was sufficient for midfacial application. Degradation rate and gas formation can be controlled by surface treatment of WE43 alloy.

Table 4. Characteristics of the in vivo studies included in this review

	Kozakiewicz et al., 2022(45)	Kozakiewicz et al., 2022 (46)
Study design	In vivo study	In vivo study
Sample	61 patients Group I- Magnesium screws (32 patients) Group II- Titanium screws (29 patients)	21 patients Group I- Ti screws (11 patients) Group II- WE43 screws (10 patients)
Inclusion/Exclusion criteria	Inclusion: early posttraumatic period, type B or type C mandibular head fracture, applied surgical treatment, preauricular surgical approach to fracture, complete radiographic records Exclusion: type A mandibular head fracture, irregular follow up, conservative treatment, long post traumatic period.	Inclusion: early posttraumatic period, type B or type C mandibular head fracture, applied surgical treatment, preauricular surgical approach to fracture, complete radiographic records Exclusion: type A mandibular head fracture, irregular follow up, conservative treatment, long post traumatic period.
Type of fixation (intervention)	Group I- 31 Mg compression screws. Group II- 29 Ti compression screws.	Group I- Ti screws Group II- WE43 screws
Duration of intervention	Bone union and osteosynthesis was evaluated after 12 months in both groups.	18 months
Potential complications		Gas formation with material resorption, angulation of screws, loss of bone height
Statistical tests	t-test and W-test	ANOVA Mann-Whitney (Wilcoxon) W-test
Conclusions	Higher density of cancellous bone in experimental group.	Hydrogen gas formation seen in early phases of WE43 resorption. Mg fixation provides similar results as Ti fixation.

Risk of Bias

The 3 animal studies included in this review were assessed for risk of bias using the SYRCLE tool. Of these, the animal studies conducted by Levorova et al.,

and Fischer et al., were rated as ‘critical’ risk of bias and 1 study conducted by Byun SH et al., was rated as ‘unclear’ risk of bias.

Cochrane Collaboration’s RoB2.0 tool was used

to evaluate the risk of bias in the 2 RCTs. 1 trial by Kozakiewicz *et al.* 2022 was rated ‘low’ risk of bias. A second RCT by Kozakiewicz *et al.*, 2022 was rated ‘moderate’ risk of bias.

Summary of findings

The findings of the animal studies are summarized in Table 5. Table 6 summarizes the results of the human trials.

Table 5. Summary of findings of animal studies

S.NO	STUDY	FINDINGS
1.	Levorova <i>et al.</i> , 2017	Greater periosteal remodeling was evident in WE43 group around 8th week. At each time point, greater macrophage infiltration was observed in the WE43 group than in the Ti group. Giant cells were present in both groups but more in WE43 groups. Increase in surface area of WE43 implant was observed at 16th week
2.	Fischer <i>et al.</i> , 2023	No significant difference in peak force at failure between Mg and Ti miniplates. With thinner plates, the amount of hydrogen gas developed in total is reduced.
3.	Byun SH <i>et al.</i> , 2019	Swelling and gas formation were observed in 3 dogs from the WE43 group at 8 weeks. At 24 weeks, the osteotomy line was not observed, and complete bone healing was observed. MicroCT revealed all plates deviated from their original positions as they were absorbed.

Table 6. Summary of findings of in vivo studies

S.NO	STUDY	SUMMARY OF FINDINGS
1.	Kozakiewicz <i>et al.</i> , 2022	Bone union achieved in both groups was similar. Union site in the reference group had a lower entropy texture pattern.
2.	Kozakiewicz <i>et al.</i> , 2022	Bone consolidation at the osteosynthesis site was achieved in the Mg group and in the reference group.

DISCUSSION

Biomechanics plays a crucial role in the success or failure of bone healing and osteosynthesis.^{44,45} The forces in the local environment influence the success of the fracture fixation device that is used. Too rigid or too flexible a fixation can compromise the bone fixation.⁴⁶ In resorbable implants, the surface undergoes modification with resorption, and, hence, with the change in implant stability, progressively higher stresses are concentrated on the bone surface. In the case of resorbable implants such as Mg-based devices, the rate at which the metal resorbs must

match the pace of osteosynthesis.⁴⁷ Uncontrolled implant resorption might result in defective bony continuity with poor stability.⁴⁸

In vivo resorptive behavior of Mg-based alloys is 1–5 times slower than in an in vitro scenario.⁴⁹ In the mandible, the healing of mandible fractures allows patients to take up complete loading again after four weeks.⁵⁰ The speed of fracture healing and resultant osteosynthesis is influenced by the fracture pattern, the patient’s age, possible concomitant diseases, and individual factors.^{51,52} In vivo observations made by Witte *et al.*,²⁷ revealed that degradation of AZ series (AZ31, AZ91) and rare earth (WE43, LAE442)

containing magnesium alloys at the bone-implant interface in guinea pigs completely depended on the alloying elements. New bone in the periosteal and endosteal regions was deposited at the bone implant interface. If it is assumed that healing occurs in the same way in the minipig as in humans,⁵³ then the native bone formation was better using magnesium-based implants.

WE43, an Mg-based alloy, is being considered as a newer alternative to conventional Ti-based devices. Our search results detected 3 animal studies comparing WE43 devices to Ti-based gold standards in fixation. While there are a few animal studies assessing the potential role of WE43 as an alternative to Ti, similar data conducted in human subjects is rather scarce. As these study designs are heterogeneous, this review summarizes the available evidence for comparing the properties and treatment outcomes of WE43 and Ti-based fixation devices in animal and human subjects. Statistical analysis of the data by performing a meta-analysis was not possible because the articles had very different objectives. Thus, the results were based on a descriptive analysis of the mechanical properties, bone density, and quality at the site of placement, adverse effects of the material used such as inflammation or hydrogen gas formation, and any failure of the device used.

In the study conducted by Levorova et al., implant volume was assessed along with histological changes in the peri-implant tissue. At 4, 8, 12, and 16 weeks, giant cells (GC) were noted in the tissues of both Ti and WE43 samples, with a significant increase in the WE43 group. An increase in surface area of the WE43 implant was recorded in the 12th week (115.2% of the initial value), with a peak value at 16 weeks (321.9%). This change corresponds to the release of degradation products into the surrounding tissues, which further accelerates the degradation of the remaining implant. The authors had noted a potential influence of the suture material as an important factor on the GC count in the peri-implant area. A similar observation was made by Reifenrath et al.,⁵⁴ who noted a higher number of macrophages and cells of foreign bodies during a 6 months follow-up after placement of WE43 device, without any compromise on the tissue healing. Reifenrath et al. also noted the accumulation of hydrogen gas bubbles in the tissue surrounding WE43 implants. The inflammatory response observed in vivo is much lesser than in vitro

conditions. This is attributed to the elimination of corrosion products and inflammatory mediators from the local environment by diffusion processes.^{55,56}

Animal studies conducted by Fischer et al., on hemi mandibles of sheep, demonstrated failure of fracture fixation devices in both Ti and WE43 groups. The biomechanical loading in hemi mandibles of sheep, however, is not identical to that of human mandibles. The placement, and resultant stress on these devices show variations from the stress patterns in corpus fracture of human mandibles. The author also noted a reduction in the evolution of hydrogen gas with use of thinner fixation plates.

Byun SH et al., tested WE43 plates and screws in a canine model following Leforte I osteotomy. In the experimental group, 3 of the beagle dogs showed swelling and gas formation, and 3 showed inflammatory signs with infraorbital fistula. 2 of the dogs who showed lesser gas formation also demonstrated faster resorption of the fixation device. A similar study conducted by Lim et al.,⁵⁷ using only Mg screws showed lesser gas formation. The authors state a possible association between the volume of Mg placed in the tissue and the amount of hydrogen gas evolution.

The 2 human trials included in this review were assessed using the GRADE tool and the quality of evidence was marked as 'low' in one study and 'moderate' in the other RCT. The RoB2.0 tool was used to assess the Risk of bias in these RCTs. Both RCTs may be subject to reporting bias as they are conducted under similar clinical parameters by the same authors. Kozakiewicz et al., reported that the bone union achieved with rigid internal fixation of mandibular head using Mg alloy was found to be qualitatively similar to that achieved with Ti alloy. However incomplete resorption was noted after 12 months, evidenced by a marked densification of the bone structure at the fracture site. Witte et al.,⁵⁸ demonstrated that hydrogen gas formation may be negligible in slow corroding alloys due to dissolution in blood and diffusion through the skin. This might explain the variations in gas formation and subsequent soft tissue inflammation among the studies. Fischer et al., noted that a greater plate deformation was observed in Ti plates. Failure of fixation occurred at the plate itself, rather than the plate-bone interface. The main limitations of these studies were the non-consideration of dynamic testing in the biomechanical

evaluation of the fixation. More evidence is needed to provide insight on the design and placement protocols for resorbable plates to comprehensively evaluate the stability of the plate and fixation under biomechanical loading.

CONCLUSION

In summary, the comparison of the properties of WE43 with Ti in the animal models has shown the non-inferiority of the Mg-based material. Complications of hydrogen gas formation have been noted with the degradation of WE43 material, but this could be controlled by alteration of critical factors such as surface modification, alteration of plate dimensions, etc. Biomechanically, the human studies revealed promising results concerning the use of WE43 as a potential alternative to Ti in fracture fixation. Further evaluation is warranted under biomechanical loading conditions to verify the clinical

performance of the material.

DECLARATIONS

Conflicts of interest and financial disclosures

The author declares that he has no conflict percent and there was no external source of funding for the research in question.

Ethical approval

The study was approved by the Institutional Ethics Committee and was conducted in accordance with the Declaration of the World Medical Association.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Source of funding

The work was not funded.

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