Majestic American Journal of Dentistry
Volume 1, **2026**, **pp.** 1-14, **Article ID:** CM2610110006

Systematic Review Article

Magnesium-Based Barrier Membranes for Guided Bone Regeneration: An Updated Systematic Review of Clinical and Preclinical Evidence

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Article History

Received: 11 July, 2026 Revised: 07 October, 2026 Accepted: 15 October, 2026 Published: 02 November, 2026

Abstract:

Introduction: Magnesium-based barrier membranes provide temporary space maintenance and biodegradability in guided bone regeneration (GBR); clinical and experimental outcomes should be analyzed individually.

Objective: To synthesize *in-vivo* evidence on the clinical performance, safety, degradation and regenerative effects of magnesium-based GBR membranes.

Methodology: The PubMed/MEDLINE and ScienceDirect electronic databases were searched till 28 September 2026, and the literature search results were analyzed and filtered using PICOS eligibility criteria. If a report was made more than once for the same experiment, it was counted as one. A critical appraisal was conducted using design-specific JBI and the SYRCLE tools, and a descriptive (narrative) synthesis of the results was undertaken.

Results: Of 499 records identified, 19 primary studies were included (11 human clinical and 8 distinct animal GBR investigations). In 2026, there were 126 patients (195 procedures) with a success rate of 94.9%, clinically visible gas of 6.2%, and dehiscence of 10.5%.

Conclusion: Material feasibility and variable regenerative performance is suggested by *in-vivo* studies; however, uncontrolled clinical designs, some heterogeneity in animal methodologies and potential correlations between measurements of defects constrain certainty. Magnesium membranes have not been shown to have greater clinical success.

Keywords: Guided bone regeneration, magnesium membrane, barrier membrane, bone augmentation, biodegradation, systematic review.

1. INTRODUCTION

Guided Bone Regeneration (GBR) is a process that involves covering the defect site with a membrane to allow on-site remodeling with osteogenic tissue while excluding growth of the faster-growing soft tissues. No material is ideal for all defects as appropriate selection of an appropriate membrane involves a balancing act between biocompatibility, space maintenance, handling, exposure behavior and need for later removal [1-2].

Magnesium (Mg) has recently become a subject of renewed interest as a biodegradable material that can support a surgical procedure mechanically while it undergoes biodegradation. The degradation products may be excreted and release hydrogen gas; safety and performance aspects of this degradation need to be evaluated and is not inherent proof of clinical superiority [3].

This research on the magnesium-membrane literature has grown beyond the initial clinical reports. Blašković *et al.* [4] combined a literature review with two human cases. Afterwards, a magnesium membrane in periodontology and implant dentistry was discussed by Gerova-Vatsova [5] and Gabrić *et al.* [6] mapped 39 publications from laboratory, preclinical, clinical and review evidence. It is therefore not a

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Cite as: Bansod S. Magnesium-based barrier membranes for guided bone regeneration: An updated systematic review of clinical and preclinical evidence. Majes. Amer. J. Dentis. 2026; 1: 1–14. Article ID: CM2610110006.

substitute for these earlier syntheses (the present one is not intended to be such). Its contribution is an updated primary *in-vivo* evidence synthesis (with separate consideration of evidence from human feasibility studies and comparative evidence from animal studies) that entails explicit conflict-of-interest reporting at study level and design-appropriate critical appraisal.

The review question was: What is the evidence for the safety, degradation and regenerating performance of magnesium-based barrier membranes in human oral/maxillofacial GBR and in the relevant *in-vivo* animal GBR models when compared to a comparator, the conventional membrane, or no membrane? None of the criteria are regarded as proof of clinical superiority in the absence of an appropriate comparative design: technical acceptability, safety observations, biological plausibility and regenerative performance, and the comparative effectiveness evaluation.

2. METHODOLOGY

2.1. Review Framework and Eligibility (PICOS)

PICOS defined eligibility as follows. Population: patients requiring oral/maxillofacial bone regeneration, or animals with alveolar, mandibular or calvarial bone-defect GBR models. Intervention: a magnesium membrane/mesh serving as the principal defect-covering barrier. Comparator: collagen, PTFE, titanium, an untreated defect, or another barrier where available. Outcomes: bone regeneration, bone volume, barrier maintenance, degradation/gas, wound healing and adverse events. Designs: primary *in-vivo* human or animal investigations; uncontrolled clinical reports were eligible only for feasibility and safety description. Subcutaneous implantation experiments without a bone defect, *in-vitro* only tests, reviews, and non-GBR magnesium devices were excluded from the core GBR effectiveness synthesis. Multiple defect sites within a single animal were distinguished from independent animals; reports describing one experiment more than once were linked and counted as one investigation. 2014-to-2026-year limit was imposed.

2.2. Information Sources and Search Strategy

PubMed/MEDLINE and ScienceDirect were searched from 1 January 2014 to 28 September 2026, retrieving 101 and 398 records, respectively. The search strategies are reported in Table **1**, and screenshots of the database searches are provided in Appendix **A** (Figs. **2**–**3**). The review is reported in accordance with the PRISMA 2020 statement and systematic review guidelines [7-8] (Appendix **C**).

Table **1A** summarizes the number of records at each stage of study selection; the corresponding flow diagram is shown in Fig. (**1**).

2.3. Study Selection and Data Collection

Titles / Abstracts and full texts were independently assessed and appraised. Extracted characteristics included study design, experimental units (patients, procedures, animals and defects), intervention/comparator, outcomes, follow-up and funding. Key extracted data were cross-checked against the primary publications.

2.4. Critical Appraisal

SYRCLE was used as a framework for animal studies [9], and corresponding JBI checklists were used for clinical reports/series and the uncontrolled prospective cohort [10–12]. ROBINS-I [13] was not applied because no included clinical study compared magnesium membranes with a control group. Domains with insufficient reporting were rated as unclear. Multiple defects from one animal are correlated by design unless an analysis explicitly accounts for clustering; the primary studies were checked for stated allocation and analytical units wherever reported. Appraisal results are presented in Appendix **B**.

2.5. Synthesis Method

No meta-analysis was undertaken because case reports, small uncontrolled series, a three-month uncontrolled cohort and heterogeneous animal experiments provide incommensurable measures, comparators, defect units and endpoints. A narrative, design-stratified synthesis informed by SWiM [8] was used. Where numerical treatment-group summaries were available, they were reported as study-specific observations without pooling or treating multiple defects from one animal as independent animals. No reporting-bias or certainty-of-evidence assessment was performed.

3. RESULTS

3.1. Study Selection and Eligibility

Nineteen primary *in-vivo* studies [4, 14-24, 25, 26-29, 30-31] were included (Fig. **1**): 11 clinical reports (Table **2**) and eight distinct animal bone-defect GBR investigations (Table **3**). The subcutaneous mouse compatibility experiment of Steigmann *et al.* [32] does not meet the bone-defect GBR population criterion. Therefore, it is retained for comparison only. Rider *et al.* [25, 33] describe overlapping canine experiments and were not counted twice. Studies of conventional membranes only were ineligible.

The database searches identified 499 records (PubMed n = 101; ScienceDirect n = 398). 499 titles and abstracts were screened and 467 were excluded. Of the 32 reports sought for retrieval, six could not be obtained; 26 full texts were assessed for eligibility, seven were excluded, and 19 studies were included (11 human clinical and eight preclinical animal studies).

3.2. Clinical Evidence and Evidence Hierarchy

Clinical indications in the 11 descriptive publications (Table **2**) include ridge/socket augmentation, sinus and periodontal defects, mandibular GBR and membrane exposure [4, 14-23]. The prospective cohort of Franke *et al.* [23] enrolled 126 individuals who underwent 195 surgical procedures, some repeatedly. Its published overall values were treatment success 94.9%, clinically detectable gas 6.2%, and wound dehiscence 10.5%. Because some patients underwent more than one procedure, these percentages should not be interpreted as patient-level rates. No comparative human treatment effect can be inferred.

Table 1. Database search strategies.

Database	Search date	Complete search string	Limits
PubMed/MEDLINE	28 Sep 2026	(("guided bone regeneration"[Title/Abstract] OR GBR[Title/Abstract] OR "alveolar ridge augmentation"[Title/Abstract] OR "bone regeneration"[Title/Abstract]) AND (magnesium [Title/Abstract] OR "magnesium-based"[Title/Abstract] OR "Mg alloy"[Title/Abstract]) AND (membrane*[Title/Abstract] OR mesh [Title/Abstract] OR barrier*[Title/Abstract]))	English; 2014-2026
ScienceDirect	28 Sep 2026	("guided bone regeneration" OR GBR OR "alveolar ridge augmentation") AND (magnesium OR "magnesium-based" OR "Mg alloy") AND (membrane OR mesh OR barrier)	Research articles; English; 2014-2026

Table 1A. Number of records at each stage of study selection.

Flow stage	Count
Database records identified	499
Duplicate records removed	0
Automation exclusions before screening	0
Other pre-screening exclusions	0
Titles/abstracts screened	499
Title/abstract exclusions	467
Reports sought for retrieval	32
Reports not retrieved/unavailable	6
Full texts assessed	26
Full-text exclusions	7
Studies included in review	19
Composition of included studies	11 clinical + 8 preclinical

Review articles, including Blašković *et al.* [4], were included only for their separately reported primary clinical cases. Steigmann *et al.* [32] tested a subcutaneous mouse implantation model and is treated as contextual tissue-compatibility evidence rather than eligible bone-defect GBR evidence. Rider *et al.* [25] and Rider *et al.* [33] describe the same beagle GBR experimental programme and are treated as one canine investigation, with [33] supplying additional degradation and 52-week findings. Yan *et al.* [30] and Wu *et al.* [31] report eligible canine/rat bone-defect GBR comparisons and were included.

3.3. Preclinical Comparative and Mechanistic Evidence

Eight distinct animal GBR experiments are tabulated (Table **3**): Barbeck [24], Rider [25], Shan [26], Zhao [27], On [28], Beitlitum [29], Yan [30] and Wu [31]. Steigmann [32] is contextual subcutaneous evidence, while the beagle analysis by Rider [33] shares the canine cohort described in [25] and is considered companion follow-up evidence. Zhao *et al.* [27] studied 12 dogs divided into three groups of four. Shan [26] included 12 rabbits with 48 defect sites (six rabbits per observation time); Beitlitum [29] analyzed nine rabbits with 36 sites, and Yan [30] included eight dogs with 32 defects. Defect-site data do not constitute independent animal replicates; reported group comparisons were not assumed to use clustered analyses unless explicitly described.

3.4. Critical Appraisal and Study-Level Conflicts of Interest

Table **B1** provides the 8 animal experiments used in the synthesis in Table **3**. Domains with inadequate reporting were given the rating unclear (U). Importantly, the Rider [25, 33] canine experiment had multiple sites on each dog; for multiple defect sites, the independence of these test results cannot be established by the animal-level statistical tests alone. Beitlitum [29] reported nine animals completed evaluation following an initial animal loss, which should be considered in completeness assessment. Tables B2–B4 illustrate the clinical JBI tools used.

Transparency information for the study-level was documented but was not automatically regarded as risk of bias. Rider, *et al.* [25] reported that they have employment / affiliations with botiss biomaterials/biotrics and received company sponsorship. Industry linked authors were also included in a few clinical reports (Palkovics, Elad, Hangyasi, Chaushu and Tabanella [14, 16-18, 21-22]). Both On *et al.* [28] and Franke *et al.* [23] stated that they had no competing

interests, and German Research Foundation funding, respectively. Beitlitum *et al.* [29] reported support from The Siegmund and Lola Fischel Fund in Oral Implantology (grant 33310000000); Botiss biomaterials supplied the study materials but was reported to have no role in study funding beyond material provision, study design, data collection or analysis, publication decisions, or manuscript preparation, and the authors declared no conflicts of interest. These relationships are reported in Tables **2** and **3** so that readers can consider them when interpreting the evidence.

Table 2. Clinical studies of magnesium-based barrier membranes.

Study	Sample	Population / Intervention	Comparator	Follow-up	Key Outcome	Funding / COI	Appraisal
Blašković *et al.* 2023 [4]	2 human cases	Ridge GBR; pure Mg membrane + Mg fixation	None	Clinical/ radiographic follow-up	Feasible regeneration; no adverse biomaterial reaction reported	Industry-linked coauthors present	JBI series: inclusion/consecutiveness unclear; uncontrolled
Palkovics *et al.* 2023 [14]	2 cases	Alveolar ridge augmentation	None	Up to 2 y	Stable hard-tissue volume in reported cases	Botiss-affiliated coauthors	JBI series: uncontrolled; consecutive/complete inclusion unclear
Frosecchi 2023 [15]	1 case	Horizontal/vertical defect; Mg + collagen membrane	None	8 mo	Augmented volume maintained; Mg no longer visible at re-entry	No material COI identified in source summary	JBI case report: descriptive evidence only
Elad *et al.* 2023 [16]	4 cases	Immediate dentoalveolar regeneration	None	Case-specific	Bone and soft-tissue healing reported	Botiss-affiliated coauthors	JBI series: uncontrolled; selection unclear
Elad *et al.* 2023 [17]	4 cases	Sinus-lift/Schneiderian membrane repair	None	4–8 mo	Bone gain and implant-supporting regeneration reported	Botiss-related competing interests disclosed	JBI series: uncontrolled; selection unclear
Hangyasi *et al.* 2023 [18]	3 cases	Intrabony periodontal defects	None	4–6 mo	Radiographic regeneration; mean PPD reduction reported	Botiss-affiliated coauthors	JBI series: small uncontrolled series
Franke & Korzinskas 2024 [19]	1 case	Posterior mandibular GBR + Mg screws	None	3 mo to re-entry	Dense vascularised bone enabled implant placement; transient tingling reported	No competing interest identified in source summary	JBI case report: descriptive evidence only
Blašković *et al.* 2024 [20]	1 case	Alveolar ridge preservation	None	6 mo	Clinical/histological bone regeneration reported	Industry-linked author affiliations	JBI case report: descriptive evidence only
Chaushu *et al.* 2025 [21]	1 case	GBR after large radicular cyst	None	16 mo	Restored palatal contour/cortication on CBCT	Industry-affiliated coauthors included	JBI case report: descriptive evidence only
Tabanella *et al.* 2025 [22]	4 cases	GBR with membrane exposure/dehiscence	None	Case-specific	Healing without infection reported despite exposure	Botiss-affiliated authors disclosed	JBI series: hypothesis-generating only; no control
Franke *et al.* 2026 [23]	126 patients; 195 procedures	Prospective observational GBR cohort	None	Up to 3 mo	94.9% success; 6.2% gas; 10.5% dehiscence.	DFG-funded; no known competing interests reported	JBI cohort: uncontrolled, ≤3 months; 195 procedures in 126 patients

Table 3. Preclinical *in-vivo* studies retained in the core translational synthesis.

Study	Sample / Model	Mg Intervention	Comparator	Follow-up	Key Outcome	Funding/COI	Risk-of-Bias Note
Barbeck *et al.* 2020 [24]	18 NZW rabbits; 4 calvarial defects each	HF-treated Mg mesh/collagen; untreated Mg/collagen	Collagen; sham	6, 12, 18 wk	HF treatment reduced gas cavities; bone regeneration assessed across groups	Industry affiliations reported	SYRCLE: randomised defect allocation reported; several blinding domains unclear
Rider *et al.* 2022 [25]	22 Yucatan minipigs (corrosion kinetics) and 20 beagle dogs (GBR; overlapping [33])	Pure Mg membrane	Collagen in performance arm	Minipigs 1–16 wk; dogs 1, 8, 16, 52 wk	Canine GBR bone formation comparable to collagen; [33] is companion µCT analysis, not an independent cohort	Botiss/biotrics employees; companies financed study	SYRCLE: canine membranes were not randomly assigned [33]; defect clustering not clearly addressed
Shan *et al.* 2022 [26]	12 rabbits; 48 defects (4/rabbit; 6 rabbits/time point)	MAO-treated pure Mg	Titanium; blank	2 and 8 wk	MAO slowed degradation and supported new bone formation	NSFC China grant 52001034; authors declared no conflicts	SYRCLE: defect-level allocation; clustering within rabbit not assumed accounted for
Zhao *et al.* 2023 [27]	12 dogs; 3 groups (n=4 dogs/group)	Pure Mg + graft	Collagen + graft; graft only	4, 12, 24 wk	24-wk CBCT bone density (HU): Mg 756.59±33.47; collagen 685.51±32.59; graft alone 579.61±35.51	Three government grants (see primary article [27])	SYRCLE: animals allocated to groups; blinding/cluster accounting not established
On *et al.* 2024 [28]	24 male rabbits; bilateral calvarial defects	PLLA-coated Mg-Dy; uncoated Mg	Positive and negative controls	4, 8, 12 wk	Coating reduced degradation; favourable bone formation/material maintenance	Authors declared no competing interests	SYRCLE: random allocation stated; some blinding domains unclear
Beitlitum *et al.* 2025 [29]	9 rabbits analyzed, 36 sites (4/rabbit); one additional animal died perioperatively	Mg membrane with/without xenograft conditions	Uncovered control conditions	8 wk	Greater bone formation in Mg-treated conditions; gas in about one-third of specimens	Fischel Fund; Botiss provided materials; authors reported no competing interests.	SYRCLE: within-rabbit comparison; perioperative attrition and site clustering require attention
Yan *et al.* 2022 [30]	8 beagle dogs; 32 defects; repeated sites per dog	MAR-Gide Mg-alloy membrane	Bio-Gide collagen membrane	3 and 6 mo	3-mo trabecular BV/TV 63.71±10.4% *vs* 59.97±8.94%; overall histological NBF similar	Authors declared no COI	SYRCLE: defect randomisation stated; animal clustering/statistical model unclear
Wu *et al.* 2021 [31]	Sprague–Dawley rats; 16 Mg meshes tested	Ca-phosphate-coated Mg mesh	Uncoated Mg mesh	4 and 8 wk	8-week mesh degradation: 21.98% coated *vs* 58.49% uncoated; early bone-volume gain, no 8-week between-group difference	Korean NRF 2018R1D1A1B07049491; no commercial COI declared	SYRCLE: allocation, blinding and effective animal n require confirmation

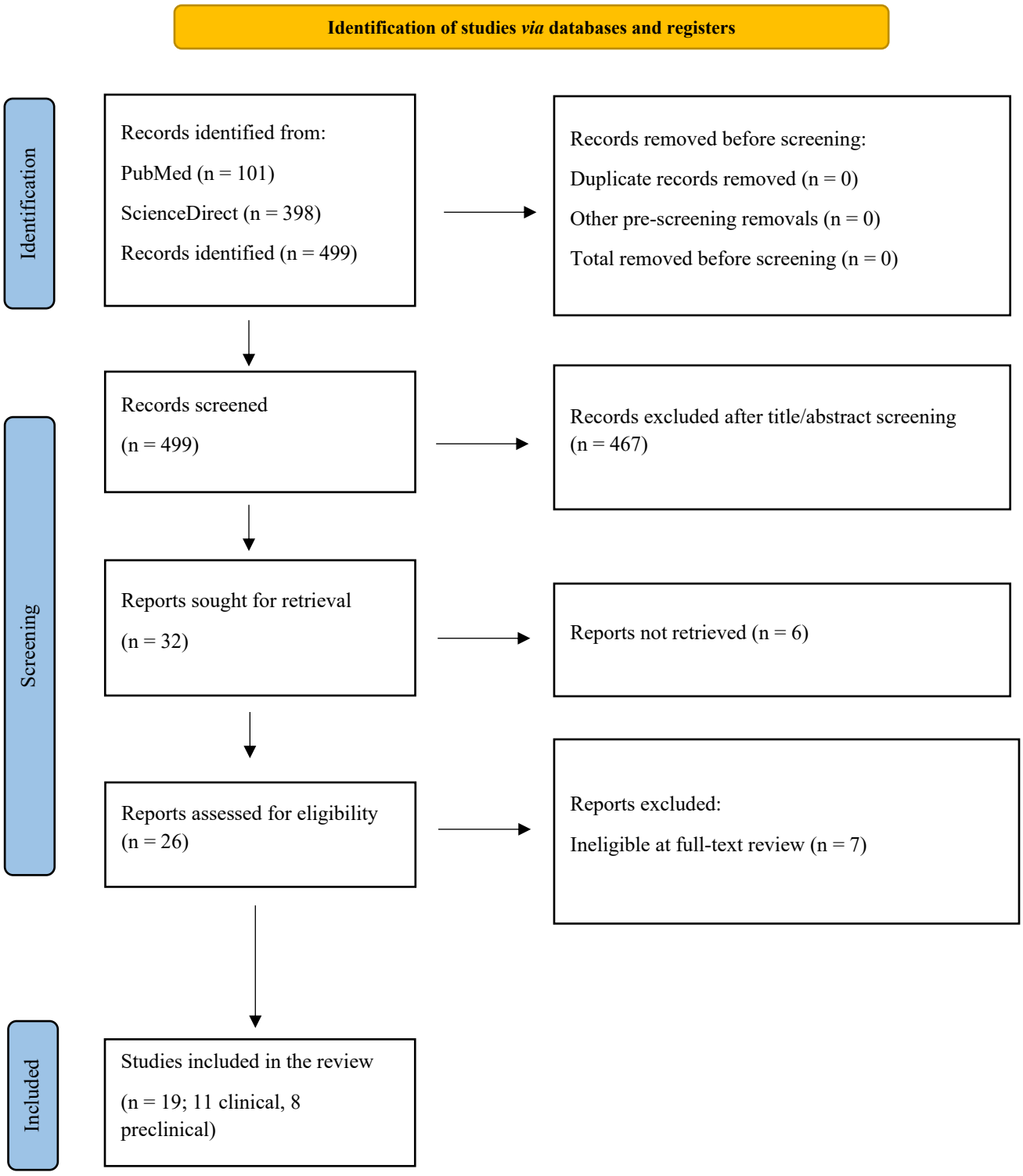


Fig. (1). PRISMA 2020 flow diagram of study selection.

4. DISCUSSION

4.1. What The Evidence Can and Cannot Establish

The clearest finding of this update is the distinction between feasibility and effectiveness. Human case reports and case series show that magnesium membranes can be shaped, positioned and secured for several GBR indications and provide descriptive information on healing, degradation and complications. These uncontrolled reports do not estimate comparative treatment effects. The 2026 cohort is larger but remains uncontrolled and has short follow-up. Accordingly, current human evidence supports reported technical feasibility and short-term safety observations, but it does not establish comparative safety, long-term effectiveness, equivalence or superiority over collagen, PTFE, titanium-reinforced or other established barriers.

4.2. Preclinical Comparative Evidence and Degradation

Preclinical findings should be interpreted as heterogeneous, model-specific results. Barbeck [24] found that fluoridation modified degradation and gas-cavity behavior without evidence of a clear between-group bone-regeneration advantage. Rider [25, 33] provides one canine GBR experiment with companion reporting through 52 weeks; defect bone formation was broadly comparable to collagen, and the membrane was no longer identifiable at 52 weeks. Yan [30] found greater early trabecular volume fraction with a Mg-alloy barrier at three months (63.71 ± 10.4% *vs* 59.97 ± 8.94% with collagen), while its overall histological new-bone fraction was not significantly different (45.44 ± 12.28% *vs* 43.49 ± 7.12%). Wu [31] reported that calcium-phosphate coating reduced 8-week mesh degradation (21.98% *vs* 58.49% for uncoated Mg), with an early bone-volume advantage that was not sustained as a significant between-group difference at eight weeks. Zhao [27], On [28] and Beitlitum [29] also offer comparative bone/degradation observations. Differences in animal unit, coating and timescale exclude conclusions about superiority in humans.

4.3. Membrane Exposure and Wound-Healing

Membrane exposure should be interpreted cautiously, as exposure of conventional barrier membranes has been associated with reduced bone gain [32-34]. Tabanella *et al.* [22] described four exposed/dehisced cases that healed without reported infection or major bone loss. This small uncontrolled series is vulnerable to selection, assessment and publication bias. It therefore provides a clinically relevant observation but cannot establish that magnesium membranes are generally tolerant of exposure or that exposure is harmless.

4.4. Relation to Previous Reviews and Novelty of This Update

This review complements earlier syntheses [4-6]. The 2026 clinical cohort [23] extends descriptive human evidence, while inclusion of *in-vivo* bone-defect studies [30-31], explicit linking of overlapping animal publications [25, 33] and unit-of-analysis precautions improve the transparency of the synthesis.

4.5. Evidence Hierarchy, Heterogeneity and Implications for Research

Clinical and methodological heterogeneity precluded a pooled effect estimate. The studies included showed variation regarding membrane, coating, defect model, grafting material and fixation, follow-up and outcome measurement. A focus on future research should be directed towards controlled clinical trials, pre-specified outcomes, adequate follow-up, independent reporting. Three-dimensional outcomes (bone gain or volume stability), implant placement/survival, membrane exposure/dehiscence, infection, gas related complications, re-intervention, patient-reported pain/swelling and quality of life should all be considered as core outcomes.

The longest follow-up is especially significant as the longest followed cohort currently published in the literature has a period of up to three months [23]. Furthermore, there is still a lack of long-term information regarding survival of the implants, stability of the regenerated bone and delayed events. Decisions to extrapolate potential *in vivo* effects to clinical practice should also be made based on preclinical work to assess the barrier time, wound healing, or patient outcomes that would be clinically relevant.

4.6. Strengths and Limitations of This Review

The advantages are the separation of uncontrolled human evidence from animal comparators, the identification of the quantitative contrast of the specific source(s) of the evidence, the recording of funding and the separation of animal and defect-site units. Some important limitations exist only two databases were searched, and there was no systematic search of grey literature, conference repositories, or trial registries, which might have resulted in negative studies being overlooked. Inference is weakened by study overlaps, unadjusted or unsuspected clusters among animal studies, further limitations in the clinical study design and suboptimal follow-up or denominator reporting. A certainty of evidence was not conducted.

CONCLUSION

There are some available human reports providing technical feasibility and short-term observations but not comparative effectiveness. Independent animal GBR investigations suggest possibly beneficial barrier characteristics and degradation modulation, but there was a variation in model and outcome; Shared canine publications counted once only. Controlled clinical trials, fully documented search and screening procedures, outcome-specific denominators, and animal analyses that respect clustering is necessary for stronger conclusions.

LIST OF ABBREVIATIONS

GBR	=	Guided Bone Regeneration
JBI	=	Joanna Briggs Institute
Mg	=	Magnesium
Mg-Dy	=	Magnesium–Dysprosium Alloy
PICOS	=	Population, Intervention, Comparator, Outcomes, and Study Design
PRISMA	=	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
ROBINS-I	=	Risk Of Bias In Non-randomized Studies of Interventions
SWiM	=	Synthesis Without Meta-analysis

AUTHOR'S CONTRIBUTION

S.B. contributed to the conception and design of the study, data collection, data analysis, and writing of the manuscript. The author reviewed and approved the final version of the manuscript.

REPORTING STANDARD

PRISMA guidelines have been followed for this study.

CONSENT FOR PUBLICATION

Not applicable, as this study is a review and does not involve human participants or animals.

AVAILABILITY OF DATA AND MATERIALS

All data supporting this review are contained in the article: search strategies in Table **1** and Appendix **A**, study selection in Fig. **1** and Table **1A**, included-study data in Tables **2**–**3** and critical appraisals in Appendix **B**. Further information is available from the corresponding author on reasonable request.

FUNDING

This review received no external funding.

CONFLICT OF INTEREST

The review author declares no conflict of interest. Funding and industry relationships reported by the included studies are presented at the study level in Tables **2** and **3** and discussed separately.

ACKNOWLEDGEMENTS

The author acknowledge that no external assistance was received in the preparation of this manuscript.

DECLARATION OF AI

The author declared that Artificial Intelligence (AI) tools like ChatGPT were used in the preparation of this manuscript for language refinement and/or proofreading purposes. The author remains fully responsible for the accuracy, originality, and integrity of the content and has reviewed and approved the final version of the manuscript.

Appendix A. Search Audit and Reproducibility Details.

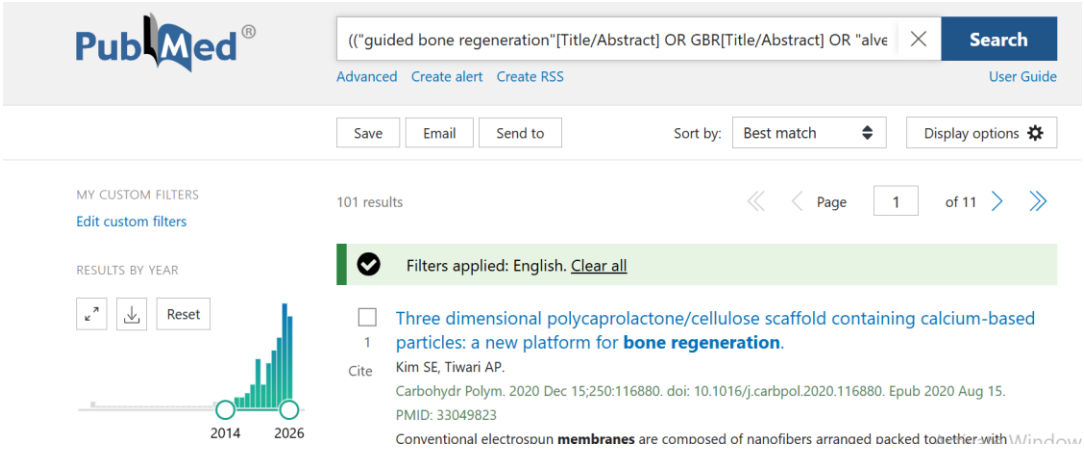


Fig. (2). PubMed search.

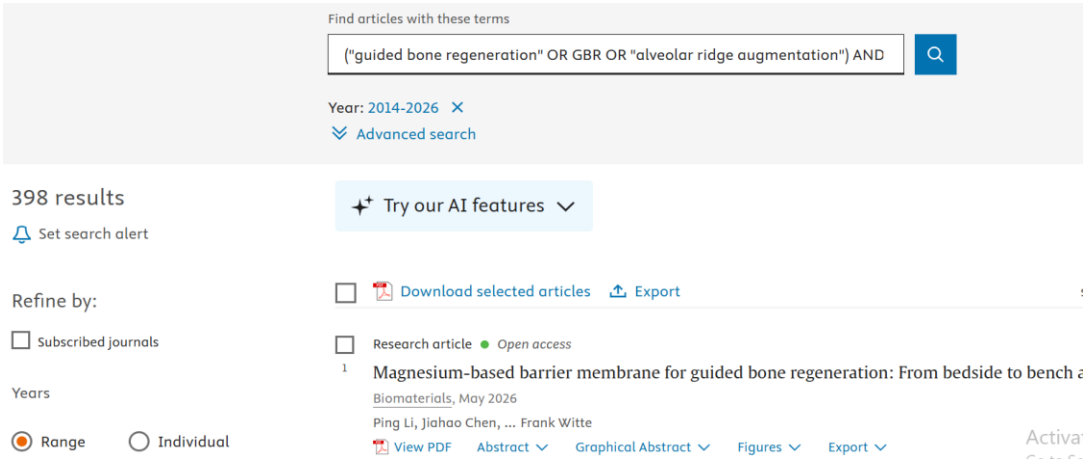


Fig. (3). ScienceDirect search.

Appendix B. Design-Appropriate Critical Appraisal

B1. SYRCLE Appraisal of Animal Studies

U is used where primary source reporting does not justify a firm judgement. Site-level randomisation or significance testing does not remove animal-level correlation, and funding information is not itself a SYRCLE risk-of-bias domain.

Table B1. SYRCLE risk-of-bias appraisal of included animal studies.

Study	Seq. Gen.	Baseline	Alloc. Conceal.	Random Housing	Caregiver Blind	Random Outcome	Assessor Blind	Incomplete Data	Selective Report	Other Bias
Barbeck, 2020	L	L	U	U	U	U	U	L	U	Industry links reported
Wu, 2021	U	U	U	U	U	U	U	U	U	Korean NRF grant; risk domains not fully documented
Rider, 2022	H	L	U	U	U	U	U	L	U	Minipig/canine models; canine dataset also reported in [33]
Yan, 2022	U	U	U	U	U	U	U	U	U	No COI reported; repeated sites/animal; randomisation reported for defects
Shan, 2022	L	U	U	U	U	U	U	L	U	NSFC grant 52001034; no COI declared
Zhao, 2023	L	U	U	U	U	U	U	L	U	Public grants disclosed; see [27]
On, 2024	L	L	U	U	U	U	U	L	U	No competing interests
Beitlitum, 2025	L	L	U	U	U	U	U	U	U	Attrition; paired sites.

Note: Legend: L = low risk on the information reported; H = high risk; U = unclear/not reported. “Unclear” is used when reporting is insufficient. Funding and conflicts are described separately and are not automatically coded as high risk.

B2. JBI Case-Report Checklist (Single-Patient Reports)

Table B2. JBI case-report appraisal of included single-patient reports.

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Overall
Frosecchi 2023	Y	Y	Y	Y	Y	Y	Y	Y	Include; descriptive
Franke 2024	Y	Y	Y	Y	Y	Y	Y	Y	Include; descriptive
Blašković 2024	Y	Y	Y	Y	Y	Y	Y	Y	Include; descriptive
Chaushu 2025	Y	Y	Y	Y	Y	Y	Y	Y	Include; descriptive

Note: JBI case-report questions [11]: Q1 demographics; Q2 history/timeline; Q3 current clinical condition; Q4 diagnostic tests/results; Q5 intervention/treatment; Q6 post-intervention condition; Q7 adverse/unanticipated events; Q8 takeaway lessons. Y = yes; N = no; U = unclear; NA = not applicable.

B3. JBI Case-Series Checklist (Multiple-Patient Reports)

Table B3. JBI case-series appraisal of included multiple-patient reports.

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Overall
Blašković 2023	U	Y	Y	U	U	Y	Y	Y	Y	NA	Include; selection unclear
Palkovics 2023	U	Y	Y	U	U	Y	Y	Y	Y	NA	Include; selection unclear
Elad-shield 2023	U	Y	Y	U	U	Y	Y	Y	Y	NA	Include; selection unclear
Elad-sinus 2023	U	Y	Y	U	U	Y	Y	Y	Y	NA	Include; selection unclear
Hangyasi 2023	U	Y	Y	U	U	Y	Y	Y	Y	NA	Include; selection unclear
Tabanella 2025	U	Y	Y	U	U	Y	Y	Y	Y	NA	Include; hypothesis-generating

Note: JBI case-series questions [10]: Q1 clear inclusion criteria; Q2 condition measured reliably; Q3 valid methods for identification; Q4 consecutive inclusion; Q5 complete inclusion; Q6 clear demographics; Q7 clear clinical information; Q8 outcomes/follow-up reported; Q9 site/demographic information; Q10 appropriate statistical analysis. Y = yes; N = no; U = unclear; NA = not applicable.

B4. JBI Cohort Appraisal of (Franke *et al.* 2026)

The JBI cohort checklist [12] contains 11 appraisal questions; items requiring comparison between exposed and unexposed groups were rated not applicable because the cohort had no comparator. Because several procedures could belong to one patient, the 195 procedures must not be treated automatically as 195 statistically independent patients.

Table B4. JBI cohort appraisal of Franke et al. 2026.

Criterion	Assessment
Comparable groups	NA - no comparator
Exposure measured similarly between exposed/unexposed groups	NA — single exposure cohort; no unexposed comparator
Exposure measured validly	Y
Confounders identified	U/partial
Strategies for confounding	N - uncontrolled design
Participants outcome-free at start	Y for postoperative outcomes
Outcome measurement valid	Y/partial; clinical definitions used
Follow-up sufficient	N for long-term efficacy; up to 3 months
Follow-up complete/reasons described	U
Strategies for incomplete follow-up	U
Appropriate statistics	Descriptive analyses performed; independence of 195 procedures within 126 patients not established
Overall interpretation	Useful short-term safety/feasibility cohort; cannot estimate comparative effectiveness

Appendix C. PRISMA 2020 Checklist (Table C1)

Table C1. PRISMA 2020 checklist for the revised systematic review.

Section and Topic	Item #	Checklist Item	Location Where Item is Reported
TITLE			
Title	1	Identify the report as a systematic review.	Title
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Abstract
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Introduction – rationale/background
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Introduction – review question/objective
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Methods – 2.1 Review framework and eligibility (PICOS)
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Methods – 2.2 Information sources and search strategy; Appendix **A**
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Methods 2.2; Table **1**; Appendix **A**
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Methods 2.3
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Methods 2.3
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (*e.g.* for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Methods – 2.1 Outcomes within PICOS
	10b	List and define all other variables for which data were sought (*e.g.* participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Methods – 2.3 Data extraction variables/evidence tables
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Methods 2.4; Appendix **B**
Effect measures	12	Specify for each outcome the effect measure(s) (*e.g.* risk ratio, mean difference) used in the synthesis or presentation of results.	Methods – 2.5 Synthesis method
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (*e.g.* tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Methods – 2.5 Synthesis method
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Methods – 2.5 Synthesis method

	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Results – Tables **2**–**3**; evidence tables
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Methods – 2.5 Synthesis method
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (*e.g.* subgroup analysis, meta-regression).	Discussion – heterogeneity section
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Not applicable (no sensitivity analysis performed)
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Not assessed; no quantitative synthesis performed
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Not assessed; certainty grading not performed
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Results 3.1; Fig. **1**; Table **1A**
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Methods 2.1; Results 3.1
Study characteristics	17	Cite each included study and present its characteristics.	Tables **2**–**3**
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Section 3.4; Appendix **B** (Tables **B1**–**B4**)
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (*e.g.* confidence/credible interval), ideally using structured tables or plots.	Tables **2**–**3**; Results 3.2–3.3
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Results – clinical and preclinical synthesis sections
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (*e.g.* confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Not applicable (no meta-analysis/statistical synthesis)
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Discussion – 4.5 Evidence hierarchy, heterogeneity and implications
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Not applicable (no sensitivity analysis performed)
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Not assessed; no reporting-bias synthesis performed
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Not assessed; certainty assessment not performed

DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Discussion – 4.1–4.5
	23b	Discuss any limitations of the evidence included in the review.	Discussion – 4.6 Strengths and limitations
	23c	Discuss any limitations of the review processes used.	Discussion 4.6; screening, deduplication, extraction, appraisal and registry-search limitations
	23d	Discuss implications of the results for practice, policy, and future research.	Discussion – research implications sections
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	"not registered"
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	No protocol information was reported.
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	"not applicable"
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Declarations – Funding
Competing interests	26	Declare any competing interests of review authors.	Declarations – Conflicts of Interest
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Data Availability Statement; Appendix **A**

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