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REVIEWER'S REPORT

Manuscript No.: IJAR-59110

Title: Biodegradable versus titanium osteosynthesis for mandibular fractures in adults: a systematic review and meta-analysis,

Recommendation:
Accept as it is .....
Accept after minor revision.....
Accept after major revision ...YES.....
Do not accept (*Reasons below*) .....

Rating	Excel.	Good	Fair	Poor
Originality		□		
Techn. Quality			□	
Clarity		□		
Significance		□		

Reviewer's ID: JPR- 094

Detailed Reviewer's Report

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Reviewer Report

Criterion	Assessment
Strengths	1. Clinically relevant comparison of biodegradable versus titanium fixation in adult mandibular fractures. 2. The manuscript appropriately recognizes the difference between mandibular trauma and orthognathic surgery. 3. The review attempts to update the evidence through September 2026 and includes a recently published randomized study. 4. Use of PRISMA 2020, RoB 2, ROBINS-I and GRADE is appropriate. 5. The authors appropriately address different denominators (patients, fractures and plates), which is an important issue in this literature. 6. The manuscript transparently reports uncertainty and does not overstate the pooled infection, dehiscence or non-union results.
Weaknesses	1. The review was **not prospectively registered in PROSPERO**. 2. Screening and data extraction were performed by **a single reviewer**, without independent duplicate screening. This creates an important risk of selection and extraction errors. 3. **Embase was not searched**, and CENTRAL and clinical trial registries had not been searched at the reported stage. 4. Scopus screening was incomplete, although the manuscript transparently states that no Scopus-only record contributed to the synthesis. 5. Only two studies could be pooled for each of the principal clinical outcomes, resulting in extremely wide confidence intervals. 6. Several included studies have incomplete or inconsistent denominator information, particularly Lim 2014 and Bhatt 2010. 7. The hardware-failure conclusion is based substantially on one study with plate-level data and very wide confidence intervals. 8. The manuscript contains some interpretive statements that are stronger than the limited

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

Criterion	Assessment
	evidence base may justify.
Key points / Novel aspects	The main potential contribution is the **adult mandibular-fracture-specific update** rather than a completely new research question. The manuscript distinguishes mandibular fracture patients from the much larger orthognathic population in the Dutch trial, incorporates newer comparative evidence, includes non-randomized comparative studies, and evaluates operating time. The analysis also highlights hardware failure as an outcome that may be clinically important but inconsistently reported.
Significance	The topic is clinically significant because biodegradable fixation is intended to reduce the need for later hardware removal, while mechanical failure is a potential disadvantage. The review provides useful evidence that infection, wound dehiscence and non-union cannot currently be distinguished confidently between the two systems because of imprecision. However, the low/very-low certainty of much of the evidence substantially limits the strength of clinical conclusions.
Methodological concern	**Major concern.** A systematic review with single-reviewer screening/extraction, incomplete Scopus screening, no Embase search, no PROSPERO registration and incomplete reporting of some screening counts has important reproducibility limitations. The authors themselves acknowledge these limitations.
Novelty concern	**Moderate to high concern.** The manuscript itself identifies a January 2026 systematic review/meta-analysis and another 2026 systematic review specifically addressing adult mandibular fractures. Therefore, the authors need to make the incremental contribution of this review exceptionally clear and demonstrate that the newly included evidence materially changes or clarifies the existing evidence.
Recommendation	**Major Revision**

Overall reviewer conclusion

The manuscript addresses an important and clinically relevant question and has several strengths, particularly its focus on **adult mandibular fractures**, separation of fracture evidence from orthognathic evidence, incorporation of newer studies, and explicit assessment of risk of bias and certainty.

However, there are substantial methodological limitations. The most important are **single-reviewer screening/extraction, lack of prospective registration, incomplete database searching, incomplete Scopus screening, limited number of studies contributing to pooled estimates, and substantial uncertainty in the effect estimates**. These limitations should be addressed before the manuscript can be considered further.

The manuscript's novelty also requires clearer justification because closely related systematic reviews/meta-analyses were already available in 2026. The authors should explicitly provide a **study-by-study comparison with the previous 2026 reviews**, showing which studies are newly identified, which outcomes are newly analyzed, and how the present conclusions differ.

Final recommendation: MAJOR REVISION.

If the journal's reviewer form requires a simple rating, I would classify it as **technically interesting but requiring substantial methodological and presentation revision before acceptance**.

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

Based strictly on the manuscript you provided, the recommendation of **Major Revision** is justified because there are important methodological, data-quality, statistical, and reporting issues that affect the reliability and reproducibility of the systematic review and meta-analysis.

Reviewer justification — issue and reason, line by line

REVIEWER REPORT

Manuscript Title: *Biodegradable versus titanium osteosynthesis for mandibular fractures in adults: a systematic review and meta-analysis*

Overall Recommendation: MAJOR REVISION

The manuscript addresses a clinically relevant question and has potential value because it focuses specifically on adult mandibular fractures and attempts to distinguish fracture evidence from orthognathic-surgery evidence. However, several methodological and reporting concerns currently limit the reliability, reproducibility, and interpretation of the findings. The following issues should be addressed before the manuscript can be considered further.

1. Protocol was not prospectively registered

Lines 93–95

Issue: The protocol was prepared before the search but was not registered in PROSPERO.

Reason: Lack of prospective registration makes it difficult to verify whether the eligibility criteria, outcomes, subgroup analyses and statistical methods were specified before the results were known. This introduces a risk of selective outcome reporting or post-hoc methodological decisions.

Required action: Provide the date on which the protocol was finalized and, if possible, a protocol document or repository record. Clearly identify which analyses were pre-specified and which were added subsequently.

2. Single-reviewer screening and data extraction

Lines 145–150

Issue: Screening and extraction were performed by a single reviewer.

Reason: Single-reviewer screening increases the possibility of missed studies, incorrect exclusions, data extraction errors and subjective eligibility decisions. Source checking does not completely replace independent duplicate review.

Required action: Ideally, a second reviewer should independently verify screening and extracted data. If this is not possible, the authors should provide a more detailed description of quality-control procedures and explicitly acknowledge this as a major methodological limitation.

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

3. Scopus search was incomplete

Lines 108–115 and 140–143

Issue: Scopus was searched, but deduplication and screening were still in progress and Scopus records were not included in the synthesis.

Reason: A database search that is not fully screened cannot be considered a completed component of a systematic review. Potential eligible studies may have been missed.

Required action: Complete the Scopus screening before finalizing the review and update the PRISMA flow diagram and all study counts accordingly.

4. Embase was not searched

Lines 116–121

Issue: Embase was not searched because institutional access was unavailable.

Reason: Embase may contain relevant clinical literature that is not indexed in MEDLINE. Although Web of Science and Scopus were searched, they should not automatically be regarded as complete substitutes for Embase.

Required action: If possible, perform an Embase search through an alternative institutional or collaborative access route. If impossible, retain this limitation but explain its potential effect on study identification more explicitly.

5. CENTRAL and clinical trial registries were not searched

Lines 416–450

Issue: Cochrane CENTRAL and ClinicalTrials.gov/WHO ICTRP were listed as "not yet run."

Reason: Failure to search trial registries and CENTRAL can result in omission of unpublished, ongoing or incompletely published randomized trials. This is particularly important for a systematic review containing only a small number of randomized studies.

Required action: Complete these searches and report the results in the supplementary material and PRISMA diagram.

6. PRISMA flow information is incomplete

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

Lines 129–144

Issue: Several screening-stage counts are reported as "NR," including duplicate records between PubMed strings, records excluded from the principal PubMed string, reports not retrieved and reports assessed for eligibility.

Reason: A systematic review should provide a transparent and reproducible flow from identification to inclusion. Missing numerical information makes it difficult for readers to reconstruct the selection process.

Required action: Update the screening log and provide complete numbers wherever possible. If a number genuinely cannot be recovered, explain this clearly and provide the available audit trail.

7. The search strategy produced different results depending on the search string

Lines 122–128

Issue: The principal PubMed search retrieved 94 records, whereas the trial-type-restricted search identified additional comparative trials.

Reason: This demonstrates that the principal search strategy may have been insufficiently sensitive. The fact that additional eligible studies were found through a second search raises concern about whether equivalent sensitivity was achieved in the other databases.

Required action: Reassess all database search strategies using a comprehensive combination of population, intervention and comparator concepts. Report the complete validated search strategies.

8. Only two studies were pooled for the principal clinical outcomes

Lines 178–184

Issue: Infection, wound dehiscence and non-union were each pooled from only two studies.

Reason: A meta-analysis based on two studies provides limited evidence for estimating a pooled treatment effect. The resulting confidence intervals are extremely wide.

Required action: The authors should emphasize that these estimates are highly uncertain and avoid language suggesting that the treatments are equivalent or clinically indistinguishable.

9. Very wide confidence intervals substantially limit interpretation

Lines 18–26 and 183–184

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

Issue: Infection RR = 1.42 (0.33–6.00), wound dehiscence RR = 0.88 (0.24–3.16), and non-union RR = 1.75 (0.24–12.97).

Reason: These intervals encompass clinically important benefit and harm. Therefore, the absence of statistical significance does not establish absence of a clinically meaningful difference.

Required action: Interpret these findings explicitly as **imprecise evidence** rather than evidence of no difference.

10. Hardware-failure conclusion is heavily dependent on one study

Lines 185–195

Issue: The main quantitative hardware-failure estimate comes from Ahmed et al., with 19/53 versus 0/52 plates and RR 38.28.

Reason: The estimate is based on a single study and has an extremely wide CI (2.37–617.9). A very large relative risk can occur when the comparator group has zero events and the sample size is small.

Required action: Avoid presenting RR 38.28 as a stable estimate of the true effect. Emphasize the study-level evidence and uncertainty.

11. Hardware-failure denominators are inconsistent

Lines 155–158 and 185–195

Issue: Ahmed et al. report plate-level events, whereas Lim et al. report screw-level events and do not provide the number of screws placed.

Reason: Patients, plates and screws represent different units of analysis. Combining or qualitatively comparing them can introduce unit-of-analysis problems.

Required action: Clearly distinguish patient-level, plate-level and screw-level outcomes throughout the manuscript. Where denominators cannot be established, do not calculate comparative effect measures.

12. Internal inconsistency in Lim et al.

Lines 188–191

Issue: Lim et al. reportedly describe two screw breakages in one section and three in another.

Reason: The discrepancy creates uncertainty regarding the underlying data and affects confidence in the reported hardware-failure evidence.

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

Required action: Recheck the original publication and, if possible, supplementary material or author correspondence. Correct the value or explicitly state that the study cannot be reliably quantified.

13. Internal inconsistency in Bhatt et al.

Lines 174–177

Issue: The reported percentages do not correspond to the stated patient numbers.

Reason: For example, 4.17% and 7.7% cannot be directly reconciled with denominators of 19 and 21 patients. The actual denominator may be fractures, plates or another unit.

Required action: Verify the original article and identify the precise denominator used for each outcome. Do not use these data quantitatively unless the denominator can be established.

14. Small fracture subgroup in the Dutch trial

Lines 81–88 and 248–256

Issue: The Dutch randomized trial included 221 patients overall, but only 18 had fractures and only 10 had mandibular fractures.

Reason: The manuscript appropriately identifies the very small fracture subgroup. However, drawing substantive conclusions from such a subgroup is statistically unstable and may be affected by post-randomization subgroup selection.

Required action: Present the fracture subgroup as exploratory and clearly distinguish it from the primary randomized population of the original trial.

15. The fracture subgroup appears not to have been pre-specified

Lines 274 and Table 4

Issue: The manuscript itself classifies the fracture subgroup as high risk of bias because it was not pre-specified.

Reason: Post-hoc subgroup analyses can produce misleading estimates because the subgroup was not necessarily part of the original trial design.

Required action: Clearly label this as subgroup evidence and avoid using it as equivalent in evidentiary strength to a randomized trial specifically designed for mandibular fractures.

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

16. Risk-of-bias assessment requires greater methodological detail

Lines 206–218 and Table 4

Issue: RoB 2 and ROBINS-I assessments are reported, but the supporting judgments are relatively brief.

Reason: Risk-of-bias tools require domain-specific judgments and supporting evidence. Statements such as "high," "serious" or "critical" risk require transparent justification.

Required action: Provide domain-level judgments and explanations for randomization, allocation concealment, deviations from intended intervention, missing outcome data, outcome measurement and selective reporting.

17. Possible inconsistency in the number of randomized studies

Lines 169–170 and 207–218

Issue: The manuscript describes nine comparative studies plus the Dutch fracture subgroup, while the risk-of-bias section refers to four studies as randomized.

Reason: Because multiple publications arise from the Dutch cohort and the subgroup is separately discussed, the unit of "study" versus "publication" versus "cohort" must be completely clear.

Required action: Provide a study-family table identifying each publication, underlying cohort, design and whether it contributes independently to each analysis.

18. Short follow-up in important trials

Lines 209–212

Issue: One trial has 8-week follow-up and another has 3-month follow-up.

Reason: Biodegradable materials may have complications associated with degradation that occur later than the early postoperative period. Short follow-up may therefore underestimate late complications.

Required action: Avoid using short-term trials to make broad conclusions regarding long-term safety. Consider stratifying outcomes by follow-up duration where sufficient data exist.

19. Operating-time conclusion is based on one study

Lines 196–197

Issue: The reported 15.6-minute difference comes from a single study.

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

Reason: A single-study estimate cannot establish a generalizable pooled effect. Operating time may depend on surgeon experience, fracture complexity, technique and implant system.

Required action: Describe this as a finding from one study rather than a definitive overall effect.

20. GRADE assessment requires reconsideration

Lines 213–218 and Table 5

Issue: The manuscript assigns low certainty to hardware failure despite the estimate being based largely on one study.

Reason: GRADE judgments should transparently consider risk of bias, inconsistency, indirectness, imprecision and publication bias. A large effect alone does not necessarily compensate for serious methodological limitations.

Required action: Reassess the GRADE ratings independently and provide explicit justification for each domain and final certainty level.

21. "Reproducible disadvantage" may be too strong

Lines 24–26 and 278–280

Issue: The manuscript describes hardware failure as the "reproducible disadvantage" of biodegradable fixation.

Reason: Although several studies point in the same direction, the underlying evidence uses different denominators and includes inconsistent reporting. Therefore, the wording may overstate the certainty of the evidence.

Required action: Consider wording such as **"a consistent signal of increased hardware breakage in the available studies"**, while retaining the appropriate uncertainty.

22. Conclusion may still be interpreted as equivalence

Lines 291–301

Issue: The conclusion states that biodegradable and titanium fixation "could not be distinguished" for several outcomes.

Reason: Non-significant statistical results do not establish equivalence. The very wide confidence intervals demonstrate that clinically important differences remain possible.

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

Required action: State explicitly that the available evidence is insufficient to determine whether the two materials have similar rates of infection, dehiscence or non-union.

23. Novelty of the review needs clearer justification

Lines 53–80

Issue: Several recent systematic reviews, including a 2026 review and a 2026 guideline-supporting review, already address biodegradable versus titanium fixation.

Reason: The topic is not entirely new. The manuscript therefore needs to demonstrate clearly what additional evidence and methodological contribution it provides beyond the most recent reviews.

Required action: Add a table comparing the present review with previous reviews, including search dates, databases, population, number of studies, study designs, outcomes and newly included studies.

24. Relationship with the January 2026 meta-analysis requires a more systematic comparison

Lines 55–61 and 236–247

Issue: The manuscript argues that restricting the Dutch trial to its fracture subgroup explains heterogeneity differently from the previous meta-analysis.

Reason: This is an important methodological claim, but it should be demonstrated quantitatively rather than primarily argued narratively.

Required action: Provide a direct comparison of included studies and outcomes between the previous meta-analysis and the current review. If feasible, perform sensitivity analyses with and without the Dutch trial/subgroup.

25. Potential concern regarding selective exclusion of data

Lines 81–90 and 248–256

Issue: The manuscript excludes the overall Dutch trial result from the mandibular-fracture interpretation and focuses on the fracture subgroup.

Reason: Restricting analysis to the clinically relevant population is reasonable, but the selection process must be demonstrably consistent with the eligibility criteria established before data inspection.

Required action: Explain clearly whether this restriction was pre-specified in the eligibility criteria and protocol. If it was decided after reviewing the study results, identify it as a post-hoc analytical decision and provide sensitivity analysis.

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

26. Magnesium subgroup is discussed but appears not to contribute substantially to the clinical synthesis

Lines 164–165 and 257–262

Issue: Magnesium is identified as a separate biodegradable material category, but the clinical evidence appears limited.

Reason: Different biodegradable materials have different degradation mechanisms and mechanical properties. Combining them under one broad "biodegradable" category may increase clinical heterogeneity.

Required action: Provide a table specifying the exact material used in every included study and, where appropriate, conduct material-specific subgroup or sensitivity analyses.

27. Clinical heterogeneity needs greater attention

Lines 97–106 and Table 1

Issue: The included studies involve different fracture sites, fixation systems, follow-up periods and study designs.

Reason: Differences in fracture location, surgical approach, implant composition, number of plates/screws and patient characteristics may influence outcomes independently of material type.

Required action: Expand the clinical heterogeneity assessment and explain why pooling is appropriate for each outcome.

28. Several included studies have incomplete information

Lines 171–177

Issue: Some studies have incomplete arm-specific data, unavailable full text, variable follow-up or unclear denominators.

Reason: Missing or incompletely reported data reduce the reliability of evidence synthesis and may introduce selective reporting concerns.

Required action: Clearly identify which studies contribute to each outcome and which were excluded from quantitative analysis because of insufficient data.

29. Publication bias cannot be meaningfully assessed

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

Lines 281–289

Issue: The manuscript correctly notes that publication bias cannot be assessed with fewer than ten studies per outcome.

Reason: This is an important limitation because the evidence base is small.

Required action: Retain this limitation and avoid language implying that the literature is free from publication bias.

30. Data availability "on request" limits reproducibility

Lines 316–317

Issue: The extraction sheet and analysis script are available only from the corresponding author on request.

Reason: Modern systematic reviews benefit from openly accessible extraction and analysis files, particularly where complex denominator decisions and linked publications are involved.

Required action: Where journal policy permits, deposit the search strategies, screening data, extraction sheet and analysis code in a recognized repository and provide a persistent identifier.

FINAL REVIEWER ASSESSMENT

Strengths

1. Clinically relevant comparison focused specifically on adult mandibular fractures.
2. Attempts to separate mandibular trauma evidence from orthognathic surgery evidence.
3. Includes both randomized and comparative evidence.
4. Uses established systematic-review methodology including PRISMA 2020, RoB 2, ROBINS-I and GRADE.
5. Transparently reports important limitations and denominator problems.

6. Identifies substantial uncertainty in the estimates rather than simply interpreting non-significant findings as equivalence.

Major Weaknesses

- Incomplete search and screening process.
- Scopus screening is unfinished.
- Embase and CENTRAL were not searched.

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

- Clinical trial registries were not searched.
- Single-reviewer screening and extraction.
- Incomplete PRISMA flow counts.
- Very small evidence base for quantitative pooling.
- Major denominator inconsistencies between studies.
- Internal inconsistencies in reported study data.
- Several conclusions depend heavily on single-study or very small subgroup evidence.
- Protocol was not prospectively registered.
- GRADE and risk-of-bias judgments require further justification.

Key Points Requiring Correction Before Publication

The most important revisions should address:

(1) completion of the literature search and screening;
(2) clarification and verification of all study denominators;
(3) correction of internal inconsistencies in Bhatt and Lim data;
(4) transparent handling of the Dutch trial and its fracture subgroup;
(5) reassessment of risk of bias and GRADE;
(6) more cautious interpretation of very wide confidence intervals; and
(7) clearer demonstration of novelty compared with the recent 2026 systematic reviews.

Recommendation

Major Revision

The manuscript has a potentially useful clinical question and several methodological strengths, but the current version requires substantial methodological clarification, data verification and revision of the interpretation before the validity of its conclusions can be adequately assessed.

The **strongest reasons for Major Revision** are the **unfinished Scopus screening, absence of Embase/CENTRAL/registry searches, single-reviewer methodology, incomplete PRISMA counts, inconsistent denominators, contradictory data in individual studies, and overinterpretation of very imprecise/single-study estimates**. These are substantive methodological issues rather than merely language or formatting problems.