



### REVIEWER'S REPORT

**Manuscript No.:** IJAR-56412

**Title:** Efficacy of Alb-PRF as Adjunctive to Non-surgical Periodontal Therapy in Management of Stage II Periodontitis,

**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 Name:** Prof. Dr Dillip Kumar Mohapatra

## Detailed Reviewer's Report

### Overall Evaluation

This randomized controlled clinical trial investigates the adjunctive use of albumin–platelet rich fibrin (Alb-PRF) with mechanical debridement (MD) in Stage II periodontitis. The study addresses an emerging regenerative biomaterial first biologically characterized by Richard J. Miron and colleagues, and clinically contextualized within the 2017 periodontal classification proposed by Maurizio S. Tonetti et al.

The topic is timely and clinically relevant, particularly given the increasing interest in autologous platelet concentrates in non-surgical periodontal therapy.

## STRENGTHS

### Study Design Strength

Randomized controlled clinical trial design.

Trial registered at ClinicalTrials.gov (NCT07080294).

Ethical approval clearly stated.

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Sample size calculation performed using G\*Power.

Blinded calibrated examiner (ICC > 0.85).

### Clinical Relevance

Focus on Stage II periodontitis according to 2017 World Workshop classification.

Practical intervention easily applicable in clinical settings.

Clear clinically meaningful outcomes (PD and CAL).

### Methodological Clarity

Detailed Alb-PRF preparation protocol.

Clear inclusion and exclusion criteria.

Standardized periodontal measurements (UNC-15 probe).

Six-site examination approach enhances reliability.

### Statistical Analysis

Normality testing (Shapiro–Wilk).

Repeated measures ANOVA appropriately applied.

Clearly defined primary outcome (PD reduction at 6 months).

### Clinical Outcomes

Statistically significant improvements in:

Probing Depth (PD)

Clinical Attachment Level (CAL)

Bleeding on Probing (BOP)

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Six-month follow-up adds short-term stability evidence.

### WEAKNESSES

#### Small Sample Size

N = 30 (15 per group).

Limits generalizability.

No subgroup analysis possible.

#### Short Follow-Up

Six months only.

Periodontitis is chronic; 12–24 months would strengthen claims of stability.

#### Lack of Microbiological and Radiographic Data

No microbial analysis.

No CBCT or radiographic bone level evaluation.

Claims of regenerative benefit are based only on clinical parameters.

#### No Double-Blinding

Operator and participants not blinded.

Potential performance bias.

#### Mechanistic Explanation Speculative

Claims regarding scaffold stability and growth factor release are extrapolated from laboratory studies rather than directly measured.

#### Minor Methodological Issues

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No CONSORT flow diagram presented.

No adverse event reporting section.

Inconsistent p-value formatting in tables.

Some grammatical and typographical errors.

## SIGNIFICANCE OF THE STUDY

### Clinical Significance

Provides preliminary clinical evidence that Alb-PRF may enhance non-surgical periodontal therapy.

Suggests a minimally invasive regenerative adjunct.

May reduce need for surgical intervention in moderate cases.

### Scientific Significance

Expands clinical application of Alb-PRF beyond regenerative surgery.

Adds to literature on autologous platelet concentrates, complementing prior work such as:

Biological characterization of an injectable platelet-rich fibrin mixture consisting of autologous albumin gel and liquid platelet-rich fibrin (Alb-PRF)

### Public Health Impact

Periodontitis is highly prevalent globally.

Cost-effective autologous adjuncts may improve treatment accessibility

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### KEY POINTS FOR EDITOR AND AUTHORS

Novel application of Alb-PRF in non-surgical Stage II periodontitis.

Significant PD reduction ( $\approx 1.6$  mm) and CAL gain at 6 months.

Proper trial registration and ethical compliance.

Limited external validity due to small sample and short follow-up

Requires language editing and formatting correction before publication.

Regenerative claims should be moderated unless supported by radiographic or histologic data.

### RECOMMENDATION

#### *Major Revision*

The manuscript is promising but requires

Language editing for grammar and clarity.

Inclusion of CONSORT flow diagram.

Clarification of statistical inconsistencies.

Addition of adverse event reporting.

Moderation of regenerative claims.

Expanded discussion comparing Alb-PRF specifically to i-PRF and L-PRF in RCT context.

Improve formatting of references and tables.

## REVIEWER'S REPORT

### Final Verdict

The study presents clinically meaningful findings with promising implications. However, methodological refinement and structural corrections are necessary before acceptance in a peer-reviewed periodontal journal.

### MAJOR REVISION JUSTIFICATION

#### *Abstract – Structural and Reporting Issues*

##### **Problem 1: Incomplete CONSORT Reporting**

Randomization method in brief

Blinding design (single blind)

Trial registration number in abstract

Confidence intervals for primary outcome

- ➔ RCT abstracts should follow CONSORT guidelines.
- ➔ Lack of structured reporting weakens transparency.

##### **Problem 2: Overstated Conclusion**

“shows promising clinical benefits”

No mention of study limitations in abstract.

Regenerative implications implied without radiographic or histologic evidence.

- ➔ Conclusion should be more cautious.

#### *Introduction – Scientific Framing Gaps*

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### Problem 3: Insufficient RCT Gap Justification

Although Alb-PRF is discussed (based on work such as Richard J. Miron et al.), the manuscript:

Does not clearly state:

How many RCTs exist on Alb-PRF in non-surgical therapy

Why existing PRF studies are insufficient

Why Stage II specifically was selected

➔ The novelty argument is weakly positioned.

### Problem 4: Mechanism Claims Not Supported

Statements about:

“prolonged growth factor release”

“space maintenance”

“superior scaffold stability”

are extrapolated from:

Biological characterization of an injectable platelet-rich fibrin mixture consisting of autologous albumin gel and liquid platelet-rich fibrin (Alb-PRF)

But:

No biological measurements were done in this study.

➔ Mechanistic claims are speculative.

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### *Methodology – Major Scientific Concerns*

#### **Problem 5: Sample Size Justification Weak**

Effect size assumed = 0.25

No justification why this value was selected.

Previous RCT (Ref 23) is on curcumin gel — not platelet concentrates.

- ➔ Effect size mismatch.
- ➔ Risk of underpowered or overestimated significance.

#### **Problem 6: No CONSORT Flow Diagram**

Missing:

Number screened

Number excluded

Dropouts

Allocation flow

- ➔ Mandatory for RCT publication.

#### **Problem 7: Single-Blind Only**

Operator not blinded.

Participants not blinded.

No placebo injection in control group.

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- ➔ Performance bias possible.
- ➔ Hawthorne effect likely.

This is a serious methodological weakness.

### **Problem 8: Site-Specific vs Full-Mouth Analysis Confusion**

PI, GI, BOP = full mouth

PD, CAL = site specific

But:

Statistical comparison not clearly adjusted for clustering effect.

No mention of multilevel modeling.

- ➔ Potential statistical unit-of-analysis error.

### **Problem 9: No Adverse Event Reporting**

No mention of:

Post-injection pain

Swelling

Infection

Allergic reactions

Even if none occurred, it must be stated explicitly.

### ***Statistical Analysis – Technical Concerns***

### **Problem 10: Inconsistent P-Values**

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Example:

BOP at 3 months shows "0.825\*" marked significant — but 0.825 is NOT significant.

Table formatting errors reduce credibility.

### **Problem 11: No Confidence Intervals**

Only p-values provided.

No 95% CI for PD and CAL difference.

High-impact journals require effect size + CI.

### **Problem 12: Multiple Testing Without Adjustment Clarity**

Repeated measures ANOVA mentioned, but:

Bonferroni adjustment not clearly detailed.

No interaction term reporting (time × group).

### ***Results Section – Interpretation Issues***

### **Problem 13: Clinical Relevance Not Discussed**

PD reduction difference:

2.13 mm vs 2.65 mm

Difference ≈ 0.52 mm

- ➔ Is 0.5 mm clinically meaningful?
- ➔ No MCID (minimal clinically important difference) discussed.

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### **Problem 14: Age Range Imbalance**

Group II age max = 64 years

Group I age max = 48 years

Though  $p > 0.05$ :

Biological healing potential differs with age.

This needs discussion.

### ***Discussion – Overinterpretation***

### **Problem 15: Regenerative Language Without Evidence**

Statements like:

“protects blood clot”

“space maintenance”

“absence of rebound effect”

But:

No radiographs

No bone fill data

No biomarker analysis

Cannot claim regenerative superiority.

### **Problem 16: Weak Comparison With Recent Meta-Analysis**

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Recent systematic review:

Autologous platelet concentrates as adjuncts to non-surgical periodontal therapy: a systematic review and meta-analysis

Not critically compared.

Discussion lacks depth in positioning Alb-PRF versus i-PRF or L-PRF.

### ***Limitations Section – Incomplete***

Current limitations mention:

Small sample

Short follow-up

But missing:

Lack of placebo control

Lack of microbiological evaluation

Lack of radiographic evaluation

Lack of double blinding

Possible operator bias

Single-center study limitation

### ***Formatting & Presentation Issues***

Typographical errors throughout.

Reference formatting inconsistencies.

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Table alignment errors.

Some p-values incorrectly written ( $>0.001$  instead of  $<0.001$ ).

Keywords not standardized to MeSH.

These require technical correction before acceptance.

**SUMMARY OF MAJOR REVISION GROUNDS**

Category	Issue Severity
Methodology	Major
Statistical Reporting	Major
Overinterpretation	Major
CONSORT Compliance	Major
Mechanistic Claims	Major
Formatting	Moderate

**FINAL JUSTIFICATION**

This manuscript has:

A relevant clinical topic

Proper ethical approval

Trial registration

Significant clinical findings

BUT

Insufficient methodological rigor

Statistical inconsistencies

Overstated regenerative claims

Missing CONSORT transparency

No adverse event reporting

No radiographic/microbiological support

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## **REVIEWER'S REPORT**

Therefore, **MAJOR REVISION** is justified before the manuscript can be considered for publication in a peer-reviewed periodontal journal.