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REVIEWER'S REPORT

Manuscript No.: IJAR-56092

Title: Clinical Effectiveness of Pre-Formed Myofunctional Appliances: A Literature Review

Recommendation:

Accept as it is

Accept after minor revision.....

Accept after major revisionYES.....

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

Strengths

The manuscript provides a **comprehensive and well-structured overview** of pre-formed myofunctional appliances (PMAs), covering biological rationale, appliance types, clinical effects, and indications.

The review incorporates **recent and relevant literature**, including studies published up to 2025, which enhances its contemporaneity and relevance.

Clear differentiation between **dentoalveolar, neuromuscular, and skeletal effects** of PMAs is a notable strength and reflects an evidence-based approach.

Inclusion of a **comparative discussion with custom functional appliances** (e.g., Twin Block) improves clinical context and decision-making relevance.

The manuscript demonstrates **balanced reporting**, explicitly acknowledging the limitations and unpredictability of skeletal effects.

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The tabulated summary of commonly used PMAs improves **readability and clinical applicability**.

The discussion integrates **orthodontic and orofacial myofunctional therapy concepts**, reflecting an interdisciplinary perspective.

Weaknesses

The review lacks a **clearly defined methodology section** (search strategy, databases used, inclusion/exclusion criteria), limiting transparency and reproducibility.

Although termed a "literature review," it does not specify whether it is **narrative or systematic**, which may raise concerns regarding methodological rigor.

Several claims regarding mandibular advancement and airway effects are based on **limited or low-level evidence**, which should be more clearly qualified.

The manuscript occasionally presents **repetitive descriptions** of biological mechanisms across sections, which could be streamlined.

Industry-associated appliances (e.g., Myobrace®, T4K®) are discussed extensively, but **potential commercial bias** is not explicitly addressed.

Long-term stability and post-treatment relapse are acknowledged but **not critically analyzed in depth**, despite their clinical importance.

Figures and tables are referenced, but **methodological heterogeneity** among cited studies is not sufficiently emphasized.

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Significance

This review addresses a **clinically relevant and timely topic**, given the growing popularity of PMAs in interceptive orthodontics.

It provides clinicians with **realistic expectations** regarding the scope and limitations of PMAs, particularly distinguishing dentoalveolar effects from skeletal modification.

The manuscript contributes to **evidence-based orthodontic practice** by synthesizing data from controlled trials, systematic reviews, and clinical studies.

It highlights the importance of **patient selection, growth timing, and compliance**, which are critical determinants of clinical success.

The discussion on airway and sleep-disordered breathing broadens the relevance of PMAs beyond traditional orthodontic outcomes.

The review may serve as a **useful reference for postgraduate students and clinicians** seeking an updated summary of PMA effectiveness.

Key Points

Pre-formed myofunctional appliances primarily exert **dentoalveolar and neuromuscular effects**, with limited and inconsistent skeletal changes.

PMAs are most effective when used during the **mixed dentition stage** in growing patients with mild to moderate malocclusions.

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Improvements in sagittal relationships are largely due to incisor inclination changes and **muscular re-education**, not true mandibular growth.

Custom functional appliances demonstrate **superior and more predictable skeletal outcomes** compared to PMAs.

PMAs offer practical advantages such as **ease of use, lower cost, and elimination of laboratory procedures**, making them suitable for interceptive therapy.

Successful outcomes depend heavily on **patient compliance and adjunctive myofunctional exercises**.

PMAs should be integrated into a **staged orthodontic treatment plan**, rather than used as standalone therapy for significant skeletal discrepancies.

JUSTIFICATION FOR MAJOR REVISION

Title

Lines 1–2: "Clinical Effectiveness of Pre-Formed Myofunctional Appliances: A Literature Review"

The title claims *clinical effectiveness*, but the manuscript does not critically evaluate the **quality, level, or hierarchy of evidence** supporting effectiveness.

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No distinction is made between **short-term outcomes**, **long-term outcomes**, or **relapse**, which overstates the strength of available evidence.

Major revision required to align the title with the actual level of evidence presented.

Abstract

Lines 10–19

The abstract does not mention the **review methodology**, databases searched, or study selection criteria.

Statements regarding effectiveness are **generalized** and not qualified by evidence strength.

Skeletal effects are described as “limited and unpredictable,” but **no quantitative or comparative context** is provided.

Major revision required to include methodological transparency and balanced claims.

Introduction

Lines 21–42

Background is well written but **purely descriptive**, lacking critical synthesis of existing reviews.

The introduction does not clearly state the **knowledge gap** this review aims to address.

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Prior systematic reviews are cited but **not contrasted** with the present review's contribution.

Major revision required to clearly justify the novelty and purpose of the review.

Section: Commonly Used Pre-Formed Myofunctional Appliances

Lines 43–97

This section reads as a **product-oriented description** rather than a critical academic review.

Commercially branded appliances (Myobrace®, T4K®, MyOSA®) are discussed in detail without **explicit acknowledgment of potential commercial bias**.

No comparative evidence hierarchy is provided among the listed appliances.

Major revision required to reduce descriptive bias and improve critical appraisal.

Table 1

Lines 105–108

The table summarizes “Documented Clinical Effects” without citing **specific study designs, sample sizes, or evidence levels**.

Effects are presented as established outcomes, which may mislead readers regarding certainty.

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Major revision required to include evidence level or reference mapping.

Biological Rationale and Mechanism of Action

Lines 111–154

The biological rationale relies heavily on **theoretical models** (equilibrium theory) without consistently linking them to high-quality clinical outcomes.

Claims of mandibular advancement and growth stimulation are presented despite **limited and conflicting evidence** in the literature.

Repetition of similar concepts across paragraphs reduces clarity and critical depth.

Major revision required to temper claims and streamline content.

Clinical Effects Section

Lines 157–167

Clinical improvements are reported without **stratification by age, compliance, appliance type, or duration of treatment**.

Long-term stability is acknowledged as uncertain but **not critically discussed**.

Major revision required to strengthen evidence interpretation and limitations.

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Comparison with Custom Functional Appliances

Lines 169–184

While comparisons are cited, the manuscript does not discuss **clinical decision thresholds**—i.e., when PMAs should *not* be used.

The reduced skeletal effectiveness of PMAs is acknowledged, yet **clinical implications are underdeveloped**.

Major revision required to enhance clinical applicability and balance.

Current Evidence and Clinical Indications

Lines 185–196

Indications are broadly stated without **clear exclusion criteria**.

Evidence levels (RCTs vs observational studies) are **not differentiated**.

Recommendations risk being interpreted as **clinical guidelines**, which is not justified by the review design.

Major revision required to prevent over generalization.

Conclusion

Lines 206–223

Conclusions reiterate effectiveness despite **methodological limitations** in the review.

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Statements on clinical success and stability are **stronger than supported by the analyzed evidence**.

The need for future high-quality trials is mentioned but **not emphasized sufficiently**.

Major revision required to align conclusions with evidence strength.

References

Lines 225–280

References are relevant and up-to-date, but:

Study quality is not graded.

Systematic reviews and RCTs are cited alongside observational studies without hierarchy.

Some newer citations are included without critical appraisal.

Revision required to incorporate evidence-based weighting.

FINAL RECOMMENDATION

MAJOR REVISION

Overall Justification

Although the manuscript addresses an important and clinically relevant topic, **significant revisions are required** to improve methodological transparency, reduce descriptive and commercial bias, strengthen critical appraisal, and align conclusions with the level of available evidence. Without these changes, the manuscript does not yet meet the scientific rigor expected for publication.