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### RESEARCH ARTICLE

## CLINICAL EFFECTIVENESS OF PRE-FORMED MYOFUNCTIONAL APPLIANCES: A LITERATURE REVIEW

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### Abstract

Pre-formed myofunctional appliances (PMAs) are increasingly utilized in early interceptive orthodontics to address malocclusion by modifying orofacial muscle function and correcting dysfunctional oral habits. Unlike custom functional appliances, PMAs are prefabricated devices designed to promote neuromuscular re-education, guide tooth eruption, and improve dentoalveolar relationships during growth. This literature review synthesizes contemporary evidence on the biological rationale, clinical effects, indications, and limitations of PMAs. Current evidence suggests that PMAs are effective in improving dentoalveolar parameters and functional habits, particularly in growing patients with mild to moderate malocclusions, while their skeletal effects remain limited and unpredictable. Appropriate case selection, treatment timing, and patient compliance are essential for achieving favorable outcomes.

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### Introduction:-

#### Introduction and Description:-

Malocclusion is a multifactorial condition influenced by genetic, environmental, and functional factors. Increasing attention has been directed toward the role of orofacial muscle imbalance, altered tongue posture, mouth breathing, and dysfunctional swallowing patterns in the development and persistence of malocclusion.<sup>1-3</sup> Orofacial myofunctional therapy aims to restore muscular equilibrium among the lips, cheeks, and tongue, thereby creating a favorable functional environment for dental and occlusal development.<sup>2</sup> Pre-formed myofunctional appliances (PMAs) have emerged as adjunctive tools within this therapeutic framework. These prefabricated, removable appliances are designed to modify abnormal muscle activity, re-educate respiratory patterns, eliminate deleterious oral habits, and guide tooth eruption during critical growth periods.<sup>2-5</sup> Unlike custom functional appliances that rely on mandibular advancement for skeletal correction, PMAs primarily influence the neuromuscular environment surrounding the dentition.<sup>6</sup> The rationale for PMA therapy is based on the equilibrium theory, which proposes that

tooth position is determined by the balance of forces exerted by the tongue, lips, and cheeks.<sup>7</sup> Excessive or deficient muscle pressures can alter incisor inclination, arch form, and sagittal relationships. Elevated perioral muscle pressure may result in incisor retrusion and deep bite tendencies, whereas reduced lip pressure may allow maxillary incisor protrusion.<sup>7-9</sup> Functional re-education through PMAs aims to restore this balance and facilitate stable dentoalveolar development.

#### **Commonly Used Pre-Formed Myofunctional Appliances:-**

Pre-formed myofunctional appliances (PMAs) are widely used during the mixed dentition stage, when growth modulation and habit correction are most effective. Their prefabricated design eliminates the need for impressions and laboratory fabrication, making them accessible and cost-effective for early intervention.<sup>4,10</sup> Common indications include Class II malocclusion with increased overjet, deep bite, mild arch discrepancies, and malocclusions associated with orofacial muscular dysfunction.<sup>4,11</sup> PMAs are frequently incorporated into orofacial myofunctional therapy protocols, either as a standalone approach in mild cases or as an adjunct to fixed orthodontic treatment.<sup>3,12</sup> They have also been explored in pediatric airway management, where improvements in tongue posture and oral breathing patterns may contribute to enhanced airway dimensions and reduced sleep-related breathing disturbances.<sup>13</sup> (See Table 1.)

#### **Examples of Preformed Myofunctional Appliances:-**

##### **Myobrace® System:-**

The Myobrace® system is a prefabricated myofunctional appliance developed by Myofunctional Research Co. (MRC), Australia, designed for early orthodontic intervention in children. It focuses on correcting the underlying functional causes of malocclusion—including mouth breathing, tongue thrusting, and improper tongue posture—rather than simply aligning teeth. The system uses a series of soft, removable appliances worn daily and overnight, combined with exercises that promote nasal breathing, proper tongue posture, and lip seal. By improving oral habits and facial muscle function, Myobrace® supports dental arch development, occlusal improvement, and favorable craniofacial growth, potentially reducing the need for later fixed orthodontic treatment.<sup>1,2,6,18</sup>

##### **T4K® (PreOrthodontic Trainer for Kids):-**

The T4K® is a prefabricated, removable myofunctional appliance introduced by Myofunctional Research Co. in 1992, designed to correct developing malocclusions in the mixed dentition by retraining orofacial muscles and eliminating dysfunctional oral habits. It guides tooth eruption, encourages proper tongue posture, promotes nasal breathing, and establishes balanced perioral musculature.

##### **The system includes two phases:**

- **Phase I:** soft silicone appliance for habit correction and muscle training.
- **Phase II:** firmer polyurethane appliance for improved tooth alignment and arch development.

Premolded to a natural arch form and requiring no impressions or laboratory work, the T4K® provides an accessible early intervention option for children, with reported benefits such as improved nasal breathing, reduced overjet, better swallowing patterns, and correction of tongue thrusting and mouth breathing.<sup>2,7,11</sup>

##### **LMActivator™ :-**

The LMActivator™ is a prefabricated, medical-grade silicone orthodontic appliance designed for early mixed dentition. It gently guides tooth eruption, improves occlusal relationships, and supports orofacial muscle function while being worn primarily at night and during additional daytime hours.<sup>8</sup>

##### **Trainer for Braces (T4B®):-**

The Trainer for Braces (T4B®) was developed to support the management of soft tissue dysfunction, tongue position issues, and potential TMJ symptoms during fixed appliance therapy. It also covers brackets and bands, reducing irritation commonly experienced in the early weeks of treatment. Although not intended to replace the functional phase of orthodontic therapy, the T4B® provides functional type effects when used alongside fixed appliances. It is a prefabricated, single-size appliance with channels that fit over orthodontic brackets. It helps accelerate treatment by minimizing undesirable myofunctional habits and enhances posttreatment stability by retraining the oral musculature. Its double-mouthguard design also helps limit bruxism.<sup>9</sup>

**MyOSA® Appliance:**

The MyOSA® appliance is designed to improve airway function in children by correcting dysfunctional oral habits, enhancing tongue posture, and balancing orofacial muscle activity, which together reduce the frequency of apneas and hypopneas during sleep.<sup>10,27</sup>

**Table 1. Summary of Common Preformed Myofunctional Appliances and Their Clinical Roles**

Appliance	Primary Mechanism of Action	Main Clinical Indications	Documented Clinical Effects
<b>Myobrace® System</b>	Corrects dysfunctional oral habits (mouth breathing, tongue thrust); promotes nasal breathing, lip seal, and correct tongue posture; reduces abnormal perioral muscle pressure.	Early interceptive treatment for Class II tendencies, increased overjet, oral habit correction, arch development in mixed dentition.	Overjet reduction, improved lip competence and tongue posture, dentoalveolar alignment with minimal and inconsistent skeletal effects.
<b>T4K® (Pre-Orthodontic Trainer for Kids)</b>	Orofacial muscle retraining; eruption guidance; phased soft and firm appliance design for habit correction and alignment.	Developing malocclusions in mixed dentition; tongue thrust; mouth breathing; lip incompetence.	Improved nasal breathing, reduced overjet, improved swallowing pattern, dentoalveolar adaptation.
<b>LMActivator™</b>	Silicone elastodontic appliance providing eruption guidance and neuromuscular adaptation.	Early mixed dentition; mild Class II malocclusion; mild crowding.	Improved eruption patterns and occlusal relationships with primarily dental effects.
<b>Trainer for Braces (T4B®)</b>	Soft-tissue re-education during fixed orthodontic therapy; bracket shielding; reduction of abnormal muscle activity.	Patients undergoing fixed orthodontic treatment; myofunctional dysfunction; bruxism.	Reduced soft-tissue irritation, improved comfort during fixed appliance therapy, enhanced post-treatment stability.
<b>MyOSA® Appliance</b>	Improves airway function by optimizing tongue posture and balancing orofacial muscle activity; promotes nasal breathing.	Mild to moderate pediatric obstructive sleep apnea; mouth breathing; low tongue posture.	Reduction in sleep-disordered breathing symptoms, improved airway patency and oral posture.

**Biological Rationale and Mechanism of Action:-**

Oral myofunctional therapy focuses on correcting orofacial muscular imbalances and restoring equilibrium among the cheek muscles, lips and tongue, thereby improving treatment effectiveness and long-term stability.<sup>2</sup> Prefabricated myofunctional appliances (PMAs) are designed to correct malocclusions by modifying abnormal orofacial muscle function, re-educating respiratory patterns, correcting deleterious oral habits, and guiding tooth eruption during critical growth periods.<sup>2,3</sup> The rationale for PMAs stems from the idea that malocclusions arise not only from genetic determinants but also from physiological factors, particularly orofacial myofunctional disorders that disrupt the balance of forces acting on the developing dentition.<sup>2,3</sup> Malocclusion can result from muscular imbalances. Hassan et al. found a close relationship between circumoral muscle strength and anterior tooth position, while Burstone identified that the normal physiologic position of maxillary and mandibular anterior teeth at rest is largely maintained by the lower lip.<sup>3</sup> Elevated labial muscle pressure can result in mandibular incisor retrusion, mandibular retraction and Angle class II division 2 malocclusion, whereas diminished pressure may allow maxillary incisors to protrude.<sup>2</sup> According to Rogers, functional training of orofacial muscles can correct dentofacial malformations as muscle changes can influence tooth position and dental arch form.<sup>3</sup>

The adjunctive use of prefabricated appliances appears to augment the efficacy of orofacial myofunctional therapy, leading to increased labial muscle strength and mandibular advancement, thereby improving maxillomandibular relationships.<sup>3</sup> The anterior positioning of the mandible stimulates mandibular growth by increased remodelling activity of the condyle.<sup>2,5</sup> These appliances are commonly prescribed along with myofunctional exercises that target the specific orofacial myofunctional disorders.<sup>5</sup> The design of Myobrace incorporates vestibular and lingual shields, which can moderate excessive orofacial pressure, a tongue tag that guides the tongue to its optimal resting position on the palate and a tongue elevator.<sup>5</sup> The shields help maintain equilibrium, whereas the tongue tag supports lip competence and nasal breathing.<sup>5</sup> Myobrace targets parafunctional habits such as mouth breathing, tongue thrusting and lip sucking for balanced dentofacial development.<sup>6</sup> Its compatibility with fixed appliances enables a combined approach of myofunctional and fixed orthodontics to address both muscular and dentoalveolar components in complex cases.<sup>5</sup>

Prefabricated myofunctional appliances can treat class II division 1 malocclusions by simultaneously advancing the mandible and guiding eruption.<sup>6</sup> A retrospective study indicated that the Myobrace i-3 ® appliance can be used for treating class III malocclusion with an underdeveloped maxilla, as it may stimulate forward growth of the maxilla, reposition the tongue to a correct resting posture and reduce mouth breathing and tongue thrusting.<sup>14</sup> But further studies are required to confirm the prolonged stability of these results.<sup>14</sup> Early intervention with myofunctional appliances can lessen the need for comprehensive orthodontic treatments in the future, as they can direct the eruption of permanent teeth to establish proper alignment and occlusal relationships if used in the early mixed dentition.<sup>5</sup>

**Clinical Effects of Pre-Formed Myofunctional Appliances:-**

Clinical studies and case reports indicate that PMAs can produce favorable dentoalveolar and functional outcomes when used during early growth phases. Improvements in overjet, overbite, incisor inclination, transverse arch dimensions, and muscle function have been reported, particularly in patients with oral habits and mild sagittal discrepancies.<sup>5,12,15</sup> Early interceptive treatment using PMAs has also demonstrated benefits in selected Class III and transverse discrepancies by eliminating functional shifts and improving neuromuscular balance.<sup>16,17</sup> However, long-term stability and skeletal predictability require further investigation. Beyond dentofacial effects, PMAs have shown potential benefits in managing pediatric sleep-related breathing disorders. Night-time use of prefabricated appliances has been associated with reductions in mouth breathing, snoring, and related symptoms.<sup>13</sup>

**Comparison with Custom Functional Appliances:-**

Comparative studies consistently demonstrate that custom functional appliances such as Twin Block produce greater and more predictable skeletal effects than PMAs in the management of Class II malocclusion.<sup>18-20</sup> Meta-analyses have shown that PMAs result in smaller changes in mandibular length, sagittal jaw relationships, and airway dimensions compared to custom appliances.<sup>18</sup> Nevertheless, PMAs offer practical advantages, including ease of use, reduced cost, and elimination of laboratory procedures. These features may justify their use as interceptive or adjunctive appliances in carefully selected cases, provided their limitations are clearly communicated.<sup>18</sup> Despite the superior skeletal effects of custom functional appliances, pre-formed myofunctional appliances retain certain clinical advantages that may justify their use in specific circumstances. It has been noted that Myobrace appliances eliminate the need for impressions and laboratory work, making them more cost-effective and accessible, particularly in

remote areas without laboratory access. However, the clinical significance of these advantages must be weighed against the substantially reduced treatment effectiveness, particularly for patients requiring significant skeletal correction.<sup>18</sup>

#### Current Evidence and Clinical Indications:-

High-quality evidence indicates that PMAs exert their primary effects through neuromuscular re-education and dentoalveolar adaptation rather than skeletal modification.<sup>21</sup> Systematic reviews emphasize that improvements in sagittal relationships are largely attributable to incisor inclination changes and altered muscle equilibrium.<sup>21,22</sup> Accordingly, PMAs are best indicated during the mixed dentition or early permanent dentition stages in growing patients with mild to moderate malocclusions associated with dysfunctional oral habits.<sup>4,11</sup> Optimal outcomes depend on growth timing, compliance, and realistic treatment expectations. Based on contemporary evidence, pre-formed myofunctional appliances are primarily indicated as interceptive orthodontic tools during the mixed dentition or early permanent dentition stages. Their use is particularly appropriate in growing patients presenting with mild to moderate malocclusions associated with orofacial muscle dysfunction.<sup>7</sup> The principal clinical indication for PMAs is the management of Class II malocclusion characterized by increased overjet, where correction is achieved through improved tongue posture, establishment of lip competence, and normalization of muscular balance rather than mandibular advancement.<sup>6</sup> (Figure 1.)<sup>23</sup>

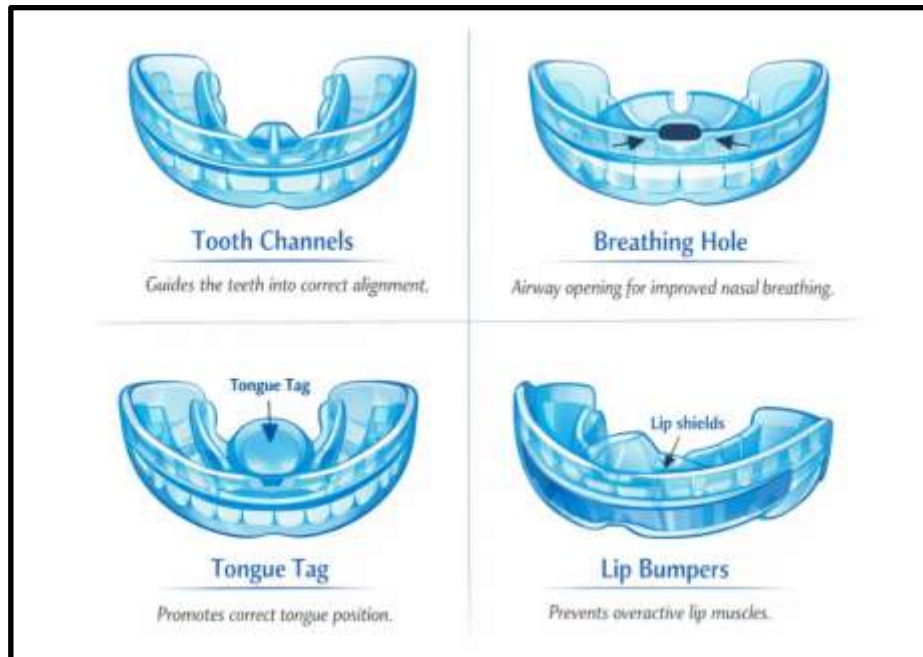


Fig.1 Components of Myobrace<sup>23</sup>

#### Conclusion:-

Pre-formed myofunctional appliances represent a valuable interceptive orthodontic modality for modifying orofacial muscle function and improving dentoalveolar relationships during growth. Contemporary evidence supports their effectiveness in correcting oral habits, reducing overjet, and facilitating early occlusal guidance in children and adolescents, particularly when treatment is initiated during the mixed dentition stage and supported by good patient compliance.<sup>2,5,11</sup> Current systematic reviews and controlled clinical studies consistently indicate that the clinical effects of PMAs are predominantly dentoalveolar and neuromuscular in nature, with limited and inconsistent evidence of true skeletal modification.<sup>6,18,21</sup> Although minor positional changes of the mandible may be observed, these changes are largely secondary to functional adaptation rather than genuine growth alteration.<sup>6,22</sup>

When compared with custom functional appliances, PMAs demonstrate reduced skeletal efficacy but offer practical advantages such as ease of use, lower cost, and suitability for early intervention.<sup>18,19</sup> Consequently, PMAs should be incorporated as part of a comprehensive, staged orthodontic treatment strategy rather than relied upon as a standalone approach for significant skeletal discrepancies. Clear communication with patients and parents regarding

realistic treatment expectations—particularly the predominance of dentoalveolar effects—is essential to ensure clinical success and long-term stability.<sup>1,21</sup>

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