

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

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5 Keywords

6 Pre-formed myofunctional appliances; interceptive orthodontics; Myobrace; dentoalveolar effects;
7 orofacial myofunctional therapy

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9 Abstract

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

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21) Introduction and Description

22 Malocclusion is a multifactorial condition influenced by genetic, environmental, and functional
23 factors. Increasing attention has been directed toward the role of orofacial muscle imbalance,
24 altered tongue posture, mouth breathing, and dysfunctional swallowing patterns in the
25 development and persistence of malocclusion.^{1- 3} Orofacial myofunctional therapy aims to restore
26 muscular equilibrium among the lips, cheeks, and tongue, thereby creating a favorable functional
27 environment for dental and occlusal development.²

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29 Pre-formed myofunctional appliances (PMAs) have emerged as adjunctive tools within this
30 therapeutic framework. These prefabricated, removable appliances are designed to modify
31 abnormal muscle activity, re-educate respiratory patterns, eliminate deleterious oral habits, and
32 guide tooth eruption during critical growth periods.^{2- 5} Unlike custom functional appliances that
33 rely on mandibular advancement for skeletal correction, PMAs primarily influence the
34 neuromuscular environment surrounding the dentition.⁶

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36 The rationale for PMA therapy is based on the equilibrium theory, which proposes that tooth
37 position is determined by the balance of forces exerted by the tongue, lips, and cheeks.⁷

38 Excessive or deficient muscle pressures can alter incisor inclination, arch form, and sagittal
39 relationships. Elevated perioral muscle pressure may result in incisor retrusion and deep bite
40 tendencies, whereas reduced lip pressure may allow maxillary incisor protrusion.⁷⁻⁹ Functional
41 re-education through PMAs aims to restore this balance and facilitate stable dentoalveolar
42 development.

432) Commonly Used Pre-Formed Myofunctional Appliances

44 Pre-formed myofunctional appliances (PMAs) are widely used during the mixed dentition stage,
45 when growth modulation and habit correction are most effective. Their prefabricated design
46 eliminates the need for impressions and laboratory fabrication, making them accessible and cost-
47 effective for early intervention.^{4,10}

48 Common indications include Class II malocclusion with increased overjet, deep bite, mild arch
49 discrepancies, and malocclusions associated with orofacial muscular dysfunction.^{4,11} PMAs are
50 frequently incorporated into orofacial myofunctional therapy protocols, either as a standalone
51 approach in mild cases or as an adjunct to fixed orthodontic treatment.^{3,12}

52 They have also been explored in pediatric airway management, where improvements in tongue
53 posture and oral breathing patterns may contribute to enhanced airway dimensions and reduced
54 sleep-related breathing disturbances.¹³ (See Table 1.)

55 Examples of Preformed Myofunctional Appliances

56 Myobrace® System

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

66 T4K® (PreOrthodontic Trainer for Kids)

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

- 72 ● **Phase I:** soft silicone appliance for habit correction and muscle training.
 - 73 ● **Phase II:** firmer polyurethane appliance for improved tooth alignment and arch development.
- 74 Premolded to a natural arch form and requiring no impressions or laboratory work, the T4K®
75 provides an accessible early intervention option for children, with reported benefits such as

76 improved nasal breathing, reduced overjet, better swallowing patterns, and correction of tongue
77 thrusting and mouth breathing.^{2,7,11}

78 **LMAActivator™**

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

83 **Trainer for Braces (T4B®)**

84 The Trainer for Braces (T4B®) was developed to support the management of soft tissue
85 dysfunction, tongue position issues, and potential TMJ symptoms during fixed appliance therapy.
86 It also covers brackets and bands, reducing irritation commonly experienced in the early weeks of
87 treatment. Although not intended to replace the functional phase of orthodontic therapy, the T4B®
88 provides functional type effects when used alongside fixed appliances.

89 It is a prefabricated, single-size appliance with channels that fit over orthodontic brackets. It helps
90 accelerate treatment by minimizing undesirable myofunctional habits and enhances
91 posttreatment stability by retraining the oral musculature. Its double-mouthguard design also
92 helps limit bruxism.⁹

93 **MyOSA® Appliance**

94 The MyOSA® appliance is designed to improve airway function in children by correcting
95 dysfunctional oral habits, enhancing tongue posture, and balancing orofacial muscle activity,
96 which together reduce the frequency of apneas and hypopneas during sleep.^{10,27}

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Table 1. Summary of Common Preformed Myofunctional Appliances and Their Clinical Roles 106
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Appliance	Primary Mechanism of Action	Main Clinical Indications	Documented Clinical Effects
Myobrace® System	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.
T4K® (Pre-Orthodontic Trainer for Kids)	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.
LMActivator™	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.
Trainer for Braces (T4B®)	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.

MyOSA® Appliance	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.
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111 **Biological Rationale and Mechanism of Action**

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113 Oral myofunctional therapy focuses on correcting orofacial muscular imbalances and restoring
 114 equilibrium among the cheek muscles, lips and tongue, thereby improving treatment effectiveness
 115 and long-term stability.² Prefomed myofunctional appliances(PMAs) are designed to correct
 116 malocclusions by modifying abnormal orofacial muscle function, re-educating respiratory patterns,
 117 correcting deleterious oral habits, and guiding tooth eruption during critical growth periods.^{2,3} The
 118 rationale for PMAs stems from the idea that malocclusions arise not only from genetic
 119 determinants but also from physiological factors, particularly orofacial myofunctional disorders
 120 that disrupt the balance of forces acting on the developing dentition.^{2,3}

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122 Malocclusion can result from muscular imbalances. Hassan et al. found a close relationship
 123 between circumoral muscle strength and anterior tooth position, while Burstone identified that the
 124 normal physiologic position of maxillary and mandibular anterior teeth at rest is largely maintained
 125 by the lower lip.³ Elevated labial muscle pressure can result in mandibular incisor retrusion,
 126 mandibular retraction and Angle class II division 2 malocclusion, whereas diminished pressure
 127 may allow maxillary incisors to protrude ². According to Rogers, functional training of orofacial
 128 muscles can correct dentofacial malformations as muscle changes can influence tooth position
 129 and dental arch form.³

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131 The adjunctive use of prefomed appliances appears to augment the efficacy of orofacial
 132 myofunctional therapy, leading to increased labial muscle strength and mandibular advancement,
 133 thereby improving maxillomandibular relationships.³ The anterior positioning of the mandible
 134 stimulates mandibular growth by increased remodelling activity of the condyle.^{2,5} These
 135 appliances are commonly prescribed alongwith myofunctional exercises that target the specific
 136 orofacial myofunctional disorders.⁵

137

138 The design of Myobrace incorporates vestibular and lingual shields, which can moderate
 139 excessive orofacial pressure, a tongue tag that guides the tongue to its optimal resting position
 140 on the palate and a tongue elevator.⁵ The shields help maintain equilibrium, whereas the tongue
 141 tag supports lip competence and nasal breathing.⁵ Myobrace targets parafunctional habits such
 142 as mouth breathing, tongue thrusting and lip sucking for balanced dentofacial development.⁶ Its

143 compatibility with fixed appliances enables a combined approach of myofunctional and fixed
144 orthodontics to address both muscular and dentoalveolar components in complex cases.⁵

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

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

158 Clinical studies and case reports indicate that PMAs can produce favorable dentoalveolar and
159 functional outcomes when used during early growth phases. Improvements in overjet, overbite,
160 incisor inclination, transverse arch dimensions, and muscle function have been reported,
161 particularly in patients with oral habits and mild sagittal discrepancies.^{5,12,15}

162 Early interceptive treatment using PMAs has also demonstrated benefits in selected Class III and
163 transverse discrepancies by eliminating functional shifts and improving neuromuscular
164 balance.^{16,17} However, long-term stability and skeletal predictability require further investigation.

165 Beyond dentofacial effects, PMAs have shown potential benefits in managing pediatric sleep-
166 related breathing disorders. Night-time use of prefabricated appliances has been associated with
167 reductions in mouth breathing, snoring, and related symptoms.¹³

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169 **Comparison with Custom Functional Appliances**

170 Comparative studies consistently demonstrate that custom functional appliances such as Twin
171 Block produce greater and more predictable skeletal effects than PMAs in the management of
172 Class II malocclusion.^{18- 20} Meta-analyses have shown that PMAs result in smaller changes in
173 mandibular length, sagittal jaw relationships, and airway dimensions compared to custom
174 appliances.¹⁸

175 Nevertheless, PMAs offer practical advantages, including ease of use, reduced cost, and
176 elimination of laboratory procedures. These features may justify their use as interceptive or
177 adjunctive appliances in carefully selected cases, provided their limitations are clearly
178 communicated.¹⁸ Despite the superior skeletal effects of custom functional appliances, pre-
179 formed myofunctional appliances retain certain clinical advantages that may justify their use in

180 specific circumstances. It has been noted that Myobrace appliances eliminate the need for
181 impressions and laboratory work, making them more cost-effective and accessible, particularly in
182 remote areas without laboratory access. However, the clinical significance of these advantages
183 must be weighed against the substantially reduced treatment effectiveness, particularly for
184 patients requiring significant skeletal correction.¹⁸

185 **Current Evidence and Clinical Indications**

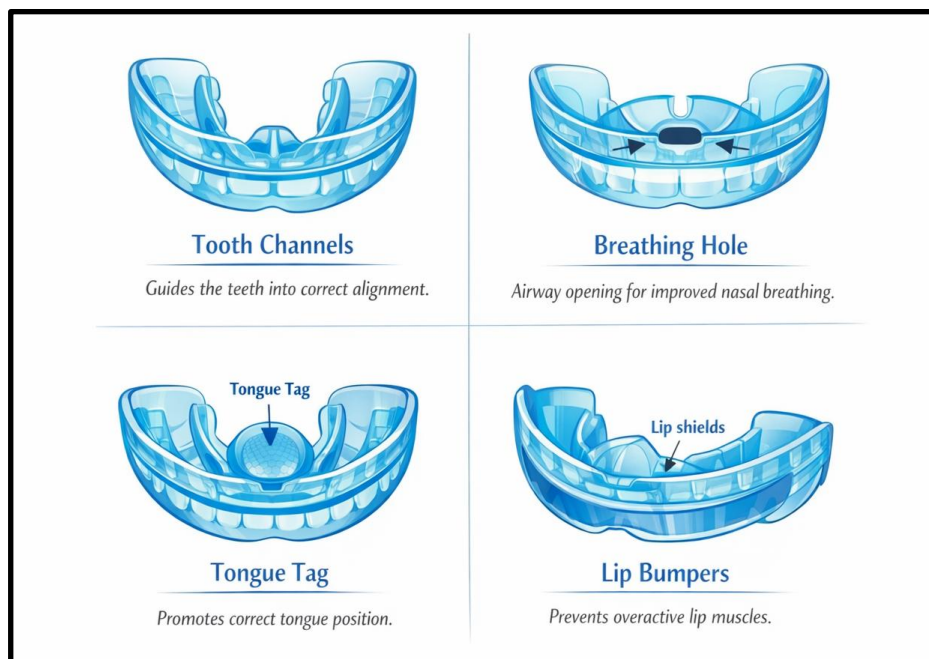
186 High-quality evidence indicates that PMAs exert their primary effects through neuromuscular re-
187 education and dentoalveolar adaptation rather than skeletal modification.²¹ Systematic reviews
188 emphasize that improvements in sagittal relationships are largely attributable to incisor inclination
189 changes and altered muscle equilibrium.^{21, 22}

190 Accordingly, PMAs are best indicated during the mixed dentition or early permanent dentition
191 stages in growing patients with mild to moderate malocclusions associated with dysfunctional oral
192 habits.^{4, 11} Optimal outcomes depend on growth timing, compliance, and realistic treatment
193 expectations.

194 Based on contemporary evidence, pre-formed myofunctional appliances are primarily indicated
195 as interceptive orthodontic tools during the mixed dentition or early permanent dentition stages.
196 Their use is particularly appropriate in growing patients presenting with mild to moderate
197 malocclusions associated with orofacial muscle dysfunction.⁷

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199 The principal clinical indication for PMAs is the management of Class II malocclusion
200 characterized by increased overjet, where correction is achieved through improved tongue
201 posture, establishment of lip competence, and normalization of muscular balance rather than
202 mandibular advancement.⁶ (Figure 1.)²³



203
204 *Fig.1 Components of Myobrace²³*

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206 **Conclusion**

207 Pre-formed myofunctional appliances represent a valuable interceptive orthodontic modality for
208 modifying orofacial muscle function and improving dentoalveolar relationships during growth.
209 Contemporary evidence supports their effectiveness in correcting oral habits, reducing overjet,
210 and facilitating early occlusal guidance in children and adolescents, particularly when treatment is
211 initiated during the mixed dentition stage and supported by good patient compliance.^{2, 5, 11}

212 Current systematic reviews and controlled clinical studies consistently indicate that the clinical
213 effects of PMAs are predominantly dentoalveolar and neuromuscular in nature, with limited and
214 inconsistent evidence of true skeletal modification.^{6, 18, 21} Although minor positional changes of the
215 mandible may be observed, these changes are largely secondary to functional adaptation rather
216 than genuine growth alteration.^{6, 22}

217 When compared with custom functional appliances, PMAs demonstrate reduced skeletal efficacy
218 but offer practical advantages such as ease of use, lower cost, and suitability for early
219 intervention.^{18, 19} Consequently, PMAs should be incorporated as part of a comprehensive, staged
220 orthodontic treatment strategy rather than relied upon as a standalone approach for significant
221 skeletal discrepancies. Clear communication with patients and parents regarding realistic
222 treatment expectations—particularly the predominance of dentoalveolar effects—is essential to
223 ensure clinical success and long-term stability.^{1, 21}

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