



# REPORT

health  
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## PREFABRICATED MYOFUNCTIONAL APPLIANCE FOR EARLY ORTHODONTIC TREATMENT

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## **EXECUTIVE SUMMARY**

Pre-fabricated myofunctional appliances for early orthodontic treatment have been developed specifically for treatment of children in the mixed dentition stage (6-11 years old). One such appliance that is available in the market and used mainly by general dental practitioners is the Trainer for Kids (T4K). It is made from polyurethane and is similar to other functional appliances. Additional features had been incorporated into the design to give orthopaedic effects of a functional appliance combined with a tooth guidance system and myofunctional training.

The objective of the assessment is to determine the safety, effectiveness, cost and legal implications of the appliance used in the orthodontic treatment of children. A comprehensive and systematic search of evidence was undertaken. However, there was insufficient evidence to draw any definitive conclusions about the safety, clinical effectiveness, cost-effectiveness of the appliance in early orthodontic treatment in children. It is recommended that research be undertaken locally to look into the efficacy and effectiveness of the prefabricated myofunctional appliance for early orthodontic treatment.

There is some evidence of benefits from local use of the technology but these are only case report.

## **1. BACKGROUND**

Orthodontics is the branch of dentistry concerned with growth of the face, development of the occlusion and prevention and correction of occlusal anomalies (Houston et al, 1992). Clinical experience and research accumulated over the years have improved our knowledge in various aspects of this field. Treatment is now based upon a thorough understanding of the aetiology of malocclusion, of facial growth and occlusal development, and of the problems of long-term occlusal stability.

Recently, the concept of early treatment of malocclusion, aimed at correcting existing or developing skeletal, dento-alveolar and muscular imbalances to improve the environment, before eruption of the permanent dentition is complete, has been advocated. By initiating treatment at the mixed dentition stage, more treatment options are available and the need for complex orthodontic treatment involving permanent tooth extraction or orthognathic surgery is also minimized.

This increased interest in early treatment has been stimulated by a number of inter-related factors. Among them is a rise in the level of awareness of preventive dentistry, and an interest not only in correcting existing problems, but also in intercepting or modifying abnormal oro-facial conditions as they are recognized. This is also due to increased competition for orthodontic patients, including from non-orthodontists. Thus, there is a change in the orthodontic patient population, so that the tradition of patients commencing treatment after the eruption of the second molars is seen far less frequently today.

There are various early treatment protocols. The one that is currently in use is the pre-fabricated myofunctional appliance for early orthodontic treatment.

## **2. INTRODUCTION**

Pre-fabricated myofunctional appliances for early orthodontic treatment have been developed specifically for treatment of children at the mixed dentition stage (6 – 11 years old). One such appliance currently available is the Trainer for Kids (T4K). This appliance is quite similar to other functional appliances, except that it has some added features.

T4K is claimed to have the orthopaedic effects of a functional appliance combined with a tooth guidance system and myofunctional training. In the early mixed dentition stage, it can be used as the sole treatment for developing / existing malocclusion by guiding the eruption of teeth. It is used as pre-orthodontic treatment for mouth breathing, tongue thrusting and thumb sucking by providing myofunctional training, and aiding in jaw positioning. It has been claimed that crowding of teeth and jaw discrepancies are mostly acquired, and less due to genetics. Malocclusion has been attributed mainly to mouth breathing, atypical swallowing habits and thumb sucking. The use of this appliance has been said to help to eliminate these habits as well as to align the developing teeth. It aims to simplify future orthodontic treatment and minimize the need for extraction.

The indications suggested are patients with lower anterior crowding, anterior open bite, Class I crowding, Class II/1, Class II/2, and mild Class III malocclusion, mouth breathing, tongue thrusters, thumb suckers, incorrect swallowing and other oral habits.

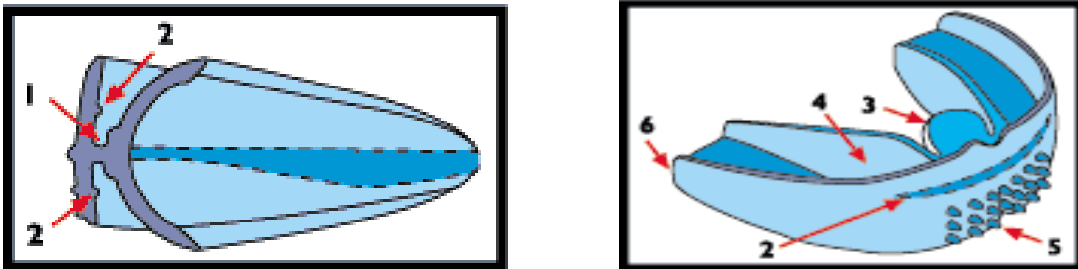
However, it is not indicated for those with posterior cross-bite, severe Class III malocclusion, complete nasal obstruction or reluctant child/parent.

This appliance was introduced into this country in early 2000 and has since been used mainly by the general dental practitioners on their patients. There has been no report concerning the safety, effectiveness, cost and legal implications of this appliance so far.

### 3. TECHNICAL FEATURES

This device is said to be made from a non-thermoplastic silicon or polyurethane, which gives it flexibility and inherent memory. It is available in a universal size for all children 6 – 11 years old (mixed dentition stage) and is pre-moulded into an edge-to-edge relationship between the upper and lower incisors ([http://www.myoresearch.com/t4k\\_prof\\_manual.html](http://www.myoresearch.com/t4k_prof_manual.html)).

This appliance incorporates various components and their functions can be illustrated below:



Source([http://www.myoresearch.nl/t4k\\_abt.html](http://www.myoresearch.nl/t4k_abt.html))

#### Tooth guidance system

1. Tooth channels – the upper and lower teeth bite into their respective channels separated by 2mm thickness of the thermoplastic material. The design of the channels, which is narrow anteriorly and wider posteriorly, corresponds to the thickness of the incisal edges and occlusal surface of the buccal teeth.
2. Labial bows – impart a light force on mal-aligned front teeth.

Myofunctional training

3. Tongue tag – for the correct positioning of the tongue tip as in myofunctional and speech therapies. It provides the proprioceptive location of the tongue tip into its correct resting place. The patient learns where this position is with the appliance in place and this act as a reminder where the “spot” is.
4. Tongue guard – stops tongue thrusting when in place and forces child to breathe through the nose.
5. Lip bumpers – discourage lip muscle activity. This component aims to stretch and deactivate overactive mentalis muscle contraction associated with tongue thrust swallow.

Jaw positioning / functional appliance

6. Jaw repositioning – lower jaw is positioned as far forward so that the upper and lower anterior teeth are about edge to edge position in their respective tooth channels. The correct jaw position is produced when in place. Corrections are achieved by the combination of preventing mouth breathing and tongue thrusting.

It is worn one hour each day plus at night when asleep. The appliance is placed by the patient in the mouth with the tongue tag uppermost. Patient is then instructed to feel the tongue tag with the tip of tongue, while keeping the lips together and breathing through the nose. Patient is cautioned not to chew on it.

#### **4. OBJECTIVES**

To determine the safety, effectiveness, cost and legal implications of pre-fabricated myofunctional appliance for early orthodontic treatment in children.

#### **5. METHODOLOGY**

The literature search on pre-fabricated myofunctional appliance was carried out as indicated in Appendix 1.. Literature was appraised and the evidence graded according to the Modified CAHTA scale (Appendix 2).

#### **6. RESULTS & DISCUSSION**

##### **6.1. Safety**

There was no evidence available on possible reaction to the patient caused by the material used in the Trainer for Kids (T4K).Consequently, attempts were made to extrapolate

evidence that may be of significance in relation to the safety of the material used to make the myofunctional appliance. A German study by Schendel et al, (1995) reported that biocompatibility tests on synthetic material used for removal of orthodontic appliances showed no mutagenic, toxic or irritating properties when used in patient appliances or from the shavings resulting from the grinding of the appliance. Another study in Poland on orthodontic appliances made from silicone elastomer concluded that the silicone appliance can be recommended for the youngest patients as it is safe (Skomro, 2000).

Other than a reaction to the material used, the safety of the patient can be compromised due to other factors such as airway obstruction, aspiration and deglutition. According to DiBiase et al, (2000) orthodontic appliances or parts of orthodontic appliances can occasionally compromise the airway and the gastrointestinal tract due to the proximity of these appliances to the oropharynx. Poukkula et al, (1988) point out that the symptoms of inhalation can be overlooked when the patient has a history of asthma or when the history of inhalation is obscure. The aspiration of a foreign body during dental treatment presents a serious problem and the symptoms will depend on where the object is being impacted. The incidence of reported cases of aspiration or ingestion of orthodontic appliances is less common, but no less varied in the types of appliance involved. However, there is no available evidence of such hazard involving pre-fabricated myofunctional appliance in the literature.

In conclusion there is insufficient evidence to support the safety of prefabricated myofunctional appliances.

## **6.2. Effectiveness**

There was limited literature on the effectiveness of pre-fabricated myofunctional appliances. Those available were related to the effects of other types of functional appliances. A survey by British Orthodontists on the use of myofunctional appliances showed that most orthodontists preferred to use the Clark Twin Block appliance (Chadwich et al., 1998).

A pilot study by Quadrelli et al., (2002) involving 6 children ranging in age from 4 to 9 years was carried out to study the effectiveness of Pre-Orthodontic Position Trainer. The results showed an improvement of Class II profile but not the dental crowding. However, the conclusion of this study was based on a small sample size with a wide age range. An unpublished case report by Kassim (2003) showed that the appliance was effective in reducing the over jet and eliminating lower lip trap within 6 to 9 months. Again the conclusion was based on a single patient.

With regard to early treatment, Tulloch et al., (1997 and 1998) found that early treatment with functional appliances did reduce the severity of Class II skeletal pattern. However, these children had considerable variation in growth either with or without treatment. They could not find any linear relationship between magnitude of treatment response and severity of initial problem, age at outset of treatment, growth pattern before or during treatment and compliance. In another randomized controlled trial (Vijayaratne et al.,

2000) with 51 subjects, it was found that there was a wide variation in the treatment response, whereby only 33% improved while 66% were worse off. They concluded that functional appliances should be used in selected cases only. A meta-analysis by Chen, et al., (2002) concluded that though functional appliances could be used for other purposes, its use to enhance mandibular growth needed to be re-evaluated.

The Trainer for Kids (T4K) is a is different from the conventional myofunctional appliances due to several features that have been incorporated into the design to give added functions.

A lip bumper used at the mixed dentition stage did result in significant differences in mandibular incisor inclination, arch length and arch perimeter between treated and untreated subjects (Moshe et al, 1997). There was also a significant arch width increase across canines, premolars and molars (Hasler & Ingervall, 2000).

Tongue thrusting was once thought to be a possible factor in the aetiology of malocclusion, particularly in the 50s' and 60s' (Proffit & Fields, 1993). However, laboratory studies indicated that individuals who placed the tongue tip forward during swallowing usually did not have more tongue force against the teeth than those who kept their tongue back. In fact, tongue pressure may be lower (Proffit, 1972). It was therefore neither necessary nor desirable to try to teach the patient to swallow differently before orthodontic treatment is begun (Proffit & Fields, 1993).

In fact only a small percentage of orthodontic problems were overcome by the appliance and in a limited number of cases (0.6%) an anterior open bite may not be permanently reduced, whatever the method of treatment, as well as in cases with poor facial pattern associated with forward tongue posture (Tulley, 1969).

Much importance has been attached to mouth breathing as an aetiological factor in mal-development of the face and occlusion. However, pattern of respiration in humans at any given time is difficult to know. Some observers tend to equate lip separation at rest with mouth breathing. In children with chronic nasal obstruction, it was found that there were only minor changes in the occlusion, which could be reversed once the obstruction was relieved (Linder-Aronsons, 1975). Impaired nasal respiration may contribute to the development of the long face syndrome with its associated malocclusion but is not the sole or even the major cause (Fields et al., 1991).

### **6.3. Cost Effectiveness.**

There was no literature that had addressed the cost implications of pre-fabricated myofunctional appliances.

Hence, data on the cost of pre-fabricated myofunctional appliances had to be extrapolated by comparing the laboratory fee charged by local private dental laboratories for the construction of some of the commonly used functional appliances in comparison to the



cost of pre-fabricated myofunctional appliance. Table 1 illustrates the laboratory fee charged by private dental laboratories in Malaysia for the construction of some of the commonly used functional appliances, compared to the cost of pre-fabricated myofunctional appliance.

**Table 1: Cost Comparison between Pre-Fabricated Myofunctional Appliance and Functional Appliance**

Pre-fabricated myofunctional appliance	RM90.00		
<b>Functional Appliance</b>	<b>Lab. A (RM)</b>	<b>Lab. B (RM)</b>	<b>Lab. C (RM)</b>
1. Bionator	250.00	240.00 – 280.00	200.00
2. Activator	200.00	240.00 – 280.00	200.00
3. Twin Block	180.00 – 215.00	280.00	150.00 – 200.00

The pre-fabricated myofunctional appliance costs less compared to the laboratory fee charged for custom-made functional appliances in the private sector.

However, in government clinic, the cost of construction of functional appliances is very much lower than the private clinics. According to the Public Health Evaluation Report (1995 to 1999) on cost of orthodontic treatment in the government clinics, the total material cost for retainer construction is RM7.06. Retainer is a type of removable appliance very similar in terms of construction to functional appliance. Therefore, the pre-fabricated myofunctional appliance would cost more than the conventional functional appliance in the government clinics.

In conclusion, the cost of pre-fabricated myofunctional appliance in comparison to custom made functional appliance cost less in the private sector compared to the government clinics, because of the high laboratory charges imposed on custom made functional appliances.

#### **6.4. Legal implications.**

There was no evidence that implicated the use of this appliance with lawsuits either due to relapse, adverse health effects or other unfavourable treatment outcome.

## **7. STUDY OF LOCAL SITUATION**

A local was carried out to determine the local practice with respect to the use of Trainer for Kids (T4K) amongst dental practitioners in the public and private sectors, focusing on the extent of its usage and the types of patients for which the treatment was advocated. However, this study could not reach any conclusion due to the small sample size as well as limitations in the methodology (see Appendix 3 for details of the study).

## **8. CONCLUSIONS**

There is insufficient evidence on the clinical safety and effectiveness of this appliance. With respect to costs, it is a cheaper option for the private practitioners, but not for the public service.

## **9. RECOMMENDATIONS**

There is insufficient evidence at this time to recommend for or against the Trainer for Kids (T4K). There is a need for local clinical research to be done on the efficacy and effectiveness of this prefabricated myofunctional appliance for early orthodontic treatment.

## **10. REFERENCES**

1. Chadwich, SM., Banks, P., Wright, JL. Use of myofunctional appliances in the UK: A survey of British orthodontists. *Dent Update*. 1998 Sept; 25(7): 302-8.
2. Chen JY, Will LA, Niederman R. *Analysis of efficacy of functional appliances on mandibular growth*. *Am J Orthod Dentofacial Orthop* 2002 Nov; 122(5): 470 – 6.
3. Dibiasi, AT., Samuels, RH., Ozler, E., Akcam, MO. and Turkhahraman, H *Hazard of orthodontics appliances and the oropharynx*. *Journal of Orthodontics* 2000, Vol 27: 295 – 301.
4. Fields HW, Warren DW, Phillips C, Black BK. *Relationship between vertical dentofacial morphology and respiration in Adolescents* *Am J Orthod Dentofac Orthop* 99, 1991: 147-154.
5. Hasler R, Ingervall B. The effect of a maxillary lip bumper on tooth positions. *Eur J Orthod* 2000 Feb; 22(1):25-32).
6. Houston WJB, Stephen CD and Tulley WJ. *A Textbook of Orthodontics, 2<sup>nd</sup> Edition, 1992: 1 – 12.*

7. Kassim, H. *Case report on treatment with T4K appliance*. HTA KKM committee meeting, 1/2003.
8. Linder Aronsons. *Effects of adenoidectomy on the dentition and facial skeleton over a 5 year period*. In Cook JT, editor: *Transaction of the 3<sup>rd</sup> International Orthodontic Congress*, St Louis, 1975, Mosby-Year Book.
9. Moshe, D., McInnis, D. and Lindauer, J. *The effects of lip bumper therapy in the mixed dentition*. *Am J Orthod Dentofac Orthop* 1997 Jan; 111: 52 – 58.
10. Poukkula, A., Ruotsalainen, E.M., Jokinen, K., Pulva, A. and Nuorvita, J. *Long term presence of a denture fragment in the airway*. *Journal of Laryngology and Otolology* 1988; 102: 190 – 193.
11. Proffit WR, Fields HW. *Contemporary Orthodontics*, 2<sup>nd</sup> edition, 1993. The development of orthodontic problems. 128-133.
12. Proffit WR. *Lingual pressure patterns in the transition from tongue thrust to adult swallowing*. *Arch Oral Biol* 1972. 17: 555 – 563.
13. Quadrelli, C., Gheorgiu, M., Margchetti, C., Ghiglione V. *Early myofunctional approach to skeletal Class II*. *Mondo Ortodontica* 2/2002, 109-122.
14. Schendel, KU. Erdinger, L., Komposch, G. and Sontag, HG. *Neon-coloured plastics for orthodontic appliance. Biocompatibility studies*. *Fortschr Kieferorthop* 1995 Jan; 56 (1) 41-8.
15. Skomro, P. *Orthodontic appliance made from silicone elastomer, evaluated clinically and from patient opinions after treatment for malocclusion*. *Ann Acad Med Stetin* 2000; 46: 293 – 304.
16. Tulloch JF, Phillips C, Koch G, Proffit WR. *The effect of early intervention on skeletal pattern in Class II malocclusion: A randomized clinical trial*. *Am J Orthod Dentofac Orthop* 1997; 111:391-400
17. Tulloch JF, Phillips, C, Proffit WR. *Benefit of early Class II treatment: Progress report of a 2- phase randomised clinical trial*. *Am J Orthod Dentofac Orthop* 1998; 113(1): 62 – 72.
18. Tulley WJ. *A critical appraisal of tongue thrusting*. *Am J Orthod Dentofac Orthop* 1969 Jun: 94 - 104.
19. Vijayaratne D and Harkness M, Herbison P. *Functional appliance treatment assessed using the PAR index*. *Aust Orthod J*. 2000 Nov; 16. 118-26.