The Efficacy of the Prefabricated T4F™ Myofunctional Appliance in Comparison to Twin Block Appliance for Class II Division 1 Malocclusion Treatment: A Randomized Clinical Trial

by

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LIST OF ABBREVIATIONS

ai	Apex inferior
ANB	A point-Nasion-B point
ANS	Anterior nasal spine
Ar	Articulare
Ar_A	Articulare- A point
Ar_B	Articulare-B point
Ar_Pg	Articulare-Pogonion
as	Apex superior
BSI	British Standards Institution
Co	Condylion
Div.1	Division 1
Gn	Gnathion
Go	Gonion
HUSM	Hospital Universiti Sains Malaysia
ICC	Intra-class Correlation Coefficient test
ii	Incision inferius
IIA	Inter-incisal angle
is	Incision superius
is_ii	Incision superius - incision inferius
L@TAFH	Facial proportion (LAFH / TAFH)
LAFH	Lower anterior facial height
Li	Lower Incisor
Li_Man	Lower incisor mandibular plane angle

Man	Mandible
Me	Menton
MMPA	Maxillary mandibular plane angle
Mx	Maxilla
N	Nasion
OB	Overbite
OJ	Overjet
PNS	Posterior nasal spine
Pog	Pogonion
S	Sella
SN	Sella-Nasion
SN_Man	Sella-Nasion Mandibular plane angle
SNA	Sella-Nasion-A point
SNB	Sella-Nasion-B point
Sv	Sella vertical
Sv_A	Sella vertical – A point
Sv_ii	Sella vertical - incision inferius
Sv_is	Sella vertical - incision superius
Sv_Pog	Selaa vertical – Pogonion
T4F™	Prefabricated re-mouldable customizable functional appliance
TAFH	Total anterior facial height
TB	Twin Block
Ui	Upper incisor
Ui_Mx	Upper incisor maxillary plane angle

Perbandingan Antara Keberkesanan Alat Pasang Siap T4F™ Miofungsi Dengan Alat Blok Berkembar Untuk Rawatan Maloklusi Kelas II Bahagian 1: Satu Kajian Percubaan Klinikal Secara Rambang

Abstrak

Alat fungsian telah digunakan secara meluas untuk merawat maloklusi Kelas II Bahagian 1. Tiada kajian terdahulu diterbitkan mengenai kesan-kesan penggunaan alat fungsian jenis pasang siap dan boleh-dibentuk-semula (T4F™) untuk maloklusi Kelas II Bahagian 1) ke atas subjek yang mempunyai bentuk kerangka Kelas II. Tujuan kajian ini adalah untuk membandingkan perubahan dalam struktur kerangka dan dentoalveolar pada pesakit Melayu (praremaja) yang dirawat dengan menggunakan peralatan miofungsi boleh-dibentuk-semula prafabrikasi (T4F™), dan peralatan Blok Berkembar (TB). Satu percubaan klinikal secara rambang telah dilakukan ke atas 43 subjek (22 lelaki + 21 perempuan) Kedua-dua kumpulan ini dikenali sebagai kumpulan kawalan aktif (TB) dan kumpulan ujikaji (T4F™). Pada akhir tempoh kajian iaitu selama enam bulan, beberapa subjek telah menarik diri, yang menyebabkan kumpulan TB terdiri daripada 17 subjek (8 lelaki & 9 perempuan), sementara kumpulan T4F™ hanya tinggal 16 subjek (9 lelaki & 7 perempuan). Min umur bagi kumpulan T4F™ adalah 13 tahun (0.7), manakala bagi kumpulan TB pula adalah 13.2 tahun (0.8). Radiograf sefalometri lateral sebelum dan selepas rawatan dilakukan ke atas setiap subjek dan overjet dinilai secara klinikal. Dua puluh satu ukuran sudut dan linear dipilih dan diukur secara berasingan, sebelum dan selepas radiograf sefalometri lateral. Perubahan yang berlaku sepanjang tempoh kajian dikira dengan membandingkan ukuran sebelum dan selepas rawatan pada setiap kumpulan. Kedua-dua kumpulan tersebut dibandingkan dari segi perubahan yang berlaku sepanjang tempoh kajian. Ujian Pekali Korelasi intra kelas (ICC) digunakan untuk menguji kesamaan di antara interpenguji dan intrapenguji daripada ukuran sefalometri. Hasil ICC asdalah dalam lingkungan 0.91 ke 0.99, yang dianggap suatu tahap ralat yang boleh diterima. Ujian t bebas digunakan untuk membandingkan perubahan di antara kedua-dua kumpulan tersebut. Perbandingan di anatara kedua-dua kumpulan dari segi perubahan semasa rawatan menunjukkan perbezaan yang signifikan di dalam overjet, kedudukan mandibular anterior-posterior dan kerangka, serta ketaksamaan dentoalveolar yang lebih baik

dalam kumpulan TB. Pengurangan overjet dalam kumpulan TB adalah dua kali lebih banyak dengan perbezaan min sebanyak 2.1mm ($p<0.01$). Sudut titik Sella-Nasion-B semakin meningkat di dalam kumpulan TB dengan perbezaan min sebanyak 1.25° ($p<0.05$). Manakala sudut titik A-Nasion-B berkurangan sebanyak 0.8° (0.9) bagi kumpulan T4F^{TM} dan 1.6° (1.1) bagi kumpulan TB dengan perbezaan min sebanyak 0.8° ($p<0.05$). Perbezaan di antara Pogomon dan garis rujukan menegak (Sv_Pog) adalah lebih baik di dalam kumpulan TB dengan perbezaan min sebanyak 1.83mm ($p<0.05$). Perbezaan di antara pinggir insisor bawah dan garis rujukan menegak (Sv_ii) adalah lebih baik di dalam kumpulan TB dengan perbezaan min sebanyak 2.55mm ($p<0.01$). Perbezaan di antara bucu insisor atas dan bucu insisor bawah (is ii) adalah berkurangan dua kali di dalam kumpulan TB dibandingkan dengan kumpulan T4F^{TM}, dengan perbezaan min sebanyak 1.83mm ($p<0.05$). Kedua-dua kumpulan tersebut menunjukkan perubahan yang baik dari segi pembetulan kerangka sagital dan ketaksamaan dentoalveolar semasa tempoh rawatan. Jumlah perbezaan adalah signifikan di antara kedua-dua kumpulan dengan lebih pembetulan dari segi skeletal sagital dan ketaksamaan dentoalveolar diperhatikan dalam kumpulan TB. Pembetulan skeletal secara keseluruhannya adalah disebabkan oleh perubahan mandibel tanpa perubahan yang signifikan dari segi kedudukan sagital maksila di dalam kedua-dua kumpulan. Sumbangan bidang pergigian dalam kedua-dua kumpulan sehinggalah ke akhir pembetulan overjet telah menghasilkan kombinasi antara retroklinasi insisor atas dan retroklinasi insisor bawah. Min proklinasi insisor bawah yang menyumbang kepada pembetulan overjet adalah lebih tinggi daripada min retroklinasi insisor atas di dalam kumpulan TB. Sementara itu, di dalam kumpulan T4F^{TM}, perubahan min insisor atas sama dengan insisor bawah. Sebagai kesimpulan, peralatan T4F^{TM} adalah suatu alat yang efektif untuk pengurusan molaklusi BSI Bahagian 1 Kelas II ke atas pola kerangka Kelas II.

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Abstract

Functional appliances are widely used to treat Class II Division 1 malocclusion. No previous studies were published about the effects of prefabricated re-mouldable functional appliance (T4F™) for Class II Division 1 malocclusion on Class II skeletal pattern subjects. The aim of this study was to compare the changes in the skeletal and dentoalveolar structures in growing Malay patients (pre-adolescent) with Class II Division 1 malocclusion treated by Prefabricated Re-mouldable Myofunctional appliance T4F™ and Twin Block appliance (TB). A randomized clinical trial was carried out with a sample of 43 subjects (22 males + 21 females) randomly assigned to active control group (Twin Block group) and experimental group (T4F™ appliance group). At the end of six months study period and due to the drop out, TB group consisted of 17 subjects (8 males + 9 females), while T4F™ group consisted of 16 subjects (9 males + 7 females). Mean age was 13 years (0.7) in T4F™ group, and 13.2 years (0.8) in Twin Block group. Pre- and post-treatment lateral cephalometric radiographs were taken for each subject and the overjet was clinically measured pre- and post- the six months treatment period. Twenty one angular and linear measurements were chosen and measured separately on the pre- and post-treatment lateral cephalometric radiographs. The changes during the study period were calculated by comparing pre- and post-treatment measurements in each group. The two groups were then compared in terms of the changes that occurred during the study period. Intra-class Correlation Coefficient test was used to test inter- and intra-examiner agreement of cephalometric measurements. (ICC) results ranged from 0.91 to 0.99 which were considered acceptable level of errors. Independent *t* test was used to compare the changes between the two groups. The between groups comparison in terms of the changes during treatment period showed significant difference in overjet, anterior posterior mandibular position and skeletal and dentoalveolar discrepancies which were changed more favourably in TB group. Overjet reduction was found to be two times more in TB group with a mean difference of 2.1mm (p <0.01). Sella-Nasion-B point angle was more increased in TB group with a mean difference of 1.25 ° (p <0.05). A point–Nasion-B point angle was

decreased by 0.8° (0.9) and 1.6° (1.1) in T4F^{TM} and TB groups respectively with a mean difference of 0.8 ° (p <0.05). The distance between Pogonion and the vertical reference line (Sv_Pog) was more favourably changed in TB group with a mean difference of 1.83mm (p <0.05). The distance between the lower incisal edge and the vertical reference line (Sv_ii) was also more favourably increased in TB group with a mean difference of 2.55mm (p <0.01). The distance between the upper and the lower incisal edges (is_ii) was decreased in TB group as two times as in T4F^{TM} group with a mean difference of 1.8mm (p <0.05). The correction of the sagittal skeletal and dentoalveolar discrepancies was favourable for both groups. The amount of changes differed significantly between the two groups with more favourable correction in terms of the sagittal skeletal and dentoalveolar discrepancy was observed in TB group. The skeletal correction was due to the mandibular changes with no significant change in terms of sagittal position of maxilla in both groups. The dental contribution in both groups to the final overjet correction was a result of combination of upper incisor retroclination and lower incisor proclination. The mean lower incisor proclination that contributed to the overjet correction was higher than the mean upper incisor retroclination in Twin Block group; while in T4F^{TM} group, the mean upper incisor inclination change was similar with the mean lower incisor inclination change. In conclusion, T4F^{TM} appliance is an effective appliance for the management of BSI Class II Division 1 malocclusion on Class II skeletal pattern.

Chapter One
Introduction

1.0 Introduction

Over the years, numerous studies have investigated the possibility of growth modification. Clinical experience and research supported our knowledge and improved our understanding on the influence of intra- and extra-oral appliances used for that, particularly in skeletal Class II patients.

Class II malocclusions are of interest to the practicing orthodontists because they constitute a significant percentage of their cases and Class II Div.1 malocclusion is among the most common (Tulloch *et al.*, 1990). In individuals with normal occlusion and skeletal relationship, the amount of maxillary and mandibular growth is synchronized resulting in a well-balanced and aesthetically pleasing profile. In individuals with Class II malocclusions, there is an anteroposterior discrepancy between the maxillary and mandibular dentitions, which may or may not be accompanied with a skeletal discrepancy. In growing individuals, the success of treatment is dependent, to a great extent, on the ability of the clinician to influence the relative growth changes in the maxilla and mandible (Bishara, 2006).

The incidence of Class II Division 1 malocclusion has been reported to be high among Western population (Jones and Oliver, 2000). Angle Class II incidence was found to be 23% among Swedish adults (Salonen *et al.*, 1992), while it was higher among adult Dutch population with about 28% (Burgersdijk *et al.*, 1991). The

incidence of Class II Division 1 incisor relationship in Caucasian population in general is 15-20 % (Mitchell *et al.*, 2001).

Approximately 15 % of American children and youths have Class II Angle's malocclusion. The malocclusion characteristics vary between countries and are due to the differences in racial and ethnic composition. It is clear that Class II is most prevalent in Northern European descent. For instance, in Denmark 25% of children are reported to have Class II malocclusion (Proffit and Fields, 2000).

A substantial number of approaches and appliances had been developed for Class II malocclusion treatment (Kim *et al.*, 1999). Class II Div.1 malocclusion can be treated with removable appliances, functional appliances, fixed appliances and orthognathic surgery. Functional appliances have been used for a long time in the treatment of malocclusion, particularly in Class II Division 1 malocclusions. It was stated that although some clinicians reject the clinical efficacy of these appliances, proof of their growth modifying effect remains elusive for some authors (Toth and McNamara, 1999).

These appliances that were designed aiming to influence the growth can be divided into removable and fixed functional appliances. Many types of removable functional appliances have been developed to treat Class II malocclusion such as Frankel appliance which is also known as a functional regulator (McNamara *et al.*, 1985; McNamara *et al.*, 1990; Toth and McNamara, 1999), Bionator (Mamandras and Allen, 1990; Illing *et al.*, 1998; Jena *et al.*, 2006), Activator (Harvold, 1974; Wieslander and Lagerstrom, 1979; Vargervik and Harvold, 1985; Baltromejus *et al.*,

2002), Twin Block appliance (Toth and McNamara, 1999; O'Brien *et al.*, 2003b), and prefabricated myofunctional appliances (www.myoresearch.com). A fixed functional appliance known as Herbst appliance was also used effectively for Class II Division 1 malocclusion treatment (Pancherz, 1982; Pancherz, 1985; Pancherz *et al.*, 1997; Pancherz *et al.*, 1998; Pancherz *et al.*, 1999; Toth and McNamara, 1999; Baltromejus *et al.*, 2002).

The prefabricated myofunctional appliances are a series of prefabricated functional appliances produced by myoresearch company, Queensland, Australia which are also known as "Trainer^{TM}". These include T4K, T4CII, and T4F^{TM} appliances. The T4K appliance was designed for young children (Usumez *et al.*, 2004; www.myoresearch.com, 2007), while the T4CII is used in corporate with a fixed orthodontic appliance (www.myoresearch.com, 2007).

The T4F^{TM} appliance is also a prefabricated appliance but re-mouldable when immersed in very hot water so it can be customized to accommodate the patient's dentition in the mouth and increase the retention. The prefabricated re-mouldable customizable functional appliance "T4F^{TM}" was suggested to be effective for Class II Division 1 malocclusion treatment (www.myoresearch.com, 2007).

All other previously known types such as Activator, Bionator and Frankel appliances are not prefabricated but it is individually customized for each patient depending on his individual dental case. The idea of prefabricated functional appliance was recently introduced to the orthodontic field and it becomes more practical with the new customizable functional appliance T4F^{TM}. This new

functional appliance has the advantage of the immediate issuing and the direct fitting of the appliance in the patient's mouth and it is also a better choice in terms of the cost for the private practitioners.

Twin Block appliance has been widely used for functional orthodontic treatment in most orthodontic private and public clinics in many countries. The Trainer^{TM} with its different types including T4F^{TM} was recently introduced to the field and became quickly in the usage in Malaysia and other countries (Burhanuddin *et al.*, 2005).

Even though the philosophy of prefabricated myofunctional appliance T4F^{TM} appliance is similar to that of known functional appliances in term of forwarding the lower jaw, the need for scientific clinical evidence about its effects on skeletal and dentoalveolar structures in Class II Div. 1 treatment is essential. Moreover, the expert orthodontic committee of the Ministry of Health of Malaysia has recommended to conduct a clinical research in Malaysian population (Burhanuddin *et al.*, 2005).

Therefore this study will evaluate the effectiveness of the prefabricated myofunctional appliance T4F^{TM} in comparison with Twin Block appliance for the treatment of Class II Div.1 malocclusion as defined by British Standards Institution (BSI) on Class II skeletal pattern.

1.1 Statement of the Problem

No study has been published about functional orthodontic treatment in Class II Div. 1 Malay growing patients, so the effects of functional orthodontic treatment on Class II patients need to be investigated.

One of the functional appliances recently used in Malaysia is the prefabricated T4F^{TM} myofunctional appliance, but there is no study about their effectiveness in Class II Div. 1 patients. There is insufficient evidence on the clinical effectiveness of this appliance particularly on Malay, consequently there is a need for local clinical research to be done on the efficacy and effectiveness of this prefabricated myofunctional appliance for orthodontic treatment.

Twin Block appliance is the most widely used functional appliance in public and private orthodontic clinics in Malaysia. Twin Block appliance was also the preferred functional appliance in the UK whereby more than 75% of British Orthodontic Society members claimed that it is their first choice (Chadwick *et al.*, 1998). The Twin Block appliance is commonly used to correct Class II dentoskeletal disharmony (Schaefer *et al.*, 2004). It has been found to be clinically useful (Mills and McCulloch, 1998), and its effectiveness was comparable to Herbst appliance which is known as the most effective functional appliance (Trenouth, 2000a). Due to its popularity and proved effectiveness, Twin Block appliance was chosen as an active control.

1.2 Justification of the Study

T4F™ appliance was designed to be worn at night time beside few hours only during day time while the Twin Block appliance is worn for full time. T4F™ appliance would be an appliance of choice for the patients who are not willing to wear a full time functional appliance; therefore it should be investigated whether it is as effective as Twin Block appliance.

A randomized clinical trial is required to provide an evidence about the efficacy of prefabricated myofunctional appliances T4F™. It is valuable though to investigate the effects of treatment with the prefabricated myofunctional appliances T4F™ as it has recently been gaining popularity and claimed to show some good clinical results in the functional phase of the treatment for Class II Div.1 patients.

This study will emphasize on the skeletal and dentoalveolar changes following functional appliance therapy. Investigating the changes that occur as the immediate effects of treatment will increase understanding of the mode of action of this appliance in the treatment of Class II Div.1 patients.

1.3 Objectives

1.3.1 General Objective

To evaluate the efficacy of treatment with prefabricated myofunctional appliance T4F™ in comparison to Twin Block appliance for growing Malay patients with Class II Division 1 malocclusion.

1.3.2 Specific Objectives

To compare the linear and angular changes in the skeletal and dentoalveolar structures between two groups of Class II Div.1 Malay patients treated with Prefabricated T4F^{TM} Myofunctional appliance and Twin Block appliance.

1.4 Research Hypothesis

1.4.1 Null Hypothesis

There is no difference in the linear and angular changes in the skeletal and dentoalveolar structures between prefabricated T4F^{TM} myofunctional and Twin Block appliance.