ORIGINAL ARTICLE

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

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ABSTRACT

Introduction: The aim of the study was to compare the changes in the skeletal and dentoalveolar structures in Malay patients with Class II Division 1 malocclusion treated by prefabricated re-mouldable customizable functional appliance (T4F™) and Twin Block (TB) appliance. **Methods:** A randomised clinical trial was carried out with samples randomly assigned to active (TB appliance) and experimental (T4F™ appliance) groups. Pre- and post-treatment lateral cephalometric radiographs were taken for each subject and the overjet was clinically measured at the same intervals. 20 angular and linear measurements were chosen and measured separately. **Results:** Independent t test was used to compare the changes between the two groups. A significant difference between the groups was seen with overjet at 2.14 mm ($p < 0.01$), Sv_Pog distance at 1.83mm ($p < 0.05$), Sv_ii distance at 2.55 mm ($p < 0.001$), horizontal distance from the upper to the lower incisor tip at 1.81 mm which was statistically significant ($p < 0.05$). The other variables SNB and ANB angles too showed a significant difference. However, all the favourable changes were noted in the TB group. **Conclusion:** T4F™ appliance could be an effective appliance for the management of British Standard Institute's Class II Division 1 malocclusion on Class II skeletal pattern. However, the TB group differed significantly and had a more favourable correction in terms of the sagittal skeletal and dentoalveolar discrepancy.

Keywords: Myofunctional appliance, T4F™, Twin Block appliance, Class II Division 1 malocclusion

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INTRODUCTION

The functional orthodontic appliances have been used for a long time for skeletal Class II Division 1 management (1). Many types have been developed over the years such as Frankel appliance, Bionator, Activator, TB appliance and prefabricated myofunctional appliances (www.myoresearch.com,2007). A fixed functional appliance such as Herbst was also used effectively for Class II Division 1 malocclusion treatment (2). The need to have a customizable and prefabricated appliance supported by myoresearch led to the idea of prefabricated functional appliances T4F™. The prefabricated myofunctional appliances are produced by myoresearch company, Queensland, Australia (3). The T4F™ are customizable prefabricated functional appliances claimed to have orthopaedic effects of a functional appliance combined with a tooth guidance system and myofunctional training and used in comprehensive early treatment. The T4F™ appliance when immersed in very hot water can be re-moulded and customized to accommodate the patient's dentition and aid retention. This appliance comes with the advantage of immediate and direct fitting of the appliance in the patient's mouth. The appliance is easy to use and maintain. The prefabricated appliances have shown to be an effective option for Class II Division 1 management, but the literature provides no evidence except for T4K type (3).

TB appliance is the most popular functional appliance for the correction of skeletal Class II malocclusions (4, 5). One of the unique features of this appliance is that it is constructed in two parts, as separate upper and lower appliances. Forward mandibular posturing is achieved by incorporating buccal blocks with interlocking inclined plates, with the lower blocks engaging in front of the upper blocks (6). Although the skeletal and dentoalveolar efficacy of TB has been well documented (7, 8), TB has potential disadvantages such as the proclination of the lower incisors, development of posterior open bites, and poor patient cooperation (9). To limit these unwarranted changes, the Trainer™ (T4F™) was utilised.

The Trainer System was developed to incorporate the philosophy of myofunctional therapy and tooth alignment into a single size and easy to use appliance. All appliances are designed to actively retrain the mode of the tongue, the perioral muscles of the mouth, correct breathing habits, and align the anterior dentition (10). Prefabricated myofunctional appliances (The Trainer System™, myoresearch company, Queensland, Australia) in general and T4F™ are claimed to be type of the functional appliances that concentrate more on the function of muscles (lips and tongue) while at the same time acting in the same way as TB by forwarding the lower jaw (10).

The T4F™ was claimed to act as an Activator or Bionator since it is retained in the upper arch while re-positioning the lower arch into Class I relationship. To our knowledge, no study has been published about the usage of T4F™ appliance for the management of Class II Division 1 among growing patients. Therefore, the objective of this study was to compare the changes in the skeletal and dentoalveolar structures between the two groups patients treated with T4F™ appliance (experimental group) against TB appliance as an active control group for the treatment of Class II Division 1 malocclusion.

MATERIALS AND METHODS

The study was approved by the human ethical committee [Ref. No. USMKK/PPP/JEPeM[195.3(8) dated 4th October 2007] of Universiti Sains Malaysia. The subjects were patients seeking orthodontic treatment at the Dental Clinic of Universiti Sains Malaysia, Kubang Kerian, Malaysia. Seventeen subjects for each group were required for evaluating the effectiveness of T4F™ appliance (experimental group) against TB appliance as an active control group for the treatment of Class II Division 1 malocclusion which formed objective of this study. Purposive sampling was used to collect a sample of 43 patients who satisfied the inclusion and exclusion criteria and agreed to participate in the study. Participants were Malay children aged 11 - 14 years old presenting with Class II Division 1 malocclusion on a Class II skeletal base. The minimum overjet was 7 mm. Subjects were excluded if they had received any kind of orthodontic appliance therapy or who showed an anterior open bite of more than 2 mm. The presence of craniofacial anomalies or history of facial trauma was ignored as well.

The sample for the study was calculated using PS software. The detectable difference of the mean change of ANB angle was 2° with the power of the study set at 80% with an alpha of 0.05. The study involved males (22 subjects) and females (21 subjects).The prospective parallel design study involved a simple randomization using an online randomization tool (www.randomization.com). The subjects were randomly allocated to either experimental (T4F™) or active control (TB) group. The primary outcome was the assessment of overjet. In the tested group, each subject received a T4F™ appliance which was moulded to the patient's dentition using the direct method in the mouth as recommended by the manufacturer. The patients were instructed to wear the appliance for 14 hours per day. It has also been claimed to provide both orthopaedic and myofunctional effects built-in through delivering simultaneous Class II correction and retraining of the tongue, swallowing pattern and mode of breathing (3).

In the active control group, a modified TB appliance was used. The appliance construction included both maxillary and mandibular removable appliances. Adams clasps constructed by 0.7mm stainless steel were retained on the first permanent molars and first permanent premolar or first deciduous molar when the premolar had not yet erupted. Ball clasps of 0.9 mm were placed in the inter-proximal areas of mandibular incisors. A 70 degrees inclined plane was incorporated into the appliance design. No expansion was carried out during the six months observation period. The bite registration was recorded with an approximate value of 8 mm protrusion and 6 mm separation in the buccal segments. The patients were instructed to wear the appliance continuously for 24 hours per day even during eating.

The patients were reviewed monthly for a period of six months following which post-treatment lateral radiographs were taken. The observation period of six months was reasonably acceptable to evaluate the level of success and the outcome of a functional appliance. Figure 1 shows the CONSORT flow of each stage of the study.

The post-treatment lateral radiographs were taken on the basis of intention-to-treat as it is the current recommended practice in orthodontic clinical trials. This approach is called a pragmatic approach which is an approach that researchers and statisticians always emphasize on. Clinical measurements were recorded, and the lateral pre- and post-treatment cephalometric radiographs were traced and analysed by a single examiner. The landmarks and variables are illustrated in Figures 2 and 3. All cephalometric linear measurements were corrected to the magnification factor of the midsagittal plane by multiplying them by 1.125.

Fourteen radiographs (> 20% of the total lateral cephalometric films) were randomly chosen from both groups. They were re-traced using a standardized protocol for inter and intraexaminer reliability. The radiographs were re-coded so that the grouping and

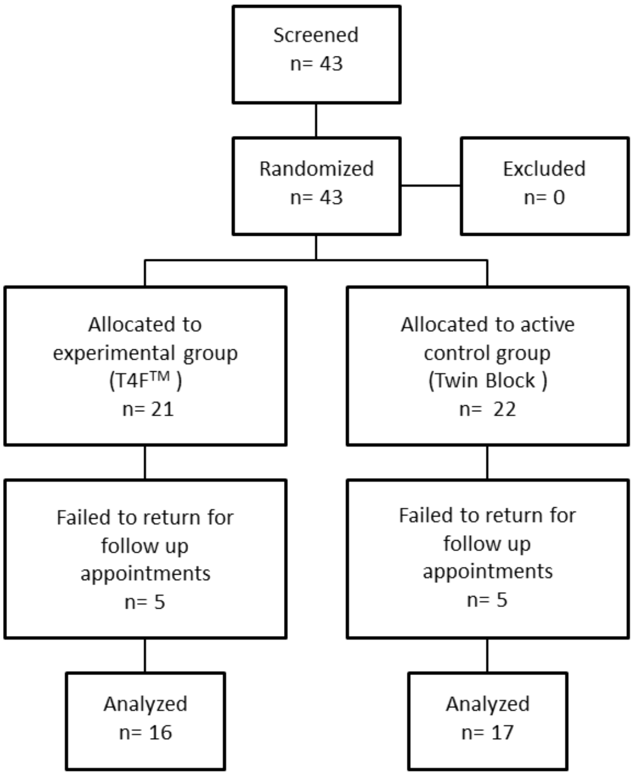

Figure 1: CONSORT flow diagram through each stage of the study

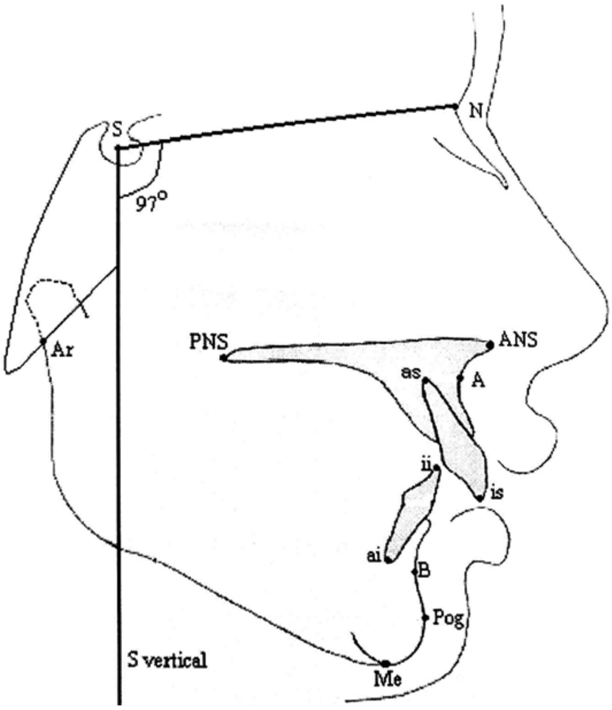

Figure 2: Landmarks utilised in the study

any identity were obscured to the investigators. The radiographs were traced by the examiner and by a second investigator who is an experienced orthodontist in order to determine the inter-observer reliability. The radiographs were also re-traced and measured twice by the first investigator [author 1] at the interval of 2 weeks

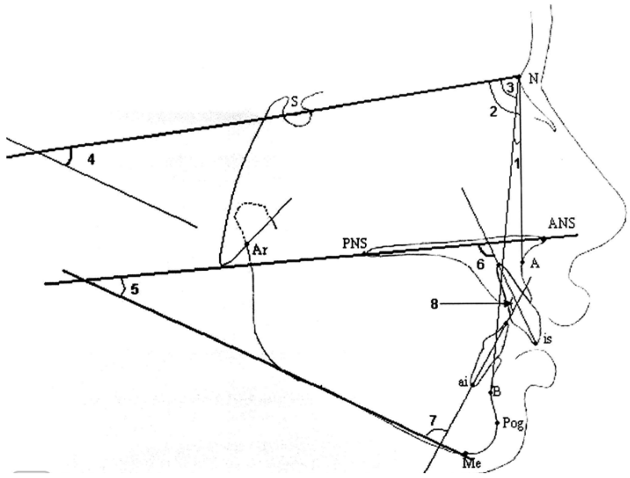

Figure 3: Angular measurements utilised in the study

for intra-observer reliability. Intra-class Correlation Coefficient test (ICC) was used to check the reliability of the two operators and also between the repeated measurements.

RESULTS

A randomised clinical trial was carried out with a sample of 43 subjects (22 males and 21 females) randomly assigned to active control (TB appliance) and experimental (T4F™ appliance) groups. The T4F™ group consisted of 21 patients (10 males + 11 females) while the TB group consisted of 22 patients (12 males + 10 females). Following six months of observation, and subject dropouts (Table I), the total number of

Table 1: Descriptive baseline data of patients who were lost to follow up

Variables	T4F (n=5) Mean (SD)	T.Block (n=5) Mean (SD)	Mean Difference
Age (year)	13.2 (0.62)	12.5 (0.98)	-0.22
Clinical			
OJ (mm)	9.60 (2.21)	8.80 (1.92)	0.80
Angular skeletal			
SNA°	84.10 (4.29)	83.70 (4.05)	0.40
SNB°	79.30 (3.66)	78.00 (3.55)	1.30
ANB°	4.80 (1.03)	5.70 (1.48)	-0.90
Sn_Man°	26.92 (3.54)	32.60 (3.08)	-5.70
MMPA°	21.50 (3.08)	26.40 (3.04)	-4.90
Angular dental			
Ui_Mx°	127.20 (7.19)	123.50 (8.32)	3.07
Li_Man°	105.10 (8.32)	101.60 (5.51)	3.50
IIA°	108.90 (10.01)	108.10 (10.54)	0.80
Linear skeletal			
Ar_A (mm)	78.99 (2.04)	75.75 (4.22)	3.24
Ar_B (mm)	87.21 (2.03)	85.38 (6.13)	1.82
Ar_Pog (mm)	96.16 (2.56)	91.97 (7.77)	4.18
Sv_A (mm)	62.12 (3.40)	59.86 (5.63)	2.25
Sv_Pog (mm)	58.01 (5.50)	52.99 (8.48)	5.01
TAFH (mm)	103.56 (4.84)	104.91 (6.78)	-1.35
LAFH (mm)	56.40 (3.38)	57.78 (5.55)	-1.37
L@TAFH (%)	0.54 (0.02)	0.55 (0.03)	-0.01
Linear dental			
Sv_is (mm)	70.01 (5.22)	67.39 (6.48)	2.62
Sv_ii (mm)	61.20 (3.39)	60.39 (5.59)	0.81
is_ii (mm)	8.81 (2.81)	7.00 (2.60)	1.81
OB (mm)	3.24 (1.60)	2.47 (2.40)	0.77

patients from whom the data was available and included for analysis were reduced to 16 patients (9 male + 7 female) with a mean age of 12.98 (SD 0.70) years in the experimental T4F™ group, and 17 patients (8 male + 9 female) with a mean age of 13.20 (SD 0.81) years in the active control TB group.

Following the completion of the 6-month period of using both the experimental T4F™ and the active control TB appliances, no unintended effects were discernible. The inter-examiner reliability ranged from 0.92 to 0.99. The results of the ICC test for intra-examiner reliability were close to 1 and ranged from 0.92 to 0.98.

Pre- and post-treatment comparisons for T4F™ group

There was a significant reduction in overjet by 2.12 mm during the observation period ($p < 0.01$). Table II showed that there was a significant correction of the skeletal ANB angle ($p < 0.01$) and dentoalveolar discrepancy ($p < 0.05$). There were four linear horizontal skeletal variables which were significantly increased in post-treatment group i.e. Ar_A, Ar_B, Ar_Pog and Sv_Pog. However, only one vertical linear skeletal measurement, TAFH was significantly increased. For linear dental, all measurements were significantly changed except Sv_is and OB. There was an increment of 1.74 mm for Sv_ii and a reduction of 2.06 mm for is_ii.

Pre- and Post-treatment Comparisons for TB Group

The pre and post treatment comparisons for the TB group can be found in Table III. The overjet showed a significant reduction by an average of 4.26 mm during the observation period ($p < 0.001$). A significant change was seen in mandibular sagittal position where SNB angle increased by 1.97 degrees ($p < 0.01$) which contributed to the significant skeletal correction of 1.65 degrees in the ANB angle ($p < 0.001$). The lower incisor to the mandibular plane angle (Li_Man) was significantly increased by 2.73 degrees ($p < 0.05$). Significant differences were found in Ar to A point distance which increased by 0.69 mm ($p < 0.05$) and both Ar to B point distance (Ar_B) and Ar to Pog point distance (Ar_Pog), (p

Table II: Pre- and Post-treatment measurements of prefabricated mouldable functional appliance T4F™ group

Variables	Pre Mean (SD)	Post Mean (SD)	Mean Difference (95% CI)	*t* statistic (df)	*P* value[b]
Clinical					
OJ (mm)	9.06 (1.92)	6.94 (1.66)	-2.12 (-2.87, -1.37)	-6.036 (15)	< 0.001
Angular Skeletal					
ANB°	5.56 (1.62)	4.72 (1.21)	-0.84 (-1.36, -0.33)	-3.511 (15)	0.276
Linear Skeletal					
Ar_A (mm)	76.35 (3.33)	77.20 (3.62)	0.85 (0.29, 1.40)	3.270 (15)	0.005
Ar_B (mm)	85.02 (3.42)	87.58 (3.75)	2.56 (1.30, 3.83)	4.314 (15)	0.001
Ar_Pog (mm)	90.83 (3.56)	93.44 (3.71)	2.61 (1.34, 3.89)	4.359 (15)	0.001
Sv_Pog (mm)	53.21 (6.21)	54.22 (6.32)	1.01 (0.01, 2.01)	2.160 (15)	0.047
TAFH (mm)	102.12 (4.99)	104.68 (6.14)	2.56 (0.88, 4.25)	3.241 (15)	0.005
Linear Dental					
Sv_is (mm)	69.13 (4.80)	68.81 (5.49)	-0.32 (-1.26, 0.62)	0.733 (15)	0.475
Sv_ii (mm)	61.92 (5.58)	63.66 (5.48)	1.74 (0.86, 2.63)	4.192 (15)	0.001
Is_ii (mm)	7.21 (2.52)	5.15 (2.12)	-2.06 (-3.16, -0.97)	-4.20 (15)	0.001
OB (mm)	3.45 (1.14)	2.86 (1.29)	-0.77 (-1.54, 0.00)	-2.125 (15)	0.051

[a] n =16, [b] Paired *t* test, *P* value is significant when < 0.05

Table III: Pre- and Post-treatment measurements of TB appliance group

Variables	Pre Mean (SD)	Post Mean (SD)	Mean Difference (95% CI)	*t* statistic (df)	*P* value[b]
Clinical					
OJ (mm)	9.56 (1.81)	5.29 (2.24)	-4.26 (-5.34, -3.18)	-8.373 (16)	< 0.001
Angular Skeletal					
ANB°	6.23 (2.56)	4.59 (2.19)	-1.65 (-2.26, -1.03)	-5.679 (16)	< 0.001
Linear Skeletal					
Ar_A (mm)	77.51 (3.47)	78.20 (3.44)	0.69 (0.12, 1.25)	2.564 (16)	0.021
Ar_B (mm)	85.54 (4.97)	88.67 (4.55)	3.13 (2.06, 4.20)	6.212 (16)	< 0.001
Ar_Pog (mm)	91.52 (5.45)	94.77 (4.97)	3.25 (2.02, 4.47)	5.618 (16)	< 0.001
Sv_Pog (mm)	61.80 (4.04)	62.44 (6.39)	0.55 (-0.11, 1.41)	1.809 (16)	0.089
TAFH (mm)	104.80 (4.16)	107.46 (5.43)	2.66 (0.98, 4.34)	3.363 (16)	0.004
Linear Dental					
Sv_is (mm)	70.82 (6.50)	71.24 (6.37)	0.42 (-0.45, 1.29)	1.026 (16)	0.320
Sv_ii (mm)	62.45 (5.92)	66.75 (5.68)	4.30 (3.06, 5.53)	7.268 (16)	< 0.001
Is_ii (mm)	8.37 (2.24)	4.49 (2.43)	-3.87 (-4.94, -2.81)	-7.692 (16)	< 0.001
OB (mm)	3.48 (1.98)	1.86 (1.43)	-1.62 (-2.89, -0.35)	-2.712 (16)	0.015

[a] n =17, [b] Paired *t* test, *P* value is significant when < 0.05

< 0.001).The horizontal skeletal linear measurements in relation to S vertical reference line increased by 2.85mm for Sv_Pog distance which was found to be significant ($p < 0.001$).

An increase of 2.66 mm in total anterior facial height was found ($p < 0.01$). There was a significant increase in the lower anterior facial height ($p < 0.01$). There was a very small but statistically significant difference in facial proportion ($p < 0.05$). A significant difference was found in the distance between the lower incisor tip and S-vertical (Sv) reference line (Sv_ii distance) which was increased by 4.30 mm ($p < 0.001$). The horizontal distance from the upper to the lower incisor tip calculated as Sv is distance minus Sv-ii distance was reduced by about 3.87 mm which was found to be statistically significant ($p < 0.001$). There was also a significant difference between pre- and post-treatment overbite ($p < 0.05$).

Comparison between T4F™ group and TB group in terms of the overjet and cephalometric changes during the observation period

There was a significant difference (Table IV) in the overjet change between the two groups where the overjet was found to have reduced more favourably in the TB group than in the T4F™ group. A significant difference of 2.14 mm ($p < 0.01$) mean was found between the two groups. The SNB and ANB angles too showed a significant difference between the two groups with more favourable changes observed in the TB group. There was a significant difference between the two groups in terms of the horizontal skeletal linear measurement of the mandible in relation to Sv reference line (Sv_Pog distance) with a more favourable increase in the TB group. The mean difference between the two groups was 1.83mm ($p < 0.05$).

A significant difference in Sv_ii distance was found between the two groups. The Sv_ii distance underwent a significantly more favourable change in the TB group. The mean difference was found to be 2.55 mm ($p < 0.001$). A statistically significant difference between groups was found in the mean change of the horizontal distance from the upper to the lower incisor tip. The distance was calculated as Sv_is distance minus Sv-ii distance which saw more reduction in the TB group than in the T4F™ group. The mean difference between groups was found to be 1.81 mm which was statistically significant ($p < 0.05$).

DISCUSSION

Reliability

The ICC results ranged from 0.92 to 0.99 which were close to 1 and in agreement with the previous cephalometric studies which ranged from 0.96 to 0.98 (11). These results showed that the reliability of cephalometric measurements for both inter- and intra-examiner as tested by ICC test was within the acceptable error levels. Consequently, it suggests a good agreement between the examiners.

The changes during the treatment period in T4F™ and TB group will be discussed under several headings for

Table IV: Between-group differences

Variable	T4F (n=16) Mean Change (SD) Post – Pre	T Block (n=17) Mean Change (SD) Post – Pre	T4F – TB Mean Difference (95%CI)	t statistic (df)	*P* value[a]
Clinical					
OJ (mm)	-2.12 (1.40)	-4.26 (2.10)	2.14 (0.86, 3.42)	3.41 (31)	0.002
Angular Skeletal					
SNA°	-0.28 (1.37)	0.32 (2.03)	-0.60 (-1.84, 0.63)	-0.99 (31)	0.328
SNB°	0.72 (1.52)	1.97 (1.90)	-1.25 (-2.48, -0.02)	-2.07 (31)	0.047
ANB°	-0.84 (0.96)	-1.65 (1.19)	0.80 (0.03, 1.58)	2.12 (31)	0.042
Sn_Man°	-0.50 (1.77)	-0.56 (2.94)	0.06 (-1.67, 1.78)	0.07 (26.5)[b]	0.945
MMPA°	-0.09 (1.83)	-0.65 (2.36)	0.55 (-0.96, 2.06)	0.75 (31)	0.460
Angular dental	-1.69 (2.56)	-1.09 (3.49)	-0.60 (-2.79, 1.59)	-0.56 (31)	0.580
Ui_Mx°	1.59 (3.03)	2.73 (4.59)	-1.14 (-3.90, 1.62)	-0.85 (27.9)[b]	0.404
Li_Man°	0.81 (4.80)	0.85 (5.63)	-0.63 (-4.35, 3.10)	-0.34 (31)	0.733
IIA°					
Linear skeletal	0.85 (1.03)	0.69 (1.10)	0.16 (-0.60, 0.92)	0.43 (31)	0.669
Ar_A (mm)	2.56 (2.37)	3.13 (2.08)	-0.57 (-2.15, 1.01)	-0.73 (31)	0.468
Ar_B (mm)	2.61 (2.39)	3.25 (2.38)	-0.63 (-2.33, 1.06)	-0.76 (31)	0.453
Ar_Pog (mm)	0.18 (0.88)	0.65 (1.47)	-0.47 (-1.33, 0.40)	-1.11 (26.4)[b]	0.277
Sv_A (mm)	1.01 (1.87)	2.85 (2.42)	-1.83 (-3.38, -0.29)	-2.42 (31)	0.022
Sv_Pog (mm)	2.56 (3.16)	2.66 (3.26)	-0.10 (-2.38, 2.19)	-0.09 (31)	0.931
TAFH (mm)	1.35 (2.59)	2.55 (2.58)	-1.19 (-3.03, 0.65)	-1.32 (31)	0.196
LAFH (mm)	-0.00 (0.02)	0.01 (0.02)	-0.01 (-0.03, 0.00)	-1.69 (31)	0.101
L@TAFH%					
Linear dental	-0.32 (1.76)	0.42 (1.69)	-0.74 (-1.97, 0.48)	-1.24 (31)	0.225
Sv_is (mm)	1.74 (1.66)	4.30 (2.40)	-2.55 (-4.03, -1.08)	-3.53 (31)	0.001
Sv_ii (mm)	-2.06 (2.05)	-3.87 (2.08)	1.81 (0.34, 3.28)	2.51 (31)	0.017
is_ii (mm)	-0.77 (1.45)	-1.62 (2.47)	0.85 (-0.59, 2.29)	1.22 (26.1)[b]	0.234
OB (mm)					

[a] Independent *t*-test. *P* value is significant when < 0.05. [b] Changes variances were significantly different (Levene's test *P* value ≤ 0.05), therefore *t'* test statistic without assuming equal variance was used

better clarity.

Skeletal: Anterior-posterior changes

Both groups showed a significant reduction in ANB angle representing a favourable skeletal correction. The favourable skeletal changes were mainly a result of mandibular changes particularly in the TB group where there was a significant change in SNB without a significant change in SNA angle. The favourable skeletal correction was significantly higher in the TB appliance group which showed 0.8 more reduction in ANB angle as compared to the T4F™ group. The ANB reduction in TB group (1.65) was less than that reported in previous studies (12) which could be merely due to the shorter observation period in our investigation.

In TB appliance group, the combined growth and treatment effect on maxillary sagittal position represented by SNA angle did not result in any significant difference during the observation period. The mean change in our investigation was similar to the findings who found it also to be very similar to the mean change in their untreated group (13).

The SNA angle in T4F™ group did not show any significant difference during the observation period and the mean decreased by 0.3 , while in TB group it was increased by 0.3 after treatment. The sagittal change was also represented by the horizontal linear measurement from A point to S vertical reference line where the increase Sv_A distance was less in T4F™ group. This suggests that T4F™ appliance may have very small effect in terms of maxillary growth restraint and not to a statistically significant amount.

With regards to the total mandibular length, both groups showed significant changes during the treatment period with no significant difference between the two groups. This suggests that T4F™ appliance has a favourable effect on total mandibular length similar to TB appliance.

Regarding the mandibular sagittal position, the findings suggest that the TB appliance had a more favourable effect in terms of mandibular sagittal position correction (SNB) which resulted in a more favourable skeletal discrepancy correction (ANB). The more favourable mandibular sagittal skeletal correction in TB appliance group was represented by both linear (Sv_Pog) and angular measurements (SNB and ANB) which showed significant anterior movements of both B point and Pogonion.

Taking into consideration that both appliances showed a similar effect on total mandibular length but different effects on mandibular sagittal position, it could be concluded that both appliances were similar in terms of the amount of growth modification but different in the direction of growth and/or the amount of mandibular repositioning. However, since there was no difference in mandibular plane angle in relation to SN line between the two groups, the more favourable sagittal skeletal correction in TB appliance group may not be considered as a result of growth direction difference between the two groups. Consequently, the results suggest that the more favourable skeletal correction in TB appliance group was a result of a combination of more anterior mandibular repositioning and slightly more growth enhancement. The forward positioning of the mandible, as well as the mandibular lengthening effect as a result of TB appliance, was supported by many previous studies (14).

Skeletal: Vertical changes

The maxillary mandibular plane angle (MMPA) and mandibular plane angle in relation to the SN line (SN_Man) did not show any significant change during the treatment period in both groups. There was also no significant difference between the two groups. These results suggest that T4F™ appliance, as well as TB appliance, do not have a significant effect on vertical dimensions. This was in agreement with the previous studies on TB appliance for both early and late-treated patients in comparison with untreated groups (13).

There was no significant difference in terms of total and lower anterior facial height and facial proportion between the two groups. This was in accordance with the angular measurement values in this investigation which did not show a considerable change in both mandibular angle in relation to SN line and also maxillary mandibular plane angle. Nevertheless, the facial proportion in the TB appliance group showed a significant increase during treatment period which was supported by previous studies (12, 18).

Dentoalveolar: anterior posterior changes (Upper incisors retroclination)

The upper incisors retroclination was small and insignificant in the TB appliance group and was supported by other studies (20). The considerable upper incisors retroclination may be attributed to the appliance design particularly when the labial bow was incorporated (12). Moreover, the amount of upper incisors retroclination may be also attributed to the treatment modality. For example, in a previous study semi-rapid maxillary expansion and alignment of the upper arch were initially performed before TB appliance therapy which may have an influence on the amount of Retroclination (15).

The great differences among previous studies in terms of the amount of upper incisor retroclination during TB appliance therapy which ranged from 2.5° to 14.3° could not be explained by the appliance design differences alone. Besides the appliance design and treatment modality, other factors such as treatment period, pre-treatment skeletal and dentoalveolar characteristics of the sample and the variation in appliance wearing time among patients have to be taken into consideration when looking into the amount of upper incisor retroclination (12).

The observation period may explain the difference amount of upper incisor retroclination between some studies. For example, Mills and McCulloch reported 2.5° upper incisors retroclination after 14 months of treatment. This was larger than our finding which was measured after a six-month observation period.

The influence of appliance design in general and labial bow incorporation in particular on the amount of dentoalveolar changes was mentioned in many previous studies but was not quantified. This influence became strongly evidenced when two designs of TB appliance were compared and a labial bow in the first group was replaced by torque control spurs. The influence of labial bow was significant producing a retroclination two times more than the other group. This was also supported by another study where a mean difference of an increased 4.1° retroclination was reported in the labial bow group versus a torque control spurs group but this was not found to be statistically significant. However, this finding was unfortunately biased by the usage of headgear in the torquing spurs group making its finding very difficult to be interpreted.

The limited upper incisors retroclination found in our investigation can be explained mainly by the short observation period and abandoning the labial bow which was recommended by Clark to minimize lingual movement of the upper incisors during treatment. Moreover, the treatment modality in general and the upper arch expansion in particular during TB appliance treatment may have a role in facilitating the upper incisors retroclination. The expansion of the upper arch was not carried out during the observation period for any case. When the expansion was needed as a part of the treatment plan, it was decided to be delayed and carried out after the six months observation period.

Dentoalveolar: Anterior posterior changes (lower incisors proclination)

The lower incisors in both groups were significantly proclined during the observation period. In contrast to the upper incisors, the lower incisors were proclined considerably more in TB group than in T4F™ group, but this was not statistically significant. This differential change in the upper and lower incisors inclination have produced a slight increase in an inter-incisal angle which was interestingly similar in both groups with no significant difference. The small increase in inter-incisal angle was supported by many previous studies (13, 16) and was in contrast to a previous study (15). With regards to the appliance design, there is evidence that the design of the part of TB appliance has no influence on the lower incisors proclination. The lower part of the TB appliance seems to have an influence on the amount of lower incisor proclination.

Linear dental measurements

The angular changes in the upper and lower incisors were supported by the results of our linear dental measurements. The total horizontal movement of the upper incisor tip in relation to Sv reference line was -0.32 mm in T4F™ group and 0.42 mm in the TB group. As long as the influence of dental angular change on the A and B skeletal points is negligible, the pure dental horizontal movement of the upper incisor can be calculated by subtracting the horizontal movement of A point from the total dental horizontal movement. This is similar to the method used previously (22, 23). It is also similar to the method which was used by another study (16) but with a different reference line which is perpendicular to the palatal plane through Sella.

The upper incisor retroclination of 1.69° in T4F™ group produced about -0.5mm pure dental horizontal movement of incisor tip. The pure dental horizontal movement of incisor tip was calculated as the change in Sv_is minus the change in Sv_A. In the TB group, the 1.09° upper incisor retroclination has resulted in -0.23 mm of horizontal upper incisor tip movement only. The differences between the two groups were not statistically significant in terms of both angular and linear measurements. In the lower arch, the horizontal lower incisor movement in TB group was much more than in the upper arch as a result of the higher dental angular changes in the lower arch relative to the upper arch. The larger dental change in the lower arch than in the upper arch among TB treated group was in contradiction with other studies (24), but supported by two studies (20).

Even though the mean change in the lower incisors inclination in the TB group was slightly less than two times of the mean change in T4F™ group, this was not statistically significant. However, the linear horizontal forward movement of lower incisor tip in relation to the Sv reference line (Sv_ii distance change) in TB group was larger than in T4F™ group with a mean difference of 2.55mm which was statistically significant. This change represents the combined skeletal and dental forward movement. The dental change alone (calculated as a change of Sv_ii distance minus change of Sv_Pog distance) was 1.85mm in TB group and only 0.73mm in T4F™ group.

The 0.73mm pure dental forward movement of lower incisor tip in T4F™ group which was resulted from 1.59° proclination in T4F™ group contributed 42% of the total forward movement of the lower incisor. The remaining 58% of the forward movement of the lower incisor was a result of the skeletal change. In the TB group, the dental contribution of 1.45 mm to the total forward movement of lower incisor tip counted for 34% of it. The remaining 2.85 mm forward movement of lower incisor tip out of the total 4.30 mm forward movement of lower incisor tip was due to skeletal change. The skeletal change was represented as a forward movement of Pogonion point which counted for 66% of the total forward movement of lower incisor tip. This showed that the contribution nature of the mandible to the overjet correction was slightly more dental than skeletal in T4F™ group versus more skeletal in the TB group.

Overjet correction

An overjet correction was significantly different between the two groups as measured clinically and radiographically represented by is_ii distance. The overjet reduction in T4F™ appliance group was relatively small and slightly less than half of that in TB appliance group. Our results suggest that both TB appliance design and treatment modality such as delay of the upper arch expansion has reduced the amount of upper incisor retroclination which could explain the moderate overjet reduction when compared with the previous studies (12). These two investigations showed a greater amount of overjet reduction as a result of greater retroclination of the upper incisors.

The observation period is another important factor. For example, the results from this study showed less overjet reduction than a previous study (19), who found 4.8mm reduction. In fact, if the reduction found by this study within 12 months observation period is annualized for 6 months period, it is less than our findings.

The pre-treatment high upper incisor inclination value was suggested as a possible reason for the unexpected large upper incisor retroclination (25). Therefore, the initial overjet may have an influence on the amount of overjet reduction. For example, 7.5 mm overjet reduction was found in a group with initial 10.8 mm, but the reduction was found to be 5.6 mm when the initial overjet was 8.2 mm. In our study, the mean initial overjet was about 9 mm which was less than some previous studies (16).

The overjet in the T4F™ group showed 2.12 mm reduction which was statistically and clinically significant. Although the reduction in the T4F™ group was significantly smaller than in the TB group, the clinically significant reduction suggests that T4F™ appliance is an effective treatment for BSI Class II Division 1 patients' but it takes longer time and hence may need more cooperative patients. The difference between the two appliances in terms of overjet reduction may be a result of less wearing time per day besides the difference in the design. Even though all patients were instructed to wear T4F™ appliance during studying, watching TV and sleeping, most of the patients claimed that they wore it only during sleeping time. In many cases, they forgot to wear it for one or more nights per week. This could have deliberately reduced the treatment effects resulted within 6 months of the observation period.

Overjet correction: Skeletal vs. Dentoalveolar

The skeletal contribution to the is_ii distance correction in the TB group was larger than in T4F™ group. The TB appliance group showed 2.2 mm skeletal discrepancy correction accounting for about 57% skeletal contribution to the total 3.8 mm is_ii distance correction. The remaining 43% correction of the is_ii distance was mainly due to lower incisor tipping and forward dental movement of 1.4mm. This movement has accounted for about 36% of the total is_ii distance correction, while the very small remaining amount was a result of dentoalveolar changes of the upper incisor.

These results suggest that the proportional skeletal contribution to the overjet correction as a result of functional appliance treatment could be higher with TB appliance than with T4F™ appliance. This may be a result of the different wearing times between the two groups and the rigidity of TB appliance in terms of holding the mandible anteriorly comparing with the T4F™ appliance.

The proportional skeletal contribution to the total is_ii distance change in TB group in this study was less than what was found by others (21). However, our finding was supported by the findings of both early and late TB treated groups in another study (17). However due to the 6-month stopping rule the amount of overjet reduction was dependant on the initial assessment and varied accordingly. This is a further limitation due to the treatment duration.

Vertical changes: Overbite

The overbite was significantly reduced in the T4F™ and the TB groups during the observation period and was supported by other studies (13, 18). The overbite was significantly reduced in the T4F™ and the TB group respectively during the observation period. The overbite reduction during the treatment period was supported by several other studies (12, 19).

Overbite reduction in the T4F™ group was smaller than in the TB group. The mean difference of 0.85 mm between the two groups was statistically insignificant. Since the difference between the two groups was less than 1 mm, it was also considered clinically insignificant (19).

The study compared the skeletal and dentoalveolar changes between the experimental T4F™ and the active control TB for the management of BSI Class II Division 1 malocclusion. The study however faced a few limitations in terms of time and subject dropout. The results also highlight the effects only for a six-month treatment period and hence affects individual cases differently. The changes noticed might have differed if a long term follow up is carried out. Due to the lack of an untreated control group, the study was able to analyse and compare the combined growth/appliance effects between the two appliances. The patient compliance is another factor which had some implications on the study.

CONCLUSION

The findings of this randomized clinical trial suggest that T4F™ appliance could be an effective appliance for the management of Class II Division 1 malocclusion in terms of the correction of the sagittal skeletal and dentoalveolar discrepancy. Although both the groups saw favourable correction, TB group differed significantly and had a more favourable correction in terms of the sagittal skeletal and dentoalveolar discrepancy.

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