Original Article

Treatment effects produced by the Twin-block appliance vs the Forsus Fatigue Resistant Device in growing Class II patients

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ABSTRACT

Objective: To compare the dentoskeletal changes produced by the Twin-block appliance (TB) followed by fixed appliances vs the Forsus Fatigue Resistant Device (FRD) in combination with fixed appliances in growing patients having Class II division 1 malocclusion.

Materials and Methods: Twenty-eight Class II patients (19 females and 9 males; mean age, 12.4 years) treated consecutively with the TB followed by fixed appliances were compared with a group of 36 patients (16 females and 20 males; mean age, 12.3 years) treated consecutively with the FRD in combination with fixed appliances and with a sample of 27 subjects having untreated Class II malocclusion (13 females and 14 males; mean age, 12.2 years). Mean observation interval was 2.3 years in all groups. Cephalometric changes were compared among the three groups by means of ANOVA and Tukey's post hoc tests.

Results: The FRD produced a significant restraint of the maxilla compared with the TB and control samples (SNA, -1.1° and -1.8°, respectively). The TB sample exhibited significantly greater mandibular advancement and greater increments in total mandibular length than either the FRD or control groups (SNB, 1.9° and 1.5°, respectively; and Co-Gn, 2.0 mm and 3.4 mm, respectively). The FRD produced a significantly greater amount of proclination of the mandibular incisors than what occurred with the TB or the control samples (2.9° and 5.6°, respectively).

Conclusion: The TB appliance produced greater skeletal effects in terms of mandibular advancement and growth stimulation while the Forsus caused significant proclination of the mandibular incisors. (*Angle Orthod.* 0000;00:000–000.)

KEY WORDS: Functional jaw orthopedics; Class II malocclusion; Cephalometrics

INTRODUCTION

A wide range of functional/orthopedic appliances is available for the correction of Class II skeletal and occlusal disharmonies, a type of malocclusion that affects one-third of the North American population.[1] Systematic reviews of the literature on the outcomes of functional jaw orthopedics in Class II malocclusion[2,3] have shown a substantial variability of reported results. These differences must be ascribed mainly to the type of appliance used (as related to the duration of active treatment needed to achieve a Class II correction and to the level of patient compliance required) as well as to the patients' maturational level at the time of intervention.

Among the different types of appliances, the Twin-block (TB) and the Forsus Fatigue Resistant Device (FRD; 3M Unitek, Monrovia, Calif) are used often for the correction of Class II malocclusion. It has been shown that the FRD is effective in correcting Class II malocclusion with a combination of skeletal (mainly restriction of maxillary growth) and dentoalveolar

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(mainly mesial movement of the mandibular incisors and first molars) modifications.[4,5] The TB corrects Class II malocclusion effectively by way of mandibular growth stimulation associated with slight dentoalveolar effects.[6–10] Multicentered, randomized, controlled trials[11,12] investigating into the effectiveness of early treatment (before puberty) with the TB found that the correction produced by that appliance was mainly at the dentoalveolar level with small skeletal changes.

Only Mahamad and coworkers[13] previously have compared the dentoskeletal effects produced by the TB vs FRD with respect to an untreated Class II control sample. These authors found that both protocols were effective in the treatment of Class II division 1 malocclusion, with the TB showing more skeletal than dentoalveolar changes and the FRD exhibiting more dentoalveolar and fewer skeletal changes. The Mahamad et al. study,[13] however, compared a comprehensive Class II treatment with the Forsus combined with fixed appliances vs Class II treatment with the TB that was not followed by fixed appliances. Moreover, no information on the duration of active therapy with the FRD in place was reported.

The aim of the present retrospective controlled clinical study was to compare the dentoskeletal changes produced by the TB followed by fixed appliances vs FRD in combination with fixed appliances in growing patients with Class II division 1 malocclusion. A sample of untreated subjects with Class II malocclusion served as the control group.

MATERIALS AND METHODS

This cephalometric study was designed to evaluate the dentoskeletal effects produced by two treatment modalities for Class II malocclusion with respect to a control group of subjects having untreated Class II malocclusion. Sample size determination revealed that for the ANOVA on three groups, with an effect size (Cohen's *d*)[14] of 1.0 for the Wits appraisal[4] (primary endpoint), an alpha level of 0.05, and a power of 0.8, a minimum of 20 subjects in each group was required (SigmaStat 3.5, Systat Software, Point Richmond, Calif).

The TB group consisted of 28 patients (19 females and 9 males) treated consecutively with the TB appliance followed by fixed appliances. The FRD group included 36 patients (16 females and 20 males) treated consecutively with the FRD in combination with fixed appliances. The two treatment groups were derived from two private practices.

All patients underwent a specific nonextraction treatment protocol with 0.022″-slot, preadjusted fixed appliances in combination with the FRD or after the TB. Treatment with the FRD consisted of leveling and aligning (mean duration, 1.1 years), followed by FRD (mean duration, 0.5 years), and detailing (mean duration, 0.7 years). Treatment with the TB lasted 1.1 years on average, and it was followed immediately by fixed appliance therapy (mean duration, 1.2 years). Specific details of the treatment protocols with TB and FRD have been described in previous studies.[4,7] Treated patients included in the current investigation were different from those described in the previous studies.[4,7]

The control group consisted of 27 subjects (13 females and 14 males) with untreated Class II malocclusion, the records of whom were selected from the files of the *University of Michigan Growth Study* (11 subjects), the *Denver Child Growth Study* (9 subjects), and the *Bolton-Brush Growth Study* (7 subjects). The lateral cephalograms for the subjects from the *Bolton-Brush Growth Study* were downloaded from the *AAOF Craniofacial Growth Legacy Collection* (http://www.aaoflegacycollection.org).

To be included in the present study, both treated and untreated subjects had to present with Class II dentoskeletal relationships having an overjet larger than 5 mm, a full cusp or end-to-end Class II molar relationship, and an ANB angle larger than 3°. Lateral cephalograms for all treated subjects were available at the beginning of orthodontic treatment (T1) and at the end of comprehensive treatment with fixed appliances (T2). Mean ages at T1 and T2 and mean durations of T1–T2 intervals for both treated and control samples were well matched (Table 1). At T1, patients were in the circumpubertal phase of skeletal development, as assessed using the cervical vertebral maturation method[15] (18% prepubertal, 64% pubertal, and18% postpubertal for the patients treated with TB; 15% prepubertal, 70% pubertal, and 15% postpubertal for those treated with FDR; and 18% prepubertal, 64% pubertal, and 18% postpubertal for the control group). At T2, all patients were in the postpubertal stage of skeletal development.

This study was exempted from review by the Medical School Institutional Review Board of the University of Florence (Exemption 4 of the 45 CFR 46.101.[b]).

Cephalometric Analysis

A customized digitization regimen and analysis provided by cephalometric software (Viewbox, version 3.0, dHAL Software, Kifissia, Greece) were utilized for all the cephalograms examined in this study.

All the lateral cephalograms were standardized to a magnification factor of 8%, which was the established enlargement factor for the treated patients' headfilms. A customized cephalometric analysis was used; it

Table 1. Sample Demographics

Variables	Twin-block Group (n = 28)		Forsus Group (n = 36)		Control Group (n = 27)	
	Mean	SD	Mean	SD	Mean	SD
Age, T1 (y)	12.4	1.0	12.3	1.2	12.2	0.8
Age, T2 (y)	14.7	1.0	14.6	1.2	14.5	0.8
T1–T2 interval (y)	2.3	0.5	2.3	0.4	2.3	0.5

consisted of 14 variables, 9 angular and 5 linear, for each tracing. The examiner who analyzed the cephalograms was blinded with regard to the origin of the films and the group to which the individual subjects belonged.

All cephalograms were traced initially by the same operator and were checked by a second operator to verify anatomical outlines, landmark placement, and superimposition. Any disagreements were resolved to the satisfaction of both observers, who were blinded as to group assignment of the examined headfilms.

Twenty randomly selected cephalograms were redigitized by the same operator, and the variables were recalculated to determine the method error. The measurements at both times for each patient were analyzed with the paired *t*-test for assessing the systematic error and with the method of moments estimator (MME)[16] for determining the random error. No systematic error was detected for any of the variables, with the *P* values ranging from a minimum of .059 (FH to palatal plane) to a maximum of .871 (palatal plane to mandibular plane). Values for the MME ranged from a minimum of 0.19° (FH to palatal plane) to a maximum of 0.95° (Co-Go-Me).

Statistical Analysis

Chi-square tests were used to assess differences in gender distribution between groups. All cephalometric data at T1 and the T1–T2 changes revealed a normal distribution (Kolmogorov-Smirnov test). Comparisons between the TB group, the FRD group, and the control sample on the dentoskeletal features at T1 (starting forms) and on the T1–T2 changes were performed with the ANOVA (Statistical Package for the Social Sciences, SPSS, version 12, Chicago, Ill) with Tukey's post hoc tests.

In that the success of therapy was not a factor for inclusion of treated patients in the study and because, in the two treatment groups, patients were treated consecutively by the same operator with a standardized protocol, an analysis of treatment-induced successful correction of initial dentoskeletal Class II discrepancy could be carried out in these two groups. Success or unsuccess (overjet greater than 3 mm or a residual half-cusp Class II molar relationship) at T2 was assessed in the two treated groups.

RESULTS

The success rates of the two treatment protocols were similar (TB, 82.1%; FRD, 83.3%). No significant difference was found as to gender distribution between the three groups (chi-square tests with Yates correction: chi-square = 1.59; *P* = .207). Descriptive statistics and comparisons of the starting forms of the three groups are reported in Table 2.

At T1, there were no statistically significant differences among the three groups for any of the variables. The only exceptions were overjet, which was significantly larger in the TB group with respect to both the FRD group and the control sample (2.2 mm and 3.3 mm, respectively), and the inclination of the maxillary incisors to Frankfort horizontal, which was significantly larger in the TB group compared with the FRD group and the control sample (8.7° and 7.7°, respectively).

With respect to the T1–T2 changes (Table 3), the FRD produced a statistically significant restraint in the sagittal skeletal position of the maxilla (SNA) compared with the TB and control samples (−1.1° and −1.8°, respectively). The TB sample exhibited significantly greater mandibular advancement as measured by the SNB angle compared with the FRD and control groups (1.9° and 1.5°, respectively). These changes led to significantly greater decreases in the ANB angle in the TB sample with respect to both the FRD and control groups (−0.8° and −0.2°, respectively) and also in the FRD sample compared with the control group (−1.4°). The TB sample showed significantly greater increments in total mandibular length (Co-Gn) than did the FRD or control groups (2.0 mm and 3.4 mm, respectively).

As for the changes in vertical skeletal relationships, no statistically significant differences were found among the three groups for any of the angular measurements except for the FH to mandibular plane angle, which showed a significantly greater increase (1.5°) in the TB sample compared with the control group.

As for the dentoalveolar changes, the TB group showed significantly greater decreases in overjet than did the FRD sample (−3.0 mm). Both the TB and FRD produced significantly greater decreases than in the controls in both overjet (−7.9 mm and −5.0 mm, respectively) and overbite (−3.2 mm and −3.0 mm,

Table 2. Descriptive Statistics and Statistical Comparisons of Starting Forms (ANOVA with Tukey's Post Hoc Tests)

Variables	TB Group (n = 28)		FRD Group (n = 36)		Ctrl Group (n = 27)		Statistical Comparisons: ANOVA	Tukey's Post Hoc Tests: TB vs FRD		TB vs Ctrl		FDR vs Ctrl	
Sagittal skeletal	Mean	SD	Mean	SD	Mean	SD	*P*	Diff	*P*	Diff	*P*	Diff	*P*
SNA (°)	81.6	2.5	80.9	3.4	80.9	3.8	.679	0.7	NS[a]	0.6	NS	0.0	NS
SNB (°)	75.4	2.9	75.4	3.0	75.8	3.3	.884	0.0	NS	−0.3	NS	−0.4	NS
ANB (°)	6.1	1.8	5.5	1.8	5.2	1.6	.109	0.6	NS	1.0	NS	0.3	NS
Co-Gn (mm)	113.4	5.2	111.1	6.5	110.4	6.6	.169	2.3	NS	3.0	NS	0.7	NS
Vertical skeletal													
FH to palatal plane (°)	−2.9	3.1	−2.9	3.1	−2.3	3.4	.715	0.0	NS	−0.6	NS	−0.6	NS
FH to mandibular plane (°)	19.7	5.3	20.9	5.0	22.1	5.1	.247	−1.2	NS	−2.3	NS	−1.2	NS
Palatal plane to mand. plane (°)	22.7	5.9	23.8	4.7	24.4	5.8	.485	−1.2	NS	−1.7	NS	−0.5	NS
Co-Go-Me (°)	122.5	7.6	122.0	4.7	120.6	6.9	.805	0.6	NS	2.0	NS	1.4	NS
Dentoalveolar													
Overjet (mm)	10.1	2.7	7.9	2.1	6.8	1.9	.000	2.2	*	3.3	*	1.1	NS
Overbite (mm)	4.1	2.8	5.1	2.3	4.5	2.2	.254	−1.0	NS	−0.4	NS	0.6	NS
Molar relationship (mm)	−2.4	1.6	−1.7	1.5	−1.5	1.7	.144	−0.6	NS	−0.8	NS	−0.2	NS
Max. inc. to FH (°)	120.4	7.3	111.7	7.3	112.6	5.8	.000	8.7	*	7.7	*	−1.0	NS
Mand. inc. to mand. plane (°)	98.8	5.9	100.9	6.7	99.7	6.7	.445	−2.1	NS	−0.9	NS	1.1	NS

[a] NS indicates not significant; * $P < .001$; Ctrl = Control; max. = maxillary; mand. = mandibular; inc. = incisor; FH = Frankfort horizontal.

respectively). The TB group exhibited significantly greater increments of change in molar relationships with respect to the FRD sample (1.5 mm). Both the TB and FRD induced significantly greater increases in molar relationships than in the controls (4.8 mm and 3.3 mm, respectively). The maxillary incisors showed a significantly greater amount of retroclination in the TB group compared with either the FRD or the control groups (−6.5° and −6.3°, respectively). The FRD produced a significantly greater amount of mandibular incisor proclination with respect to either the TB or the control sample (2.9° and 5.6°, respectively).

DISCUSSION

With one exception, no previous study has analyzed the dentoskeletal effects of the TB vs the FRD with respect to a sample of subjects having untreated Class II malocclusion. Mahamad et al.[13] compared comprehensive Class II treatment with the FRD combined with fixed appliances vs Class II treatment with the TB not followed by fixed appliances. No information on the duration of active therapy with the FRD in place was reported by these authors. Thus, a direct comparison of the present study with the Mahamad et al. study[13] was difficult because those authors performed the statistical between-group comparisons only on the percentage changes.

The sagittal skeletal correction of Class II relationships in the FRD group was due mainly to a significant restriction of maxillary growth with respect to both the TB and control groups (SNA, −1.1° and −1.8°, respectively). This effect has also been reported in other studies that analyzed the dentoskeletal effects produced by the FRD appliance.[4,5] Patients treated with the TB underwent a significantly greater increase in mandibular length than did those treated with the FRD or the controls (Co-Gn, 2.0 mm and 3.4 mm, respectively). Similar findings were reported by Singh et al.[9] for the TB followed by fixed appliances in Class II patients treated during the pubertal growth spurt compared with untreated Class II controls (Co-Gn, 3.9 mm).

In the present study, these favorable mandibular growth increments were associated with a significantly greater mandibular advancement in the TB group than in the FRD or control groups (SNB, 1.9° and 1.5°, respectively). Consequently, the TB induced a more favorable correction in intermaxillary sagittal relationships than did the FRD or what occurred in the controls (ANB, −0.8° and −2.2°, respectively). These outcomes are similar to those reported by Mahamad et al.,[13] who found that the TB produced a larger effect on the growth and position of the mandible than did the FRD or what occurred in the controls.

It should be noted that in the present study, most of the subjects were treated during the circumpubertal growth period, which has been shown to be an optimal time to stimulate mandibular growth.[8,9] Though FRD patients were also treated during the circumpubertal period, no significant stimulation of mandibular growth nor significant mandibular advancement was recorded

Table 3. Descriptive Statistics and Statistical Comparisons of T1–T2 Changes (ANOVA with Tukey's Post Hoc Tests)

Variables	TB Group (n = 28)		FRD Group (n = 36)		Ctrl Group (n = 27)		Statistical Comparisons: ANOVA	Tukey's Post Hoc Tests: TB vs FRD				TB vs Ctrl				FRD vs Ctrl			
Sagittal skeletal	Mean	SD	Mean	SD	Mean	SD	*P*	Diff	*P*	CI 95%		Diff	*P*	CI 95%		Diff	*P*	CI 95%	
SNA (°)	−0.2	1.3	−1.3	1.6	0.5	1.3	.000	1.1	**	0.22	1.93	−0.8	NS[a]	−1.68	0.15	−1.8	***	−2.70	−0.98
SNB (°)	2.4	1.2	0.5	1.5	0.9	1.0	.000	1.9	***	1.11	2.66	1.5	***	0.68	2.34	−0.4	NS	−1.16	0.41
ANB (°)	−2.6	1.3	−1.8	1.3	−0.4	1.0	.000	−0.8	*	−1.53	−0.08	−2.2	***	−3.02	−1.47	−1.4	***	−2.17	−0.70
Co-Gn (mm)	9.4	3.1	7.4	3.5	6.0	2.1	.169	2.0	*	0.17	3.84	3.4	***	1.44	5.36	1.4	NS	−0.45	3.25
Vertical skeletal																			
FH to palatal plane (°)	0.3	2.3	−0.1	1.8	0.3	2.6	.682	0.4	NS	−0.91	1.78	0.0	NS	−1.41	1.48	−0.4	NS	−1.76	0.96
FH to mandibular plane (°)	0.2	2.8	−0.9	2.0	−1.3	2.0	.049	1.0	NS	−0.34	2.42	1.5	*	0.02	2.97	0.5	NS	−0.93	1.85
Palatal plane to mand. plane (°)	−0.1	3.0	−0.7	2.2	−1.2	1.9	.244	0.6	NS	−0.84	2.03	1.1	NS	−0.45	2.62	0.5	NS	−0.95	1.94
Co-Go-Me (°)	0.8	4.4	−0.5	2.3	−0.6	2.8	.185	1.4	NS	−0.60	3.30	1.4	NS	−0.70	3.47	0.0	NS	−1.94	2.00
Dentoalveolar																			
Overjet (mm)	−8.0	2.9	−5.1	2.1	−0.1	0.7	.000	−3.0	***	−4.24	−1.67	−7.9	***	−9.32	−6.58	−5.0	***	−6.29	−3.70
Overbite (mm)	−3.3	3.0	−3.1	2.0	−0.1	1.0	.000	−0.1	NS	−1.44	1.19	−3.2	***	−4.58	−1.76	−3.0	***	−4.38	−1.72
Molar relationship (mm)	5.0	1.4	3.5	1.6	0.2	1.3	.000	1.5	***	0.62	2.39	4.8	***	3.84	5.73	3.3	***	2.39	4.17
Max. inc. to FH (°)	−6.3	7.7	0.2	8.0	0.0	3.4	.000	−6.5	***	−10.64	−2.40	−6.3	**	−10.67	−1.84	0.3	NS	−3.90	4.43
Mand. inc. to mand. plane (°)	3.3	3.4	6.2	5.9	0.6	3.1	.000	−2.9	*	−5.60	−0.21	2.7	NS	−0.19	5.58	5.6	***	2.87	8.32

[a] NS indicates not significant; * $P < .005$; ** $P < .01$; *** $P < .001$; Ctrl = control; max. = maxillary; mand. = mandibular; inc. = incisor; FH = Frankfort horizontal.

with respect to the untreated Class II controls. The lack of significant mandibular skeletal modification might have been due to the short duration of active FRD treatment (on average, less than 6 months).[4,17]

As for vertical skeletal changes, the TB induced a significant posterior rotation of the mandible with respect to the control sample (FH to mandibular plane, 1.5°), while the FRD group did not show any significant difference in angular measurements compared with the control group. Singh et al.[9] found a similar trend toward an increase in vertical skeletal relationships in the TB sample treated during the pubertal growth spurt with respect to controls, though it did not reach statistical significance (FMA, 1.8°). Our findings confirm those reported by other investigators, who found that the FRD did not produce any significant change in vertical skeletal relationships.[4,5]

Both treatment protocols were effective in significantly reducing both overjet (−7.9 mm and −5.0 mm, respectively) and overbite (−3.2 mm and −3.0 mm, respectively) and in improving molar relationships (4.8 mm and 3.3 mm, respectively) compared with controls. The TB produced a significantly greater reduction in overjet (−3.0 mm) and a significantly greater improvement in molar relationship (1.5 mm) than did the FRD. The overjet correction in the TB sample could be attributed mainly to significant retroclination of the maxillary incisors compared with either the FRD sample (−6.5°) or the control group (−6.3°). It should be noted, however, that the TB group required a greater correction of both overjet and maxillary incisor inclination with respect to the FRD group (Table 1).

On the contrary, overjet reduction in the FRD group was associated with a significant proclination of the mandibular incisors with respect to both the TB sample (2.9°) and the control group (5.6°). A similar amount of mandibular incisor proclination has been reported previously.[4,5]

This proclination, which was about double that reported for the TB group vs controls (2.7°), could have contributed to the smaller amount of mandibular growth and advancement with respect to the TB group. It appears prudent clinically to prevent incisor proclination when using the FRD in order to increase mandibular skeletal changes produced by this appliance. Recently, the use of miniscrew anchorage in the mandibular anterior region has been proposed to limit flaring of the incisors.[18] Proclination of the mandibular incisors was effectively minimized by using miniscrews (L1/MP, 3.6° in the FRD and miniscrew group vs 9.3° in the FRD group with no miniscrews), although the duration of treatment was relatively short (6 months).

CONCLUSIONS

- Both treatment protocols (TB and FRD) were effective in correcting Class II malocclusion, with over an 80% success rate noted in consecutively treated patients in both groups.
- The TB produced greater skeletal effects than did the FRD in terms of mandibular advancement and growth stimulation.
- The Class II correction induced by the FDR was more dentoalveolar than was the TB, with a large amount of proclination of the mandibular incisors.

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