Effectiveness of comprehensive fixed appliance treatment used with the Forsus Fatigue Resistant Device in Class II patients

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ABSTRACT

Objective: To assess the dental, skeletal, and soft tissue effects of comprehensive fixed appliance treatment combined with the Forsus Fatigue Resistant Device (FRD) in Class II patients.

Materials and Methods: Thirty-two Class II patients (mean age 12.7 ± 1.2 years) were treated consecutively with the FRD protocol and compared with a matched sample of 27 untreated Class II subjects (mean age 12.8 ± 1.3 years). Lateral cephalograms were taken before therapy and at the completion of comprehensive therapy. The mean duration of comprehensive treatment was 2.4 ± 0.4 years. Statistical comparisons were carried out with the Student's t-test ($P < .05$).

Results: The success rate was 87.5%. The FRD group showed a significant restraint in the sagittal skeletal position of the maxilla (also at the soft tissue level), a significant increase in mandibular length, and a significant improvement in maxillo-mandibular sagittal skeletal relationships. The treated group exhibited a significant reduction in overjet and a significant increase in molar relationship. The lower incisors were significantly proclined and intruded, while the lower first molars moved significantly in a mesial and vertical direction.

Conclusions: The FRD protocol is effective in correcting Class II malocclusion with a combination of skeletal (mainly maxillary) and dentoalveolar (mainly mandibular) modifications. (*Angle Orthod.* 2011;81:678–683.)

KEY WORDS: Class II malocclusion; Fixed functional appliances; Cephalometrics

INTRODUCTION

Class II malocclusion is the most frequent sagittal problem in orthodontics, as it affects one third of the population.[1] One of the recommended therapeutic approaches to Class II malocclusion in growing patients is functional jaw orthopedics through the primary mechanism of mandibular advancement.[2]

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Fixed devices for sagittal advancement of the mandible that do not require the patient's collaboration and that can be worn in association with fixed appliances have been introduced to the orthodontic community in order to overcome two major limitations of removable functional appliances: the need for patient collaboration and the lack of the possibility of combining the use of the functional appliance with multibracket therapy in order to shorten treatment duration.[3]

The effects of several compliance-free appliances for mandibular anterior repositioning in association with fixed appliances have been investigated in the literature. The Eureka Spring proved to be efficient in correcting Class II malocclusions without increasing the vertical dimension.[4] The Jasper Jumper appliance produced very similar outcomes by improving both the skeletal imbalance and the profile in growing Class II patients.[5] Very recently, Jena and Duggal[6] reported a combination of favorable maxillary and mandibular dentoskeletal effects leading to correction of Class II malocclusion induced by the Mandibular Protraction Appliance-IV. An increasingly popular fixed functional appliance is the Forsus device. The Forsus (also
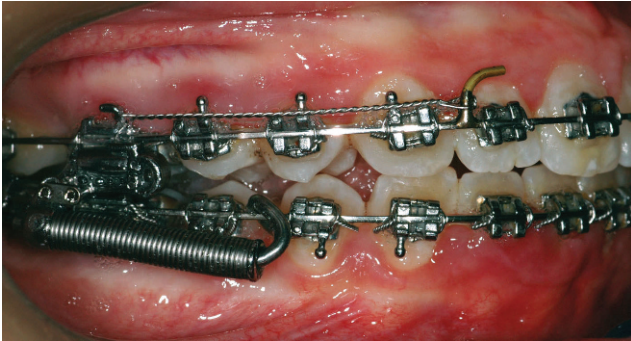
Figure 1. Forsus Fatigue Resistant Device (FRD) in association with complete fixed orthodontic appliances.

known as the Forsus Fatigue Resistant Device [FRD]) is a semirigid telescoping system incorporating a superelastic nickel-titanium coil spring that can be assembled chair-side, and it can be used in conjunction with complete fixed orthodontic appliances (Figure 1). The FRD attaches at the maxillary first molar and onto the mandibular archwire, distal to either the canine or first premolar bracket (the latter option making the appliance less visible and more comfortable). The clinical application of the FRD was described by Vogt[7] in 2006 and was evaluated in a sample of 34 Class II patients (in comparison with a group treated with fixed appliances and Class II elastics) by Jones et al.[8] in 2008. No previous study assessed the effectiveness of FRD when compared with untreated Class II controls.

The aim of the present controlled clinical trial was to evaluate the dentoskeletal outcomes of FRD in combination with fixed appliances in a group of consecutively treated Class II growing patients. Main features of the study include the comparison with matched untreated Class II controls; the use of FRD during the circumpubertal ages; and the appraisal of dental, skeletal, and soft tissue profile changes at the end of comprehensive treatment.

SUBJECTS AND METHODS

Study Design

A sample of 32 subjects with Class II division 1 malocclusion (overjet larger than 5 mm, full Class II or Class II tendency molar relationship, and ANB larger than 3°) was treated consecutively at a single private practice by one of the authors. All treated patients were in the permanent dentition at the start of treatment, and they underwent a specific treatment protocol with preadjusted fixed appliances in combination with the FRD. The FRD was applied at the end of the aligning and leveling phase of orthodontic treatment, when a 0.019 × 0.025–inch stainless-steel archwire was inserted at both arches. The mandibular

archwire was consistently cinched distal to the molars. In addition, brackets on the lower incisors presented with a torque of −6° to limit the buccal inclination of the lower incisors. The management of the maxillary archwire varied according to the individual need in terms of upper molar distalization. The rods of the FRD were placed on the mandibular archwire distal to the first bicuspids.

The phase with the FRD was undertaken until Class II occlusion was overcorrected to an edge-to-edge incisor relationship. The mean duration of the FRD active phase was 5.2 ± 1.3 months. Thereafter, fixed appliances were maintained in order to finalize the occlusion. Comprehensive treatment of Class II malocclusion was performed during the circumpubertal phases of skeletal development, as assessed with the cervical vertebral maturation method.[9] Lateral cephalograms taken before (T1) and after (T2) treatment were analyzed, with T1 corresponding to the initiation of therapy with the fixed appliances and T2 corresponding to the completion of the comprehensive treatment.

A sample of 27 subjects was selected from the files of the University of Michigan Growth Study (12 subjects) and of the Denver Child Growth Study (15 subjects); subjects presented with the same dentoskeletal characteristics and skeletal maturational levels at T1 as did the FRD sample subjects. The duration of T1-T2 observation interval in the control group matched the T1-T2 interval of the treatment group. Differences in the male:female ratios in treatment vs control groups were not significant (chi-square = 0.744; $P = .388$) in order to avoid the effects of sexual dimorphism on craniofacial size and changes. Mean ages at T1 and T2, mean duration of T1-T2 intervals, gender distribution, and skeletal maturation during treatment or observation intervals for both treatment and control groups are shown in Table 1.

The examiners who analyzed lateral cephalograms of treated and control patients before and after treatment were blind with regard to the origin of the films and the group to which individual subjects belonged. The T2 observations were collected and analyzed, regardless of the treatment outcomes, in terms of correction of Class II malocclusion in the individual patients. This allowed for a further reduction in potential selection biases in the study.

Cephalometric Analysis

Evaluation of dentoskeletal relationships. A customized digitization regimen and analysis provided by cephalometric software (Viewbox, ver 3.0, dHAL Software, Kifissia, Greece) were utilized for all of the cephalograms that were examined in this study. The

Table 1. Demographics for the Treated and Untreated Class II Groups[a]

	n	Female	Male	Prepubertal	Pubertal	Postpubertal	Age at T1, y		Age at T2, y		T1-T2 Interval, y	
							Mean	SD	Mean	SD	Mean	SD
FRD group	32	13	19	2	14	16	12.7	1.2	15.1	1.0	2.4	0.4
Control group	27	14	13	–	12	15	12.8	1.3	15.3	1.4	2.6	0.9

[a] T1 indicates before treatment; T2, after treatment; SD, standard deviation; and FRD, Forsus Fatigue Resistant Device.

customized cephalometric analysis containing measurements from the analyses of Steiner,[10] Jacobson,[11] Ricketts,[12] and McNamara[13] was used and generated 33 variables, 11 angular and 22 linear, for each tracing. For the analysis of the soft tissue profile changes the method of Arnett et al.[14] was used, with modifications (Figure 1).[15]

Error of the method. A total of 40 lateral cephalograms randomly chosen from all observations were re-traced in random order and re-digitized to calculate method error by means of the Dahlberg's formula.[16] The operator who re-traced and re-digitized the cephalograms was blinded with regard to time period and group. The error for linear measurements ranged from 0.25 mm (overjet) to 0.75 mm (Pg to Nasion perpendicular), while the error for angular measurements varied from 0.35° (ANB) to 1.40° (interincisal angle).

The assessment of the stages in cervical vertebral maturation[9] on lateral cephalograms for each subject was performed by one investigator and then verified by a second. Any disagreements were resolved to the satisfaction of both observers.

The magnification values of the data sets with regard to the treated Class II patients and the untreated Class II subjects were different, with the lateral cephalograms of treated subjects showing 0% enlargement and those from the control group showing a magnification of either 12.1% (UMGS) or 4% (DCGS). The lateral cephalograms of all treated and untreated subjects were corrected to match an 8% enlargement factor.

Statistical Analysis

Descriptive statistics of craniofacial measurements in all treated and untreated Class II samples at T1 and T2 were calculated, as were the between-stage changes. Kolmogorov-Smirnov test revealed normality of distribution for the measurements used in the study. Therefore, parametric statistics (Student's *t*-test for independent samples) were utilized (SPSS Version 12.0, SPSS Inc, Chicago, Ill). The following comparisons were carried out for the dentoskeletal variables:

- Treated group vs untreated group at T1 (comparison on starting forms); and
- T2-T1 changes in treated group vs untreated group (dentoskeletal and soft tissue profile variables).

The power of the study was calculated on the basis of the sample size of the two groups and of an effect size equal to 1.[17] The power exceeded 0.90 at an alpha level of .05.

RESULTS

The statistical comparison on starting forms for hard tissue measurements between the two groups did not reveal any significant differences, with the exception of the FH to palatal plane measurement, which yielded a greater value in the controls (3.2°).

Results for statistical comparisons on the T2-T1 changes for the FRD group and the Class II untreated controls are shown in Table 2. The statistical comparison showed a significant restraint in the sagittal skeletal position of the maxilla (SNA, Pt A to Nasion perp, and Co-A). The increase in effective mandibular length (Co-Gn) was significantly greater in the FRD group when compared to natural growth changes in Class II controls. Comparison of changes in intermaxillary relationships revealed a significantly greater decrease in ANB angle and Wits appraisal as well as a significant increase in the maxillo-mandibular differential in the treatment group. With regard to changes in vertical skeletal relationships, the increase in lower anterior facial height (ANS to Me) was significantly greater in the treatment group compared to the untreated controls.

With regard to the interdental changes, the treatment group exhibited a significant reduction in overjet, overbite, and interincisal angle, as well as a significant improvement in molar relationship. A significantly more retruded position of the upper incisors (U1 to Pt A vertical and U1 horizontal) was assessed in the treated group, as was a greater vertical eruption of the upper incisors (U1 vertical). All of the changes in the mandibular dentoalveolar parameters were statistically significant in the FRD group when compared with the untreated control group. As a result of therapy the lower incisors were significantly proclined and intruded, while the lower first molars extruded significantly and moved significantly in a mesial direction.

The analysis of the changes in the soft tissue measurements between treated Class II patients and untreated controls showed significantly greater backward movement of the soft tissue A point in the FRD group.

Table 2. Descriptive Statistics and Statistical Comparisons of the Pretreatment (T1)–Posttreatment (T2) Changes Between Class II Patients Treated With Forsus Fatigue Resistant Device (FRD)/Fixed Appliances and Untreated Class II Controls[a]

Cephalometric Measures	FRD Group (N = 32)		Control Group (N = 27)		Difference	P	Significance
	Mean	SD	Mean	SD			
Cranial base							
NSBa, °	0.8	2.0	−0.2	1.8	1.0	0.052	NS
Maxillary skeletal							
SNA, °	−1.6	1.4	0.5	1.3	−2.1	0.000	***
Pt A to Nasion perp, mm	−0.7	1.8	0.5	1.1	−1.2	0.005	**
Co-Pt A, mm	2.2	2.4	3.6	2.2	−1.4	0.032	*
Mandibular skeletal							
SNB, °	0.3	1.4	0.7	0.9	−0.4	0.151	NS
Pg to Nasion perp, mm	2.2	3.7	1.8	2.2	0.4	0.603	NS
Co-Gn, mm	7.5	3.4	5.7	1.7	1.8	0.014	*
Co-Go, mm	5.8	3.6	4.3	2.8	1.5	0.071	NS
Maxillary/mandibular							
ANB, °	−1.9	1.2	−0.2	0.8	−1.7	0.000	***
WITS, mm	−2.0	3.0	0.5	1.5	−2.5	0.000	***
Maxillary/mandibular difference, mm	5.1	2.5	2.7	1.7	2.4	0.000	***
Vertical skeletal							
FH to palatal plane, °	−0.1	1.2	−0.2	1.4	0.1	0.922	NS
FH to mandibular plane, °	−1.1	2.2	−1.2	1.5	0.1	0.922	NS
Palatal plane to mandibular plane, °	−1.0	2.2	−1.0	2.3	0.0	0.994	NS
ArGoMe, °	−1.4	2.6	−1.6	2.2	0.2	0.807	NS
CoGoMe, °	−0.4	2.2	−0.6	2.0	0.2	0.690	NS
N to ANS, mm	2.8	2.2	2.1	1.4	0.7	0.114	NS
ANS to Me, mm	4.0	2.6	2.7	1.4	1.3	0.012	*
Interdental							
Overjet, mm	−5.4	2.0	0.1	1.1	−5.5	0.000	***
Overbite, mm	−2.5	2.0	−0.1	1.0	−2.4	0.000	***
Interincisal angle, °	−3.8	12.6	2.3	5.1	−6.1	0.016	*
Molar relationship, mm	3.4	1.3	0.0	1.4	3.4	0.000	***
Maxillary dentoalveolar							
U1 to Pt A vertical, mm	−1.2	2.3	0.2	0.9	−1.4	0.003	**
U1 to FH, °	−1.2	8.9	−0.9	2.6	−0.3	0.865	NS
U1 horizontal, mm	−1.1	2.3	0.4	1.0	−1.5	0.002	**
U1 vertical, mm	1.6	1.7	0.6	0.9	1.0	0.011	*
U6 horizontal, mm	1.0	1.5	1.4	1.1	−0.4	0.234	NS
U6 vertical, mm	1.6	1.5	1.6	0.8	0.0	0.989	NS
Mandibular dentoalveolar							
L1 to Pt A-pogonion, mm	3.4	2.0	−0.2	1.1	3.6	0.000	***
L1 to mandibular plane, °	6.1	6.3	0.9	4.1	5.2	0.001	**
L1 horizontal, mm	2.3	2.0	−0.2	1.6	2.5	0.000	***
L1 vertical, mm	−0.5	1.4	1.5	1.1	−2.0	0.000	***
L6 horizontal, mm	2.4	1.6	0.9	1.5	1.5	0.000	***
L6 vertical, mm	3.6	1.5	1.4	1.1	2.2	0.000	***
Soft tissue							
A′-VL, mm	−0.8	1.1	0.3	1.2	−1.1	0.000	***
B′-VL, mm	1.8	2.3	0.5	2.7	1.3	0.051	NS
Pg′-VL, mm	0.9	2.6	0.4	2.9	0.5	0.488	NS

[a] SD indicates standard deviation; NS, not significant.
* $P < .05$; ** $P < .01$; *** $P < .001$.

DISCUSSION

The aim of the present study was to assess the dental, skeletal, and soft tissue changes produced by a fixed interarch appliance for Class II treatment, the FRD, within a comprehensive orthodontic treatment with preadjusted fixed appliances. Significant features of this study were the analysis of patients treated consecutively by a single operator and the blind methodology employed in the analysis of the data, in conjunction with the use of an historical sample of untreated Class II controls at the same skeletal maturation phases as the treated subjects, for the evaluation of treatment effectiveness vs physiological growth in Class II malocclusion. The methodology used reduced the potential selection and proficiency biases of the study. Furthermore, the treated and control groups exhibited very similar characteristics in terms of responsiveness to mandibular growth stimulation, as assessed by the pretreatment Co-Go-Me angle.[18] Both groups showed a prevalence rate of "good responders" (Co-Go-Me smaller than 125.5°) of about 81%. This similarity controlled for a potential susceptibility bias on the basis of pretreatment morphological characteristics.

While not ideal, the use of historical controls with untreated Class II malocclusions was due mainly to the ethical issue involved in leaving subjects with full-cusp Class II malocclusions without orthodontic treatment during the pubertal and postpubertal stages of development, a biological period that has been demonstrated[19–21] to be associated with the most favorable treatment effects in Class II patients.

The treatment regimens proved to be effective on occlusal parameters. A net reduction of 5.5 mm was recorded for the overjet, while a net improvement of 3.4 mm was obtained for the molar relationship. In terms of overall correction of Class II division 1 malocclusion, the success rate (87.5%) was very high in the treated group; this value is very similar to those reported[22] for other comprehensive Class II treatment modalities incorporating either the Herbst appliance or headgear and Class II elastics.

The most relevant skeletal changes occurred in the maxillary region, and they were confirmed by all the angular and linear measurements used in the present study. These changes revealed a significant effect of the FRD protocol in restraining sagittal growth of the maxilla, ranging from 1.2 mm for Pt A to Nasion perp to −2.1° for SNA. A significant improvement in the sagittal position of the maxillary soft tissues was recorded in the treated group as well. The maxillary changes accounted for significant improvements in maxillo-mandibular sagittal relationships that ranged from −1.7° for the ANB angle to −2.5 mm for the Wits appraisal.

The FRD protocol also induced a significantly (1.8 mm) greater increase in total mandibular length (Co-Gn) with respect to untreated controls. However, this favorable skeletal change was not associated with a significant improvement in the sagittal position of the bony and soft tissue chin.

The dentoalveolar changes were highly significant both at the maxillary and mandibular arches. The upper incisors demonstrated a significant, though modest, amount of retrusion and extrusion (≤1.5 mm). On the other hand, the lower incisors exhibited a large amount of proclination (5.2°), forward movement (2.5 mm), and intrusion (2.0 mm). The mandibular first molars also showed a significant amount of mesial movement (1.5 mm) and extrusion (2.2 mm). These outcomes are similar to those reported by Jones et al.[8] for both the FRD and Class II elastics.

A general overview of the effects of Class II treatment with fixed appliances and FRD leads to the consideration that skeletally one of the main outcomes of this protocol consists of a significant restraint in the sagittal position of the maxilla. This effect has been reported previously for the Herbst appliance in combination with fixed appliances at puberty,[22] for the FRD without controls,[8] and for the Jasper Jumper appliance.[5] The skeletal maxillary effect was reflected also by a modest, though significant, improvement in the sagittal position of the maxillary soft tissues. On the other hand, the skeletal outcomes of the FRD protocol with regard to the mandible appeared to be rather limited. Although an enhancement in total mandibular length of about 2 mm was found in the treated group vs the untreated controls, this growth modification did not significantly affect the sagittal position of either the bony or soft tissue chin. The lack of a significant effect of the FRD on the sagittal position of the chin might be correlated with the short duration of active treatment (on average less than 6 months).[23]

The changes at the dentoalveolar level showed a reverse pattern with respect to the skeletal changes. In fact, the upper incisor exhibited modest changes, while the mandibular dentition displayed highly significant modifications. The FRD protocol produced a large amount of mesial movement of the lower arch, with proclination of the lower incisors. This effect occurred in spite of the cinching back of the mandibular archwire distal to the molars and despite the torque of −6° embedded in the brackets on the lower incisors. It is therefore recommended that practitioners implement all those procedures that can prevent the proclination and protrusion of the lower incisors during treatment (the use of mandibular rectangular archwires of greater size, the addition of a negative torque also to the archwire in the lower incisor region, etc).

The outcomes reported in the current study refer to the end of comprehensive Class II treatment, without follow-up observation. However, it should be noted that more than half of the patients in the FRD group completed their treatment protocols at very advanced postpubertal stages in skeletal maturation (CS5 or CS6). The amount of craniofacial growth occurring after those stages is very limited in Class II subjects, and, more importantly, growth differences between Class II and normal occlusion subjects after late puberty are insignificant.[24] When orthodontic therapy of Class II malocclusion is completed at late puberty, close to completion of active craniofacial growth, relapse tendency due to a reestablishment of Class II growth characteristics is expected to occur less often.[24,25]

CONCLUSIONS

- The FRD protocol led to a successful correction of Class II malocclusion in 87.5% of the patients.
- The protocol had a greater skeletal effect on the maxillary structures by restraining the sagittal advancement of the maxilla.
- The effects on the mandible were mainly at the dentoalveolar level, with a large amount of mesial movement of the lower incisors and first molars.

ACKNOWLEDGMENT

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