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Original article

Treatment timing for functional jaw orthopaedics followed by fixed appliances: a controlled long-term study

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Summary

Objective: To evaluate the role of treatment timing on long-term dentoskeletal effects of Class II treatment with removable functional appliances followed by full-fixed appliance therapy.
Materials and methods: A group of 46 patients (23 females and 23 males) with Class II malocclusion treated consecutively with either Bionator or Activator, followed by fixed appliances was compared with a matched control group of 31 subjects (16 females and 15 males) with untreated Class II malocclusion. The treated sample was evaluated at T1, start of treatment (mean age: 9.9 ± 1.3 years); T2, end of functional treatment and prior to fixed appliances (mean age: 11.9 ± 1.3 years); and T3, long-term observation (mean age: 18.3 ± 2.1 years). The treated and the control samples were divided into pre-pubertal and pubertal groups according to skeletal maturity observed at the start of treatment. Statistical comparisons were performed with independent sample *t*-tests.
Results: When treatment was initiated before puberty, Class II correction was mostly confined to the dentoalveolar changes, with significant improvements of both overjet and molar relationships. On the other hand, treatment with the outset at puberty produced significant long-term improvement of sagittal skeletal relationships, which were mainly sustained by mandibular changes.
Conclusions: Treatment with removable functional appliances (Bionator or Activator) followed by full-fixed appliances produced significant skeletal long-term changes when it begins at puberty. Prepubertal Class II treatment results primarily in dentoalveolar changes.

Introduction

Class II malocclusion is one of the most common orthodontic problems, as it occurs in about one-third of the population (1–3). This malocclusion has been extensively studied regarding skeletal and dental characteristics, timing, and methods of treatment (4–7). When Class II, division 1 malocclusion is associated with mandibular skeletal retrusion, a viable treatment option is the alteration of the amount and direction of mandibular growth by using functional appliances (8, 9). Several studies in the literature have investigated the mechanisms of action and the effects of functional jaw orthopaedics (FJO) in Class II division 1 malocclusion (4). Despite controversies on the efficacy of functional therapy, recent systematic reviews and meta analyses have shown that, in the short term, FJO produces greater skeletal mandibular effects when performed at puberty (7, 10). On the other hand, in Class II patients treated before the pubertal period, the significant effects are confined to the dentoalveolar level (11–15).

Few controlled studies have followed up the long-term effects produced by FJO (9, 16–18). Information on the role of treatment timing on the long-term effects produced by FJO is even more restricted. Faltin *et al.* (14) found significantly greater mandibular skeletal long-term changes in pubertal versus pre-pubertal Class II patients. However, these findings were not conclusive due to the small sample sizes of either pre-pubertal or pubertal treated and control groups.

The purpose of the current investigation study was to evaluate the role of treatment timing on the long-term dentoskeletal effects of Class II treatment with functional appliances (Bionator or Activator) followed by fixed appliances.

Materials and Methods

The study project was approved by the Ethical Committee at the University of Rome Tor Vergata (201/16), and informed consent was obtained from the subjects' parents.

Sample size was calculated using the sagittal position of the chin (Pg to Nasion perpendicular) as the primary outcome variable. In a previous long-term study (17), the combined standard deviation between early treated and late treated groups was 2.8 mm. If a clinically significant long-term difference between the treated and control means is set at 3.0 mm, a minimum sample size of 15 subjects in either treated or control groups is required to reject the null hypothesis that the population means of the treated and control groups are equal with probability (power) of 0.8. The Type I error was set at 0.05 (PS Power and Sample Size Calculations, Version 3.0).

Cephalometric records of 46 patients (23 females and 23 males) with Class II division 1 malocclusion consecutively treated either with the Bionator (26 subjects) or Activator (20 subjects) were collected. Class II patients were retrieved from an orthodontic practice (Bionator) and from the records of patients treated in the Department of Orthodontics at the University of Rome Tor Vergata (Activator). Inclusion criteria consisted of an overjet greater than 5 mm, full Class II or end-to-end molar relationships, ANB angle greater than 4 degrees, and an improvement in facial profile when the lower jaw was postured in a forward position (19). Moreover, patients had to present with lateral cephalograms available at three time points: T1, at the start of treatment (mean age: 9.9 ± 1.3 years); T2, at the end of FJO and before fixed appliance insertion (mean age: 11.9 ± 1.3 years); and T3, at long-term observation after completion of growth (CS5 or CS6 according to the cervical vertebral maturation method) (20) (mean age: 18.3 ± 2.1 years).

Class II patients received non-extraction treatment protocols consisting of either a Bionator constructed without coverage of the lower incisors (9, 14) or an acrylic monobloc attached to the upper arch by Adams clasps and with capping of the upper and lower incisors (21). Treatment with functional appliances was discontinued with the achievement Class I molar relationships; the second phase of treatment consisted of full-fixed appliance therapy in the permanent dentition. The T3 observations were collected and analysed regardless of the treatment outcomes in terms of correction of Class II malocclusion in the individual patients. This approach contributed in further reducing potential selection bias of the study.

All patients in both the private practice and the University clinic were treated by two expert clinicians. The clinical experience of the two operators in the management of the two functional appliances was similar. All patients involved in the study were asked to wear the appliance 16 hours a day until the end of treatment. As occurs in studies involving any removable device, compliance with the instructions of the orthodontist and staff varied among the patients.

Each Bionator and Activator was constructed with the same amount of mandibular advancement, and the construction bites were obtained in the same way in both groups. In that both the mechanism of action and the efficiency in stimulating mandibular growth of these two monobloc appliances are similar, the decision was made to combine patients treated with the two functional appliances (3).

Thirty-one subjects (16 females, 15 males) with untreated Class II division 1 malocclusion were selected from the American Association of Orthodontists Foundation Craniofacial Growth Legacy Collection (http://www.aaoflegacycollection.org, Bolton–Brush Growth Study, Michigan Growth Study, Denver Growth Study, Oregon Growth Study, and Iowa Growth Study) to comprise the control group. Cephalograms from the AAOF legacy were obtained at high resolution. The magnification factor of each collection was retrieved from the AAOF legacy website.

The treated and the control samples were divided into two groups according to skeletal maturity at the start of treatment evaluated by means of the cervical vertebral maturation (CVM) method (20). The CVM method can be used to identify individual skeletal maturity in growing subjects and it can replace the hand-wrist radiograph (22). CVM staging was performed by an expert examiner.

The demographic data of the early treatment group (ETG), late treatment group (LTG), early control group (ECG), and late control group (LCG) are reported in Table 1.

Lateral cephalograms of each patient and untreated subjects were hand traced at a single sitting by one investigator. Landmark location and accuracy of the anatomical outlines were verified by a second investigator. Any discrepancies as to landmark placement were resolved by mutual agreement. A customized digitization regimen (Viewbox, version 3.0, dHAL Software, Kifissia, Greece) was created and used for cephalometric evaluation.

Lateral cephalograms for each patient at T1, T2, and T3 were digitized, and a custom cephalometric analysis was used. Seventeen variables (8 linear and 9 angular) were generated for each tracing. Lateral cephalograms of treated and control groups at T1, T2, and T3 were first standardized to life size (0%) and after were magnified to 8% enlargement that is the most common magnification factor used orthodontics.

Method Error and Statistical Analysis

As for the method error, 11 subjects from the final samples (33 cephalograms) were selected at random. All films were retraced and digitized a second time by the same observer. Intra-operator agreement for the CVM method was tested with weighted kappa coefficient while the systematic and random errors for the cephalometric variables were analysed with the paired *t*-test and Dahlberg's formula, respectively.

The primary aim of the study was to evaluate the role of treatment timing on the long-term dentoskeletal effects of Class II treatment with functional appliances (Bionator or Activator) followed by fixed appliances. Therefore, statistical between-group comparisons (ETG versus ECG and LTG versus LCG) were calculated for the craniofacial starting forms at T1 and for the T1–T3 changes.

Table 1. Demographics for the treated and control groups.

	Age at T1 (years)		CVM stages at T1	Age at T2 (years)		CVM stages at T2	Age at T3 (years)		CVM stages at T3	T1–T2 interval (years)		T2–T3 interval (years)		T1–T3 interval (years)	
	Mean	SD		Mean	SD		Mean	SD		Mean	SD	Mean	SD	Mean	SD
Early treated group (*n* = 23, 13f 10m)	9.5	1.2	19 CS1 4 CS2	11.4	1.2	5 CS1 6 CS2 12 CS3	17.9	2.3	10 CS5 13 CS6	1.9	0.6	6.5	2.4	8.4	2.5
Early control group (*n* = 16, 5f 11m)	9.4	0.7	9 CS1 7 CS2	11.3	0.7	2 CS1 2 CS2 12 CS3	17.0	1.8	5 CS5 11 CS6	1.9	0.3	5.7	1.9	7.6	1.8
Late treated group (*n* = 23, 10f 13m)	10.2	1.3	6 CS2 17 CS3	12.5	1.2	19 CS4 4 CS5	18.5	2.1	8 CS5 15 CS6	2.3	0.7	6.0	1.9	8.3	2.0
Late control group (*n* = 15, 11f 4m)	10.8	1.1	2 CS2 13 CS3	12.7	1.2	10 CS4 5 CS5	18.3	1.3	3 CS5 12 CS6	1.9	0.4	5.6	1.7	7.5	1.6

In presence of normally distributed data (Kolmogorv–Smirnov test), statistical between-group comparisons were performed with independent sample *t*-tests. If data were not normally distributed, statistical between-group comparisons were carried out with the Mann–Whitney test.

As secondary statistical analysis, between-group comparisons (ETG versus ECG and LTG versus LCG) for the T1–T2 and T2–T3 changes were performed. Finally, comparisons between ETG versus LTG and between ECG versus LCG also were carried out for the craniofacial starting forms at T1 and for the T1–T3 changes.

Results

Weighted kappa coefficient for the intraobserver agreement for the CVM method was 0.959 (95% confidence interval 0.902–1.00). No systematic error was detected for any of the variables. The error for linear measurements ranged from 0.2 mm (OVJ) to 0.9 mm (Wits), while the error for the angular measurements ranged from 0.19° (SN to palatal plane) to 0.88° (CoGoMe). There were no significant differences between ETG and ECG, and between LTG and LCG in the dentoskeletal features at T1 (Tables 2 and 3).

In the long-term evaluation (T1–T3; Table 4), ETG showed a significant decrease in the OVJ (−3.6 mm), as well as a significantly higher improve in molar relationship (+3.9 mm), as compared with respect to ECG. There were no significant between-group differences for any of the skeletal sagittal maxillary and mandibular measures, while a significant increase in facial divergency (SN to Mand Pl +1.9 degrees) was recorded in ETG.

As for the comparisons between LTG and LCG in the long-term interval (T1–T3; Table 5), a significantly higher increase in total mandibular length (Co–Gn +5.5 mm), in addition to a significantly higher increase in chin projection (Pg to N perp +3.1 mm) were observed in LTG. The intermaxillary skeletal sagittal changes were significantly different between groups, as the treated one demonstrated a decrease in Wits measurement (−5.8 mm), as well as a higher decrease in ANB angle (−1.8°). Both lower anterior facial height (ANS–Me) and the mandibular ramus (Co–Go) increased significantly more in LTG (+3.8 and +2.4 mm, respectively). LTG showed a significantly higher decrease in overjet (−3.0 mm) and a significantly higher improvement in molar relationship (+4.4 mm) with respect to LCG.

As secondary analysis, the between-group comparisons in the T1–T2 and T2–T3 intervals are reported in Supplementary Tables 1–4. Finally, comparisons between ETG versus LTG and between ECG versus LCG for the craniofacial starting forms at T1 and for the T1–T3 changes are described in Supplementary Tables 5–8.

Discussion

The aim of the present study was to analyze the role of treatment timing on the skeletal and dentoalveolar effects induced by functional treatment in growing patients with Class II malocclusion versus matched untreated Class II controls. Although historical control groups may be considered as a limitation (23), they were used in the current study for ethical reasons, as it would have been impossible to recruit a contemporary control group of subjects with untreated Class II malocclusion for long-term observation. A recent investigation (24) showed that trials with historical controls showed smaller treatment effects compared to trials with concurrent controls. In other words, historical controls do not seem to amplify treatment effects with respect to concurrent controls. Another limitation of the current study is its retrospective nature.

Table 2. Descriptive statistics and statistical comparisons (independent samples *t*-tests) of the starting forms (cephalometric values at T1) in the early treated group (ETG) versus the early control group (ECG).

	ETG		ECG				95% CI of the difference	
Variables	Mean, *median*	SD, *25/75*	Mean, *median*	SD, *25/75*	Diff.	*P* value	Lower	Upper
SNA (deg)	81.0	2.6	79.6	2.7	1.4	0.118	−0.4	3.2
SNB (deg)	74.7	2.8	74.0	2.3	0.7	0.417	−1.0	2.4
Pg to N perp (mm)	−7.7	4.8	−7.9	5.8	0.2	0.880	−3.2	3.7
Co–Gn (mm)	106.2	6.4	104.2	3.8	2.0	0.262	−1.6	5.7
ANB (deg)	6.3	1.9	5.6	1.5	0.7	0.235	−0.5	1.9
Wits (mm)	1.9	3.1	1.8	2.5	0.1	0.947	−1.8	1.9
SN to Pal. Pl. (deg)	8.7	3.2	8.1	2.4	0.6	0.532	−1.3	2.5
SN to Mand. Pl. (deg)	35.7	5.5	35.0	3.1	0.7	0.648	−2.4	3.8
Pal. Pl. to Mand. Pl. (deg)	*28.3*	22.6/30.6	*28.3*	25.0/29.8	0.0	0.767		
ANS–Me (mm)	63.2	4.6	62.6	4.1	0.6	0.682	−2.3	3.5
Co–Go (mm)	50.2	4.6	50.0	3.7	0.2	0.864	−2.6	3.1
CoGoMe (deg)	124.5	6.4	124.7	4.2	−0.2	0.892	−3.9	3.4
OVJ (mm)	7.4	2.0	6.3	1.7	1.1	0.069	−0.1	2.4
OVB (mm)	2.8	2.6	3.3	2.5	−0.5	0.560	−2.2	1.2
Molar relationship (mm)	−2.0	1.4	−1.6	1.1	−0.4	0.304	−1.3	0.4
Upper Inc. to Pal. Pl. (deg)	112.7	5.9	110.6	4.7	2.1	0.252	−1.5	5.7
Lower Inc. to Mand. Pl. (deg)	97.2	7.3	96.4	4.3	0.8	0.682	−3.3	5.0

SD, standard deviations; Diff., differences; 25/75, 25th/75th percentile; CI, confidence interval; perp., perpendicular; deg, degrees; Pal., palatal; Pl., plane; Mand., mandibular; Inc., incisor.

Table 3. Descriptive statistics and statistical comparisons (independent samples *t*-tests) of the starting forms (cephalometric values at T1) in the late treated group (LTG) versus the late control group (LCG).

	LTG		LCG				95% CI of the difference	
Variables	Mean, *median*	SD, *25/75*	Mean, *median*	SD, *25/75*	Diff.	*P* value	Lower	Upper
SNA (deg)	81.7	4.1	81.7	2.7	0.0	0.943	−2.3	2.5
SNB (deg)	74.6	3.7	75.5	2.5	−0.9	0.409	−3.1	1.3
Pg to N perp (mm)	−9.0	5.3	−5.7	5.7	−3.3	0.079	−7.0	0.4
Co–Gn (mm)	107.3	5.8	106.6	6.2	0.7	0.722	−3.3	4.7
ANB (deg)	7.2	1.8	6.2	1.6	1.0	0.093	−0.2	2.2
Wits (mm)	3.6	3.1	2.5	3.0	1.1	0.328	−1.1	3.1
SN to Pal. Pl. (deg)	9.0	1.7	7.2	3.7	1.8	0.089	−0.3	4.0
SN to Mand. Pl. (deg)	35.0	4.6	32.6	5.1	2.4	0.138	−0.8	5.6
Pal. Pl. to Mand. Pl. (deg)	25.9	4.1	25.4	5.3	0.5	0.712	−2.5	3.6
ANS–Me (mm)	64.9	3.8	62.3	4.1	2.6	0.054	0.0	5.3
Co–Go (mm)	51.5	4.2	51.6	5.6	−0.1	0.903	−3.4	3.0
CoGoMe (deg)	123.5	4.2	121.6	4.5	1.9	0.197	−1.0	4.8
OVJ (mm)	*7.4*	6.2/8.1	*6.3*	5.9/7.5	1.1	0.107		
OVB (mm)	3.9	1.6	3.1	1.2	0.8	0.116	−0.2	1.7
Molar relationship (mm)	−2.3	1.7	−1.4	1.3	−0.9	0.088	−2.0	0.1
Upper Inc. to Pal. Pl. (deg)	112.6	4.8	113.2	5.7	−0.6	0.752	−4.0	2.9
Lower Inc. to Mand. Pl. (deg)	99.0	5.6	96.9	7.3	2.1	0.328	−2.2	6.3

SD, standard deviations; Diff., differences; 25/75, 25th/75th percentile; CI, confidence interval; perp., perpendicular; deg, degrees; Pal., palatal; Pl., plane; Mand., mandibular; Inc., incisor.

There were no differences between the treated and control groups in race, chronologic age, gender distribution, cervical stage maturation, or dentoskeletal relationships at T1.

Mandibular skeletal effects produced by functional therapy of Class II malocclusions in growing subjects remain a controversial topic in orthodontics. A recent systematic review and meta-analysis (7) pointed out that treatment with removable functional appliances can produce clinically relevant skeletal effects in the short term when it is performed during the pubertal growth phase. Only one study with small sample sizes of either treated or control groups analysed the role of treatment timing on the long-term dentoskeletal changes induced by the Bionator (14).

The results of the present study confirmed that treatment timing plays a major role also on the long-term mandibular skeletal changes produced by treatment with functional appliances (Activator or Bionator) followed by fixed appliances in the permanent dentition.

Table 4. Descriptive statistics and statistical comparisons (independent samples *t*-tests) of the T1–T3 changes in the early treated group (ETG) versus the early control group (ECG).

	ETG		ECG				95% CI of the difference	
Variables	Mean	SD	Mean	SD	Diff.	*P* value	Lower	Upper
SNA (deg)	−0.2	2.0	0.6	1.6	−0.8	0.177	−2.0	0.4
SNB (deg)	1.4	2.0	2.2	1.6	−0.8	0.209	−2.0	0.4
Pg to N perp (mm)	4.3	3.8	3.4	4.1	0.9	0.479	−1.7	3.5
Co–Gn (mm)	16.8	4.6	17.5	4.7	−0.7	0.632	−3.8	2.3
ANB (deg)	−1.6	1.2	−1.6	1.1	0.0	0.859	−0.8	0.7
Wits (mm)	−0.5	2.9	1.2	3.5	−1.7	0.098	−3.8	0.3
SN to Pal. Pl. (deg)	0.9	2.2	0.3	1.5	0.6	0.393	−0.7	1.8
SN to Mand. Pl. (deg)	−1.6	2.3	−3.5	2.1	1.9	0.012	0.4	3.4
Pal. Pl. to Mand. Pl. (deg)	−2.5	2.8	−3.9	2.4	1.4	0.108	−0.3	3.1
ANS–Me (mm)	8.7	3.0	8.8	2.8	−0.1	0.947	−2.0	1.9
Co–Go (mm)	10.9	4.6	11.8	2.7	−0.9	0.482	−3.5	1.7
CoGoMe (deg)	−3.0	1.7	−3.7	2.3	0.7	0.346	−0.7	1.9
OVJ (mm)	−4.3	1.8	−0.7	1.9	−3.6	0.000	−4.8	−2.4
OVB (mm)	0.1	1.9	0.6	2.2	−0.5	0.421	−1.9	0.8
Molar relationship (mm)	4.4	1.3	0.5	1.7	3.9	0.000	2.9	4.8
Upper Inc. to Pal. Pl. (deg)	−2.6	7.7	−0.1	6.1	−2.5	0.290	−7.2	2.2
Lower Inc. to Mand. Pl. (deg)	0.2	3.8	2.3	3.8	−2.1	0.093	−4.7	0.4

SD, standard deviations; Diff., differences; CI, confidence interval; perp., perpendicular; deg, degrees; Pal., palatal; Pl., plane; Mand., mandibular; Inc., incisor.

Table 5. Descriptive statistics and statistical comparisons (independent samples *t*-tests) of the T1–T3 changes in the late treated group (LTG) versus the late control group (LCG).

	LTG		LCG				95% CI of the difference	
Variables	Mean, *median*	SD, *25/75*	Mean, *median*	SD, 25/75	Diff.	*P* value	Lower	Upper
SNA (deg)	−1.3	2.7	−0.6	2.0	−0.7	0.391	−2.4	1.0
SNB (deg)	2.1	2.1	1.0	1.9	1.1	0.105	−0.2	2.5
Pg to N perp (mm)	6.8	2.3	3.7	3.4	3.1	0.001	1.3	5.0
Co–Gn (mm)	20.5	3.7	15.0	2.5	5.5	0.000	3.3	7.7
ANB (deg)	−3.4	1.5	−1.6	1.4	−1.8	0.001	−2.8	−0.8
Wits (mm)	−4.0	3.9	1.8	3.7	−5.8	0.000	−8.3	−3.2
SN to Pal. Pl. (deg)	−0.1	2.1	0.2	1.4	−0.3	0.630	−1.6	1.0
SN to Mand. Pl. (deg)	−2.0	2.8	−2.3	2.3	0.3	0.753	−1.5	2.0
Pal. Pl. to Mand. Pl. (deg)	−1.9	3.1	−2.5	1.5	0.6	0.504	−1.2	2.3
ANS–Me (mm)	9.1	3.2	5.3	2.2	3.8	0.000	1.9	5.7
Co–Go (mm)	14.0	3.7	11.6	3.0	2.4	0.036	0.2	4.8
CoGoMe (deg)	−1.6	2.6	−1.9	2.4	0.3	0.707	−1.4	2.0
OVJ (mm)	*−3.8*	*−5.1/−2.7*	*−0.8*	*−1.5/0.2*	−3.0	0.000		
OVB (mm)	−1.1	1.5	0.0	1.5	−1.1	0.042	−2.1	0.0
Molar relationship (mm)	4.9	1.9	0.5	1.0	4.4	0.000	3.3	5.5
Upper Inc. to Pal. Pl. (deg)	−1.9	6.2	−0.8	4.7	−1.1	0.571	−4.9	2.8
Lower Inc. to Mand. Pl. (deg)	−0.8	6.0	1.7	4.4	−2.5	0.185	−6.1	1.2

SD, standard deviations; Diff., differences; CI, confidence interval; perp., perpendicular; deg, degrees; Pal., palatal; Pl., plane; Mand., mandibular; Inc., incisor.

Bionator and Activator were constructed with the same mandibular advancement as the construction bites were registered in the same way in both treated groups. The mechanism of action of these two monobloc appliances appears to be similar. As a matter of fact, Cozza *et al.* (3) evaluated the efficiency of functional appliances in stimulating mandibular supplementary elongation. Efficiency was appraised by dividing the supplementary elongation of the mandible obtained during the overall treatment period with the functional appliance by the number of months of active treatment (coefficient of efficiency). Both the Bionator and the Activator presented intermediate scores of efficiency (0.17 and 0.12 mm per month, respectively).

When treatment with functional appliances was performed and completed before puberty, the long-term effects were mostly limited to the dentoalveolar level, with a significant improvement in both overjet and molar relationships (−3.6 mm and +3.9 mm, respectively) (Table 4). The only significant skeletal effect consisted of an increase of about 2 degrees in facial divergency (SN to Mand Pl), which does not represent clinical relevance. No other significant long-term sagittal or vertical skeletal changes could be recorded in the comparison of ETG to ECG.

A few statistically significant (though probably not clinically relevant) skeletal changes could be observed immediately after functional treatment (T1–T2 interval, Supplementary Table 1) in terms of mandibular growth stimulation (Co–Gn +2.3 mm) and reduction of ANB angle (−1.2 degrees). These changes, however, were not maintained during the T2–T3 interval (Supplementary Table 3). In particular, the ANB angle increased significantly by about 1 degree, probably due to a significant decrease of about the same amount (−1.5 degrees) of the SNB angle, while mandibular growth decreased significantly (−3.0 mm) in ETG when compared to ECG.

These unfavourable changes in the post-treatment period after the application of removable functional appliances were similar to those reported by De Vincenzo (25) who described an increase in mandibular length during the functional phase. During the post-functional phase, however, the growth never reached the one observed for the control group; in the final analysis, there was no long-term additional mandibular length over controls. Similarly, Wieslander (26) in 1993 analysed the long-term effects of early treatment with the headgear-Herbst appliance in pre-pubertal children with severe Class II malocclusions. The patients were studied out of retention at the mean age of 17 years 4 months and compared with an untreated control group. Part of the sagittal correction relapsed. As compared with the control group, the average 3.9 mm protrusive effect of treatment on the mandible decreased to a non-significant 1.5 mm out of retention. The significant 2.0 mm therapeutic increase of the condylion–gnathion distance decreased to 1.2 mm after retention, and it was not significantly different from control values at age 17 years 4 months.

The greatest skeletal effects of the functional appliance seem to emerge when the pubertal growth spurt was included in the active treatment period with removable functional appliances. A significant increase in total mandibular length (Co–Gn + 5.5 mm), a significant chin advancement (Pg to N perp + 3.1 mm) and a significant reduction in the Wits appraisal of −5.8 mm were observed when LTG and LCG were compared (Table 5). All these favourable sagittal skeletal changes can be considered significant not only at a statistical level but, more importantly, at a clinical level (3.0–5.0 mm) as they can contribute substantially to the improvement of skeletal Class II relationship in the long term (27).

Significant chin advancement might have occurred as a result of a favourable balance between vertical long-term growth changes in the posterior (Co–Go +2.4 mm) and anterior (ANS–Me +3.8 mm) facial regions with a minimal change in facial divergency (SN to Mand. Pl. +0.3 degrees). The significant long-term dentoalveolar improvements in both overjet (−3.0 mm) and molar relationship (+4.4 mm) in LTG versus LCG might have been primarily sustained by the favourable sagittal skeletal changes, with no significant modifications in the inclinations of either upper or lower incisors. Interestingly enough, all the favourable dentoskeletal changes were produced mainly during the active phase with FJO (Supplementary Table 2), and they remained stable during the post-treatment period, with T2–T3 changes within 2.0 mm or degree (Supplementary Table 4).

The results of the present long-term study are in agreement with those of a previous study (9) that found a 5.1-mm increase in mandibular length in patients treated at puberty with the Bionator who were examined 8 years 4 months after FJO and compared with untreated Class II controls.

Another recent study (17) reported that treatment of Class II malocclusion with functional appliances during the pubertal peak is able to produce significantly greater increases in total mandibular length and mandibular ramus height associated with a significant advancement of the bony chin when compared with treatment before puberty. Although more long-term controlled studies are needed to confirm the findings of the present investigation, treatment timing seems to play a major role on the efficacy of mandibular growth stimulation produced by functional appliance therapy. It is interesting to note that the current investigation confirmed the results of Franchi *et al.* (17) for the comparison of the long-term changes (T1–T3) between ETG and LTG (Supplementary Table 6). Treatment with a functional appliance that includes the peak in mandibular growth appears to be more effective than treatment performed before the peak, as it induces more favourable mandibular skeletal modifications. No significant T1–T3 changes were found when comparing the two control samples (Supplementary Table 8). The only exceptions were a significantly greater increase in the lower anterior facial height (ANS–Me +3.5 mm) and a significantly greater decrease of the mandibular angle (Co–Go–Me −1.8 degrees) in ECG with respect to LCG.

Thus, if the aim of treatment is to produce skeletal mandibular changes (effective mandibular growth stimulation and chin advancement), the onset of intervention with removable functional appliances should be postponed until puberty. On the other hand, if the correction of the Class II problem requires mainly dentoalveolar modifications, treatment timing can be initiated before puberty.

Conclusions

- Treatment with removable functional appliances at puberty induced a significant long-term enhancement of mandibular growth with an increase in mandibular ramus height and protrusion of the chin.
- When treatment was performed before puberty, Class II correction was mostly confined to the dentoalveolar level, with significant improvements of both overjet and molar relationships.

Supplementary Material

Supplementary data are available at *European Journal of Orthodontics* online.

Conflict of Interest

None to declare.

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