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Long-term treatment effects of the FR-2 appliance: a prospective evalution 7 years post-treatment

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SUMMARY

AIM To examine the long-term effects induced by treatment with the function regulator (FR-2) appliance 7 years post-treatment compared with untreated class II subjects.

SUBJECTS AND METHODS The FR-2 sample was collected prospectively and comprised 17 subjects (10 boys and 7 girls, mean age 10.8 years) who were treated with the FR-2 appliance for 1.7 years and re-evaluated 7.1 years after treatment. The step-by-step mandibular advancement was performed gradually (increments up to 3–4 mm), until a 'super class I' molar relationship was obtained. The control group consisted of 17 class II subjects (9 boys and 8 girls, mean age 11.3 years) with class II malocclusion, excessive overjet, and class II molar relationship, matched to the treated group as to ages at all times, gender distribution, and stages of skeletal maturity (evaluated by the cervical vertebral maturation method). The lateral cephalograms were analysed at T1 (initial), T2 (final), and T3 (7.1 years post-treatment). The compatibility between the groups and the comparisons of their changes at T1–T2, T2–T3, and T1–T3 intervals were examined by independent sample *t*-tests ($P < 0.05$).

RESULTS FR-2 treatment provided a significant improvement in the maxillomandibular relationship due to an increase in mandibular length compared with controls, which remained stable over time. Also overjet, overbite, and molar relationship corrections demonstrated stability. Among dentoalveolar changes, only the increased mesial movement of the mandibular molars in the FR-2 group demonstrated stability.

CONCLUSIONS Correction of class II malocclusion remained stable 7 years after FR-2 treatment mainly due to the stability of the skeletal changes.

Introduction

Class II malocclusion has been studied frequently in orthodontics because it is found in one-third of the population (Proffit *et al.*, 2013). Mandibular retrognathism has been associated with skeletal class II malocclusion (McNamara, 1981). For these patients, a therapy for stimulating mandibular growth by means of forward positioning of the mandible provided by functional appliances often is indicated (McNamara and Brudon, 2001).

Functional appliances were introduced in the early 1900s and since then have gained popularity worldwide. One of these appliances is the function regulator (FR-2), proposed in the 1960s by Fränkel (1966, 1969a,b). The FR-2 appliance was designed by Fränkel as an exercise device used to correct the function of the circumoral musculature. According to Fränkel (1966, 1969a,b), a normal pattern of muscular behaviour promotes normal skeletal and dental development, maintaining the new mandibular position.

There is consensus in the literature that FR-2 treatment corrects class II malocclusion. However, some studies have shown that class II correction was achieved due to an increase in mandibular growth in comparison with untreated subjects (McNamara *et al.*, 1985; Falck and Fränkel, 1989; Perillo *et al.*, 1996; Toth and McNamara, 1999; Almeida *et al.*, 2002a,b; Cevidanes *et al.*, 2003; Cevidanes *et al.*, 2005); others also report restriction of maxillary growth (Creekmore and Radney, 1983; Nielsen, 1984). On the other hand, some investigations observed only dentoalveolar effects (Robertson, 1983; Remmer *et al.*, 1985).

Nevertheless, the stability of the changes promoted by FR-2 treatment over time is of great clinical significance. There are only four long-term studies (Falck, 1991; Perillo *et al.*, 1996; Freeman *et al.*, 2009; Perillo *et al.*, 2011) of FR-2 treatment. Fixed and removable appliances were utilized in the post-treatment period in two studies (Perillo *et al.*, 1996; Perillo *et al.*, 2011); for the two other studies (Falck, 1991;

Freeman *et al.*, 2009), the absence of radiographs taken immediately after FR treatment prevented the evaluation of treatment and post-treatment effects separately. Moreover, the post-treatment observation included a few years post-retention (Falck, 1991; Perillo *et al.*, 1996; Freeman *et al.*, 2009) or there was no comparison with a control group (Perillo *et al.*, 2011).

The aim of the present study was to examine the skeletal and dentoalveolar effects induced by FR-2 treatment and their stability at 7 years post-treatment compared with a matched untreated class II control group.

Subjects and methods

The size of the samples was estimated to be 17 subjects for an effect size of 1 (Cohen, 1992) for the mandibular length (Co-Gn) variable, with a power calculation of 0.80, and an alpha of 0.05 (SigmaStat 3.5, Systat Software, Point Richmond, California, USA). The FR-2 sample was collected prospectively and was comprised 17 Caucasian patients (7 girls and 10 boys) in the mixed dentition with a class II division 1 malocclusion. Eleven of them had full-cusp class II molar relationships and six had an end-to-end molar relationship. Each late mixed dentition patient was characterized by clinically mandibular skeletal retrusion, distal step, and excessive overjet (at least 5 mm). All patients had a skeletal class II malocclusion (ANB angle > 2 degrees) which defines the maxillomandibular relationship. The mean age at the onset of treatment was 10.8 years, and the stages of skeletal maturity were either pre-pubertal or pubertal (Table 1).

The FR-2 appliances were fabricated according to Fränkel's (1974) and McNamara and Huge's (1981) principles. The step-by-step mandibular advancement was performed gradually with increments up to 3−4 mm (Cevidanes *et al.*, 2003), executed with a mean interval of 6 months, until a 'super class I' molar relationship was obtained. The FR-2 appliance was worn full-time (except at mealtimes and for oral hygiene) for 1.7 years and then only at night for 6 additional months. Patient compliance was adequate, as monitored by a home daily journal of hours of appliance wear. At the end of treatment, all patients had a class I molar relationship.

Lateral cephalograms were obtained at three observation times: T1, at the onset of treatment; T2, at the end of FR-2 therapy; and T3, 7.1 years post-treatment. All patients were treated exclusively with FR-2 appliance; no fixed orthodontic appliances were used.

The untreated group consisted of 17 late mixed dentition subjects (8 girls and 9 boys) with skeletal class II malocclusion (ANB angle > 2 degrees), excessive overjet, and class II molar relationship (at least cusp-to-cusp molar relationship). The cephalograms of the untreated subjects were obtained from the University of Michigan Growth Study and the Denver Child Growth Study. Significant effort was directed towards matching the control sample to the treatment sample as closely as possible regarding ages, gender distribution, and skeletal maturity [evaluated with the cervical vertebral maturation method (Baccetti *et al.*, 2005) at all time periods; Table 1].

This study was approved by Institutional Review Board from the Methodist University of São Paulo.

Cephalometric analysis

All lateral cephalograms were hand traced by one investigator (F.A.) and the accuracy of the anatomic outlines and the landmark location were verified by a second investigator (J.A.M.). Regional superimpositions were accomplished by hand, as described by Ricketts (1981) and McNamara (1984). Tracings at T1, T2, and T3 were oriented along basion–nasion line and registered at the most posterosuperior aspect of the pterygomaxillary fissure. The contour of the skull posterior to the foramen magnum also was used for orientation to verify the accuracy of the superimposition. The enlargement of the lateral cephalograms was standardized at 10 per cent.

Maxillary and mandibular dentoalveolar changes were measured by maxillary and mandibular regional

Table 1 Ages and stages in skeletal maturation at observation times in FR-2 and control groups (independent sample *t*-tests and chi-square tests—$P < 0.05$). CS, cervical stage; SD, standard deviation.

	FR-2 group (7 girls and 10 boys)		Control group (8 girls and 9 boys)		*P* value
	Mean	SD	Mean	SD	
T1	10.8	0.6	11.3	0.6	NS
T2	12.5	0.6	12.7	0.6	NS
T3	19.7	0.7	18.9	2.0	NS
CS at T1	CS1 = 6; CS2 = 4; CS3 = 7		CS1 = 4; CS2 = 6; CS3 = 7		NS
CS at T2	CS1 = 1; CS2 = 6; CS3 = 5; CS4 = 5		CS2 = 4; CS3 = 6; CS4 = 7		NS
CS at T3	CS5 = 16; CS6 = 1		CS5 = 16; CS6 = 1		NS

NS, not significant.

superimpositions, respectively. The superimposition of the maxilla was made by registering on bony internal details of the maxilla superior to the incisors and the superior and inferior surfaces of the hard palate. The mandible was superimposed posteriorly on the outline of the inferior alveolar nerve canal and anteriorly on the anterior contour of the bony chin and the internal structures of the mandibular symphysis.

The functional occlusal plane was identified on each tracing. A customized digitization regimen (version 2.5, Dentofacial Planner, Toronto, Ontario, Canada), including 78 landmarks and 4 fiducial markers was created and used for the cephalometric evaluation. All landmarks from each of the three serial lateral cephalogram were digitized, and a customized cephalometric analysis based on the analyses of Steiner (1953), Jacobson (1975), Ricketts (1981), and McNamara (1984) was used. Thirty-two cephalometric variables were evaluated for each tracing.

Method error

Lateral cephalograms at T1, T2, and T3 of 10 randomly selected patients were retraced and redigitized by the same examiner with a 15 days interval after the first evaluation. Three variables presented errors greater than 1.5 degrees (Houston, 1983; U1-SN, I/I, and IMPA), with differences between the means from 0.5 to 1.3 degrees. For linear measurements, three variables (U6H, L1V, and L6V) demonstrated errors greater than 1 mm (Houston, 1983), with the differences between means from 0.1 to 0.2 mm.

Statistical analysis

Means and standard deviations were calculated for patient age and for the changes during treatment (T1–T2), post-treatment (T2–T3), and overall intervals (T1–T3) for both FR-2 and control groups. All data demonstrated normal distribution determined by the Kolmogorov–Smirnov test.

Statistical comparisons between the FR-2 and control groups were performed on the cephalometric measures of starting forms at T1, and on the T1–T2, T2–T3, and T1–T3 changes by means of the independent sample *t*-test. Independent sample *t*-test was used also to compare chronological age between the two groups at T1, T2, and T3. The distribution of the stages in skeletal maturity at all observation times was analysed with chi-square tests. All tests were performed with a statistical software package (Statistica, version 5.1, Tulsa, Oklahoma, USA), at $P < 0.05$.

Results

Descriptive data and statistical comparisons between the FR-2 and the control groups for cephalometric changes from T1 to T2, T2 to T3, and T1 to T3 are showed in Tables 2–4, respectively.

Analysis of starting forms

The FR-2 and control groups generally presented with similar starting forms (Supplementary data). Skeletally, there were significant differences between the FR-2 and control groups only in increased vertical skeletal relationships in FR-2 group (FH-Mand.Pl. and ANS-Me variables), which also led to a slightly more retruded chin point (Pg-Nperp) in the FR-2 group (−6.9 mm) versus controls (−2.8 mm). Dentally, the FR-2 group demonstrated more protruded maxillary incisors (U1-Avert), which resulted in greater overjet in the FR group (7.6 mm) versus the controls (6.1 mm). Furthermore, the control group showed an average larger value for the interincisal angle.

Analysis of treatment effects

The FR-2 treatment (T1–T2) produced an improvement of the maxillomandibular relationship, as shown by the ANB angle (−1.0 degree), Wits (−2.9 mm), and Mx/Md difference (2.4 mm) in comparison with control values (Table 2). The FR-2 group exhibited significantly greater increments in mandibular length (5.1 mm) in comparison with controls (3.2 mm), a difference that was statistically different. There was no significant difference in vertical skeletal relationships between the FR-2 and control groups.

The dental relationships in the FR-2 group improved in comparison with controls. Overjet and overbite decreased significantly (−3.2 and −2.3 mm, respectively), whereas molar relationship increased significantly in the FR-2 group (4.4 mm). Moreover, the FR-2 appliance produced significant dentoalveolar effects represented by retroclination and retrusion of the maxillary incisors (−3.3 degrees and −1.2 mm, respectively), absence of the natural forward movement of the maxillary first molars (0.1 mm in the FR-2 group versus 1.3 mm in the control sample), and mesial movement and extrusion of the mandibular first molars (1.3 and 0.7 mm, respectively).

Post-treatment changes

The changes between the FR-2 and control groups in the post-treatment period (T2–T3) were small (Table 3). In the FR-2 group, there was a significant upward rotation of the palatal plane (FH-Palatal Pl. −1.6 degrees). The FR-2 patients demonstrated significantly greater protrusion and extrusion of the maxillary incisors (1.2 and 1.1 mm, respectively) and extrusion of the maxillary first molars (1.3 mm) compared with the control group.

Overall evaluation

In the overall evaluation (T1–T3; Table 4), there was stability in the correction of the maxillomandibular relationship (ANB −1.3 degrees, Wits −2.6 mm, and Mx/Md differential 3.3 mm), increase in total mandibular length (3.7 mm), and

Table 2 Comparison of changes during FR-2 treatment (T1–T2)—independent *t*-test ($P < 0.05$). SD, standard deviation.

Variables	FR-2 ($N = 17$)		Control group ($N = 17$)		Difference	*P* value
	Mean	SD	Mean	SD		
Cranial base						
Ba-S-N (°)	1.4	2.0	0.3	1.9	1.1	NS
Maxillary A-P skeletal						
SNA (°)	−0.4	1.1	0.3	1.7	−0.7	NS
A-Nperp (mm)	0.6	1.0	0.3	1.3	0.3	NS
Co-A (mm)	1.5	1.4	2.0	1.2	−0.5	NS
Mandibular A-P skeletal						
SNB (°)	0.7	1.0	0.5	1.1	0.2	NS
Pg-Nperp (mm)	2.9	2.0	0.9	1.6	2.0	**
Co-Gn (mm)	5.1	1.7	3.2	1.4	1.9	**
Intermaxillary						
ANB (°)	−1.2	0.7	−0.2	0.9	−1.0	**
Wits (mm)	−2.9	1.5	0.0	1.3	−2.9	***
Mx/Md difference (mm)	3.5	1.7	1.1	1.2	2.4	***
Vertical skeletal						
FH-Palatal Pl. (°)	0.0	1.4	0.0	1.1	0.0	NS
FH-Mand. Pl. (°)	−1.1	1.3	−0.4	1.4	−0.7	NS
ANS-Me (mm)	1.6	1.6	1.3	1.2	0.3	NS
Interdental						
Overjet (mm)	−3.4	1.0	−0.2	0.8	−3.2	***
Overbite (mm)	−2.0	1.2	0.3	1.1	−2.3	***
I/I (°)	2.5	6.4	0.0	4.1	2.5	NS
6/6 (mm)	4.3	1.3	−0.1	1.2	4.4	***
Maxillary dentoalveolar						
U1-SN (°)	−3.3	4.7	0.0	2.4	−3.3	*
U1-Avert (mm)	−1.0	1.7	0.2	0.7	−1.2	*
U1H (mm)	−0.8	1.0	0.3	0.7	−1.1	**
U1V (mm)	0.6	0.8	0.5	0.7	0.1	NS
U6H (mm)	0.1	1.1	1.3	0.9	−1.2	**
U6V (mm)	1.1	1.0	0.8	0.6	0.3	NS
Mandibular dentoalveolar						
IMPA (°)	0.8	4.4	0.7	3.6	0.1	NS
L1H (mm)	0.5	0.9	0.2	0.7	0.3	NS
L1V (mm)	0.0	0.9	0.8	0.8	−0.8	**
L6H (mm)	2.1	0.7	0.8	0.7	1.3	***
L6V (mm)	1.3	0.9	0.6	0.7	0.7	*

NS, not significant.
*$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.

in the correction of overjet (−3.4 mm), overbite (−2.2 mm), and molar relationship (4.0 mm). The significant upward rotation of the palatal plane that occurred in the FR-2 group during T2–T3 interval was recorded also during the T1–T3 interval (−1.7 degrees).

Among the dentoalveolar changes, only the increased mesial movement of the mandibular molars in the FR-2 group showed stability (1.7 mm). A significant extrusion of the maxillary incisors (1.1 mm) and a mesial movement of mandibular incisors (1.0 mm) also were recorded in the FR-2 group with respect to the control sample.

Discussion

This present investigation consisted of a prospective long-term evaluation of FR-2 treatment (7.1 years post-treatment). The FR-2 treatment was performed by one orthodontist, and all FR-2 appliances were fabricated by a single technician. The treatment and post-treatment periods were observed distinctly in that lateral cephalograms were obtained at T1, T2, and T3 on each patient. In the post-treatment period, the patients wore the FR-2 appliance for retention only for 6 months, and no fixed orthodontic appliances were used. All patients were at a post-pubertal stage of skeletal development (CS5 or CS6; Baccetti *et al.*, 2005) at T3.

Although historical control groups may present with limitations (Pandis, 2012), in the current study, the use of historical controls was necessary due to the lack of ethical rational to leave class II patients untreated during a long-term observation interval.

The FR-2 and control groups showed no significant differences as to gender distribution, mean ages at all time periods, durations of observation periods, and stages of skeletal maturity at all phases. The type of malocclusion and race

Table 3 Comparison of post-treatment RF-2 changes (T2–T3)—independent *t*-test ($P < 0.05$). SD, standard deviation.

Variables	FR-2 ($N = 17$)		Control group ($N = 17$)		Difference	P value
	Mean	SD	Mean	SD		
Cranial base						
Ba-S-N (°)	0.0	1.6	−0.7	1.6	0.7	NS
Maxillary A-P skeletal						
SNA (°)	0.7	1.4	0.5	1.5	0.2	NS
A-Nperp (mm)	1.0	1.3	0.5	1.5	0.5	NS
Co-A (mm)	4.7	2.8	3.7	2.5	1.0	NS
Mandibular A-P skeletal						
SNB (°)	1.5	1.9	1.1	1.7	0.4	NS
Pg-Nperp (mm)	3.7	3.7	2.6	2.7	1.1	NS
Co-Gn (mm)	10.1	5.3	8.2	3.8	1.9	NS
Intermaxillary						
ANB (°)	−0.8	1.4	−0.5	1.3	−0.3	NS
Wits (mm)	0.6	2.1	0.3	1.9	0.3	NS
Mx/Md difference (mm)	5.4	3.7	4.4	2.8	1.0	NS
Vertical skeletal						
FH-Palatal Pl. (°)	−0.8	1.8	0.8	1.8	−1.6	*
FH-Mand. Pl. (°)	−2.7	2.4	−1.9	1.8	−0.8	NS
ANS-Me (mm)	5.4	3.7	4.3	1.7	1.1	NS
Interdental						
Overjet (mm)	−0.3	1.3	−0.1	1.3	−0.2	NS
Overbite (mm)	0.0	1.2	−0.1	1.3	0.1	NS
I/I (°)	−0.7	7.5	2.5	7.6	−3.2	NS
6/6 (mm)	−0.1	1.7	0.2	1.3	−0.3	NS
Maxillary dentoalveolar						
U1-SN (°)	2.6	4.5	0.0	4.7	2.6	NS
U1-Avert (mm)	1.5	1.6	0.3	1.3	1.2	*
U1H (mm)	1.5	1.7	1.0	1.0	0.5	NS
U1V (mm)	1.7	1.1	0.6	1.1	1.1	*
U6H (mm)	3.0	1.7	2.5	1.9	0.5	NS
U6V (mm)	3.4	1.8	2.1	1.2	1.3	*
Mandibular dentoalveolar						
IMPA (°)	0.7	4.7	−0.4	4.4	1.1	NS
L1H (mm)	0.6	1.3	0.0	1.0	0.6	NS
L1V (mm)	3.2	2.1	2.4	1.7	0.8	NS
L6H (mm)	1.9	1.0	1.6	1.1	0.3	NS
L6V (mm)	2.7	1.8	2.6	1.4	0.1	NS

NS, not significant.
*$P < 0.05$.

were the same for both groups. Only two cephalometric characteristics of starting forms were statistically different between the FR-2 and control groups, i.e. the FR-2 group showed increased vertical relationships and more protruded maxillary incisors than controls. Thus, the FR-2 and control groups can be considered as reasonably well matched at the beginning of the study.

In spite of the many studies (Robertson, 1983; McNamara *et al.*, 1985; Remmer *et al.*, 1985; Falck and Fränkel, 1989; Perillo *et al.*, 1996; Toth and McNamara, 1999; Almeida *et al.*, 2002a,b; Cevidanes *et al.*, 2003, 2005) that have examined treatment effects produced by the FR-2 appliance, no one has evaluated the post-treatment period distinctly without the use of additional fixed or removable appliances. Clearly, the permanence over time of the skeletal changes obtained by FR-2 treatment assumes significant clinical importance. De Vincenzo (1991) stated that the increase of mandibular length obtained during the treatment with a functional appliance (he used two separate posterior biteplates) 'evaporated' 4 years post-treatment because the rate of mandibular growth decreased in the treated group in relation to controls.

In the present study, the FR-2 appliance corrected the class II malocclusion by producing skeletal and dentoalveolar changes during treatment. The maxillomandibular relationship improved due to an increase in mandibular length (Table 2), as has been reported in many other studies (McNamara *et al.*, 1985; Falck and Fränkel, 1989; Perillo *et al.*, 1996; Toth and McNamara, 1999; Almeida *et al.*, 2002a,b; Cevidanes *et al.*, 2003, 2005). No short- or long-term maxillary changes were noted during FR-2 treatment, confirming the findings of others (McNamara *et al.*, 1985; Perillo *et al.*, 1996; Toth and McNamara, 1999; Almeida *et al.*, 2002b).

Table 4 Comparison of changes during the long-term overall interval (T1–T3)—independent *t*-test ($P < 0.05$). SD, standard deviation.

Variables	FR-2 ($N = 17$)		Control group ($N = 17$)		Difference	P value
	Mean	SD	Mean	SD		
Cranial base						
Ba-S-N (°)	1.5	1.7	−0.4	3.1	1.9	*
Maxillary A-P skeletal						
SNA (°)	0.2	1.4	0.9	1.7	−0.7	NS
A-Nperp (mm)	1.6	1.4	0.9	1.8	0.7	NS
Co-A (mm)	6.2	2.6	5.7	2.9	0.5	NS
Mandibular A-P skeletal						
SNB (°)	2.3	1.9	1.7	1.8	0.6	NS
Pg-Nperp (mm)	6.6	4.0	3.6	2.8	3.0	*
Co-Gn (mm)	15.2	4.3	11.5	4.3	3.7	*
Intermaxillary						
ANB (°)	−2.1	1.3	−0.8	1.9	−1.3	*
Wits (mm)	−2.2	2.2	0.4	2.2	−2.6	**
Mx/Md difference (mm)	8.9	3.1	5.6	3.1	3.3	**
Vertical skeletal						
FH-Palatal Pl. (°)	−0.9	1.8	0.8	2.0	−1.7	*
FH-Mand. Pl. (°)	−3.8	3.1	−2.4	2.4	−1.4	NS
ANS-Me (mm)	7.1	3.2	5.7	2.1	1.4	NS
Interdental						
Overjet (mm)	−3.7	2.0	−0.3	1.3	−3.4	***
Overbite (mm)	−2.0	1.4	0.2	1.6	−2.2	**
I/I (°)	1.7	7.2	2.4	7.3	−0.7	NS
6/6 (mm)	4.1	2.1	0.1	1.3	4.0	***
Maxillary dentoalveolar						
U1-SN (°)	−0.7	5.7	−0.1	4.0	−0.6	NS
U1-Avert (mm)	0.5	1.9	0.5	1.6	0.0	NS
U1H (mm)	0.7	1.8	1.4	1.0	−0.7	NS
U1V (mm)	2.3	1.3	1.2	1.2	1.1	*
U6H (mm)	3.2	1.9	3.8	1.5	−0.6	NS
U6V (mm)	4.5	1.8	2.9	1.4	1.6	**
Mandibular dentoalveolar						
IMPA (°)	1.5	3.8	0.2	3.8	1.3	NS
L1H (mm)	1.2	1.3	0.2	1.1	1.0	*
L1V (mm)	3.2	1.9	3.2	1.8	0.0	NS
L6H (mm)	4.1	1.0	2.4	1.1	1.7	**
L6V (mm)	4.1	1.5	3.3	1.4	0.8	NS

NS, not significant.
*$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.

The amount of increased mandibular length noted in the FR-2 group relative to controls in the current study was similar to that observed in other studies (McNamara *et al.*, 1985; Toth and McNamara, 1999; Almeida *et al.*, 2002a) in which the majority of the patients were in pre-pubertal stage of skeletal maturity at onset. This increase in mandibular length relative to controls remained stable over 7.1 years post-treatment, with no statistically significant difference relative to control group evident in the post-treatment period (Table 3) and a significant elongation of the mandible over controls in the overall period (Table 4).

Mandibular length was 3.7 mm greater in the FR-2 group than in the class II untreated subjects, corroborating the findings of other studies (Perillo *et al.*, 1996; Freeman *et al.*, 2009). These data indicate that the rate of the mandibular growth did not decrease during post-treatment period (Table 3), as previously suggested by De Vincenzo (1991). Despite the statistical similarity, there was a slightly greater mandibular length increase in the FR-2 group than in the controls at the end of the post-treatment period. This increase might have occurred because most of FR-2 patients were at the pubertal stage at the end of active treatment and wore the FR-2 appliance as a night-time retainer for the first 6 months of the retention period.

The stability of correction in the maxillomandibular relationship produced by FR-2 treatment, along with significant improvements in ANB angle and Wits appraisal (Table 4), has also been shown in other studies (Perillo *et al.*, 1996; Freeman *et al.*, 2009; Perillo *et al.*, 2011) demonstrated the efficacy of this therapy over time. At the occlusal level, the FR-2 treatment resulted in the improvement of overjet (3.4 mm) and molar relationship (4.3 mm; Table 2), which remained stable 7 years post-treatment (Table 4). Moreover, there was stability in the decreased overbite (2 mm) over time.

In the present investigation, there were no significant vertical skeletal changes between the FR-2 and control groups evident at the end of the treatment period. This result differed from those of several studies (Creekmore and Radney, 1983; Remmer *et al.*, 1985; Almeida *et al.*, 2002a) that observed increases in the vertical skeletal components as an effect of the FR-2 appliance. In the current study, a slight counterclockwise rotation of the palatal plane in FR-2 patients was recorded at the end of the post-treatment period; however, this change in morphology was not relevant clinically. These findings are similar to those reported by Freeman *et al.* (2009) and Perillo *et al.* (2011).

According to Fränkel (1966), the maxillary labial bow of the FR-2 appliance should not tip the maxillary incisors lingually in that the labial wire should not be active. Retroclination and retrusion of the maxillary incisors during the FR-2 treatment were found (Table 2), corroborating other studies (Creekmore and Radney, 1983; Robertson, 1983; McNamara *et al.*, 1985; Almeida *et al.*, 2002a). In the long term, these changes demonstrated relapse (Table 4), in disagreement with the findings of Freeman *et al.* (2009), probably the longer retention time in that study (3–3.5 years compared with 6 months in the present study) can explain the stability of the retroclination and retrusion of the maxillary incisors over time.

In addition, there was an inhibition of the mesial movement of the maxillary first molars during FR-2 treatment compared with controls (Table 2). This decrease in maxillary mesial migration was associated with more mesial movement of the mandibular molars, following the principles advocated by Harvold and Vargervik (1971), with no vertical effects in maxillary molars and extrusion of the mandibular molars observed. These findings have been confirmed by other studies (Creekmore and Radney, 1983; McNamara *et al.*, 1985).

Nonetheless, changes in maxillary and mandibular molars did not remain stable long term, with the exception of the greater mesial movement of the mandibular molars relative to controls (Table 4). Furthermore, there was an increased extrusion of the maxillary molars in the treated group during the post-treatment period, which can be explained by the closure of the posterior open bite created during the FR-2 treatment (Tables 3 and 4).

Even though there have been several previous studies (Creekmore and Radney, 1983; Robertson, 1983; McNamara *et al.*, 1985; Remmer *et al.*, 1985; Perillo *et al.*, 2011) that have shown that FR-2 appliance promoted significant proclination of the mandibular incisors, no significant proclination of the mandibular incisors was observed during FR-2 treatment in the current study (Table 2). Nevertheless, in the overall period, the mandibular incisors demonstrated a slight protrusion (1.2 mm; Table 4) in the FR-2 group in comparison with controls (0.2 mm), similarly to the findings of the study by Freeman *et al.* (2009).

Comparing the results obtained during FR-2 treatment (Table 2) and in long-term overall period (Table 4), all skeletal effects (the increase of the mandibular length, the improvement of ANB angle and Wits appraisal, and the greater maxillomandibular difference) obtained by the FR-2 treatment remained stable 7 years post-treatment, confirming previous findings (Perillo *et al.*, 1996, Freeman *et al.*, 2009). Of the maxillary and mandibular dentoalveolar effects, only the greater mesial movement of the mandibular molars demonstrated stability over time. Thus, the present results support Fränkel's (1966, 1969a,b) assertion that FR-2 treatment promotes the correction of the class II malocclusion due to more skeletal than dentoalveolar changes, with stability of the treated result occurring over time.

Conclusions

The correction of class II malocclusion by the FR-2 appliance occurred mainly by the improvement of the maxillomandibular relationship due to the increase in mandibular length, with the stability of these changes observed over 7 years post-treatment. The dentoalveolar changes demonstrated lesser stability over time, with the exception of the greater mesial movement of the mandibular molars in the FR-2 patients than controls.

Supplementary material

Supplementary material is available at *European Journal of Orthodontics* online.

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