The effects of Frankel's function regulator (FR-4) therapy on the treatment of Angle Class I skeletal anterior open bite malocclusion

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The present study attempts to evaluate cephalometrically the effects of Fränkel's function regulator (FR-4) appliance on the treatment of Angle Class I skeletal anterior open bite malocclusion. Forty Turkish children (26 girls and 14 boys), with Angle Class I skeletal anterior open bite, were randomly divided into two groups of 20 (13 girls and 7 boys). Patients who had not undergone treatment served as the control group, whereas a second group was treated with lip-seal training and the FR-4 appliance. Chronologic mean decimal age at initial period of the investigation was 8.7 years in the treated group, and 8.9 years in the control group. Treatment and observation periods were 2 years. Investigation was carried out on lateral cephalograms taken before and after the study period. The results indicate that a spontaneous downward and backward growth direction of the mandible observed in the control group could be changed to a upward and forward direction by FR-4 therapy. The skeletal anterior open bite was successfully corrected through upward and forward mandibular rotation. (AM J ORTHOD DENTOFAC ORTHOP 1995;108:9-21.)

On the basis of recent investigations, it is apparent that skeletal anterior open bite malocclusion is generally more difficult to treat and results harder to maintain than other malocclusions. Even if there were no arch length discrepancies, orthodontic tradition generally applied in treatment of skeletal anterior open bite is extraction of permanent premolars or molars. In contrast, Fränkel[1,2] successfully treated skeletal anterior open bite cases with the function regulator appliance, generally without extraction. Fränkel[2,3] considered the deficiency of an anterior oral seal, the incompetent lip posture, is due to poor postural performance of the lip-valve musculature, and is the most important factor in the cause of skeletal anterior open bite malocclusion. Fränkel and Fränkel[4-6] suggest that lip seal training with the function regulator appliance is an effective means of activating and improving muscle tone. This creates the anterior oral seal and suspends the mandible in a proper postural position. Consequently, functional, as well as morphologic aberrations, are improved.

From our literature references, it is evident that up to the date Fränkel and Fränkel's study[4-6] was introduced, all publications related to orthodontic treatment of skeletal anterior open bite cases were mostly presented as case reports. However, Fränkel and Fränkel[4-6] evaluated the changes biometrically that occurred in the control and treated groups over the study period, to evaluate the effect of lip seal training with the FR appliance in the treatment of skeletal anterior open bite.

We attempted to make a new study on the same subject, as we had detected the following points lacking in Fränkel and Fränkel's study.[4-6]

- The authors did not classify the cases according to arch relationship in the sagittal plane and perhaps due to this fact did not identify which type of function regulator appliance or appliances were used.
- The latest lateral cephalometric radiographs of the treated group were taken after a minimum of 4 years out of retention.
- There is approximately 1 year between the mean ages of the treated and control groups at initial stage of the investigation and the observation period.
- There was no information on whether a sexual dimorphism existed.
- To evaluate the changes in skeletal pattern of the skeletal anterior open bite that occurred during treatment with a function regulator and lip-seal training, Fränkel and Fränkel[4-6] have used only the cephalometric measurements in the vertical plane.

The aim of this study was to investigate cephalometrically the effects, in the sagittal and vertical

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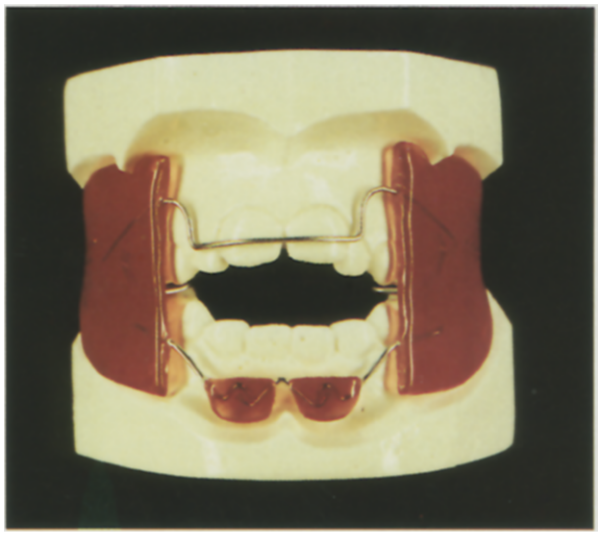

Fig. 1. FR-4 on both maxillary and mandibular casts.

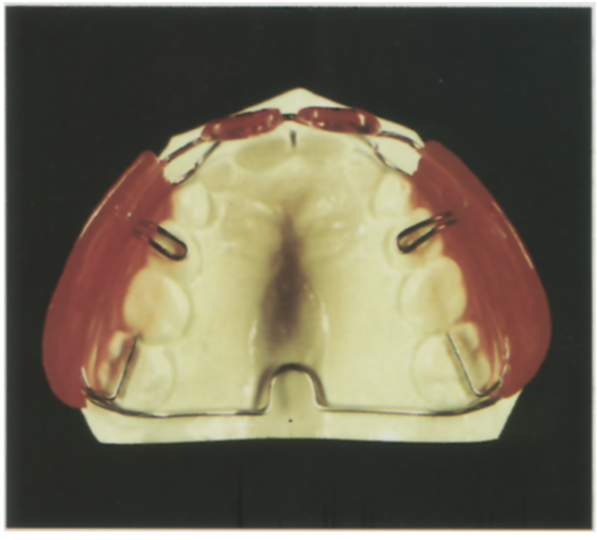

Fig. 2. FR-4 on maxillary cast.

Table I. Sample characteristic chronologic and skeletal mean decimal ages (year)

	N	*Mean Ages*	$\bar{X}$	*S*	$S\bar{x}$	*Min.*	*Max.*
Treated group (girls)	13	Chronologic	8.7	0.5	0.1	7.9	9.3
		Skeletal	7.7	0.8	0.2	6.8	8.8
Treated group (boys)	7	Chronologic	8.6	0.6	0.2	7.5	9.4
		Skeletal	8.0	1.6	0.6	6.0	10.0
Control group (girls)	13	Chronologic	8.7	1.2	0.3	7.0	10.1
		Skeletal	7.5	1.3	0.4	5.8	8.8
Control group (boys)	7	Chronologic	9.3	1.2	0.4	7.6	11.0
		Skeletal	8.3	1.4	0.5	6.0	10.0
Treated group (pooled)	20	Chronologic	8.7	0.5	0.1	7.5	9.4
		Skeletal	7.8	1.1	0.2	6.0	10.0
Control group (pooled)	20	Chronologic	8.9	1.2	0.3	7.0	11.0
		Skeletal	7.8	1.3	0.3	5.8	10.0

Min. = Minimum.
Max. = Maximum.

planes, of Fränkel's function regulator (FR-4) appliance[5,7] and lip-seal training for treatment of Angle Class I skeletal anterior open bite malocclusion.

MATERIALS AND METHODS

Forty Turkish children with Angle Class I skeletal anterior open bite malocclusion were included in this study. Subjects were selected from the patients referred for orthodontic treatment to the Department of Orthodontics at the Faculty of Dentistry, University of Istanbul. The criteria used for sample selection were (1) Angle Class I molar relationship; (2) anterior open bite of at least 1 mm when the incisal points of the upper and lower central incisors were projected onto N-Me line; and (3) a steep mandibular plane angle (SN/GoMe angle $\geq 37°$).

All cases were in the mixed dentition stage and no deciduous or permanent teeth were extracted over the study period. These patients were randomly divided into two groups which closely matched in age and sex. Patients who did not undergo treatment served as the control group and a second group they were treated with lip-seal training and the FR-4 appliance.[5,7] The FR-4 appliance has two buccal shields, two lower lip pads, a palatal bow, an upper labial wire, and four occlusal rests on the upper permanent first molars and upper deciduous first molars (Figs. 1 and 2).

As seen in Table I, the treated and control groups were comprised of 13 girls and 7 boys. Both groups were divided into subgroups according to sex.

The chronologic and skeletal mean decimal ages for all groups at initial stage of the study are given in Table I. Skeletal age was established by means of the standardized hand-wrist radiograph that was scored with the standards of Greulich and Pyle.[8] Children in the treated and control groups were followed up for 2 years. In the

Table II. The pretreatment and posttreatment mean values of cephalometric measurements in girls of the treated group (N : 13) and comparison of differences according to the Wilcoxon test

	Pretreatment		Posttreatment		Difference		
	$\bar{X}$	S	$\bar{X}$	S	$\bar{D}$	S	Wilcoxon test
Linear							
1. N-Me	107.7	3.5	111.7	4.1	+4.0	1.7	**
2. N-ANS	45.6	1.6	49.0	1.7	+3.4	1.2	**
3. ANS-Me	62.0	3.0	62.7	3.7	+0.7	1.6	
4. S-Go	62.2	4.5	66.6	5.1	+4.4	1.3	**
5. S-Ar	28.2	2.3	30.3	2.0	+2.1	1.0	**
6. Ar-Go	36.9	3.1	39.4	3.6	+2.5	1.1	**
7. N-ANS/ANS-Me	0.7	0.0	0.8	0.1	+0.1	0.0	**
8. S-Go/N-Me × 100	57.8	3.7	59.6	4.0	+1.8	0.9	**
9. N-S	63.6	2.8	65.7	2.9	+2.1	0.7	**
10. Go-Me	60.5	2.4	64.2	2.8	+3.7	1.6	**
11. ANS-PNS	45.7	2.4	48.3	2.5	+2.6	1.6	**
12. Overbite	−3.8	1.3	1.1	0.9	+4.9	1.2	**
13. $\underline{6}^{+}$ ANSPNS	18.6	1.3	19.7	1.8	+1.1	0.8	**
14. $\overline{6}^{+}$ GoMe	27.1	2.0	29.1	2.5	+2.0	1.0	**
15. $\underline{1}^{+}$ ANSPNS	24.4	1.6	27.0	2.0	+2.6	1.2	**
16. $\overline{1}^{+}$ GoMe	34.1	3.1	37.2	2.3	+3.1	2.6	**
Angular							
17. SN/GoMe	43.0	4.4	40.6	4.3	−2.4	0.9	**
18. SN/ANSPNS	8.9	1.5	10.4	2.4	+1.5	1.5	**
19. ANSPNS/GoMe	34.1	3.8	30.2	4.1	−3.9	2.1	**
20. NSAR	124.0	6.2	123.9	6.2	−0.1	2.8	
21. SArGo	147.2	6.5	146.5	7.2	−0.7	2.2	
22. ArGoMe	133.1	5.5	130.3	5.3	−2.8	1.2	**
23. {<20 − <21 − <22	404.3	4.6	400.6	4.6	−3.7	2.3	**
24. SN/U.occ.plane	19.5	3.6	23.4	4.0	+3.9	2.1	**
25. GoMe/L.occ.plane	16.2	2.9	18.4	5.1	+2.2	3.6	*
26. SNA	78.4	3.0	78.1	2.9	−0.3	1.2	
27. SNB	74.3	2.8	74.4	2.7	+0.1	1.4	
28. ANB	4.1	1.6	3.7	1.3	−0.4	0.6	*
29. $\underline{1}$/ANSPNS	114.0	4.2	108.8	4.0	−5.2	3.5	**
30. $\overline{1}$/GoMe	91.7	5.7	91.4	5.4	−0.3	3.0	

*$p \leq 0.05$; **$p \leq 0.01$.
U.occ.plane, Upper occlusal plane; *L.occ.plane,* lower occlusal plane

treated group the patients were instructed to use their appliances for an average of 18 hours per day with lip-seal training. As already emphasized by Fränkel and Fränkel,[4-6] the most difficult part of functional orthopedics with the FR-4 is to obtain the child's cooperation in lip-seal training. Therefore, on the basis of Fränkel's experience, parents and children were informed that the most important aim of functional orthopedics was to correct the existing facial disfigurement resulting from a deviant postural performance of the facial muscles. Accordingly, an understanding was achieved of how the FR-4 appliance worked as an exercise device and that lip-seal training was indispensable for overcoming a poor postural behavior of the orofacial musculature. Parents and children were informed that competent lip seal could only be established when "keeping the lips sealed" was performed continuously. The parents were involved in supporting the child and reminding him or her of the need to maintain lip seal, and a plastic spatula was given to each child to hold between the lips during homework and while watching television. Adequate overbite was successfully established in all patients of the treated group.

Cephalometric analysis

All lateral cephalometric radiographs were traced by a single investigator. All cephalometric reference points used in the present study are shown in Fig. 3. Fourteen linear measurements (Fig. 4), 13 angular measurements (Fig. 5), and 2 ratios were analyzed on each radiograph.

Statistical analysis

Descriptive statistics were calculated for prestudy and poststudy values and changes over the study period, which were defined as the poststudy value minus the prestudy value for each patient in all groups.

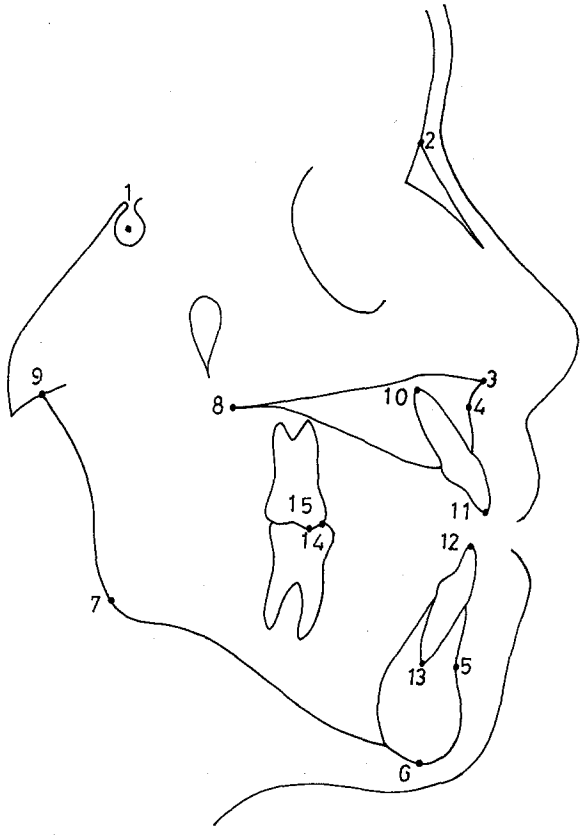

Fig. 3. Cephalometric reference points.

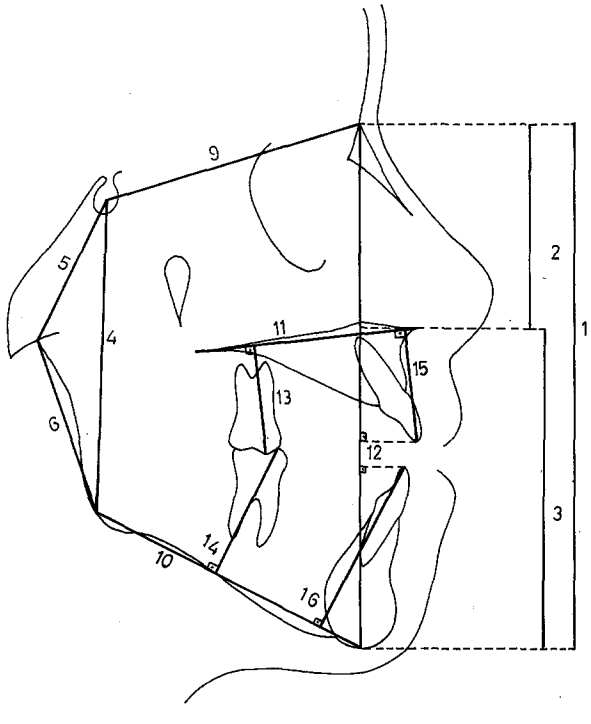

Fig. 4. Linear measurements.

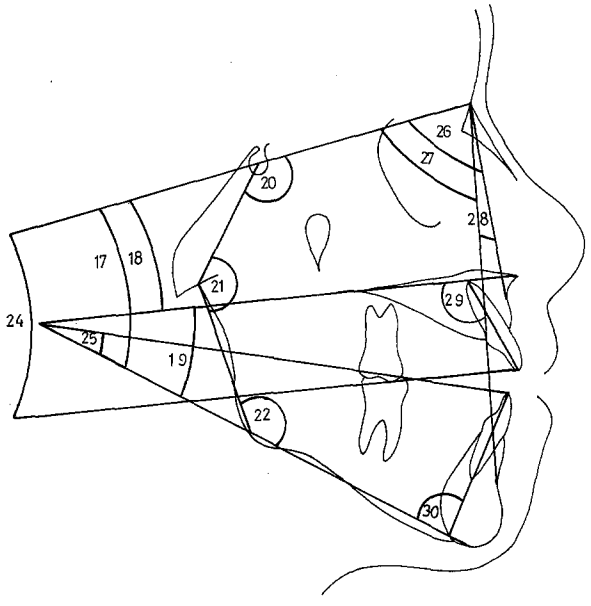

Fig. 5. Angular measurements.

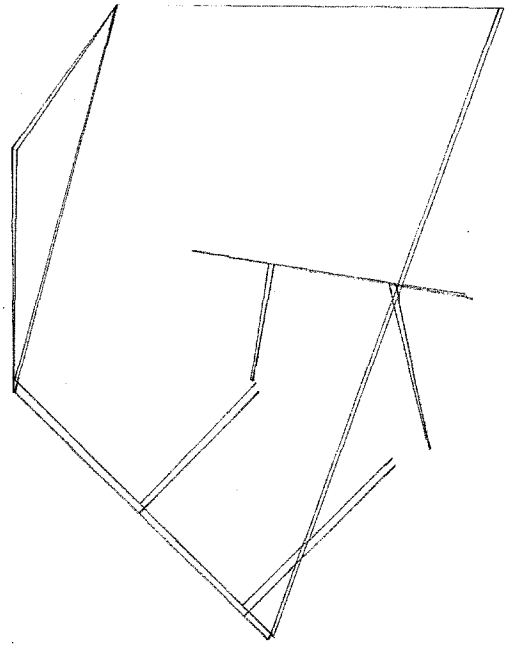

Fig. 6. Initial skeletal patterns of treated (red line) and control (black line) groups.

Statistical analysis was performed by nonparametric methods. The significance of changes across time that occurred in all groups was determined with the Wilcoxon matched-pairs signed-ranks test. The significance of differences between independent groups was also studied by means of the Mann-Whitney U test.

Table III. The pretreatment and posttreatment mean values of cephalometric measurements in boys of the treated group (N : 7) and comparison of differences according to the Wilcoxon test

	Pretreatment		*Posttreatment*		*Difference*		
	$\bar{X}$	*S*	$\bar{X}$	*S*	$\bar{D}$	*S*	*Wilcoxon test*
Linear							
1. N-Me	112.2	5.5	115.9	5.7	+3.7	2.3	*
2. N-ANS	46.0	3.1	49.1	3.5	+3.1	1.2	*
3. ANS-Me	66.1	4.3	66.7	4.9	+0.6	1.6	
4. S-Go	65.2	2.1	70.0	2.1	+4.8	2.2	*
5. S-Ar	29.8	1.9	32.4	2.1	+2.6	1.5	*
6. Ar-Go	39.2	1.5	41.4	1.8	+2.2	0.9	*
7. N-ANS/ANS-Me	0.7	0.1	0.8	0.1	+0.1	0.0	*
8. S-Go/N-Me × 100	58.1	1.4	60.4	2.2	+2.3	1.2	*
9. N-S	66.9	3.0	68.7	3.0	+1.8	0.9	*
10. Go-Me	60.6	1.6	64.7	2.1	+4.1	0.9	*
11. ANS-PNS	47.6	1.3	51.1	2.4	+3.5	2.1	*
12. Overbite	−4.2	1.4	1.2	0.9	+5.4	1.4	*
13. $\underline{6}^{+}$ ANSPNS	18.9	1.6	21.8	2.4	+2.9	1.6	*
14. $\bar{\underline{6}}^{+}$ GoMe	28.1	1.2	29.2	1.3	+1.1	1.1	*
15. $\underline{1}^{+}$ ANSPNS	25.5	3.1	28.4	3.3	+2.9	1.4	*
16. $\bar{\underline{1}}^{+}$ GoMe	36.5	1.8	39.3	1.4	+2.8	1.4	*
Angular							
17. SN/GoMe	43.9	3.4	40.5	3.8	−3.4	1.1	*
18. SN/ANSPNS	5.7	3.7	6.9	4.0	+1.2	0.7	*
19. ANSPNS/GoMe	38.2	5.5	33.7	6.2	−4.5	1.1	*
20. NSAr	124.9	6.1	122.1	5.2	−2.8	2.1	*
21. SArGo	143.4	7.4	144.6	6.6	+1.2	2.3	
22. ArGoMe	137.1	5.7	133.4	4.9	−3.6	2.2	*
23. {<20 − <21 − <22	405.4	3.8	400.2	3.6	−5.2	1.6	*
24. SN/U.occ.plane	17.9	2.0	18.5	4.1	+0.6	3.5	
25. GoMe/L.occ.plane	17.7	3.0	22.5	2.6	+4.8	4.2	*
26. SNA	77.9	2.0	78.5	1.4	+0.6	1.4	
27. SNB	73.4	2.1	75.0	2.4	+1.6	1.0	*
28. ANB	4.5	1.1	3.6	1.2	−0.9	0.9	*
29. $\underline{1}$/ANSPNS	109.1	5.5	107.2	8.8	−1.9	5.9	
30. $\bar{\underline{1}}$/GoMe	91.4	5.8	91.1	4.3	−0.3	3.1	

*$p \leq 0.05$.

RESULTS

Descriptive statistics and findings of the Wilcoxon test for both sexes in treated and control groups are found in Tables II to V.

Comparisons of sex showed that statistically significant differences were seen in three parameters ($13.\underline{6}^{+}$ ANSPNS, 24. SN/Upper Occlusal Plane Angle, 27. SNB) between girls and boys in the treated group (Table VI), whereas in two parameters (24. SN/Upper Occlusal Plane Angle, 27. SNB) between girls and boys in the control group (Table VII).

Separations of sex in the treated and control groups were eliminated to evaluate the whole material, because sexual dimorphism in control and treated groups amounted to only two and three parameters, respectively, out of 30 measurements.

As will be seen in Table VIII, the statistically significant changes in the treated group were detected in 24 parameters. A proportion of changes observed during the treatment period was a result of growth. With the intention of determining the treatment-induced genuine alterations by elimination of those spontaneous changes due to growth, changes occurring in the treated group were compared with those evoked spontaneously in the control group (Table IX). Therefore only the changes in 16 parameters that occurred in the treated group were determined to be essentially related to the treatment by FR-4 and lip-seal training (Table X).

The data in Table X show that most linear incremental changes in facial, mandibular, and

Table IV. The pretreatment and postobservation mean values of cephalometric measurements in girls of the control group (N : 13) and comparison of differences according to the Wilcoxon test

	Preobservation		*Postobservation*		*Difference*		
	$\bar{X}$	*S*	$\bar{X}$	*S*	$\bar{D}$	*S*	*Wilcoxon test*
Linear							
1. N-Me	107.8	4.7	114.5	4.3	+6.7	2.8	**
2. N-ANS	46.0	2.1	49.1	2.9	+3.1	1.8	**
3. ANS-Me	61.8	3.9	65.4	3.7	+3.6	1.7	**
4. S-Go	62.9	3.7	65.8	3.3	+2.9	1.3	**
5. S-Ar	28.3	2.0	30.7	2.1	+2.4	0.8	**
6. Ar-Go	37.9	3.1	39.5	3.3	+1.6	1.8	**
7. N-ANS/ANS-Me	0.8	0.1	0.8	0.1	0.0	0.0	
8. S-Go/N-Me × 100	58.3	2.1	57.5	2.0	−0.8	1.2	*
9. N-S	62.8	2.1	64.8	2.4	+2.0	1.0	**
10. Go-Me	58.6	3.8	64.2	4.4	+5.6	1.3	**
11. ANS-PNS	46.1	1.9	48.5	2.0	+2.4	1.6	**
12. Overbite	−3.2	1.5	−1.5	1.8	+1.7	2.1	*
13. $\underline{6}^{+}$ ANSPNS	18.2	2.2	21.4	1.6	+3.2	2.1	**
14. $\overline{6}^{+}$ GoMe	26.9	2.1	28.5	2.6	+1.6	1.2	**
15. $\underline{1}^{+}$ ANSPNS	24.7	2.1	27.4	2.4	+2.7	1.4	**
16. $\overline{1}^{+}$ GoMe	34.8	2.8	37.1	2.7	+2.3	1.1	**
Angular							
17. SN/GoMe	43.8	2.1	44.5	2.8	+0.7	2.1	
18. SN/ANSPNS	9.7	2.6	9.7	3.7	0.0	2.9	
19. ANSPNS/GoMe	34.1	2.3	34.9	2.1	+0.8	1.3	
20. NSAr	126.3	7.0	128.7	7.7	+2.4	2.6	**
21. SArGo	144.2	9.5	142.9	10.3	−1.3	3.2	
22. ArGoMe	133.4	4.1	133.9	5.1	+0.5	2.2	
23. {<20− <21− <22	404.0	2.2	405.6	3.0	+1.6	2.3	*
24. SN/U.occ.plane	19.7	3.6	21.2	3.9	+1.5	3.1	
25. GoMe/L.occ.plane	17.4	3.0	19.6	4.0	+2.2	2.9	*
26. SNA	77.7	4.3	77.4	4.9	−0.3	1.5	
27. SNB	73.4	3.5	73.0	3.9	−0.4	1.4	
28. ANB	4.3	1.8	4.4	1.9	+0.1	0.9	
29. $\underline{1}$/ANSPNS	112.6	5.4	112.0	5.7	−0.6	4.5	
30. $\overline{1}$/GoMe	91.1	3.3	92.2	4.3	+1.1	2.9	

*$p \leq 0.05$; **$p \leq 0.01$.

maxillary dimensions in both groups were significant over the time period studied.

The salient finding of this investigation was the closing of the anterior open bite in the treated group. The mean overbite was improved from −3.95 to 1.1 mm with a mean increase of 5.0 mm in the treated group (Table VIII). However, overbite remained negative with a mean increase of 1.4 mm in the control group (Table IX).

In the treated group, total anterior facial height (N-Me) and upper anterior facial height (N-ANS) showed an incremental increase of 3.9 mm and 3.3 mm, respectively. However, the control group demonstrated a significantly greater increase in total anterior facial height (N-Me: 7.3 mm), but a similar change in upper anterior facial height (N-ANS: 3.1 mm) when compared with the treated group.

Measurement of lower anterior facial height (ANS-Me) indicated that significant growth increment occurred in the control group but remained almost constant in the treated group during the same period. The mean incremental linear value for lower anterior facial height in the control group (ANS-Me: 4.3 mm) was also significantly greater than in the treated group (ANS-Me: 0.6 mm).

The comparison of mean changes found for total posterior facial height (S-Go) in both groups showed a statistically significant difference. The rate of growth in total posterior facial height in the treated group (S-Go: 4.5 mm) exceeded that of the control group (S-Go: 3.6 mm).

Both the ratio of upper to lower anterior facial height (N-ANS/ANS-Me) and the quotient determining the total anterior to posterior facial height

Table V. The preobservation and postobservation mean values of cephalometric measurements in boys of the control group (N : 7) and comparison of differences according to the Wilcoxon test

	Preobservation		*Postobservation*		*Difference*		
	$\bar{X}$	*S*	$\bar{X}$	*S*	$\bar{D}$	*S*	*Wilcoxon test*
Linear							
1. N-Me	114.7	3.7	123.2	5.1	+8.5	2.0	*
2. N-ANS	46.4	1.9	49.4	2.8	+3.0	1.4	*
3. ANS-Me	68.3	4.4	73.8	6.7	+5.5	2.8	*
4. S-Go	67.9	3.7	72.8	6.4	+4.9	3.7	*
5. S-Ar	31.7	2.7	34.3	2.3	+2.6	1.7	*
6. Ar-Go	40.1	3.6	43.1	5.8	+3.0	3.6	
7. N-ANS/ANS-Me	0.7	0.1	0.7	0.1	0.0	0.0	
8. S-Go/N-Me × 100	59.2	2.8	59.1	4.0	−0.1	2.2	
9. N-S	65.9	2.5	68.5	3.2	+2.6	0.9	*
10. Go-Me	60.7	2.6	67.6	3.6	+6.9	1.8	*
11. ANS-PNS	48.5	1.4	51.5	2.0	+3.0	1.2	*
12. Overbite	−3.9	1.1	−3.0	1.6	+0.9	0.9	*
13. $\underline{6}^{\perp}$ ANSPNS	21.3	2.4	24.6	3.3	+3.3	2.8	*
14. $\overline{\underline{6}}^{\perp}$ GoMe	29.9	1.4	31.9	1.9	+2.0	1.5	*
15. $\underline{1}^{\perp}$ ANSPNS	27.5	3.4	29.4	3.0	+1.9	0.8	*
16. $\overline{\underline{1}}^{\perp}$ GoMe	37.7	1.6	40.6	2.6	+2.9	1.4	*
Angular							
17. SN/GoMe	43.7	4.9	44.4	5.5	+0.7	1.6	
18. SN/ANSPNS	7.8	3.7	7.7	3.2	−0.1	1.4	
19. ANSPNS/GoMe	35.9	4.9	36.7	5.0	+0.8	1.8	
20. NSAr	126.0	2.4	126.4	3.5	+0.4	1.9	
21. SArGo	141.2	3.8	141.2	4.6	0.0	2.5	
22. ArGoMe	137.3	4.3	136.6	5.0	−0.7	2.5	
23. {<20 − <21 − <22	404.5	4.7	404.2	6.1	−0.3	3.1	
24. SN/U.occ.plane	19.1	3.7	18.0	3.6	−1.1	0.8	*
25. GoMe/L.occ.plane	16.9	3.9	19.5	4.3	+2.6	3.4	
26. SNA	77.8	3.4	78.4	3.4	+0.6	1.0	
27. SNB	73.6	2.8	74.7	3.5	+1.1	2.1	
28. ANB	4.2	2.1	3.7	3.0	−0.5	1.4	
29. $\underline{1}$/ANSPNS	112.6	4.5	113.0	5.1	+0.4	5.0	
30. $\overline{\underline{1}}$/GoMe	90.5	6.0	90.4	3.9	−0.1	3.9	

*$p \leq 0.05$.

ratio (S-Go/N-Me × 100) in the treated group showed a significant increase of 0.1 and 2.0, respectively, during the treatment period. In contrast, the ratio of N-ANS/ANS-Me was unchanged and a significant decrease was observed in the quotient expressing the ratio S-Go/N-Me in the control group over the time period studied.

The data in Table X show that differential mandibular corpus growth was observed in both groups for the same period. The amount of mean mandibular corpus incremental growth (Go-Me) in the treated group was 3.8 mm, and this value was approximately two thirds of the corresponding control groups value (Go-Me: 6.0 mm).

The upper posterior dentoalveolar height ($\underline{6}^{\perp}$ ANSPNS) increased significantly in both groups. However, it is of interest that the mean incremental increase of upper posterior dentoalveolar height in the control group ($\underline{6}^{\perp}$ ANSPNS: 3.2 mm) was almost twice that of the treated group ($\underline{6}^{\perp}$ ANSPNS: 1.8 mm) for the same period.

The data in Table X show that most angular changes in the treated group were statistically significant compared with the changes of the control group over the study period.

The SN/GoMe and ANSPNS/GoMe angles showed a significant decrease of 2.8° and 4.6°, respectively, whereas the SN/ANSPNS angle increased an average of 1.4° in the treated group. In contrast, the data of the control group showed that the SN/GoMe and ANSPNS/GoMe angles increased, whereas the SN/ANSPNS angle decreased slightly during the observation period.

In the treated group, the NSAr angle decreased

Table VI. Comparison of differences between girls and boys in the treated group according to the Mann-Whitney U test

	Treated group girls (N : 13)			*Treated group boys (N : 7)*			
	$\overline{D}$	*S*	*Wilcoxon test*	$\overline{D}$	*S*	*Wilcoxon test*	*Mann-Whitney U test*
Linear							
1. N-Me	+4.0	1.7	**	+3.7	2.3	*	
2. N-ANS	+3.4	1.2	**	+3.1	1.2	*	
3. ANS-Me	+0.7	1.6		+0.6	1.6		
4. S-Go	+4.4	1.3	**	+4.8	2.2	*	
5. S-Ar	+2.1	1.0	**	+2.6	1.5	*	
6. Ar-Go	+2.5	1.1	**	+2.2	0.9	*	
7. N-ANS/ANS-Me	+0.1	0.0	**	+0.1	0.0	*	
8. S-Go/N-Me × 100	+1.8	0.9	**	+2.3	1.2	*	
9. N-S	+2.1	0.7	**	+1.8	0.9	*	
10. Go-Me	+3.7	1.6	**	+4.1	0.9	*	
11. ANS-PNS	+2.6	1.6	**	+3.5	2.1	*	
12. Overbite	+4.9	1.2	**	+5.4	1.4	*	
13. $\underline{6}^{\perp}$ ANSPNS	+1.1	0.8	**	+2.9	1.6	*	##
14. $\overline{6}^{\perp}$ GoMe	+2.0	1.0	**	+1.1	1.1	*	
15. $\underline{1}^{\perp}$ ANSPNS	+2.6	1.2	**	+2.9	1.4	*	
16. $\overline{1}^{\perp}$ GoMe	+3.1	2.6	**	+2.8	1.4	*	
Angular							
17. SN/GoMe	−2.4	0.9	**	−3.4	1.1	*	
18. SN/ANSPNS	+1.5	1.5	**	+1.2	0.7	*	
19. ANSPNS/GoMe	−3.9	2.1	**	−4.5	1.1	*	
20. NSAr	−0.1	2.8		−2.8	2.1	*	
21. SArGo	−0.7	2.2		+1.2	2.3		
22. ArGoMe	−2.8	1.2	**	−3.6	2.2	*	
23. {<20 − <21 − <22	−3.7	2.3	**	−5.2	1.6	*	
24. SN/U.occ.plane	+3.9	2.1	**	+0.6	3.5		#
25. GoMe/L.occ.plane	+2.2	3.6	*	+4.8	4.2	*	
26. SNA	−0.3	1.2		+0.6	1.4		
27. SNB	+0.1	1.4		+1.6	1.0	*	#
28. ANB	−0.4	0.6	*	−0.9	0.9	*	
29. $\underline{1}$/ANSPNS	−5.2	3.5	**	−1.9	5.9		
30. $\overline{1}$/GoMe	−0.3	3.0		−0.3	3.1		

*$p \leq 0.05$; **$p \leq 0.01$; #$p \leq 0.05$; ##$p \leq 0.01$.

an average of 1.0°, whereas the average change in the ArGoMe angle was a decrease of 3.1°. Similarly, the treated group demonstrated a considerable decrease of 4.2° in the sum of the saddle (NSAr), joint (SArGo), and gonial (ArGoMe) angle. All these changes were significantly different from the changes determined in the control group.

The SN/Upper Occlusal Plane angle increased an average of 2.8° in the treated group, whereas the change in this measurement was an increase of only 0.6° in the control group. An increase of this angle in the treated group was significantly greater than in the control group.

The angulation of the upper incisors to the palatal plane ($\underline{1}$/ANSPNS) remained almost constant during the study period, decreasing an average of only 0.3° in the control group. However, in the treated group, the degree of retrusion of the upper incisors relative to palatal plane was 4.0°. The improvement in axial inclination of the upper incisors was found to be statistically significant in the treated group.

DISCUSSION

For better understanding of the findings of this study, polygons were drawn by using mean values obtained at initial and terminal stages of both treated and control groups, and these polygons were superimposed at Sella along the SN line (Figs. 6, 7 and 8). The initial skeletal patterns of the treated and control groups are seen to be analogous in Fig. 6. In Fig. 7, spontaneous changes due

Table VII. Comparison of differences between girls and boys in the control group according to the Mann-Whitney U test

	Control group girls (N: 13)			Control group boys (N: 7)			
	$\bar{D}$	S	Wilcoxon test	$\bar{D}$	S	Wilcoxon test	Mann-Whitney U test
Linear							
1. N-Me	+6.7	2.8	**	+8.5	2.0	*	
2. N-ANS	+3.1	1.8	**	+3.0	1.4	*	
3. ANS-Me	+3.6	1.7	**	+5.5	2.8	*	
4. S-Go	+2.9	1.3	**	+4.9	3.7	*	
5. S-Ar	+2.4	0.8	**	+2.6	1.7	*	
6. Ar-Go	+1.6	1.8	**	+3.0	3.6		
7. N-ANS/ANS-Me	0.0	0.0		0.0	0.0		
8. S-Go/N-Me × 100	−0.8	1.2	*	−0.1	2.2		
9. N-S	+2.0	1.0	**	+2.6	0.9	*	
10. Go-Me	+5.6	1.3	**	+6.9	1.8	*	
11. ANS-PNS	+2.4	1.6	**	+3.0	1.2	*	
12. Overbite	+1.7	2.1	*	+0.9	0.9	*	
13. $\underline{6}^{\perp}$ ANSPNS	+3.2	2.1	**	+3.3	2.8	*	
14. $\overline{6}^{\perp}$ GoMe	+1.6	1.2	**	+2.0	1.5	*	
15. $\underline{1}^{\perp}$ ANSPNS	+2.7	1.4	**	+1.9	0.8	*	
16. $\overline{1}^{\perp}$ GoMe	+2.3	1.1	**	+2.9	1.4	*	
Angular							
17. SN/GoMe	+0.7	2.1		+0.7	1.6		
18. SN/ANSPNS	0.0	2.9		−0.1	1.4		
19. ANSPNS/GoMe	+0.8	1.3		+0.8	1.8		
20. NSAR	+2.4	2.6	**	+0.4	1.9		
21. SArGo	−1.3	3.2		0.0	2.5		
22. ArGoMe	+0.5	2.2		−0.7	2.5		
23. {<20 − <21 − <22	+1.6	2.3	*	−0.3	3.1		
24. SN/U.occ.plane	+1.5	3.1		−1.1	0.8	*	#
25. GoMe/L.occ.plane	+2.2	2.9	*	+2.6	3.4		
26. SNA	−0.3	1.5		+0.6	1.0		
27. SNB	−0.4	1.4		+1.1	2.1		#
28. ANB	+0.1	0.9		−0.5	1.4		
29. $\underline{1}$/ANSPNS	−0.6	4.5		+0.4	5.0		
30. $\overline{1}$/GoMe	+1.1	2.9		−0.1	3.9		

*$p \leq 0.05$; **$p \leq 0.01$; #$p \leq 0.05$.

to growth observed in the control group during a 2-year period are seen. However, in Fig. 8, alterations that arose during a 2-year period in the treated group are observed.

Upward and forward mandibular rotation in the treated group was a most important finding in this investigation (Table X, Figs. 7 and 8). The reduction in mandibular plane angles (17. SN/GoMe, 18.ANSPNS/GoMe) occurred despite a concomitant increase in total anterior facial height. However, the rate of growth increase in total anterior facial height in the treated group was diminished, while the increase in total posterior facial height was stimulated. The overall diminishment in total anterior facial height growth was due to successful inhibition of lower anterior facial growth by the FR-4 appliance. It appears most likely that this reduction in mandibular plane angles was the result of differential increase between total posterior and anterior facial height (4.5 and 3.9 mm, respectively) over the study period. Greater posterior vertical growth would result in a lowering of the gonial region and subsequent upward and forward mandibular rotation. Theoretically, Fränkel and Fränkel[4-6] explained this rotation mechanism with the possible effect of the function regulator's buccal shields and lip seal exercises. They hypothesized that the posterior edges of the buccal shields are deeply positioned in the vestibular sulcus and provoke pressure sensation in this area. This could cause the inferior translation of the posterior part of the mandible with a compensatory translative

Table VIII. The pretreatment and posttreatment mean values of cephalometric measurements in the treated group (N : 20 = 13 girls and 7 boys) and comparison of differences according to the Wilcoxon test

	Pretreatment		*Posttreatment*		*Difference*		
	$\bar{X}$	*S*	$\bar{X}$	*S*	$\bar{D}$	*S*	*Wilcoxon test*
Linear							
1. N-Me	109.3	4.7	113.2	5.0	+3.9	1.8	***
2. N-ANS	45.8	2.2	49.1	2.4	+3.3	1.2	***
3. ANS-Me	63.5	3.9	64.1	4.5	+0.6	1.6	
4. S-Go	63.3	4.1	67.8	4.5	+4.5	1.6	***
5. S-Ar	28.8	2.2	31.0	2.3	+2.2	1.2	***
6. Ar-Go	37.7	2.8	40.1	3.2	+2.4	1.0	***
7. N-ANS/ANS-Me	0.7	0.1	0.8	0.1	+0.1	0.0	***
8. S-Go/N-Me × 100	57.9	3.1	59.9	3.4	+2.0	1.0	***
9. N-S	64.7	3.2	66.8	3.2	+2.1	0.7	***
10. Go-Me	60.6	2.1	64.4	2.5	+3.8	1.4	***
11. ANS-PNS	46.4	2.2	49.3	2.8	+2.9	1.8	***
12. Overbite	−3.9	1.3	1.1	0.9	+5.0	1.3	***
13. $\underline{\underline{6}}^{+}$ ANSPNS	18.7	1.4	20.5	2.2	+1.8	1.4	***
14. $\underline{\underline{6}}^{+}$ GoMe	27.5	1.8	29.2	2.1	+1.7	1.1	***
15. $\underline{1}^{+}$ ANSPNS	24.8	2.2	27.5	2.6	+2.7	1.2	***
16. $\underline{\underline{1}}^{+}$ GoMe	34.9	2.9	37.9	2.3	+3.0	2.3	***
Angular							
17. SN/GoMe	43.3	4.0	40.1	4.1	−2.8	1.1	***
18. SN/ANSPNS	7.8	2.8	9.2	3.4	+1.4	1.3	***
19. ANSPNS/GoMe	35.5	4.8	30.9	4.8	−4.6	2.6	***
20. NSAr	124.3	6.0	123.3	5.8	−1.0	2.8	
21. SArGo	145.9	6.9	145.8	6.9	−0.1	2.4	
22. ArGoMe	134.5	5.7	131.4	5.3	−3.1	1.6	***
23. {<20 − <21 − <22	404.7	4.2	400.5	4.2	−4.2	2.2	***
24. SN/U.occ.plane	19.0	3.2	21.7	4.6	+2.7	3.0	**
25. GoMe/L.occ.plane.	16.7	3.0	19.8	4.7	+3.1	3.9	**
26. SNA	78.3	2.6	78.3	2.5	0.0	1.3	
27. SNB	74.0	2.6	74.6	2.5	+0.6	1.5	
28. ANB	4.2	1.4	3.6	1.2	−0.6	0.7	**
29. $\underline{1}$/ANSPNS	112.3	5.2	108.3	5.9	−4.0	4.6	**
30. $\underline{\underline{1}}$/GoMe	91.6	5.6	91.3	5.0	−0.3	2.9	

$^{**}p \leq 0.01$; $^{***}p \leq 0.001$.

growth at the condyles, leading to an increase in ramus length. They suggested that, concomitant with the lowering of the posterior part of the mandible, its anterior part could be raised with the posterior edges of the FR as a rotational center. They concluded that such a forward rotation of the mandible was brought about by the force of the vertical muscle chain being strengthened by lip seal exercises. This hypothesis is supported by the findings of Ingervall and Bitsanis.[9] They found considerable anterior mandibular rotation in children with long-face structure during muscle training with chewing gum. However, Ingervall and Bitsanis[9] suggested the anterior mandibular rotation could be explained by reduced midfacial vertical growth due to increased masticatory muscle strength, instead of increased mandibular condylar growth.

Another noteworthy finding in this study was a reduction of the rate of mandibular corpus growth. Mandibular corpus growth increment value in the treated group was nearly two thirds that of the control group. As suggested by Fränkel and Fränkel,[6] "no wax is applied to the frontal region of the mandibular cast because the lip pads are not intended to stimulate alveolar basal development by exerting tension on the connective tissue fibers in the depth of frontal vestibular sulcus." So it seems reasonable to assume that this finding might be attributable to the effect of the FR-4 appliance.

Incremental increase in the upper posterior

Table IX. The preobservation and postobservation mean values of cephalometric measurements in the control group (N : 20 = 13 girls and 7 boys) and comparison of differences according to the Wilcoxon test

	Preobservation		*Postobservation*		*Difference*		
	$\bar{X}$	*S*	$\bar{X}$	*S*	$\bar{D}$	*S*	*Wilcoxon test*
Linear							
1. N-Me	110.2	5.4	117.5	6.2	+7.3	2.6	***
2. N-ANS	46.2	2.0	49.2	2.8	+3.0	1.7	***
3. ANS-Me	64.1	5.1	68.3	6.3	+4.2	2.3	***
4. S-Go	64.6	4.4	68.2	5.6	+3.6	2.5	***
5. S-Ar	29.5	2.8	32.0	2.7	+2.5	1.2	***
6. Ar-Go	38.7	3.4	40.8	4.5	+2.1	2.5	**
7. N-ANS/ANS-Me	0.7	0.1	0.7	0.1	0.0	0.0	
8. S-Go/N-Me × 100	58.6	2.4	58.0	2.9	−0.6	1.6	*
9. N-S	63.9	2.7	66.2	3.2	+2.3	1.0	***
10. Go-Me	59.3	3.5	65.3	4.4	+6.0	1.6	***
11. ANS-PNS	46.9	2.1	49.5	2.4	+2.6	1.5	***
12. Overbite	−3.5	1.4	−2.1	1.8	+1.4	1.8	**
13. $\underline{\underline{6}}^{+}$ ANSPNS	19.3	2.7	22.5	2.7	+3.2	2.3	***
14. $\underline{\underline{6}}^{+}$ GoMe	28.0	2.3	29.7	2.7	+1.7	1.3	***
15. $\underline{1}^{+}$ ANSPNS	25.7	2.9	28.1	2.7	+2.4	1.3	***
16. $\underline{\underline{1}}^{+}$ GoMe	35.9	2.8	38.4	3.1	+2.5	1.2	***
Angular							
17. SN/GoMe	43.8	3.2	44.5	3.8	+0.7	1.9	
18. SN/ANSPNS	9.0	3.1	9.0	3.6	0.0	2.4	
19. ANSPNS/GoMe	34.7	3.4	35.5	3.4	+0.8	1.5	*
20. NSAr	126.2	5.7	127.9	6.5	+1.7	2.6	**
21. SArGo	143.2	8.0	142.3	8.6	−0.9	3.0	
22. ArGoMe	134.8	4.5	134.9	5.1	+0.1	2.3	
23. {<20 − <21 − <22	404.2	3.2	405.1	4.3	+0.9	2.7	
24. SN/U.occ.plane	19.5	3.5	20.1	4.0	+0.6	2.8	
25. GoMe/L.occ.plane	17.2	3.2	19.6	4.0	+2.4	3.0	**
26. SNA	77.7	3.9	77.7	4.4	0.0	1.4	
27. SNB	73.4	3.2	73.6	3.7	+0.2	1.8	
28. ANB	4.3	1.9	4.2	2.3	−0.1	1.1	
29. $\underline{1}$/ANSPNS	112.7	5.0	112.4	5.5	−0.3	4.6	
30. $\underline{\underline{1}}$/GoMe	90.9	4.3	91.6	4.2	+0.7	3.2	

*$p \leq 0.05$; **$p \leq 0.01$; ***$p \leq 0.001$.

dentoalveolar height in the treated group was found to be almost half that in the control group. The occlusal rests of the FR-4 appliance on the upper first molars appear to restrict the rate of growth in upper posterior dentoalveolar structures. Several authors[9-12] have stressed that the intrusion of the posterior teeth can cause autorotation of the mandible anteriorly. However, the inhibition of growth in upper posterior dentoalveolar height found in this study is not in agreement with the opinion of Fränkel and Fränkel.[4-6] They suggest that "the FR appliance may not have had any intrusive effect on the maxillary molars or a depressive function on the vertical development of the posterior midfacial structures and the correction on the mandibular steepness, therefore, apparently is not due to mechanical interruption of sutural or alveolar growth of the posterior portion of the maxilla." However, their assumption is limited to the on the tracing of a single case.[4-6]

The decrease in upper incisor angulation to the palatal plane in the treated group was remarkably greater than that of the control group. The labial bow of the FR-4 contacts the upper incisors when the lips are sealed.[6] Therefore the effect of lip seal training with the FR-4 appliance also becomes apparent by the improvement in axial inclination of the upper incisors.

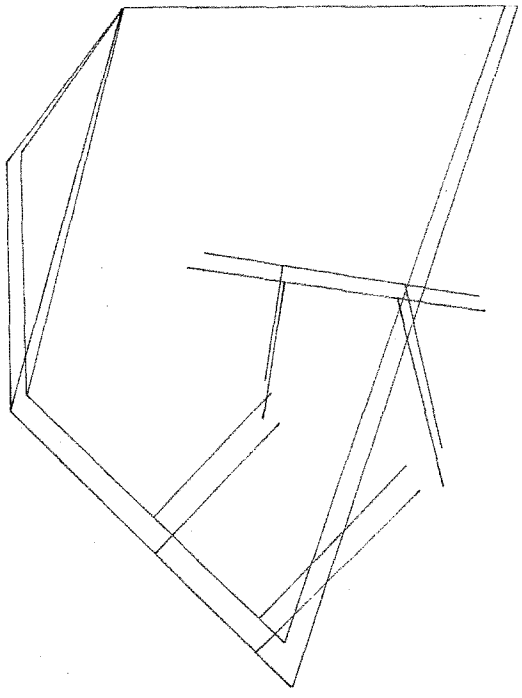

Fig. 7. Spontaneous changes in control group during 2-year observation period (red line; initial skeletal pattern and black line; terminal skeletal pattern).

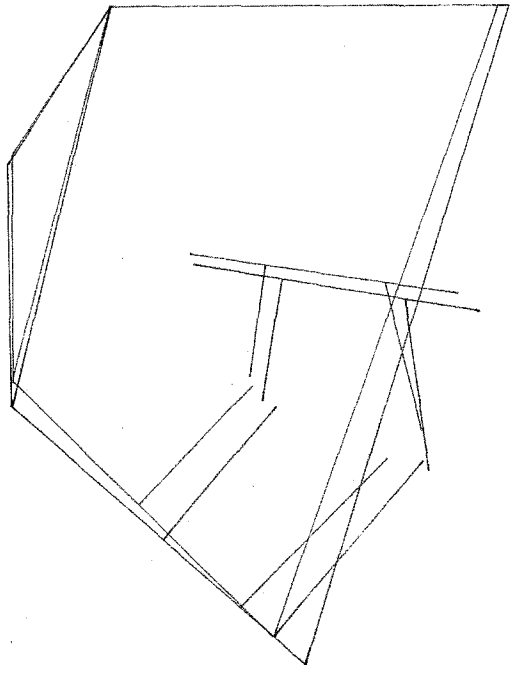

Fig. 8. Alterations arising during 2-year treatment period in treated group (red line; initial skeletal pattern and black line; terminal skeletal pattern).

Table X. Comparison of differences between the treated and control groups according to the Mann-Whitney U test

	Treated group (N : 20)			*Control (N : 20)*			
	$\overline{D}$	*S*	*Wilcoxon test*	$\overline{D}$	*S*	*Wilcoxon test*	*Mann-Whitney U test*
Linear							
1. N-Me	+3.9	1.8	***	+7.3	2.6	***	###
2. N-ANS	+3.3	1.2	***	+3.0	1.7	***	
3. ANS-Me	+0.6	1.6		+4.2	2.3	***	###
4. S-Go	+4.5	1.6	***	+3.6	2.5	***	#
5. S-Ar	+2.2	1.2	***	+2.5	1.2	***	
6. Ar-Go	+2.4	1.0	***	+2.1	2.5	**	
7. N-ANS/ANS-Me	+0.1	0.0	***	0.0	0.0		###
8. S-Go/N-Me × 100	+2.0	1.0	***	−0.6	1.6	*	###
9. N-S	+2.1	0.7	***	+2.3	1.0	***	
10. Go-Me	+3.8	1.4	***	+6.0	1.6	***	###
11. ANS-PNS	+2.9	1.8	***	+2.6	1.5	***	
12. Overbite	+5.0	1.3	***	+1.4	1.8	**	###
13. $\underline{\underline{6}}^{+}$ ANSPNS	+1.8	1.4	***	+3.2	2.3	***	#
14. $\overline{6}^{+}$ GoMe	+1.7	1.1	***	+1.7	1.3	***	
15. $\underline{\underline{1}}^{+}$ ANSPNS	+2.7	1.2	***	+2.4	1.3	***	
16. $\overline{1}^{+}$ GoMe	+3.0	2.2	***	+2.5	1.2	***	
Angular							
17. SN/GoMe	−2.8	1.1	***	+0.7	1.9		###
18. SN/ANSPNS	+1.4	1.3	***	0.0	2.4		#
19. ANSPNS/GoMe	−4.6	2.6	***	+0.8	1.5	*	###
20. NSAr	−1.0	2.8		+1.7	2.6	**	##
21. SArGo	−0.1	2.4		−0.9	3.0		##

Table X. Cont'd.

	Treated group (N : 20)			Control (N : 20)			
	$\bar{D}$	S	Wilcoxon test	$\bar{D}$	S	Wilcoxon test	Mann-Whitney U test
Angular							
22. ArGoMe	−3.1	1.6	***	+0.1	2.3		###
23. {<20 − <21 − <22	−4.2	2.2	***	+0.9	2.7		###
24. SN/U.occ.plane	+2.7	3.0	**	+0.6	2.8		##
25. GoMe/L.occ.plane	+3.1	3.9	**	+2.4	3.0	**	
26. SNA	0.0	1.3		0.0	1.4		
27. SNB	+0.6	1.5		+0.2	1.8		
28. ANB	−0.6	0.7	**	−0.1	1.1		
29. 1/ANSPNS	−4.0	4.6	**	−0.3	4.6		##
30. $\bar{1}$/GoMe	−0.3	2.9		+0.7	3.2		

*$p \leq 0.05$; **$p \leq 0.01$; ***$p \leq 0.001$; #$p \leq 0.05$; ##$p \leq 0.001$.

SUMMARY AND CONCLUSIONS

We found that a 2-year period of treatment with the FR-4 appliance had significant effects on the treatment of Angle Class I skeletal anterior open bite malocclusion.

It was concluded that as a result of treatment of these anomalies with the FR-4 appliance and lip-seal training, the growth and development pattern of the mandible was altered. The spontaneous downward and backward growth direction of the mandible which was observed in the control group was changed to a upward and forward direction by FR-4 therapy, allowing the skeletal anterior open bite to be successfully corrected through upward and forward mandibular rotation.

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