European Journal of Orthodontics 25 (2003) 311–318

The effect of Fränkel's function regulator type III on the apical base

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SUMMARY Dento-alveolar and skeletal effects of orthopaedic treatment have always been the subject of controversial scientific discussions. The objective of this retrospective study was to demonstrate the changes in the dental arch and the apical base of both jaws following therapy with Fränkel's function regulator type III (FR III).

For this purpose, 42 Class III patients (28 females, 14 males, mean age 7.5 years) were selected according to strict criteria. The control group consisted of 16 patients (eight females, eight males, mean age 8.3 years) with minor malocclusion symptoms. Study models of all patients at the beginning and end of treatment were evaluated using a sophisticated measuring system.

Apart from common parameters of model analysis, cusp inclination of the first molars, and apical bases of the maxilla and mandible were recorded to facilitate a comprehensive evaluation of treatment effects (including growth).

The FR III stimulated the development of the maxilla, thus resulting in a more physiological growth pattern. Mandibular prognathism, however, was still discernible after therapy in the Class III patients, even though mandibular growth did not differ significantly between the two groups.

Introduction

Among a great variety of appliances, Fränkel's function regulators (FR) have become a well-established adjunct for functional orthopaedics. Their mode of action, however, is still a subject of controversy (McNamara, 1973; Neumann, 1975; Fränkel, 1984; Firatli and Ülgen, 1996).

According to Fränkel, a Class III is the result of a maxillary growth deficit and concomitant excessive mandibular growth (Fränkel and Fränkel, 1992). Thus, the FR III (Figure 1) aims to counteract the forces of the surrounding muscles which presumably restrict maxillary growth. Due to the appliance design, a reciprocal growth-restricting force is believed to affect the mandible (Fränkel and Fränkel, 1992).

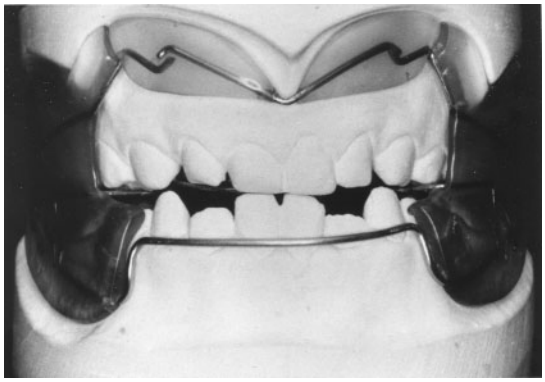

Figure 1 Function regulator type III (FR III) according to Fränkel.

Whenever discussing an orthodontic treatment procedure, a distinction should be made between its effect on the dental arch (dento-alveolar effect) and on the apical base (skeletal effect). In general, as stated by its inaugurator, Lundström (1923), the influence of any orthodontic therapy on the apical base is rather limited (Hausser, 1962; Nawrath, 1962; Rottsahl, 1962; Rinderer, 1965; Mühlberg *et al.*, 1966, 1968). However, due to their construction, Fränkel claims that FRs have a remarkable skeletal effect, i.e. a dimensional change in the apical base.

To evaluate if treatment effects were dento-alveolar or skeletal, various methods have been employed: measuring models at the crown and apex level (Falck, 1969; Firatli and Ülgen, 1996), cutting models sagittally/transversally at specific areas (Hausser, 1962), placing indicator devices on teeth (Chateau, 1975), or analysing cephalograms in antero-posterior (Rinderer, 1965; Owen, 1983, 1988; Firatli and Ülgen, 1996), lateral (Hausser, 1962; Rottsahl, 1962; Ruhland, 1964; Mühlberg *et al.*, 1968; Falck, 1981; Kerr and Tenhave, 1988; Kerr *et al.*, 1989; Ülgen and Firatli, 1996) or fronto-occipital (Mühlberg *et al.*, 1966, 1968; Mühlberg and Zill, 1969) projection, partially again with tooth inclination indicator devices (Mühlberg *et al.*, 1968).

The limitation of all cephalometric studies so far is that any effect of growth and/or treatment is only described in one plane and two dimensions. Model cast studies also have shortcomings because as sections take place in only a few areas, reference points cannot be established or are not reproducible, and conclusions can only be

drawn indirectly (e.g. tipping of teeth indicating a minimal effect on the apical base).

The present study was designed to examine, using a new method, the influence of the FR III on the maxilla and mandible, differentiating between dento-alveolar and skeletal treatment effects.

Subjects and methods

Forty-two patients (28 females, 14 males) in the FR group were consecutively selected from the orthodontic sections of two different dental clinics in Berlin. The selection criteria were:

- Class III malocclusion with anterior crossbite and mesio-occlusion;
- availability of high-quality models with precise reproduction of the dentition as well as the alveolar process into the region of the apical base;
- treatment exclusively with the FR III except in some patients with initial minor interventions, such as elimination of prematurities, spatula exercises, and chin cap therapy, for only a very short period as compared with FR therapy time;
- no extraction of any permanent teeth;
- no aplasia of teeth;
- no gingival recessions.

The average patient age at the beginning and end of treatment was 7.5 ± 1.5 and 11.1 ± 2.2 years, respectively. The average treatment time with the FR III was 42.6 ± 25.8 months.

The 16 patients (eight females, eight males) of the control group were selected from the same clinics. This sample comprised subjects with minor malocclusions, i.e. ectopic position of single teeth, midline diastemas or Class II (distocclusion less than half cusp). Their average age at the beginning and end of treatment was 8.3 ± 1.3 and 10.9 ± 1.2 years, respectively. The average treatment time with various appliances was 32.0 months.

All measurements on the initial and final models were carried out with a sophisticated three-dimensional (3D) co-ordinate measuring device (Type DKM 330, Carl Zeiss, Jena, Germany) (Schenk, 1987; Schenk and Wiemann, 1982). Its core component is a 3D measuring probe. When contacting a reference point on a model with the tip of the probe, the 3D point co-ordinates are automatically recorded. According to the manufacturer, the measurement error is $\pm(1.5 + L/200)$ µm (L = measured distance in mm) (Schenk, 1987). Thus, a minimum precision of 0.1 mm is regularly obtained. During all measurements, the study casts were fixed in a special positioning device which guarantees 3D orientation of the maxillary to mandibular model (Figure 2). For further processing, all data were transferred to a computer.

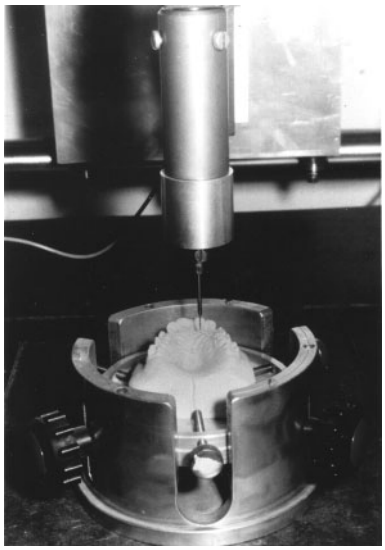

Figure 2 The measuring device used in this investigation. The study cast is fixed in the positioning device and measurements are carried out with a three-dimensional probe. The positioning device guarantees reproducible orientation of the maxillary and mandibular model.

Prior to any recording, all reference points were marked on each individual model. Subsequently, the 3D reference system was established. The respective reference points and their definitions as well as locations are shown in Figure 3.

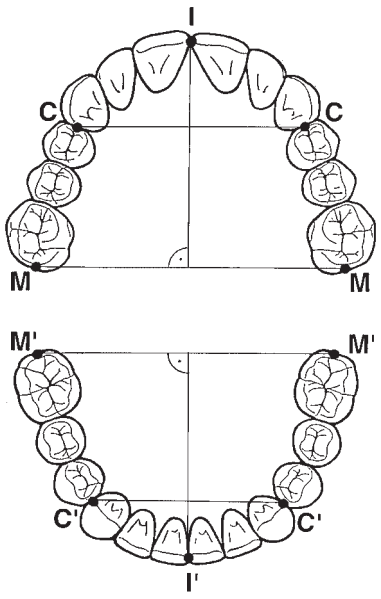

Figure 3 Definition of reference points and calculated parameters on patient models. Reference points: I, contact point of the permanent maxillary central incisors; C, distal contact point of the primary or permanent maxillary canines; M, distal contact point of the maxillary first permanent molar. The respective points in the mandibular arch are labelled I′, C′, M′. Calculated parameters: anterior dental arch width: C–C and C′–C′, respectively; posterior dental arch width: M–M and M′–M′, respectively; dental arch length: perpendicular from M–M and M′–M′ to I and I′, respectively.

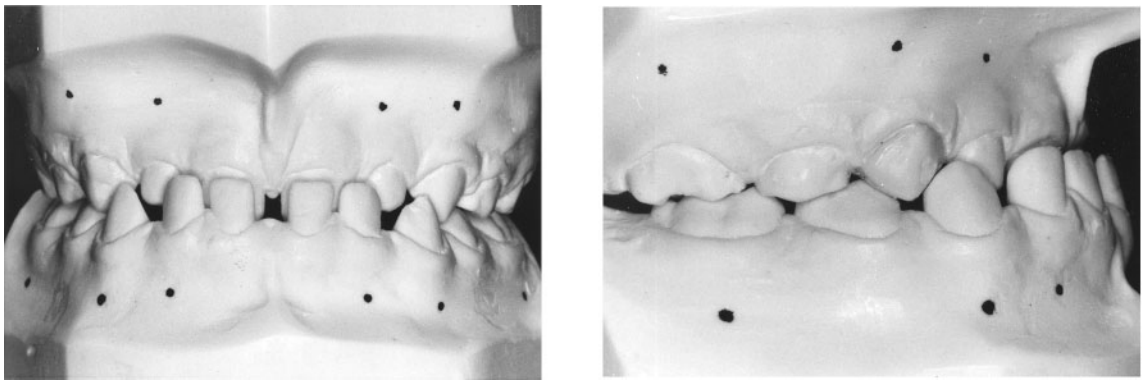

Figure 4 Additional reference points for defining the apical base. These were located 5 mm below the most apical point of the gingival margin of the lateral incisors, canines and second primary molars/premolars.

The measuring system calculated the following values (Figure 3; I, C, M = reference points in the maxillary dental arch; I′, C′, M′ = reference points in the mandibular dental arch):

- dental arch width: anterior width: C–C and C′–C′, respectively; posterior width: M–M and M′–M′, respectively;
- dental arch length: perpendicular from I to M–M and I′ to M′–M′, respectively;
- cusp inclination: the angle between the occlusal plane and a line connecting the buccal and lingual cusps of the first molars;
- apical base: area resulting from a peripheral connection of six additionally recorded reference points which were located 5 mm below the most apical points of the gingival margin of the lateral incisors, canines and second primary molars/second premolars (Figure 4).

Pre- and post-therapeutic situations were evaluated metrically and subjectively by visual inspection of the study casts: sagittal and vertical incisor positions as well as occlusions were recorded metrically according to established model analysis procedures. The maxillary and mandibular transverse relationships (crossbite etc.) and incisor inclination were scored visually, using a scoring system similar to Eismann (1971) and Miethke and Fischer (1987). This system was designed to result in high scores for patients with mandibular prognathism/maxillary retrognathism (Table 1).

Table 1 Scoring system for visual model evaluation.

	mm	Points
Occlusion (each right/left)		
Distal (Class II)	3	0
	2	1
	1	2
Neutral (Class I)		3
Mesial (Class III)	1	4
	2	5
	3	6
	4	7
	5	8
Crossbite (right and left/antagonistic pair)		
Physiological transverse intercuspation		0
Crossbite tendency (half tooth width)		1
Crossbite		2
Crossbite with buccal cusp of the maxillary tooth occluding on lingual cusp of antagonist		3
Mandibular lingual crossbite		4
Maxillary incisor inclination		
Proclined		0
Physiological		1
Retroclined		2
Mandibular incisor inclination		
Retroclined		0
Physiological		1
Proclined		2

Statistical analysis

For all measurements, an in-built statistical program calculated arithmetic means, medians, and standard deviations. Differences between the start and end of treatment within a group and between the two groups were evaluated for significance using non-parametric tests due to the non-normality of the sample groups. Within groups, the Wilcoxon rank test was performed, whereas the FR and control groups were compared by means of the Mann–Whitney *U*-test. The level of significance was set at less than 0.05.

For those results obtained by conventional model analysis and subjective visual inspection, only arithmetic means were calculated.

Error analysis

To reduce the measurement error, the apical base area was calculated three times and the arithmetic mean was taken as the final value. To evaluate the localization error of the employed reference points for the apical

base, one model was selected at random and every single point was re-marked independently (after being removed during the previous session) on nine occasions with intervals of at least 14 days. Simultaneously, the values for the maxillary and mandibular apical base were independently calculated. Thus, 10 independent data sets were used to analyse the individual localization error as the variation coefficient $s \times 100/m$ (s = standard deviation, m = arithmetic mean).

Results

The error analysis revealed an error of 1.2 per cent for the apical base size in both arches.

Tables 2 and 3 show all calculated parameters at the start and the end of treatment for the FR and control groups. Significant differences are marked with an asterisk.

Table 2 Arithmetic mean values, standard deviation (SD) at the beginning and end of treatment for measured parameters, and calculated differences in the function regulator group, $n = 42$.

Parameter	Beginning of treatment		End of treatment		Difference		
	Mean	SD	Mean	SD	Mean	(%)	SD
Dental arch width (mm)							
Anterior width maxilla	32.8	2.5	35.8	2.3	2.9*	9.3	2.4
Posterior width maxilla	42.4	2.9	46.7	2.9	4.4*	10.8	3.4
Anterior width mandible	29.2	2.1	31.1	2.5	2.0*	7.2	2.9
Posterior width mandible	44.7	2.9	46.6	2.5	2.0*	4.8	2.6
Dental arch length (mm)							
Maxilla	33.0	4.6	35.4	2.4	2.3*	8.8	4.0
Mandible	32.2	4.5	33.0	3.1	0.7	3.9	4.5
Cusp inclination (°)							
Maxillary right first molar	14.7	6.0	12.2	5.5	–2.5*	l†	5.8
Maxillary left first molar	14.7	6.1	10.9	4.3	–3.8*		5.6
Mandibular left first molar	12.3	7.2	7.1	4.4	–5.2*		5.5
Mandibular right first molar	14.9	6.4	9.4	4.9	–5.5*		6.3
Apical area (mm²)							
Maxilla	856.4	101.2	898.9	103.1	48.6*	6.1	63.5
Mandible	815.4	111.0	865.5	94.8	51.2*	7.1	57.9

*Statistically significant, $P < 0.05$.
†Calculation not meaningful (no standard reference).

Table 3 Arithmetic mean values, standard deviation (SD) between the beginning and end of treatment for measured parameters, and calculated differences in the control group, $n = 16$.

Parameter	Beginning of treatment		End of treatment		Difference		
	Mean	SD	Mean	SD	Mean	(%)	SD
Dental arch width (mm)							
Anterior width maxilla	34.7	1.6	36.6	1.8	1.9*	5.8	2.3
Posterior width maxilla	43.0	2.0	46.9	4.0	3.9*	8.9	2.6
Anterior width mandible	31.2	2.6	31.4	1.9	0.2	1.2	2.7
Posterior width mandible	43.2	2.2	45.4	2.4	2.2*	5.1	1.5
Dental arch length (mm)							
Maxilla	39.0	1.5	38.2	2.2	–0.9	–2.2	2.1
Mandible	36.0	1.9	34.5	2.9	–1.6*	–4.4	1.5
Cusp inclination (°)							
Maxillary right first molar	7.7	4.9	6.2	4.0	–1.6	†	3.1
Maxillary left first molar	6.9	5.0	5.6	2.8	–1.3		3.9
Mandibular left first molar	10.3	4.5	8.9	3.8	–1.4		5.6
Mandibular right first molar	13.0	4.1	7.5	4.6	–5.4*		4.9
Apical area (mm²)							
Maxilla	942.8	107.9	971.7	98.1	29.0	3.4	5.4
Mandible	826.6	48.7	842.1	78.3	12.5	1.4	4.7

*Statistically significant, $P < 0.05$.
†Calculation not meaningful (no standard reference).

Anterior and posterior dental arch width

Both groups showed a significant increase in anterior and posterior maxillary dental arch width.

In the mandible, there was a significant increase in the anterior and posterior dental arch width in the FR group. In contrast, only the posterior dental arch width increased significantly in the control group.

Dental arch length

The maxillary dental arch length increased significantly in the FR group.

In the mandible, the dental arch length decreased significantly in the control group.

Cusp inclination

At the start of treatment, the first molars in the FR group were more buccally inclined in the maxilla and more lingually inclined in the mandible than in the control group. The inclination decreased significantly (i.e. the first molar uprighted) during treatment in the FR group. In the control group, the inclination only decreased significantly for the lower right first molar.

Apical base

There was a significant increase in the maxillary and mandibular apical base in the FR group during treatment. The ratio between the maxillary and mandibular jaw base was smaller in the FR group at the start (1.05) and at the end (1.04) of treatment than in the controls (1.14 and 1.15, respectively). It is also obvious that the ratio decreased in the FR group but increased in the control group. These ratio changes were not significant.

Model evaluation

Model evaluation was performed for the FR group only. Table 4 shows that all parameters except mandibular incisor inclination shifted towards 'normal' scores.

Table 4 Parameters of model evaluation at the beginning and end of treatment in the function regulator group, $n = 42$; overjet and overbite in mm, all other parameters in scores according to Table 1.

Parameters	Treatment	
	Beginning	End
Overjet	–1.8	1.2
Overbite	1.6	1.8
Occlusion		
Right	4.0	3.1
Left	4.2	2.8
Crossbite		
Right	2.2	1.1
Left	2.1	1.2
Incisor inclination		
Maxilla	1.0	1.0
Mandible	0.9	0.7

Discussion

Subjects and method

The number of patients in the FR group (42; 28 females, 14 males) seems to be sufficient, at least for a clinical study with meaningful results. The number of individuals in the control group (16; eight females, eight males) is much more critical. However, all individuals in this group had to fulfil a criterion which is hard to meet in orthodontic patients: only minimal malocclusion symptoms. Whilst the sample size of the control group could have been enlarged by choosing children from other dental practices, this, however, would have negatively influenced the homogeneity of this group.

Whilst all the subjects in the experimental group wore an FR III for most of the total treatment time, it cannot be excluded that the other applied treatment procedures also influenced the results. However, these procedures comprised just minor interventions and only for a very limited time span. Therefore, it is felt that the FR III was the appliance which had the strongest impact on treatment outcome. Also, it has to be considered that in any retrospective study one will seldom find sufficient patients treated with just one single appliance. The fact that the treatment time extended over such a long period is not surprising and in accordance with Fränkel, who recommended that FR therapy should be started in the early mixed dentition and continued until the permanent dentition is complete when fixed appliances can be placed to refine the occlusion.

With regard to the control group, two samples would have been optimal: either untreated Class III patients or individuals with ideal occlusions (also untreated). However, untreated individuals with an ideal occlusion are extremely rare and not found in an orthodontic environment. On the other hand, it would be ethically unreasonable to follow Class III patients on average for 32 months without treating them. The same argument holds true for patients with minor malocclusion symptoms.

Another criticism could be that no cephalometric analysis was performed to verify the diagnosis of a Class III malocclusion. However, cephalostats were not standard equipment in orthodontic practices of the former German Democratic Republic where the material of this study was selected. This possible flaw seems to be compensated for by the fact that a thorough model analysis was used instead and all orthodontists had

excellent training in the handling of the FR III. Thus, the appliances inserted in the patients of this study were probably closest to the ones intended by Fränkel.

The measuring procedure was performed with a sophisticated device (Schenk and Wiemann, 1982; Schenk *et al.,* 1986; Schenk, 1987) which helped to keep the localization error small. Whilst, the accuracy of the method could have possibly been compromised by the model production process, this inaccuracy would, however, influence all models and can therefore be regarded as a negligible systematic error. Finally, it could be criticized that there is no error analysis for the model evaluation. On the other hand, the impact of the model evaluation is so minor that this lack seems again to be negligible.

The apical base was evaluated by electronically connecting six defined points on the alveolar process, thus establishing a surface which could be measured in square millimetres (Figure 5). This surface consists not only of bone, but also includes the mucosa.

By simultaneously recording molar cusp inclination, additional information could be gained on the development of the osseous structures during FR III treatment. Specifically, this means that any increase in molar cusp inclination is an indication that the FR III has a more dento-alveolar than skeletal effect.

Overall, all previous studies had methodological limitations and the same holds true for this investigation. Its methods, however, can be looked upon as another attempt to gain a more comprehensive insight into the effect of the FR III on the dentition and the underlying skeletal structures.

Falck (1969) used a somewhat similar method to that used in this study. However, his reference points for the apical base evaluation were located near the vestibular fold, on average about 14 mm away from the buccal cusp of the first primary molars and first premolars. The problem with such reference points is that in the mixed dentition the first primary molars can be replaced by the first premolars which in consequence would lead to an inaccuracy in reference point localization. In the present study, reference points at a constant distance from the gingival margin were chosen to avoid this problem. To make the gingival margin an even more reliable reference structure, all patients with gingival recessions were excluded. Because all the children underwent oral hygiene measures their gingiva was healthy and therefore its condition did not influence the localization process. Still, it is a flaw that the distance from the gingival margin was only 5 mm thus not truly reflecting the apical base. On the other hand, the greater the distance between the reference points and the occlusal surfaces the more they are influenced by individual alveolar morphology and the quality of the impression.

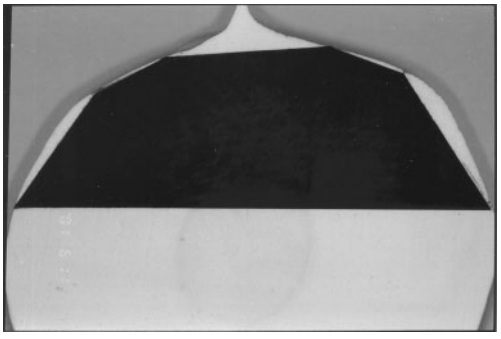

Figure 5 Depiction of the area resulting from electronically connecting the six reference points which define the apical base. The measuring device calculates this surface in square millimetres.

The inclination of posterior teeth has been studied in other investigations in two different ways. One was to place small metal onlays with indicators on the respective teeth (Gehring, 1950; Chateau, 1975). When light shone on these models the indicators appeared as shadows on a screen. Even if the angle between the two shadows could be readily measured, the overall process has to be considered as rather costly. The other method worked with similar indicators but was based on postero–anterior (PA) radiographs (Mühlberg *et al.*, 1966, 1968; Mühlberg and Zill, 1969). The disadvantage of this method can be seen in an unjustified exposure to X-rays. However, studies of patients treated with the FR III using the latter method showed that the inclination of the first premolars varied widely from not discernible to remarkable. The same was true for the influence on the apical base which developed very well in some patients but not at all in others.

Results

Anterior and posterior dental arch width. Initially, the FR group had a reduced anterior and posterior maxillary dental arch width compared with the controls. This is in accordance with the existing malocclusion, assuming that the Class III in these patients was mainly a consequence of a maxillary deficiency. The transverse parameters increased significantly in both groups, but were more pronounced in the FR group. This positive development could be attributed to the FR III treatment. Similar changes were found by Firatli and Ülgen (1996) on study models. Those authors could, however, not confirm their findings on PA radiographs of the same patients.

The fact that the maxillary dental arch width increased is *per se* of limited value. Assuming that the average Class III is a skeletal malocclusion, it is of definite importance whether any change in dental arch dimension is only a result of tooth tipping or of an actual increase in the size of the maxillary/mandibular apical base. In other words, all changes in dental arch dimensions have to be evaluated in relation to the respective changes in molar inclination and the apical base.

In the mandible, the anterior dental arch width was smaller in the FR group than in the control group, the reverse holds true for the posterior dental arch width. Both parameters increased significantly in the FR group during treatment. This is apparently a symptom of non-physiological mandibular growth in combination with a low tongue posture. At the same time it should not be taken as a sign of the inefficacy of the FR III because it is not proven how the dental arch width would have developed if these patients had not been treated at all.

Dental arch length. The fact that both the maxillary and mandibular arch length were shorter in the FR group than in the control group is difficult to interpret with the existing malocclusion. The significant increase in maxillary arch length in the FR group, however, could be explained as a treatment effect, especially as this length decreased (although not significantly) in the control group. The arch length increase in the maxilla was obviously not a consequence of proclination of the maxillary incisors, as the model evaluation revealed a normalization of their position. On the other hand, the non-significant increase in mandibular arch length could be an indication of restricted growth inhibition by the FR. Again, the final interpretation has to take molar inclination and the apical base into consideration.

Cusp inclination. It cannot be ruled out that cusp inclination is influenced by occlusal wear. However, it is felt that the first molars will not undergo undue attrition during a period of 2.5 (control group) to 3.5 years (FR group), which was the average treatment time. Besides, any occlusal wear will be another systematic error because it would affect patients in both groups to the same degree. Obviously, FR therapy does not increase the inclination (flaring) of the maxillary first molars. However, the buccal crown inclination remained larger in the FR group than in the control group, which again could be seen as a dento-alveolar compensation tendency.

As in the maxilla, the mandibular first molars also uprighted. In the FR group this uprighting was significant in contrast to the control group where it was significant only at the mandibular right first molar. The increase in buccal crown inclination in the FR group can again be interpreted as an expression of increased mandibular growth and/or non-physiological tongue posture.

Size of the apical base. Initially, the maxillary and mandibular apical base in the FR group was smaller compared with the control group. This is again an indication that the Class III was primarily due to a maxillary deficiency. If growth stimulation of the maxilla is more feasible than growth restriction in the mandible, this could be an explanation for the fact that the increase in the maxillary apical base was significant in the FR group but not in the control group. Even so, the maxillary apical base of the control group was on average still about 73 mm^2 larger than that of the FR group. This can either be taken as a limitation of the therapeutic efficacy of the FR III and/or an indication of the ongoing abnormal skeletal growth. The limitation of FR III treatment becomes clearer with the fact that the mandibular apical base was not significantly increased in the control sample but was in the FR group. This significant increase was so large that the mandibular apical base in the FR group at the end of treatment was greater than that of the control group. Finally, the efficacy but also the limitations of the FR III are evident when comparing the ratios of maxillary/mandibular apical bases of the FR group at the beginning (1.05) and end (1.04) of treatment, taking into consideration that during physiological growth (control group) the ratio at the end of treatment was 1.14 and thus larger.

Falck (1969), with his similar method, found a corresponding increase in the maxillary apical base in those patients treated with the FR.

Model evaluation. The model analysis revealed an overall improvement in all Class III malocclusion symptoms with one exception, mandibular incisor inclination. These teeth became more lingually inclined, which could be considered as a dento-alveolar adaptation to compensate the non-physiological growth of the mandible.

Conclusions

1. Under the conditions of this investigation, the FR III was found to be an effective appliance, as indicated by a comparison between pre- and post-treatment study models.
2. This effect probably takes place in the maxilla, as indicated by an increase in different dental arch parameters in combination with a decrease in cusp inclination and a significant increase in apical base.
3. FR treatment never results in 'normalization' but only an approximation to normal parameters of the respective dental or skeletal structures.
4. The present study did not prove the FR III to be an appliance to correct every Class III malocclusion. This is not a negative remark because the FR III will remain an indispensable treatment adjunct until replaced by a more effective one.
5. This study, with all its limitations, was an attempt to evaluate objectively the treatment effect of the FR III. Although the results were subjectively disappointing, the FR III will continue to be used until a more effective and comparably simple appliance for early treatment of patients with a Class III malocclusion is developed.

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