A comparison of skeletal and dental changes produced by Function Regulators (FR–2 and FR–3)

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SUMMARY The lateral skull radiographs of subjects taken before and after treatment with the FR–2 (N=99) and FR–3 (N=30) of Fränkel were compared to contrast the effects of each appliance. The major skeletal effect of both appliances was on the mandible, the FR–2 group showing a significantly greater annual increase in total length and ramus height (P<0.001) and the FR–3 group a significant change in position downward and backward facilitated by an opening of the cranial base angle. The greater annual increase in lower facial height, compared with a control group, seen in both FR groups was accompanied by a reduction in overbite, which was greater in the FR–2 group. The favourable change in overjet seen in both FR groups was contributed to by alteration in upper and lower incisor inclination.

Introduction

Fränkel (1980a) has stated that a faulty postural performance pattern may play an important causative role in the development of skeletal deformities. He maintains that the primary therapeutic problem in functional orthopaedics is to overcome these postural disorders. It is this concept that has promoted the use of Function Correctors or Regulators, particularly in the treatment of Class II and Class III malocclusions in which an anteroposterior skeletal discrepancy is one of the main aetiological factors.

In addition to its role as a muscle training appliance, the Function Regulator also has application in influencing the development of the jaws. In the case of Class II malocclusion, Fränkel maintains that the artificial forward displacement of the mandible produced by the appliance stimulates adaptive changes in the associated skeletal structures, similar to those demonstrated in animal studies (e.g., Stockli and Willert, 1971, McNamara, 1972, McNamara and Bryan, 1987). Similarly, the main therapeutic principle in operation in the treatment of Class III malocclusion is the elimination of all factors which may impede maxillary development, while at the same time restricting mandibular development (Fränkel, 1970).

Several studies have examined the treatment effects produced by either the FR–2 or the FR–3 appliance of Fränkel. For example, McNamara et al. (1985), in a study of the treatment effects produced by the FR–2 appliance in comparison to untreated Class II subjects, demonstrated that this appliance had little effect on maxillary structures, with the exception of point A which moved slightly posteriorly. They also noted the advancement of the mandible along the facial axis, and they noted that the increments of increase in mandibular length were greater in the treated group than in the controls. They also reported an increase in the development of lower facial height in the treated group.

Gianelly et al. (1984), on the other hand, when comparing the effects of light wire, edgewise and Fränkel appliances in the treatment of Class II, division I malocclusion were unable to demonstrate any additional mandibular effect with the Fränkel appliance.

The first study which examined the effect of the FR–3 appliance was published by Fränkel in 1970. He compared a group of subjects treated with the FR–1 appliance (similar in most respects to the FR–2 appliance) with Class II malocclusion to a group of subjects treated with the FR–3 appliance for Class III malocclusion, thereby seeking to compare and contrast the modes of
action of the two appliances on the skeletal tissues. Fränkel used linear cephalometric measurements made from the Occipital point (Fränkel, 1980b) as a reference base, a point close to Basion. Highly significant differences (P < 0.001) were shown between the groups in the behaviour of point A and point B during treatment. He noted a greater forward movement of point A in the FR-3 sample, and a greater movement of point B in the FR-2 sample during treatment.

More recently, Loh and Kerr (1985) examined the effect of the FR-3 appliance in cases of Class III malocclusion. This study demonstrated only a minimal treatment effect on the maxilla. Although mandibular size continued to increase, the postural position of the mandible was considered altered in a downward and backward direction.

Robertson (1983), however, in describing two groups of 12 subjects treated with the FR-1 and FR-3 appliances concluded that the principal effect of each was dento-alveolar.

With the exception of Fränkel's 1970 study, no reports appear in the literature that directly compare the effect of Function Regulators in the treatment of Class II and Class III malocclusion. The purpose of the present study was to compare the Class II sample of McNamara et al. (1985) which was treated with the FR-2 appliance with the augmented sample previously described by Loh and Kerr (1985), so that the treatment effects produced by each type of appliance could be contrasted in more detail. In addition, these two samples were compared with a control group so that any deviation from normal growth trends would become more apparent.

Subjects and methods

The material examined in this study consisted of lateral cephalometric radiographs of patients with Class II, division I and Class III malocclusion available before and after active correction with the FR-2 and FR-3 appliances respectively. The Class II sample of 99 individuals was derived from the records of patients treated in eight private practices in the United States, as previously described by McNamara et al. (1985). The sample was composed of 43 males and 56 females who had a mean age of 10.2 years (s.d. = 1.8 years) at the beginning of the study.

The average interval between films was 1.9 years (s.d. = 0.7 years).

The FR-3 sample was gathered from patients treated at the Glasgow Dental Hospital and School in Scotland. For the purpose of the investigation this material was confined to subjects who initially exhibited lingual occlusion of the maxillary central incisors and for whom lateral cephalometric radiographs were available immediately prior to and after FR-3 treatment and whose co-operation in wearing the appliance was judged as good. On average, this sample began treatment at 10.5 years of age (s.d. = 2.2 years). The average interval between films was slightly longer in the FR-3 group than in the FR-2 group, with an average interval of 2.5 years (s.d. = 1.3 years) between films. A total of 30 subjects with Class III malocclusion was studied, 10 males and 20 females.

For comparison, a group of 61 untreated individuals (24 males and 37 females) was studied. These records were obtained from The University of Michigan Elementary and Secondary School Growth Study which has longitudinal records on untreated individuals. The average age at the time of the initial film was 10.4 years (s.d. = 1.7 years), and the interval between films was 2.2 years (s.d. = 0.6 years). It should be noted that the individuals in this group represent a normative rather than ideal sample of growing individuals. Various types of malocclusion were represented in this group with a bias toward Class II rather than Class III malocclusion, and with an overall tendency toward an increased lower anterior facial height.

Fifty-seven hard tissue points were digitized on each film according to the protocol previously described by Riolo et al. (1974) and modified by McNamara et al. (1985). For the purpose of this study only the 21 points listed below and shown in Fig. 1 were utilized:

1. Nasion
2. Fronto-maxillary nasal suture
3. Sphenoid registration point
4. Sella
5. Condylion
6. Basion
7. Gonion
8. Menton
9. Pogonion
10. Point B
11. Infrafrente

Results

Analysis of starting form (Table 1)

As in the previous study of McNamara et al. (1985), a comparison of mean pre-treatment measures was carried out on the sample in order to determine differences among groups at the start of treatment.

Cranial base relationships

No significant differences in starting form could be demonstrated between the Class II group and the control group, with regard to the angle formed between Basion, Sella and Nasion. In contrast, the cranial base angle was more acute in the Class III sample (126.5 degrees in comparison to controls 130.1 degrees). Similar findings were observed in the angle Bu-Se-FMN.

Maxillary skeletal relationships

No differences in maxillary skeletal position were noted between the control and Class II sample with regard to the SNA angle, although the Class II sample had a slight tendency towards a more retrusive maxilla. This relationship was confirmed when the maxillary skeletal measure of Enlow was used. A significant difference between control and Class II values was noted.

The Class III sample demonstrated significant skeletal retrusion compared with the other two groups. The SNA angle was 78.9 degrees and Enlow's maxillary skeletal distance was 48.3 mm in the Class III sample, as opposed to 53.7 mm in the control and 52.3 mm in the Class II group.

Mandibular skeletal relationships

Mandibular dimensions were all significantly smaller in the Class II and Class III groups as compared with the control group. The only dimension that differed between the two treatment groups was the length of the mandibular corpus (Go-Pog), a measure that was smaller in the FR-2 group. The gonial angle was more obtuse in the FR-3 group compared with the other two samples. All the comparisons for
angles SNA and SN-Pogonion and Enlow’s skeletal mandibular distance were significant. The Class II group exhibited skeletal retraction (SNA = 74.8°, Mand.Sk. = 48.0° mm) and the Class III group skeletal protrusion (SNA = 81.4°, Mand.Sk. = 55.6 mm), while the control group values fell in between these extremes. The Enlow skeletal ratio and the angle ANB confirmed the retrognathia of the prognathic and orthognathic character of the FR-2, FR-3 and control groups respectively.

**Vertical skeletal relationship**
Lower face height was similar in the FR-2 and FR-3 groups, but significantly less (P<0.001) than in the control group.

**Dental relationships**
The upper incisors in the FR-2 group were, on average, more proclined than in the controls, but because of a wide variation within the group the difference was not significant. In contrast the upper incisors in the FR-3 group were significantly more retroclined than in the other two groups. The lower incisors were significantly more retroclined in the FR-3 group than in the other two groups. The overbite was deepest in the Class II group but similar in the other two groups.

The Enlow dental distances showed the maxilla to be of similar length in the FR-2 and control groups but significantly smaller in the FR-3 group. Conversely, the mandibular dental distance was smaller in the FR-2 group (50.5 mm) and larger in the FR-3 group (57.2 mm) compared with the control group (54.2 mm), all comparisons being significant.

**Annual treatment changes. (Table 2)**
Because of the variation in time interval between radiographs in the three groups it was decided to compare the observed changes with reference to the average change per year.

**Cranial base relationship**
On average, flexure of the cranial base did not alter significantly in either the FR-2 or control groups during treatment whereas it increased significantly in the FR-3 group, particularly when assessed by angle Ba-S-N.

**Maxillary skeletal relationships**
Enlow’s maxillary skeletal distance showed a comparable increase in all three groups, there being no significant difference between them. On the other hand, angle SNA showed a significant decrease in the FR-2 group compared with a small increase in the other two groups.

**Mandibular skeletal relationships**
Total mandibular length (Co-Pog), mandibular ramus height (Co-Go) and mandibular corpus length (Go-Pog) increased in all the groups. The mean increases in the FR-3 group, although marginally less than in the control group, did not differ significantly from those of that group, whereas the mean increases in total mandibular length (3.6 mm) and mandibular ramus height (2.5 mm) in the FR-2 group were significantly greater (P<0.001) than in either of the other two groups. Angles SNA and SN-Pogonion increased significantly more in the FR-2 group compared with the FR-3 and control groups, while these angles reduced significantly more in the FR-3 group compared with the FR-2 and control groups. Enlow’s mandibular skeletal distance increased significantly in the FR-2 group and decreased significantly in the FR-3 group, all comparisons being significant. The change in angle ANB and Enlow’s skeletal ratio reflected the combined maxillary and mandibular effects of the appliances such that the FR-2 group...
showed a decrease in both measures and the FR-3 group an increase, all comparisons being highly significant (P < 0.001).

Vertical skeletal relationship

The increase in ANS-Me did not differ significantly between the FR-2 and FR-3 groups but both increased significantly more than controls (P < 0.001).

Dental relationships

The upper incisors in the FR-2 group were retroclined an average of 1.0° per year and in the FR-3 group were proclined 2.3° while the controls remained unchanged. The lower incisors in the FR-2 group were slightly proclined (1.4°) as compared with those in the FR-3 group which were slightly retroclined (2.5°), while the control group lower incisors remained unchanged.

Enlow's dental distances showed that, while the maxillary distance increased in all groups, it did so less in the FR-2 group compared with the control (P < 0.05), while the mandibular distance showed a significantly greater increase in the FR-2 group and a significant reduction in the FR-3 group, all comparisons being significant (P < 0.001). The overbite reduced significantly in both the FR-2 and FR-3 groups compared with the controls but the reduction was significantly greater in the FR-2 group. The major dental effect was the change in overjet in the treatment group, a mean annual decrease of 2.7 mm in the FR-2 group and a mean annual increase of 3.0 mm in the FR-3 group being recorded.

Discussion

It must be stressed that the selection of Class II and Class III malocclusions analysed here is not random. Consciously, or sub-consciously, they were being suitable for Function Regulator therapy since and, as Fränkel has pointed out, this must also particularly in achieving an oral seal. Consequently, apart from the fact that the two appliance groups exhibit classical pre-treatment features of skeletal 2 and skeletal 3 dental bases, which are mainly characterized by mandibular retrognathism and prognathism respectively, the most significant skeletal differences from the control are in the mandibular dimensions and lower face height. Both FR-2 and FR-3 groups had reduced lower face heights and small, with a more obtuse gonial angle in the case of the FR-3 group, the mandible being further forward due to the reduced cranial base flexure.

The major effect of each appliance is mandibular posture, which, in the case of the FR-2, is altered downward and forwards, producing significant mean increases over the control group in respect of mandibular ramus height and total mandibular length (1.0 mm and 1.2 mm per year, respectively) accompanied by a greater increase in lower facial height. The modest annual increase in angle SNB and the increments in mandibular growth would seem to rule out the possibility of a mandibular posture forward from centric relation being a factor in these subjects. In the case of the FR-3, mandibular dimensions were not affected and one can only hypothesize that the downwards and backwards posture produced by the appliance transmitted pressure to the area of the posterior and base via the gneid fossa producing an increase in cranial base flexure and a more posterior position of the condyle accompanied by an increase in lower facial height.

The vertical effect of both appliances compared with the controls is exceptional in view of the fact that the control sample had a tendency towards an increased lower face height and therefore would be expected to exhibit a considerable increase in the vertical dimension.

Although mandibular position is undoubtedly altered by FR-3 treatment, its effect in restraining mandibular growth is less clear. Increases in mandibular dimensions are comparable with controls, considering their starting form, but Enlow's mandibular skeletal distance indicates a reduction in size of the mandibular dental base. It is possible that this anomaly may be explained by the fact that this measure utilizes point B and the Functional Incisal Plane, both of which may thus be affected by movement of the incisors and molars.

The effect of both appliances on the maxilla is less marked. The mean increase in angle SNA and Maxillary skeletal distance In the FR-3 group do not differ significantly from those in the control group and it is probable that Fränkel's finding of a significant increase in the distance Occipital point to point A may be explained by

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opening of the cranial base angle and distal had reduced lower face heights and small, with a more obtuse gonial angle in the case of the FR-3 group, the mandible being further forward due to the reduced cranial base flexure.

In the case of the FR-2, apart from a slight reduction in lower face height, the proximal movement of the posterior cranial base relative to the anterior maxillary profile.

In the case of the FR-2, apart from a slight reduction in lower face height, there is again little evidence to show a marked effect. Dentally the increase in lower facial height and changes in mandibular position were accompanied by a significant reduction in overbite in the Fränkel groups, more so in the FR-2 group.

Mandibular dental distance closely mirrored the change in mandibular skeletal distance, showing an increase in the FR-2 group, accounted for, to some extent, by the proclination of the lower incisors as conversely was the reduction in the FR-3 group by the retroclination of the lower incisors.

The most significant visual change in these conclusions as a result of treatment is the decrease in overjet in the FR-2 group and the increase in overjet in the FR-3 group. These changes can be explained partly by changes in incisor inclination but also by changes in mandibular size, the treatment effect being more marked in the FR-2 group in mandibular position in the FR-3 group accompanied by opening of the cranial base angle. Gianelly, et al. (1983) feel that for any growth effect with Function Regulators to be of clinical importance, it should be greater than that achieved by other types of appliance, for example Edgewise. Rolo and TenHave (1985) and Kerr and TenHave (1992) have compared both the materials in this study with Edgewise treatments, particularly with regard to soft tissue profile. Rolo and TenHave (1985) were able to show a significantly better improvement in lower lip and soft tissue pogonion in the FR-2 group as compared with an Edgewise group treated by extraction. The differences were less significant when comparing the FR-2 group with a non-extraction Edgewise group. Although the changes in lower lip position and soft tissue pogonion shown by Kerr and TenHave were on average negative for the FR-3 group as opposed to positive for the Edgewise group, no significant difference was recorded. Consequently, although the FR-2 and FR-3, on average, seem to do better than the Edgewise appliance with regard to soft tissue profile, the differences are not always significant.

Function Regulators, therefore, alter jaw posture and in so doing change jaw relationship, the major effect being on the mandible.

In the case of Class II malocclusion an increase in mandibular length and prognathism in excess of that which might be expected as a result of normal growth is observed. In the case of Class III malocclusion, downward and backward rotation of the mandibular symphysis relative to cranial base with opening of the cranial base angle is encountered and, although mandibular growth is not inhibited, the change in position and posture of the mandible is advantageous.

Conclusions

The annual treatment effects of the FR-2 and FR-3 appliances of Fränkel were contrasted by comparison with each other and a normative control group. The results afforded the following conclusions:

(1) Neither appliance has any appreciable effect on maxillary skeletal structures and the perceived changes may largely be accounted for by changes in dental architecture.

(2) The FR-2 affects the position of the mandible, the former by increasing total mandibular and ramus length and the latter producing significant opening of the cranial base angle and vertical repositioning of the mandible.

(3) Increase in the vertical dimension, encountered with both appliances, was accompanied by a reduction in overbite, both being greater with the FR-2 appliance.

(4) Changes in incisor inclination contributed to the favourable change in overjet in both groups. While the movement of upper and lower incisors in opposite directions was comparable in the FR-3 group, the lower incisors in the FR-2 group proclined only half as much as the upper incisors.

(5) While Function Regulators, as investigated here, may not entirely achieve the effects postulated by Fränkel, particularly in regard to the maxilla, there is evidence to support the concept that their effect on the profile is superior to that achieved by more conventional appliances.

Only the short term treatment effects of the FR-2 and FR-3 have been discussed here and long term follow-up will be necessary to see if the skeletal benefits of Function Regulator therapy
are sustained. Nevertheless the benefits of early dental correction of malocclusion may be considerable in enabling achievement of optimum harmony in jaw development.

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Profile changes in Class II, division 1 malocclusions: a comparison of the effects of Edgewise and Fränkel appliance therapy

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SUMMARY Changes in facial profile following orthodontic treatment were examined, using the lateral skull radiographs of 62 children exhibiting Class II, division 1 malocclusions and an average starting overjet in excess of 11 mm. Thirty were treated by the extraction of upper first premolars and Edgewise mechanics whilst the remainder wore Fränkel appliances. Lineal and angular measurements were made to record both soft tissue profile and the underlying dento-skeletal structures.

In the Edgewise group, overjet reduction was accompanied by a 2.4 degree reduction in SNA together with distal movement of A' point and the upper incisor. At the same time both the nose and chin grew forwards. Despite good positioning of the lower incisor with respect to A–Po, both lips finished well behind the aesthetic plane and the resulting profile was undesirably retrusive. By contrast, the Fränkel appliance produced a more pleasing, well-balanced profile with a more ideal relationship of the lips to the aesthetic plane. Maxillary dento-skeletal structures maintained a more prominent position within the face whilst the mandibular structures moved actively forwards.

Introduction

Whilst there appears to be general agreement that orthodontic treatment influences soft tissue profile, the question remains as to the extent of this effect (Finnøy et al., 1987). Considerable attention has been focused on the correlation between incisor retraction and lip movement following the treatment of Class II, division 1 malocclusions (Roos, 1977; Lo and Hunter, 1982; Waldman, 1982; Remmer et al., 1985) and there is appreciable variation in the reported response. Initial lip strain, variations in lip thickness, the amount of incisor retraction (Koch et al., 1979), whether or not extractions have been carried out (Stromboni, 1979; Lo and Mills, 1986; Finnøy et al., 1987) and the type of appliances used (Remmer et al., 1985; Lo and Mills, 1986) may all affect the result.

Despite the current interest in the potential of functional appliances to improve facial appearance, studies including soft tissue analyses are relatively rare (Forsberg and Odenrick, 1981; Remmer et al., 1985; Lo and Mills, 1986; Haynes, 1986; Owen, 1986). The reports by Remmer et al. and Owen investigate the Fränkel and Edgewise systems but in neither of these was the initial malocclusion particularly severe. The aim of the present study was to examine the soft tissue and underlying dento-skeletal responses in two groups of patients with dentofacial handi-capping Class II, division 1 incisor relationships. One was treated by the extraction of upper premolars and an Edgewise technique and the other non-extraction, using Fränkel appliances.

Subjects and Methods

The subjects for this study comprised 62 children with a Class II, division 1 malocclusion and an average starting overjet in excess of 11 mm. Thirty-two patients (16 males and 16 females) were treated non-extraction using FR1 or FR2 appliances. The remaining 30 (15 males and 15 females) were treated by the extraction of upper first premolars, conventional Edgewise mechanics and extra oral traction. Lower arch extractions were carried out if necessary in this group, to relieve crowding. Many of the patients in the Edgewise group were treated several years ago.