European Journal of Orthodontics 25 (2003) 301–309

Class II treatment effects of the Fränkel appliance

Guilherme R. P. Janson, Jorge Luis Alegria Toruño, Décio Rodrigues Martins,
José Fernando Castanha Henriques and Marcos Roberto de Freitas
Department of Orthodontics, Bauru Dental School, University of São Paulo, Brazil

SUMMARY The objective of this work was to evaluate prospectively and cephalometrically the effects of the function regulator (FR) on dentoskeletal components during a treatment period of 28 months. The subjects consisted of 18 patients presenting with a Class II division 1 malocclusion, with a mean chronological age of 9 years 3 months at the beginning of treatment. The treated group was compared with a compatible control group of 23 untreated subjects observed during the same time period. Lateral cephalometric head films were obtained for the treated group at the beginning and after 28 months of treatment. The subjects in the control group belonged to a serial growth study sample from the Orthodontic Department at Bauru Dental School, University of São Paulo, for whom cephalometric head films were obtained annually from 4 to 18 years of age. The data for the control group were calculated from these head films. A student's *t*-test was used to compare the changes observed in the treated group with those in the control group. Differences were considered statistically significant at $P < 0.05$.

The results demonstrated that the FR produced a statistically significant increase in the mandibular body, in the proportional size of the mandible to the maxilla and in lower anterior face height (LAFH); induced greater vertical development of the mandibular molars; reduced the overjet and overbite and produced an improvement in the molar relationship. Retrusion and palatal tipping of the maxillary incisors was also observed. However, the appliance did not produce any changes in maxillary development, in the growth pattern, or any improvement in the basal relationship. Therefore it was concluded that the effects of the FR in the correction of Class II malocclusions are primarily dento-alveolar, with a smaller participation of skeletal changes.

Introduction

The function regulator 1 (FR-1) was developed by Fränkel in 1967 (Fränkel and Fränkel, 1989). Its conceptual method of action is based on orthopaedic principles that consider muscle exercise as an important factor in bone development (Bishara and Ziaja, 1989). It differs from other functional appliances by protruding the mandible, ideally without contacting any mandibular teeth, and by causing an increase in both apical bases and maxillary and mandibular arch widths (Fränkel, 1969; Lubit, 1983; Bishara and Ziaja, 1989; Turner, 1991).

Studies of the effects of the FR in the treatment of Class II malocclusions have variously demonstrated greater mandibular growth development, an absence of maxillary growth changes, an increase in lower anterior face height (LAFH), palatal tipping of the maxillary incisors, labial tipping of the mandibular incisors, and a greater vertical development of the mandibular molars compared with control samples (Creekmore and Radney, 1983; Falck, 1983; Haynes, 1983, 1986; Righellis, 1983; McNamara *et al.*, 1985, 1990; Falck and Fränkel, 1989; Perillo *et al.*, 1996; Toth and McNamara, 1999). Additionally, statistically significant increases in mandibular intercanine and mandibular and maxillary intermolar distances have been reported (Hamilton *et al.*, 1987). Other investigators have found no increase in mandibular growth as a consequence of the use of the FR in the treatment of Class II malocclusions (Hamilton *et al.*, 1987; Nielsen, 1984).

The effects of the FR in Class II treatment have also been compared with those of fixed appliances associated with cervical extra-oral traction. The respective studies revealed that there was no difference in the amount of mandibular growth between these groups. There was a greater maxillary forward growth restriction and a greater increase in LAFH in the fixed appliance/cervical headgear groups (Gianelly *et al.*, 1983; Adenwalla and Kronman, 1985; Remmer *et al.*, 1985; Ghafari *et al.*, 1998). When compared with the activator, the FR demonstrated greater mandibular development, counter-clockwise mandibular rotation, and greater stability of the mandibular incisor position (Nelson *et al.*, 1993; Stüber, 1989, 1990). The increase in LAFH was greater with the activator (Courtney *et al.*, 1996).

However, most of the above results were derived from retrospective investigations, and only two evaluated the effects of this appliance after a treatment period of 2 years (McNamara *et al.*, 1985; Hamilton *et al.*, 1987). Therefore, the objective of this study was to evaluate prospectively and cephalometrically the treatment effects of the Fränkel appliance in the treatment of Class II malocclusions as compared with a matched control sample in an effort to elucidate some of the persisting controversies of its effects, after a treatment period of 28 months. The following areas of the craniofaciodental complex were investigated: (1) maxillary skeletal component; (2) mandibular skeletal component; (3) maxillo-mandibular skeletal relationship; (4) facial growth pattern; (5) maxillary dento-alveolar component; (6) mandibular dento-alveolar component; (7) relationship between the maxillary and mandibular incisors and molars.

Subjects

Treated group

The treated group consisted of 18 patients, eight females and 10 males, with an initial mean age of 9 years 3 months. All presented with a Class II division 1 malocclusion with at least an end-to-end Class II molar relationship (1/2 cusp Class II). These patients were under treatment (for a mean period of 28 months) at the Orthodontic Department graduate clinic at Bauru Dental School, University of São Paulo, with the FR-1. The subjects were selected from a total sample of 23 patients who had begun treatment at the same time. Five were excluded because of lack of co-operation, detected after 1 year of treatment. Lateral cephalometric radiographs were obtained in centric occlusion (Broadbent, 1931; Williamson, 1981) for this group, at the start and after 28 months of treatment.

Control group

The control sample's cephalometric lateral films were obtained from the files of a longitudinal growth study at the Orthodontic Department of the same dental school and consisted of 23 subjects: 10 females and 13 males. All had Class II division 1 malocclusions with at least an end-to-end Class II molar relationship. In order to match the control group ages to the mean ages of the study group at the start and the end of treatment, four longitudinal sets of lateral head films for each control subject were used. The sets yielded values for each measurement at the mean ages of 8 years 5 months, 9 years 6 months, 10 years 6 months and 11 years 6 months. Based on these, the value for each variable at the mean ages of 9 years 3 months and 11 years 7 months were calculated. To obtain the value of the variable at the age of 11 years 7 months, that is beyond the last mean age of the control group, the monthly changes for each variable were added to the value of the variables at 11 years 6 months of age. The changes were evaluated for this 28 month period.

Characteristics of the appliances

The construction, adaptation, and use of the FR-1 were followed according to Fränkel and Fränkel (1989) and McNamara (1982, 1993). A maximum initial mandibular advancement of 6 mm was performed in patients with an overjet equal to or larger than this. Therefore, in subjects with an overjet larger than 6 mm, a second advancement was needed (Fränkel and Fränkel, 1989). In patients with an overjet less than 6 mm, the mandible was advanced until an edge-to-edge incisor antero-posterior relationship was obtained (McNamara, 1982, 1993).

Method

The lateral cephalometric tracings were performed on acetate paper by a single investigator and then digitized (DT-11 digitizer; Houston Instruments, Houston, Texas, USA). These data were stored on a 586 Pentium IBM computer and analysed with the Dentofacial Planner 7.0 (Dentofacial Planner Software Inc., Toronto, Canada) which corrected the 6 per cent image magnification factor of the control group (Janson *et al.*, 1997) and of the initial treated group radiographs. The magnification of the treated group radiographs after 28 months was 9.2 per cent, as a different X-ray machine was used. These radiographs were also corrected for enlargement. Figures 1–3 illustrate the measurements used.

Error study

Ten randomly selected radiographs were retraced, redigitized and remeasured by the same examiner. The

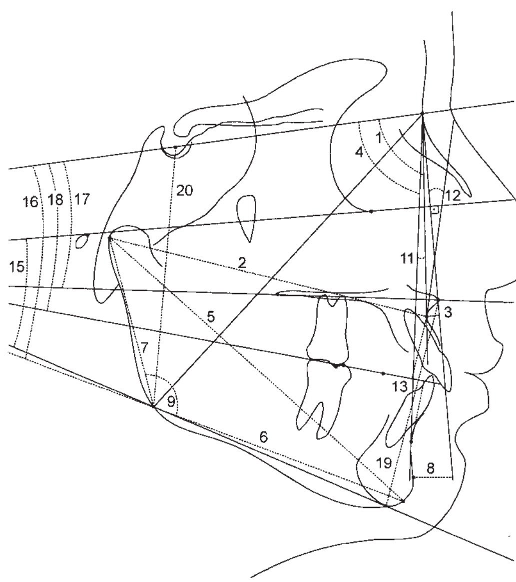

Figure 1 Skeletal cephalometric variables: 1, SNA; 2, Co–A; 3, A–Nperp; 4, SNB; 5, Co–Gn; 6, Go–Gn; 7, Co–Go; 8, Pog–Nperp; 9, Co.Go.Me; 10, Co.Go.N/N.Go.Me (not shown); 11, ANB; 12, NAP; 13, Wits; 14, Co–A/Co–Gn (not shown); 15, FMA; 16, SN.GoGn; 17, SN.PP; 18, SN.OP; 19, lower anterior face height (LAFH: ANS–Me); 20, S–Go; 21, S–Go/ANS–Me (not shown).

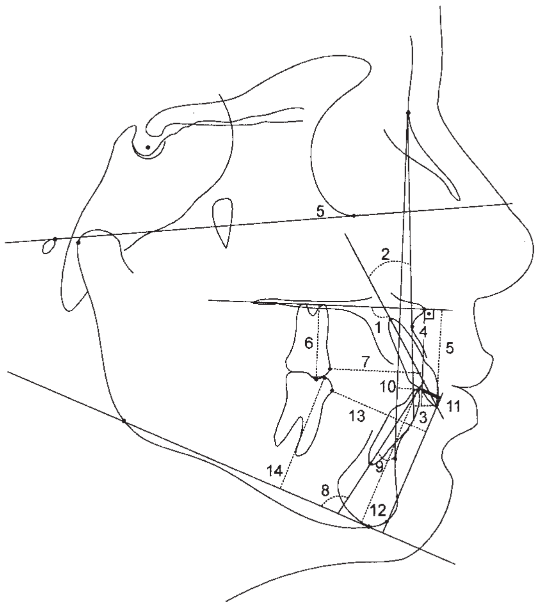

Figure 2 Dental cephalometric variables: 1, $\underline{1}$.PP; 2, $\underline{1}$.NA; 3, $\underline{1}$-NA; 4, $\underline{1}$-ANSperp; 5, $\underline{1}$-PP; 6, $\underline{6}$-PP; 7, $\underline{6}$-ANSperp; 8, IMPA; 9, $\bar{1}$.NB; 10, $\bar{1}$-NB; 11, $\bar{1}$-Pogperp (incisal edge of the mandibular incisor to a perpendicular to the mandibular plane, through pogonion); 12, $\bar{1}$-GoMe; 13, $\bar{6}$-Pogperp (mesial surface of the mandibular first molar to a perpendicular to the mandibular plane, through pogonion); 14, $\bar{6}$-GoMe.

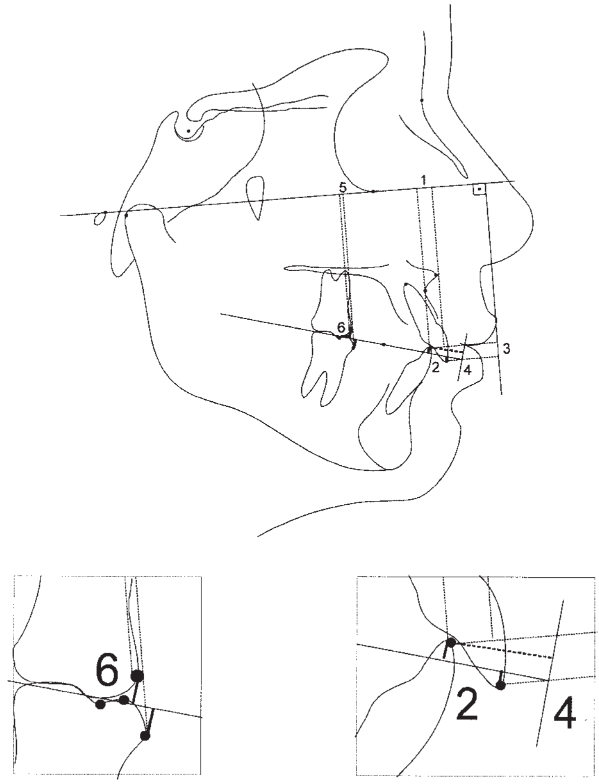

Figure 3 Dental relationships: 1, overjet (measured parallel to the Frankfort plane); 2, overjet (OP) (measured parallel to the occlusal plane); 3, overbite (measured perpendicular to the Frankfort plane); 4, overbite (OP) (measured perpendicular to the occlusal plane); 5, molar relationship (MR) (measured parallel to the Frankfort plane); 6, molar relationship (MR–OP) (measured parallel to the occlusal plane).

systematic error was calculated with dependent *t*-tests (Baumrind and Frantz, 1971a,b; Gravely and Benzies, 1974; Houston, 1983; Richardson, 1966), for $P < 0.05$ and the casual error, according to Dahlberg's formula (Dahlberg, 1940), $S^2 = \Sigma d^2/2n$, where S^2 is the error variance and d is the difference between the two determinations of the same variable. Only four of the total 41 variables presented a systematic error. Four variables presented a casual error above 2 degrees or 2 mm (Table 1). The respective landmarks were located in anatomically complex structures (Chan *et al.*, 1994; Trpkova *et al.*, 1997).

Statistical analysis

The mean and standard deviation for each measurement was calculated to enable characterization of both the treated and control group. The *t*-test for independent samples was used for normal distributions verified by the Kolmogorov–Smirnov test (for initial and final values, as well as any differences). The results of these tests were not significant for any of the variables. A P value of <0.05 was considered as significant.

Therefore, *t*-tests were used to evaluate: (1) any initial differences in the dentoskeletal components between the treated and control groups, and (2) the differences in changes in each variable, between the treated and control groups during the 28 month treatment period.

Table 1 Results of the systematic and casual errors investigation (figures in italics were statistically significant).

Variable	Difference (absolute values)		Casual error	*P*
	Mean	Standard deviation		
SN.GoGn	1.07	0.86	0.95	*0.02669*
SN.OP	2.88	1.83	*2.38*	0.66277
1.PP	2.05	1.74	1.86	*0.01276*
1.NA	2.61	1.77	*2.20*	*0.02918*
6-GoMe	0.73	0.38	0.57	*0.00018*
MR	2.40	2.05	*2.18*	0.26370
MR (OP)	2.36	2.36	*2.30*	0.15387

Results

Both groups were initially similar, with the exception of the following variables: SN.OP, overjet, overjet (OP), MR, MR (OP). The results of the comparison between the groups are presented in Table 2.

Table 2 Comparison of the changes after 28 months between the treated group (n = 18) and the control group (n = 23) (figures in italics were statistically significant).

Variable	Treated group		Control group		P
	Change	SD	Change	SD	
Maxillary					
SNA	–0.14	1.57	–0.03	2.35	0.877906
Co–A	2.35	2.05	2.94	1.68	0.471279
A–Nperp	0.15	1.42	0.06	2.31	0.887312
Mandibular					
SNB	1.00	1.56	0.44	1.69	0.212540
Co–Gn	5.53	2.52	5.03	1.48	0.432429
Go–Gn	*4.49*	*1.82*	*2.93*	*1.25*	*0.002367*
Co–Go	2.93	2.01	3.16	1.86	0.708427
Pog–Nperp	1.92	2.40	1.04	3.11	0.326480
Co.Go.Me	–1.48	1.89	–1.32	2.42	0.814686
Co.Go.N/N.Go.Me	–2.68	3.12	–0.53	3.67	0.054827
Maxillomandibular relationships					
ANB	–1.18	1.47	–0.49	1.56	0.155664
NAP	–2.49	3.03	–1.29	3.33	0.240590
Wits	–1.15	2.12	–0.26	2.34	0.214888
Co–A/Co–Gn	*–2.01*	*2.12*	*–0.44*	*1.78*	*0.013710*
Facial growth pattern					
FMA	–0.30	1.91	–1.41	2.46	0.122435
SN.GoGn	–0.18	2.38	–0.87	1.57	0.270083
SN.PP	–0.08	1.56	–0.06	1.80	0.969988
SN.OP	–0.28	4.05	–2.53	5.82	0.172477
ANS–Me	*3.30*	*1.66*	*1.97*	*1.29*	*0.006630*
S–Go	4.05	1.81	4.07	1.59	0.966345
S–Go/ANS–Me	*0.65*	*4.31*	*3.54*	*3.50*	*0.022744*
Maxillary dento-alveolar component					
$\underline{1}$.PP	*–8.10*	*6.14*	*0.79*	*4.50*	*0.000004*
$\underline{1}$.NA	*–7.96*	*5.17*	*0.55*	*3.68*	*0.000000*
$\underline{1}$-NA	*–1.70*	*1.66*	*0.84*	*1.85*	*0.000049*
$\underline{1}$-ANSperp	*1.93*	*1.85*	*–0.54*	*2.37*	*0.000805*
$\underline{1}$-PP	1.98	1.07	1.21	1.87	0.125808
$\underline{6}$-PP	1.47	1.33	1.08	1.66	0.417296
$\underline{6}$-ANSperp	–0.12	1.36	–0.47	1.53	0.450726
Mandibular dento-alveolar component					
IMPA	0.74	3.58	0.91	4.52	0.896230
$\overline{1}$.NB	1.68	3.27	0.54	4.69	0.381067
$\overline{1}$-NB	1.12	1.04	0.52	1.71	0.192460
$\overline{1}$-Pogperp	0.27	1.31	–0.63	1.51	0.050046
$\overline{1}$-GoMe	1.67	0.84	1.87	1.30	0.54536
$\overline{6}$-Pogperp	0.70	1.09	0.10	1.44	0.152879
$\overline{6}$-GoMe	*2.04*	*0.92*	*0.75*	*1.48*	*0.002555*
Dental relationships					
Overjet	*–3.81*	*1.48*	*0.13*	*2.09*	*0.000000*
Overjet (OP)	*–3.83*	*1.39*	*0.44*	*1.55*	*0.000000*
Overbite	*–0.17*	*1.76*	*1.42*	*1.70*	*0.005755*
Overbite (OP)	*0.39*	*1.89*	*1.88*	*1.67*	*0.010995*
MR	*2.49*	*1.51*	*0.39*	*1.49*	*0.000069*
MR (OP)	*2.47*	*1.60*	*0.04*	*1.81*	*0.000059*

Discussion

It is known that a Class II division 1 malocclusion is generally considered a heterogeneous generic malocclusion, with individuals presenting either with a prognathic maxilla and a normal mandible, or a normal maxilla and a retrognathic mandible, or even a combination of both. However, in this study the treated patients were selected solely on the basis of their occlusal relationship of at least an end-to-end Class II molar relationship. Therefore, the results obtained can only be extrapolated to patients with similar characteristics. On the other hand, it has been observed that usually one of the predominant characteristics of Class II patients is a poorly developed mandible (McNamara, 1981; Karlsen, 1994; Sarhan and Hashim, 1994), which is an indication for functional appliance treatment.

Apical bases

Maxilla. The results demonstrated no statistically significant influence on maxillary development because the changes in maxillary position and effective length were similar for both groups (Table 2). Although redirection of maxillary growth is regarded as one of the mechanisms to correct Class II antero-posterior discrepancies by functional orthopaedic appliances (FOA) (Bishara and Ziaja, 1989; Woodside, 1998) this effect is not expected with the FR (Falck, 1983; Righellis, 1983; McNamara *et al.*, 1985, 1990; Hamilton *et al.*, 1987). McNamara (1982) considered this to be an advantage of the FR over FOAs because many Class II patients present normally positioned or retruded maxillae (McNamara, 1981).

Mandible. The mandibular position variables also did not show any statistically significant differences, similar to the maxillary position variables. In contrast with other studies, where a mandibular growth increase was found with use of the FR (Creekmore and Radney, 1983; Falck, 1983; Righellis, 1983; Falck and Fränkel, 1989; McNamara *et al.*, 1990; Perillo *et al.*, 1996), there was no statistically significant difference in the effective mandibular length (Co–Gn). Similar results were reported by Nielsen (1984) and Hamilton *et al.* (1987). However, changes in mandibular body length were statistically significant and 1.63 mm greater in the treated group than in the control group, showing the bone remodelling of the mandibular ramus, attributed to the FOA by several authors (Bishara and Ziaja, 1989; Petrovic and Stutzmann, 1997; Woodside, 1998). The increase in ramus height was similar for both groups. It could be expected that a significant increase in mandibular body length would produce a significant increase in mandibular effective length. Nevertheless, this did not occur, probably because the difference in the increase in mandibular ramus height was not significant.

Both groups presented a similar tendency for a slight decrease in Co.Go.Me as would be expected during mandibular development (Petrovic, 1994; Petrovic and Stutzmann, 1997).

As is known, the increase in mandibular body size could contribute to an improvement in mandibular protrusion (Pog–Nperp). However, although the mandibular protrusion was slightly greater in the treated group than in the control group, it was not statistically significant, probably because the greater increase in mandibular body length was not sufficiently large.

Maxillomandibular relationship

Interestingly, the changes in the angular maxillomandibular variables (ANB and NAP) did not present statistically significant differences between the two groups. This is in contrast to other authors who reported a significant reduction in ANB (McNamara *et al.*, 1985; Falck and Fränkel, 1989; Courtney *et al.*, 1996; Perillo *et al.*, 1996). Only a few investigators have not found a statistically significant reduction in this angle (Creekmore and Radney, 1983; Webster *et al.*, 1996). Investigations with the Wits appraisal are not frequent but have demonstrated a significant reduction in the Class II basal relationship with FR treatment (McNamara *et al.*, 1985).

Despite the absence of statistically significant differences when individually analysed, the changes in the proportion between maxillary and mandibular effective lengths (Co–A:Co–Gn) were statistically significant between the two groups. This seems to indicate that the treatment effects are more evident when the changes in different facial components are simultaneously considered as opposed to an analysis of single variables.

Facial growth pattern

There was no statistically significant difference for the variables FMA, SN.GoGn, SN.PP and SN.OP, as previously reported (Righellis, 1983; Gianelly *et al.*, 1984; McNamara *et al.*, 1985, 1990). The results of the variables SN.GoGn and SN.OP could be criticized because they presented, respectively, a statistically significant systematic error and a casual error above 2 degrees (Table 1). Nevertheless, the other two variables did not demonstrate any intra-examiner error and showed a similar result. Both groups showed a slight tendency for a decrease in these measurements. However, with the exception of the variable SN.PP, it should be noted that this decrease was always smaller for the treated group, probably because of the differential eruption of the posterior teeth and the consequent increase in LAFH. As expected, the angle SN.OP showed a great variability in both groups, probably as a result of the replacement of the primary molars and canines by the premolars and permanent canines, especially if one considers that the occlusal contact of the primary molars or premolars was used to construct the functional occlusal plane.

The increase in LAFH in the treated group was significantly larger than in the control group, agreeing with several previous studies (Creekmore and Radney, 1983; Kerr *et al.*, 1989; McNamara *et al.*, 1990; Nelson *et al.*, 1993; Courtney *et al.*, 1996; Webster *et al.*, 1996; Ghafari *et al.*, 1998). This increase is considered to be the result of posterior bite opening due to mandibular protrusion as induced by the construction bite (Fränkel and Fränkel, 1989). Especially in subjects with an excessive overbite, this allows greater dento-alveolar vertical development of the mandibular posterior teeth.

The lower posterior face height (LPFH; S–Go) increased similarly in both the treated and the control groups. However, there was a statistically significant difference in the proportion between the LPFH and LAFH (S–Go/ANS–Me). Evidently this significant difference between the two groups was caused by the significantly larger increase in LAFH in the treated group.

Maxillary dento-alveolar component

The treated group had significant palatal tipping and a decrease in protrusion of the maxillary incisors compared with the control group (Table 2). Even considering that the variables $\underline{1}$.PP and $\underline{1}$.NA had statistically significant systematic errors and that $\underline{1}$.NA also had a casual error greater than 2 degrees, this would not compromise the comparison because the difference in the changes between the groups was accentuated and greater than the errors. According to Fränkel and Fränkel (1989), this movement is consequent to the unfavourable contact of the maxillary incisors by the labial arch. They recommended that the labial arch should not contact these teeth and should not be activated. Fränkel and Fränkel (1989) also stressed that antero-posterior activations greater than recommended cause a greater uprighting of the maxillary incisors. However, an uprighting and retrusion of the maxillary incisors as found in this study was also reported by other authors (Schulhof and Engel, 1982; McNamara *et al.*, 1985, 1990; Kerr *et al.*, 1989; Nelson *et al.*, 1993; Courtney *et al.*, 1996; Webster *et al.*, 1996; Ghafari *et al.*, 1998). McNamara (1982) stated that the labial arch should barely touch the labial surfaces of the maxillary incisors and recommended the use of the FR-2 in Class II division 1 because the upper lingual wire would help in controlling the tipping and vertical position of the maxillary incisors. Additionally, uprighting of the maxillary incisors can be very favourable in subjects with large overjets and accentuated labial tipping of the maxillary incisors, characteristic of Class II division 1 malocclusions. This is considered to be a mechanism to help in the correction of the overjet by the FOA (Bishara and Ziaja, 1989; Graber, 1994). Therefore, in these cases, contact of the labial arch on the maxillary incisors might be desirable, although not originally recommended by Fränkel (Fischer *et al.*, 1987; Fränkel and Fränkel, 1989). There was no restriction of the vertical development of the maxillary incisors in the treated group. This might be explained by the absence of contact of any part of the appliance on the incisal edges of these teeth. This is the reason why McNamara (1982) used the FR-2 in Class II division 1 cases, because this FR modification helps in controlling the vertical position of the maxillary incisors.

The dento-alveolar height as well as the antero-posterior position of the maxillary molars did not present statistically significant differences between the two groups. These results are similar to those of Hamilton *et al.* (1987) and McNamara *et al.* (1985) who did not find any restriction to the vertical development of the maxillary molars. Although it seems logical to expect that the contact between the occlusal rests and the molars could restrict their vertical development, emulating an activator (Harvold and Vargervik, 1971) in achieving the differential eruption principle of Harvold (McNamara *et al.*, 1985), the vertical force transmitted to them is probably not sufficiently great (Table 2). In fact, the occlusal rests were not designed for this purpose (Fränkel and Fränkel, 1989). Some authors (McNamara *et al.*, 1985, 1990; Falck and Fränkel, 1989; Courtney *et al.*, 1996) associate a restriction of the forward displacement of the maxillary molars with FR treatment. The effect of the FR on the maxillary first molars is considered to result from the palatal arch that contacts the mesial surface of the molars to provide the antero-posterior stability of the appliance (Fränkel and Fränkel, 1989; McNamara, 1993). It would be expected that at least some of the distal muscle force would be transmitted against the maxillary molar (McNamara, 1982; Graber, 1994), preventing the physiological mesial displacement, which would help in correcting the Class II relationship. However, Fränkel and Fränkel (1989) considered that molar distalization was due to construction and/or manipulation errors of the appliance producing an accentuated activation and causing the appliance to work like a lip bumper, transmitting the mentalis and the retraction muscle forces to the maxillary molars. These errors, according to Fränkel and Fränkel (1989) should be avoided, especially in patients where the action of the appliance on the molars is not desirable. When increased changes on the maxillary molars are required, other more effective FOA are recommended, especially in association with extra-oral forces (Levin, 1985; Kigele, 1987; Lehman and Hulsink, 1989; Cura *et al.*, 1996).

Mandibular dento-alveolar component

The treated group did not present statistically significant antero-posterior changes in the mandibular incisors, in relation to the control group, contrary to the greater protrusion of these teeth reported previously (Schulhof and Engel, 1982; McNamara *et al.*, 1985). Eirew *et al.* (1986) considered a protrusion of the mandibular incisors to be beneficial in subjects with mandibular crowding as well as in Class II division 2 cases and in patients with sucking habits and lingually tipped mandibular incisors. This effect has been termed as the 'activator effect' (Falck and Fränkel, 1989).

The behaviour of the mandibular incisor dento-alveolar height ($\overline{1}$-GoMe) was similar in both groups. The explanation for an absence of restriction of the dento-alveolar development of these teeth is similar to that of the maxillary incisors, that is, the absence of acrylic in contact with them (Fränkel and Fränkel, 1989; McNamara, 1993). It has been claimed that the action of the two lower lingual wires in the presence of a deep bite is to prevent further eruption of the mandibular incisors (Fränkel and Fränkel, 1989). However, this did not occur in this study. Other FOAs with an acrylic coverage of these teeth present a restriction of their vertical development (Harvold, 1974).

There was no statistically significant difference in mandibular molar mesial displacement between the two groups ($\bar{6}$-Pogperp). Probably the most interesting finding is the greater vertical development of the mandibular molars in the treated group: on average, almost 1.5 mm greater than in the control group ($\bar{6}$-GoMe). This difference between the groups was large enough to override the statistically significant systematic error presented by this variable (Table 1). This vertical development has also been reported previously (Creekmore and Radney, 1983; Righellis, 1983; McNamara *et al.*, 1985, 1990; Nelson *et al.*, 1993) and is considered a determining factor to correct the deep overbite and the curve of Spee (McNamara, 1982). Harvold (1974) considered that a greater vertical development of the mandibular molars, as compared with the maxillary molars, is essential to correct the molar relationship because it induces a more anterior positioning of the mandibular molars as compared with the maxillary molars.

Dental relationships

The changes in dental relationships were all statistically different between the two groups, showing an improvement in the treated group as compared with the control group. In the control group there was even a tendency for the overbite to increase (Table 2).

Correction of the overjet and molar relationship are the basis to evaluate the treatment success of a Class II malocclusion. These changes are consequent to other changes in several dentoskeletal areas. Few studies (Creekmore and Radney, 1983; Courtney *et al.*, 1996; Webster *et al.*, 1996) have cephalometrically evaluated the interdental changes with the FR. An association of several factors might have contributed to the overjet correction. There was a significant retrusion of the maxillary incisors ($\underline{1}$-ANSperp) as well as a non-significant protrusion of the mandibular incisors ($\bar{1}$-Pogperp) and improvement in the basal relationship (ANB, Wits) (Table 2). Therefore, it can be concluded that the overjet correction resulted primarily from dental changes. Creekmore and Radney (1983) found that overjet correction was in 37 per cent due to a retraction of the maxillary incisors and in 26 per cent due to a protrusion of the mandibular incisors. Similarly, Courtney *et al.* (1996) associated overjet correction to maxillary incisor retraction.

For overbite correction, both groups demonstrated a similar increase in the distance from the maxillary and mandibular incisal edges to the respective apical bases, evidence that the FR did not restrict the vertical development of these teeth. However, the control group showed a tendency for an increase in overbite and the treated group a slight tendency towards a decrease. Because there was no restriction of the vertical development of the maxillary and mandibular incisors, the explanation for the improvement of the overbite can only be based on the greater vertical development of the mandibular molars. Interestingly, Courtney *et al.* (1996) also reported a greater vertical development of the mandibular molars but did not find a difference in the changes between the patients treated with the FR-2 and the control group. This was probably because their evaluation period was only 18 months.

As previously discussed, the molar relationship improved as a result of the statistically non-significant individual changes in the maxillary and mandibular molars to their respective apical bases ($\underline{6}$-ANSperp and $\bar{6}$-Pogperp). Another factor that may have contributed to this significant molar relationship improvement could have been differential eruption (Harvold, 1974; McNamara, 1982; Righellis, 1983; Graber, 1994). As an example of the influence of vertical molar development in correcting the molar relationship, Graber (1994) estimated that it corresponds to approximately 1.5 mm of a total of 6 mm Class II relationship correction. In contrast to the present study, Creekmore and Radney (1983) reported greater distalization of the maxillary molars and mesialization of the mandibular molars. However, the improvement in the molar relationship observed in this investigation must be regarded with caution, because the two variables used as parameters presented a casual error larger than 2 mm (Table 1).

Clinical considerations

Considering the importance of individual variation, it should not be assumed that all patients respond to treatment identically, i.e. the same magnitude and in the same time frame (Petrovic and Stutzmann, 1997). The results of the present investigation indicate that the FR is efficient in correcting the Class II relationship. Originally this appliance was designed to obtain this correction by altering the apical base relationship, chiefly by stimulating mandibular growth, with minimum contact with dental structures (Fränkel and Fränkel, 1989). The results showed that most of the changes were dento-alveolar, with fewer skeletal changes, as also found by Bishara and Ziaja (1989).

Conclusions

FR treatment of Class II malocclusions, after an experimental period of 28 months, produced the following changes:

1. An increase in mandibular body length.
2. A proportionally greater increase in mandibular growth as compared with maxillary growth.
3. An increase in LAFH without altering the facial growth pattern.
4. Pronounced vertical development of the mandibular molars.
5. A reduction in the overbite and overjet, and improvement in the molar relationship.
6. Retrusion and palatal tipping of the maxillary incisors.

Address for correspondence

Guilherme R. P. Janson
Department of Orthodontics
Bauru Dental School
University of São Paulo
Alameda Otavio Pinheiro Brisolla 9–75
Bauru—SP—17012–901
Brazil

Acknowledgements

The authors would like to acknowledge Professor Rainer-Reginald Miethke for his critical review of the manuscript and CNPQ (Brazilian National Research Foundation) for its support.

References

Adenwalla S T, Kronman J H 1985 Class II, division 1 treatment with Fränkel and edgewise appliances—a comparative study of mandibular growth and facial esthetics. Angle Orthodontist 55: 281–298

Baumrind S, Frantz R 1971a The reliability of head film measurements. 1. Landmark identification. American Journal of Orthodontics 60: 111–127

Baumrind S, Frantz R 1971b The reliability of head film measurements. 2. Conventional angular and linear measurements. American Journal of Orthodontics 60: 505–517

Bishara S E, Ziaja R R 1989 Functional appliances: a review. American Journal of Orthodontics and Dentofacial Orthopedics 95: 250–258

Broadbent B H 1931 A new X-ray technique and its application to orthodontia. The introduction to cephalometric radiography. Angle Orthodontist 1: 45–66

Chan C K, Tng T H, Hägg V, Cooke M S 1994 Effects of cephalometric landmark validity on incisor angulation. American Journal of Orthodontics and Dentofacial Orthopedics 106: 487–495

Courtney M, Harkness M, Herbison P 1996 Maxillary and cranial base changes during treatment with functional appliances. American Journal of Orthodontics and Dentofacial Orthopedics 109: 616–624

Creekmore T D, Radney L J 1983 Fränkel appliance: orthopedic or orthodontic? American Journal of Orthodontics 83: 89–108

Cura N, Saraç M, Öztürk Y, Sürmeli N 1996 Orthodontic and orthopedic effects of Activator, Activator-HG combination, and Bass appliances: a comparative study. American Journal of Orthodontics and Dentofacial Orthopedics 110: 36–45

Dahlberg G 1940 Statistical methods for medical and biological students. Interscience Publications, New York

Eirew H L, McDowell F, Phillips J G 1986 The Fränkel appliance—avoidance of lower incisor proclination. International Journal of Orthodontics 24: 3–4

Falck F 1983 Sagittale und vertikale Veränderungen bei mandibulärer Retrognathie. Stomatologie DDR 33: 182–195

Falck F, Fränkel R 1989 Clinical relevance of step-by-step mandibular advancement in the treatment of mandibular retrusion using the Fränkel appliance. American Journal of Orthodontics and Dentofacial Orthopedics 96: 333–341

Fischer C, Miethke R R, Seelbach M, Thimm C 1987 Arbeiten mit den Funktionsreglern nach Fränkel. Praktische Kieferorthopädie 1: 261–275

Fränkel R 1969 The treatment of Class II, division 1 malocclusion with functional correctors. American Journal of Orthodontics 55: 265–275

Fränkel R, Fränkel C 1989 Orofacial orthopedics with the function regulator. Karger, Basel

Ghafari J, Shofer F S, Jacobson-Hunt U, Markowitz D L, Laster L L 1998 Headgear versus function regulator in the early treatment of Class II, division 1 malocclusion: a randomized clinical trial. American Journal of Orthodontics and Dentofacial Orthopedics 113: 51–61

Gianelly A, Brosnan P, Martignoni M, Berstein L 1983 Mandibular growth, condyle position and Fränkel appliance therapy. Angle Orthodontist 53: 131–142

Gianelly A A, Arena S A, Bernstein L 1984 A comparison of Class II treatment changes noted with the light wire, edgewise and Fränkel appliances. American Journal of Orthodontics and Dentofacial Orthopedics 86: 269–276

Graber T M 1994 Functional appliances. In: Graber T M, Vanarsdall Jr R L (eds) Orthodontics, current principles and technics. Mosby, St Louis, pp. 383–436

Gravely J F, Benzies P M 1974 The clinical significance of tracing error in cephalometry. British Journal of Orthodontics 1: 95–101

Hamilton S D, Sinclair P M, Hamilton R H 1987 A cephalometric, tomographic, and dental cast evaluation of Fränkel therapy. American Journal of Orthodontics and Dentofacial Orthopedics 92: 427–436

Harvold E P 1974 The activator in interceptive orthodontics. CV Mosby, St Louis

Harvold E P, Vargervik K 1971 Morphogenetic response to activator treatment. American Journal of Orthodontics 60: 478–490

Haynes S 1983 Anterior vertical changes in function regulator therapy. European Journal of Orthodontics 53: 219–223

Haynes S 1986 A cephalometric study of mandibular changes in modified function regulator (Fränkel) treatment. American Journal of Orthodontics and Dentofacial Orthopedics 90: 308–320

Houston W J B 1983 Analysis of errors in orthodontic measurements. American Journal of Orthodontics 83: 382–390

Janson G R P, Pereira A C J, Bergersen E A, Henriques J F C, Pinzan A, Almeida R R 1997 Cephalometric evaluation of the eruption guidance appliance in Class II, division 1 treatment. Journal of Clinical Orthodontics 31: 299–306

Karlsen A T 1994 Craniofacial morphology in children with Angle Class II-1 malocclusion with and without deepbite. Angle Orthodontist 64: 437–446

Kerr W J S, TenHave T R, McNamara J A 1989 A comparison of skeletal and dental changes produced by function regulators (FR-2 and FR-3). European Journal of Orthodontics 11: 235–242

Kigele E 1987 Cephalometric changes from activator–headgear treatment of Class II, division 1 malocclusion. Journal of Clinical Orthodontics 21: 466–469

Lehman R, Hulsink J H 1989 Treatment of Class II malocclusion with a headgear–activator combination. Journal of Clinical Orthodontics 23: 430–433

Levin R I 1985 Activator headgear therapy. American Journal of Orthodontics 87: 91–109

Lubit E C 1983 Functional orthodontic therapy with the Fränkel appliance. Journal of Pedodontics 7: 257–275

McNamara J A Jr 1981 Components of Class II malocclusion in children 8–10 years of age. Angle Orthodontist 51: 177–202

McNamara J A Jr 1982 On the Fränkel appliance. Part 2—Clinical management. Journal of Clinical Orthodontics 16: 390–407

McNamara J A Jr 1993 Orthodontic and orthopedic treatment in the mixed dentition. Needham Press, Ann Arbor

McNamara J A Jr, Bookstein F L, Shaughnessy T G 1985 Skeletal and dental changes following functional regulator therapy on Class II patients. American Journal of Orthodontics 88: 91–110

McNamara J A Jr, Howe R P, Dischinger T G 1990 A comparison of the Herbst and Fränkel appliances in the treatment of Class II malocclusion. American Journal of Orthodontics and Dentofacial Orthopedics 98: 134–144

Nelson C, Harkness M, Herbison P 1993 Mandibular changes during functional appliance treatment. American Journal of Orthodontics and Dentofacial Orthopedics 104: 153–161

Nielsen I L 1984 Facial growth during treatment with the function regulator appliance. American Journal of Orthodontics 85: 401–410

Perillo L, Johnston L E Jr, Ferro A 1996 Permanence of skeletal changes after function regulator (FR-2) treatment of patients with retrusive Class II malocclusions. American Journal of Orthodontics and Dentofacial Orthopedics 109: 132–139

Petrovic A 1994 Auxiologic categorization and chronobiologic specification for the choice of appropriate orthodontic treatment. American Journal of Orthodontics and Dentofacial Orthopedics 105: 192–205

Petrovic A G, Stutzmann J J 1997 Research methodology and findings. In: Graber T M *et al.* (eds) Applied craniofacial growth studies. Dentofacial orthopedics with functional appliances, 2nd edn. Mosby Yearbook, St Louis, pp. 13–63

Remmer K R, Mamandras A H, Hunter W S, Way D C 1985 Cephalometric changes associated with treatment using the activator, the Fränkel appliance, and the fixed appliance. American Journal of Orthodontics 88: 363–372

Richardson A 1966 An investigation into the reproducibility of some points, planes, and lines used in cephalometric analysis. American Journal of Orthodontics 52: 637–651

Righellis E G 1983 Treatment effects of Fränkel, Activator and extraoral traction appliances. Angle Orthodontist 53: 107–121

Sarhan O A, Hashim H A 1994 Dento-skeletal components of Class II malocclusions for children with normal and retruded mandibles. Journal of Clinical Pediatric Dentistry 18: 99–103

Schulhof R J, Engel G A 1982 Results of Class II functional appliance treatment. Journal of Clinical Orthodontics 16: 587–599

Stüber P 1989 Vergleichende Untersuchungen bei der Behandlung der mandibulären Retrognathie mit Funktionsreglern und Aktivatoren. Stomatologie DDR 39: 446–451

Stüber P 1990 Zur Stimulierbarkeit des Unterkieferwachtums bei der mandibulären Retrognathie mit Funktionsreglern und Aktivatoren im Vergleich mit einer Kontrollgruppe: eine sechsjährige kephalometrische Längsschnittstudie. Fortschritte der Kieferorthopädie 51: 361–365

Toth L R, McNamara J A Jr 1999 Treatment effects produced by the Twin-block appliance and the FR-2 appliance of Fränkel compared with an untreated Class II sample. American Journal of Orthodontics and Dentofacial Orthopedics 116: 597–609

Trpkova B, Major P, Prasad N, Nebbe B 1997 Cephalometric landmark identification and reproducibility. A meta analysis. American Journal of Orthodontics and Dentofacial Orthopedics 112: 165–170

Turner P J 1991 Functional appliances: a systematic approach. Dental Update 18: 72–76

Webster T, Harkness M, Herbison P 1996 Associations between changes in selected facial dimensions and the outcome of orthodontic treatment. American Journal of Orthodontics and Dentofacial Orthopedics 110: 46–53

Williamson E H 1981 On occlusion and TMJ dysfunction—Part 1. Journal of Clinical Orthodontics 15: 333–350

Woodside D G 1998 Do functional appliances have an orthopedic effect? American Journal of Orthodontics and Dentofacial Orthopedics 113: 11–14