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Functional regulator treatment of Class II division 1 malocclusions

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SUMMARY This controlled retrospective study aimed to identify the contribution of skeletal and dental changes in the correction of Class II division 1 malocclusions using Fränkel's functional regulator II (FRII), with reference to a concurrently recruited control group. One hundred and thirty-eight patients with Class II division 1 malocclusions were identified, those accepting treatment forming the study group and those declining treatment the control group. The study group ($n = 70$) were treated with a Fränkel appliance. Pre- and post-treatment observation cephalometric radiographs were analysed and compared. Mean values for both skeletal and dental variables in the control group were remarkably consistent throughout the study period; however, this masked individual variations in this group.

The skeletal variables in the study group that showed statistically significant differences from the control group were SNB, ANB, BaNA and ANS-Me, but none of these was sufficiently large to be regarded as clinically significant. Dental variables showed clinically and statistically significant differences, including a 10 degree reduction in UI-Max and 3.1 degree increase in LI-Mand. The Fränkel appliance was thus found to be effective in producing desirable occlusal and dental changes in the majority of patients treated.

Introduction

A functional appliance can be defined as one that engages both dental arches and acts principally by holding the mandible away from its normal resting position (Isaacson *et al.*, 1990). In the debate on the effect of functional appliances, protagonists seem to have a great deal of enthusiasm but little evidence, whereas sceptics have a great deal of evidence, but little enthusiasm. Some of the reasons for this controversy are demonstrated in the following review of the literature.

Literature review

Treatment effects on mandibular growth

Many authors have reported an increase in total mandibular length during functional regulator treatment of 3.3–4.5 mm (Creekmore and Radney, 1983; Righellis, 1983; McNamara *et al.*, 1985; Fränkel and Fränkel, 1989; Kerr *et al.*, 1989; Perillo *et al.*, 1996).

Creekmore and Radney (1983) reported that the functional regulator was not associated with a statistically significant increase in mandibular length compared with untreated controls. Instead an increase in lower face height was noted with no improvement in the skeletal pattern. Gianelly *et al.* (1983) found no significant difference between mandibular growth in a group of 15 patients treated with edgewise fixed appliances and 10 with the functional regulator. Gianelly *et al.* (1984) found there were no significant differences in either skeletal or dental changes when they compared the effects of non-extraction treatment in Class II division 1 subjects using edgewise, Begg or functional regulator therapy. This was supported by McNamara *et al.* (1985) who studied the growth of 100 patients treated with the functional

regulator with a matched group of untreated controls with Class II malocclusions.

Perillo *et al*. (1996), in a retrospective study, looked at the pre-, post-treatment and out of retention radiographs of 14 patients treated with the FRII. These were compared with untreated controls and published standards. The authors reported that FRII treatment produced a statistically and perhaps clinically significant increase in mandibular length (3.28 mm).

Treatment effects on maxillary growth

Righellis (1983) found no significant horizontal effect on the maxilla in patients treated with the Fränkel appliance when compared with a group of Class II subjects treated with extra-oral traction. Robertson (1983) found no appreciable treatment effect on the position of the maxilla but more dentoalveolar change with the functional regulator compared with other types of functional appliances.

Creekmore and Radney (1983) reported reduced forward growth of the maxilla and McNamara *et al*. (1985) stated that there was little effect of treatment upon maxillary skeletal structures. Perillo *et al*. (1996) found the functional regulator had no effect on the maxilla and concluded that reductions in the value of SNA could be attributed to incisor retraction.

Treatment effects on the dentition

The effects of the functional regulator on the dentition are less controversial. McDougall *et al*. (1982) compared 60 functional regulator subjects with 47 untreated controls over a 4 year period. Expansion of the maxillary and mandibular dental arches was found predominately in the molar and premolar regions. Several authors (Adams, 1969; Creekmore and Radney, 1983; Robertson, 1983) agreed that the effect of the Fränkel appliance on the lower incisors was to procline them compared with untreated controls.

Robertson (1983), Creekmore and Radney (1983) and McNamara *et al*. (1985) all reported that the maxillary incisors were tipped lingually during functional regulator therapy, on average between 2–3 mm. They also found that the occlusal rests of the appliance impeded mesial movement of the maxillary molars. This finding has been supported by Righellis (1983) and Remmer *et al*. (1985).

Fränkel (1984) reported that the functional regulator was less likely to cause proclination of the lower incisors since the appliance was not designed to be in contact with these teeth. Nielsen (1984) supported this view but McNamara *et al*. (1985) emphasized that the position of the labial pads could produce a lip bumper effect if placed too far occlusally.

Treatment effects on soft tissue

Fränkel (1969) recommended the use of his appliance in Class II division 1 subjects and particularly for patients with severe malocclusions where there is an identifiable contribution from the soft tissue to the abnormality in the arch relationship. The appliance is most effective in patients with noticeable lower lip activity during swallowing, facial expression and speech. Nielsen (1984) found that although all 10 subjects in his functional regulator group showed an improvement in their soft tissue profile because of an improved lip position, in seven there was no change in facial convexity.

Battagel (1989) analysed the cephalometric records of 62 Class II division 1 patients, half of whom had been treated using the functional regulator and the other 50 per cent using edgewise mechanics, extra-oral traction and the extraction of upper first premolars. In the functional appliance group the average lip change was small. However, the behaviour of the labiomental fold differed markedly between the two groups. The lower lip opened significantly more using the functional regulator compared with standard edgewise mechanics.

Battagel and Battagel (1994) found children treated with the functional regulator showed a more normal relationship of lips to the Ricketts' aesthetic line and a greater prominence in the lower face. Following treatment no children treated with the functional regulator showed adverse facial profiles and almost all functional regulator cases finished with the lower incisors ahead of APog. However, selection bias existed

as allocation to the edgewise, functional regulator and control groups was not randomized.

Aim

The aim of this study was to identify the contribution of skeletal and dental changes in the correction of subjects with Class II division 1 malocclusions using the functional regulator II (FRII), with reference to a concurrently recruited control group.

Subjects and methods

This was a retrospective cephalometric study of the effects of functional regulator therapy in growing patients compared with a concurrently recruited control group.

The subjects for both the study and control groups were selected from those seen at a single centre by a single operator (JCA). The following selection criteria were used:

1. Attended the centre consecutively from 1st January 1990;
2. Age 9–12 years;
3. Overjet greater than 6 mm on initial cephalometric radiograph;
4. Class II molar relationship on initial cephalometric radiograph;
5. Initial and follow-up cephalometric radiographs in occlusion;
6. Minimum 1 year and maximum 3 years between radiographs.

It is the practice of the operator at this centre to offer treatment with a functional regulator to patients satisfying these criteria. Patients declining functional regulator treatment are subsequently monitored prior to re-assessment for alternative treatment. The records of the patients were therefore examined and divided into the following groups:

1. *Study group*. Treatment instituted with a functional regulator, as shown in Figure 1, regardless of outcome or co-operation.
2. *Control group*. Treatment offered with functional regulator, but declined by patient.

The findings of a sub-group of this study group, selected as those that achieved a successful clinical outcome, have been previously reported (Rushforth *et al.*, 1999).

Data collection

The pre- and post-treatment cephalometric and pre- and post-observation radiographs were randomly coded and then digitized by one person (SMC) blind to group and timing of radiograph. The points digitized and measurements taken are shown in Figure 2.

Error of the method

Thirty radiographs were randomly selected and re-digitized 6 weeks after the initial digitization. A paired samples *t*-test was performed to assess error.

Data analysis

Descriptive data were generated and checked for normality with the Kolmogrov–Smirnov test. There was mild skewness in the data for pre-treatment overjet and overbite, as might be expected, but the sample size meant that parametric analysis was valid. Definitive data analysis was carried out with the relevant *t*-test.

Results

One hundred and thirty eight subjects were identified for inclusion in the study. The demographic data for the control and study groups are shown in Table 1. The mean, standard deviation, 95 per cent confidence intervals and significance for the repeated measurements are shown in Table 2. The lower incisor angulation showed greatest error, but the upper 95 per cent confidence limit of 2.1 degrees was considered acceptable.

The pre- and post-treatment observation cephalometric findings, and the difference between these for the two groups are shown in Tables 3 and 4. Also shown are the 95 per cent confidence intervals and significance for the difference between pre- and post-treatment/observation values

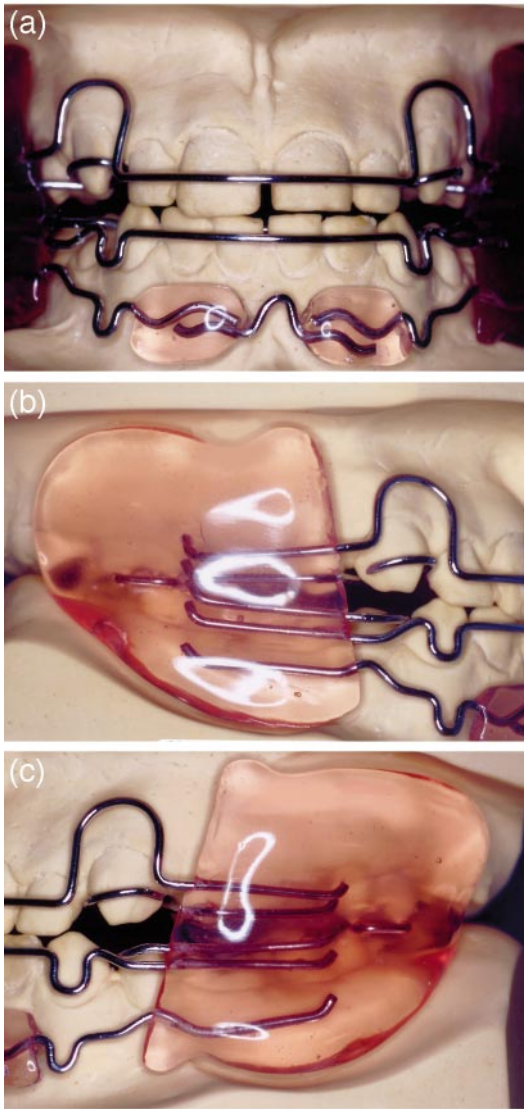

Figure 1 (a–c) Design of the functional regulator used in this study.

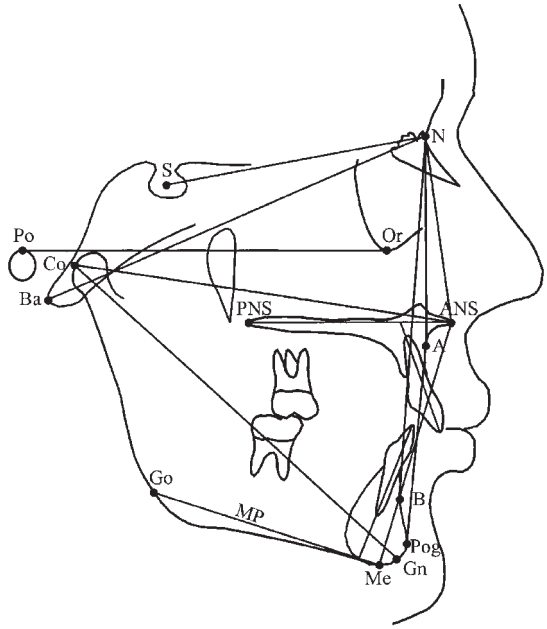

Figure 2 Points digitized and reference planes used in this investigation. Sella (S), mid point of sella turcica; Nasion (N), most anterior point of fronto-nasal suture; A, deepest concavity of anterior maxilla; B, deepest concavity of anterior mandibular symphysis; ANS, superior point where anterior nasal spine is 2 mm deep; PNS, posterior nasal spine; Basion (Ba), anterior margin of foramen magnum; Porion (Po), most superior point of bony external auditory meatus; Condylion (Co), most posterior superior point of the condyle; Orbitale (Or), most inferior point of the orbital rim; Gonion (Go), most posterior inferior point of the angle of the mandible; Menton (Me), most inferior point on the mandibular symphsis; Pogonion (Pog), most anterior point of the bony chin; Gnathion (Gn), most anterior inferior point on the mandibular symphsis; SNA, maxillary prominence (sella-nasion-A); SNB, mandibular prominence (sella-nasion-B); ANB, maxillary-mandibular relationship; MMPA, maxillary (ANS-PNS)-mandibular (Gonion-Menton) planes angle; BaNA, maxillary prominence (Basion-Nasion-A); MP-FH, mandibular plane-Frankfort horizontal (Porion–Orbitale); Facial proportion, ratio of lower face height (ANS-Me) to total face height (Nasion-Menton); ANS-Me, lower anterior face height; mandibular length, Condylion-gnathion; maxillary length, Condylion-anterior nasal spine; Nperp-point A, maxillary prominence (point A to Nasion perpendicular); Nperp-Pog, mandibular prominence (Pogonion to Nasion perpendicular); LI-MP, lower incisor inclination to mandibular plane; LI-APog, lower incisor to A–Pogonion; UI-MaxP, upper incisor inclination to maxillary plane; UI Prom, upper incisor prominence (upper incisor to Nasion perpendicular); IIA, interincisal angle; Overbite, vertical distance from upper incisor tip to lower incisor tip; Overjet, horizontal distance from upper incisor tip to lower incisor tip.

from a paired samples *t*-test. Figures 3 and 4 show the changes in overjet achieved for the individual subjects in the control and study groups, respectively.

The pre-treatment/observation values for the control and study groups and the differences between them, tested for significance using an independent *t*-test to demonstrate pre-treatment

Table 1 Demographic details of pre- and post-treatment observation groups.

	n	Mean age (range)	Mean age (range)	Observation period (range)
Control group		Pre-observation	Post-observation	
Female	37	10.92 (9.19–12.72)	12.78 (10.72–14.90)	1.87 (1.09–3.00)
Male	31	10.87 (9.00–12.90)	12.72 (10.09–15.76)	1.85 (1.05–2.91)
All	68	10.89 (9.00–12.90)	12.75 (10.09–15.76)	1.86 (1.05–3.00)
Study group				
		Pre-treatment	Post-treatment	
Female	37	11.16 (9.42–12.91)	12.77 (10.63–14.98)	1.61 (1.00–2.81)
Male	33	11.31 (9.20–12.92)	13.03 (10.53–15.64)	1.72 (1.00–2.81)
All	70	11.23 (9.20–12.92)	12.89 (10.53–15.64)	1.66 (1.00–2.81)

Table 2 Mean difference, 95 per cent confidence intervals and significance for repeated measurements (paired sample *t*-test).

		95% Confidence interval		
Variable	Mean difference	Lower	Upper	Significance (*P* value)
SNA	0.09	–0.41	0.05	0.15
SNB	0.08	–0.48	0.14	0.18
ANB	0.06	–0.03	0.21	0.12
MMPA	0.21	–0.41	0.45	0.93
BaNA	0.06	–0.27	0.03	0.05
SN-Max	0.11	–0.14	0.32	0.43
MP-FH	0.30	–0.53	0.72	0.74
Facial proportion	0.01	–0.02	0.02	0.16
ANS-Me	0.09	–0.06	0.32	0.17
Mandibular length	0.07	–0.12	0.18	0.68
Maxillary length	0.09	–0.28	0.12	0.42
Nperp-point A	0.24	–0.52	0.46	0.90
Nperp-Pog	0.47	–0.88	1.05	0.86
LI-MP	0.45	0.25	2.10	0.01
LI-APog	0.08	0.09	0.42	0.01
UI-MaxP	0.35	–0.37	1.08	0.32
UI-Prom	0.11	–0.29	0.16	0.53
IIA	0.54	–2.68	–0.45	0.00
Overbite	0.09	–0.28	0.09	0.31
Overjet	0.07	–0.33	0.04	0.15

equivalence are shown in Table 5. The study group had slightly increased skeletal and dental measurements before treatment, but these were small, for example ANB was 0.7 degrees greater than the control group, and overjet 1.6 mm greater.

Table 6 reports the changes observed for the two groups, and the results of a *t*-test for

Table 3 Control group: pre- and post-observation measurements during the study period.

Variable	Pre-observation	Post-observation	Change	Confidence interval		Significance (*P* value)
				Lower	Upper	
SNA	81.1	81.1	0.0	–0.49	0.40	0.84
SNB	75.7	76.1	0.4	–0.02	0.77	0.06
ANB	5.4	5.1	–0.3	–0.04	0.67	0.08
MMPA	30.1	29.7	–0.4	–0.19	0.88	0.20
BaNA	62.7	63.0	0.3	–0.17	0.64	0.25
SN-Max	6.0	6.2	0.2	–0.18	0.66	0.26
MP-FH	27.3	26.9	–0.3	–0.64	1.27	0.50
Facial proportion	0.55	0.55	0.0	–0.2	0.65	0.36
ANS-Me	65.4	66.6	1.2	0.54	1.81	<0.01
Mandibular length	110.1	113.7	3.6	2.62	4.60	<0.01
Maxillary length	88.6	90.5	1.9	1.02	2.72	<0.01
Nperp-point A	–0.1	0.1	0.2	–0.64	1.15	0.57
Nperp-Pog	–8.4	–7.4	–1.0	–0.58	2.68	0.20
LI-MP	91.8	92.2	0.4	–0.52	1.37	0.37
LI-APog	0.17	0.29	0.11	–0.25	0.47	0.54
UI-MaxP	114.1	114.5	0.4	–0.66	1.37	0.48
UI-Prom	6.8	7.2	0.4	–0.02	0.94	0.06
IIA	124.0	123.5	–0.5	–0.84	1.75	0.48
Overbite	4.3	4.5	0.2	–0.27	0.58	0.46
Overjet	8.7	8.7	0.0	–0.38	0.44	0.87

Table 4 Study group: pre- and post-treatment measurements during the study period.

Variable	Pre-treatment	Post-treatment	Change	Confidence interval		Significance (*P* value)
				Lower	Upper	
SNA	81.7	81.4	–0.3	–0.2	0.8	0.17
SNB	75.6	76.7	1.1	0.6	1.4	<0.01
ANB	6.1	4.8	–1.4	0.94	1.76	<0.01
MMPA	28.1	28.3	0.2	–0.5	0.8	0.60
BaNA	64.2	63.6	–0.6	0.1	1.1	0.01
SN-Max	6.1	6.0	–0.1	–0.5	0.6	0.80
MP-FH	26.0	26.5	0.4	–1.2	0.4	0.28
Facial proportion	0.55	0.55	0.0	–0.01	0.00	0.10
ANS-Me	64.7	67.0	2.3	1.8	2.9	<0.01
Mandibular length	111.8	116.0	4.2	3.3	9.7	<0.01
Maxillary length	91.6	92.5	0.9	0.0	1.9	0.04
Nperp-point A	–0.1	–0.6	–0.5	–0.2	1.3	0.16
Nperp-Pog	–9.1	–8.1	0.9	–0.5	2.4	0.20
LI-MP	92.7	96.2	3.5	2.2	4.7	<0.01
LI-APog	–1.0	1.7	2.6	2.1	3.1	<0.01
UI-MaxP	116.3	106.7	–9.7	7.9	11.4	<0.01
UI-Prom	7.0	4.3	–2.7	2.1	3.3	<0.01
IIA	122.9	128.7	5.9	3.8	7.9	<0.01
Overbite	5.1	3.4	–1.7	1.1	2.2	<0.01
Overjet	10.3	4.1	6.2	5.6	6.9	<0.01

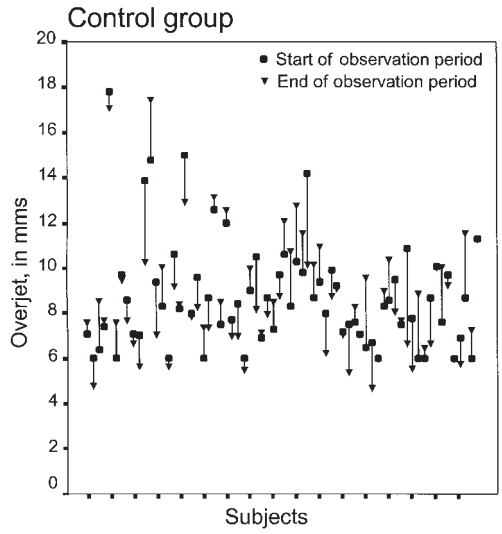

Figure 3 Overjet change for individual subjects in the control group during the observation period.

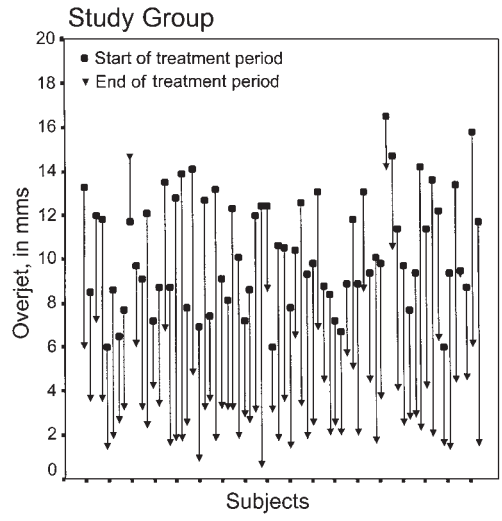

Figure 4 Overjet change for individual subjects in the treatment group during the study period.

significant differences in that change. In view of the multiple comparisons, a Bonferroni correction was made, taking into consideration the correlation between some of the variables, indicating that a value of $P < 0.025$ was required to show a difference significant at the $P < 0.05$ level. The skeletal variables in the study group that showed a statistically significant difference from the control group were SNB, ANB, BaNA and ANS-Me. Dental variables showed clinically and statistically significant differences, including a 10 degree reduction in UI-Max and 3.1 degree increase in LI-Mand.

Discussion

Study design

The optimum study design to investigate treatment effects is a randomized prospective controlled trial and previous research into the treatment effects of functional appliances has been criticized and recommendations have been published on study design by Tulloch *et al.* (1990). They recommended the use of a concurrently selected control group for comparison with the treatment group. To reduce sampling bias all patients receiving the selected treatment must be included, regardless of outcome, with efforts to minimize the size of the 'lost to follow-up' group. All retrospective studies are liable to sampling bias as clinicians will actively recruit patients who they feel will respond favourably to treatment. Whilst a prospective randomized clinical trial is the ideal approach for research into functional appliance effectiveness, this study design still presents difficulties. If the patients are recruited early it is acceptable for them to be randomly placed into a no treatment control group therefore allowing direct comparison of the effects of early treatment with normal growth. However, it may not be clinically or ethically acceptable to deny treatment to an older patient, having reached the conventional age for functional appliance therapy, because if treatment is withheld a successful outcome may not be attainable. Randomized controlled trials will, therefore, only be able to compare effects of early treatment against a control group and will not be able to compare treatment during puberty with normal growth. Randomized clinical trials with older subjects will only be able to compare the outcome of treatment with alternative appliances.

This investigation, whilst retrospective, aimed to meet as many as possible of the criteria of Tulloch *et al.* (1990). All patients who commenced functional regulator treatment were included in the treatment group regardless of

Table 5 Control and study groups pre-treatment observation comparison of variables.

Variable	Control pre-treatment	Study pre-treatment	Difference	Confidence interval		Significance (*P* value)
				Lower	Upper	
SNA	81.1	81.7	0.6	–0.7	1.9	0.33
SNB	75.7	75.6	0.1	–1.0	1.1	0.89
ANB	5.4	6.1	0.7	–0.1	1.5	<0.01
MMPA	30.1	28.1	1.9	0.2	3.7	0.03
BaNA	62.7	64.2	1.5	0.3	2.7	0.01
SN-Max	6.0	6.1	0.1	–0.9	1.1	0.80
MP-FH	27.3	26.0	1.2	–0.5	2.9	0.16
Facial proportion	0.55	0.55	0.0	–0.0	0.1	0.15
ANS-ME	65.4	64.7	0.7	–1.0	2.4	0.41
Mandibular length	110.1	111.8	1.7	–0.4	3.4	0.10
Maxillary length	88.6	91.6	3.0	1.2	4.8	<0.01
Nperp-point A	–0.1	–0.1	0.0	–1.1	1.2	0.91
Nperp-Pog	–8.4	–9.1	0.6	–1.7	3.0	0.59
LI-MP	91.8	92.7	0.9	–1.6	3.4	0.48
LI-APog	0.1	–1.0	1.1	–0.1	1.1	0.20
UI-MaxP	114.1	116.3	2.1	–0.2	4.5	0.07
UI-Prom	6.8	7.0	0.2	–0.6	1.1	0.54
IIA	124.0	122.9	1.1	–1.8	4.0	0.45
Overbite	4.3	5.1	0.8	–0.2	1.8	0.11
Overjet	8.7	10.3	1.6	0.7	2.5	<0.01

Table 6 Control and study groups pre-treatment to post-treatment change: mean values, mean difference and confidence intervals and significance for mean difference (i.e. significantly different from no difference).

Variable	Control group change	Study group change	Difference	Confidence interval		Significance (*P* value)
				Lower	Upper	
SNA	0.0	–0.3	0.3	–0.2	1.0	0.26
SNB	0.4	1.1	0.7	0.1	1.2	0.02
ANB	–0.3	–1.4	1.1	0.5	1.6	<0.01
MMPA	–0.4	0.2	0.5	–0.3	1.4	0.22
BaNA	0.3	–0.6	0.9	0.2	1.5	<0.01
SN-Max	0.2	–0.1	0.3	–0.3	0.9	0.37
MP-FH	–0.3	0.4	0.7	–0.5	1.9	0.22
Facial proportion	0.00	0.00	0.00	–0.01	0.01	0.12
ANS-ME	1.2	2.3	1.1	0.3	2.0	<0.01
Mandibular length	3.6	4.2	0.6	–0.7	1.9	0.39
Maxillary length	1.9	0.9	0.9	–0.3	2.2	0.14
Nperp-point A	0.2	–0.5	0.8	–0.4	2.0	0.18
Nperp-Pog	1.0	0.9	0.1	–2.0	2.2	0.90
LI-MP	0.4	3.5	3.1	1.5	4.6	<0.01
LI-APog	0.1	2.6	2.5	1.9	3.1	<0.01
UI-MaxP	0.4	–9.7	10.0	8.0	12.1	<0.01
UI-Prom	0.4	–2.7	3.2	2.4	3.9	<0.01
IIA	–0.5	5.9	6.3	3.9	8.7	<0.01
Overbite	0.2	–1.7	1.8	1.1	2.5	<0.01
Overjet	0.0	–6.2	6.2	5.5	7.1	<0.01

outcome. This group included patients who did not comply with treatment and also those who reported appliance wear as prescribed but failed to achieve the anticipated clinical improvement. It is felt that this approach of assessing the effectiveness rather than the efficacy of the functional regulator goes some way to meeting criticism of previous retrospective studies. Similarly, having a concurrently recruited control group rather than using archival material allows more valid comparisons to be drawn from the data. This approach has only been possible because of the strict clinical protocol of the operator. The key factors include the routine follow-up of all cases, regardless of compliance or treatment success or treatment provision. However, despite this, it is recognized that it is impossible for all sampling biases to be eliminated.

Control group findings

Table 3 shows the changes observed in the control group over the study period. The most notable feature is the remarkable consistency in the skeletal and dental angular measurements in the control group. The only variables to show significant change were the linear measurement of mandibular and maxillary length, which reflects the normal growth of the jaws in the control group. The overjet and overbite are unchanged in mean value, but examining the range shown in Figure 3 indicates that there were examples in this group where there was spontaneous improvement in the incisor relationship. The mandibular length increased by a mean value of 3.6 mm and the maxilla by 1.8 mm, showing the expected greater growth in the length of the mandible. Again the individual variation in growth should be noted. This is evident in the large standard deviations for both mandibular and maxillary growth. These findings are consistent with previously reported data for untreated subjects (Creekmore and Radney, 1983).

Treatment effects on mandibular growth

Mandibular length increased by 4.2 mm in the study group which was not significantly different from the control group. This finding is in agreement with previous studies, most of which found changes in the region of 3–5 mm. Creekmore and Radney (1983) found no significant difference between the study and control group patients. This is in conflict with Perillo *et al.* (1996) who, in a small study using untreated controls and published standards, suggested that a clinically significant increase in mandibular length was achievable.

The SNB angle increased by 1.1 degrees in the study group compared with 0.4 degrees for the control group. Although this was statistically significant it was not regarded as a clinically significant effect. A reduction in ANB of 1.4 degrees compared with 0.3 degrees for the control group, while statistically significant, is also of debatable clinical significance.

Treatment effects on maxillary growth

The parameters used for assessing maxillary growth, SNA, maxillary length and N perpendicular to point A, all showed a trend towards decreased antero-posterior maxillary development in the study group, but this did not reach statistically or, in the opinion of the authors, clinically significant levels. This is in accordance with most previous published findings (McNamara *et al.*, 1985, 1990; Courtney *et al.*, 1996; Perillo *et al.*, 1996).

Treatment effects on the dentition

The Fränkel appliance produced clinically and statistically significant changes in all the parameters used to assess the effects on the dentition. Lower incisors proclined by 3.5 degrees and the incisal tip moved forwards 2.6 mm relative to APog. The upper incisors retroclined by 9.7 degrees and upper incisor prominence was reduced by 2.7 mm. The net effect was a mean overjet reduction of 6.2 mm compared with no change in the control group. These findings, while in agreement with previous studies (Creekmore and Radney, 1983; McNamara *et al.*, 1990), perhaps indicate a greater contribution to overjet correction (5.3 mm) by incisor tipping.

Overbite was reduced on average by 1.7 mm compared with a slight increase in the control group. This is an interesting finding, as the design

of the Fränkel appliance does not incorporate a bite plane effect as seen in the activator type of functional appliances.

Effectiveness of the Fränkel appliance

The term 'effectiveness' is a measure of the effect of a treatment when applied to a population in a 'real world' environment. This compares with efficacy, which is a measure of the effect of a treatment in ideal circumstances, such as in a tightly controlled drug trial. The design of this study allows assessment of the effectiveness of the functional regulator as no suppositions were made concerning treatment outcome. Patients were included in the treatment group only on the basis that an appliance was provided. Overjet is perhaps the key variable of interest to the patient and the changes detected were interesting. Some subjects in the study group experienced an increase in overjet during the study period (Figure 4), perhaps those who failed to comply with appliance wear, and the range of overjet reduction in the other subjects was large. It is suggested that it is appropriate to make an assessment of the effectiveness of the functional regulator using this data. If the criteria of success is established as a 5 mm or greater reduction in overjet then none of the control group fulfil this criteria (the largest reduction in overjet in this group was 4.2 mm). In the study group 44 subjects, 62 per cent, attained a successful outcome judged by this criterion. The data shows that the operator in this study can expect a 'real world' success rate of 62 per cent, that is about two-thirds, with the functional regulator appliance. This compares favourably with an efficacy of 80 per cent found by Tulloch *et al*. (1997) where patients were tightly controlled as part of a randomized controlled trial in which efficacy rather than effectiveness was being tested. Morris *et al*. (1998) reported a 15 per cent discontinuation rate while Hunt and Ellisdon (1985) a 25 per cent discontinuation rate with functional appliance therapy. This information while interesting is perhaps less useful than the measure of effectiveness used in this research, as the latter encompasses both non-compliance which is evident to the clinician, as well as non-compliance that is not evident. In addition, those patients who do not respond to the treatment despite being compliant are included in a measure of effectiveness.

It is up to each individual clinician to decide if this is a satisfactory criterion of success, if it is an acceptable success rate, and whether this level of success would be achieved in their clinical practice. It is the responsibility of all clinicians to assess the clinical effectiveness of the treatment techniques they employ and to use this information to inform patients and parents of the likelihood of achieving a successful clinical outcome.

Conclusions

1. A remarkably stable mean facial and dental form during growth was seen in the untreated subjects; however, individual variation was masked.
2. The functional regulator of Fränkel does not produce clinically significant skeletal changes.
3. The functional regulator produces clinically and statistically significant changes in dental occlusion.
4. In this study, 62 per cent of subjects in the Fränkel group achieved reduction of overjet greater than 5 mm, while none of the control group achieved this change.

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