European Journal of Orthodontics 20 (1998) 501–516

A prospective evaluation of Bass, Bionator and Twin Block appliances. Part I—the hard tissues

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SUMMARY A prospective clinical study with a random allocation of 47 adolescent patients to three different functional appliance groups was established and compared with an untreated control group over a 9-month period. Treatment was undertaken with either a Bionator, Twin Block, or Bass appliance. Pre- and post-treatment cephalograms were used to quantify the skeletal and dentoalveolar changes produced by the appliances and compared with those observed in the control group as a result of growth.

Both the Bionator and Twin Block appliances demonstrated a statistically significant increase in mandibular length (3.9 ± 2.7 mm; 3.7 ± 2.1 mm, respectively) compared with the control group ($P < 0.05$), with an anterior movement of pogonion and point B. Highly statistically significant increases ($P < 0.01$) were seen in lower face heights for all the appliance groups compared with the control group. The Twin Block group showed the least forward movement of point A due to a change in the inclination of the maxillary plane. The Bionator and Twin Block groups showed statistically significant reductions in the inclination of the upper incisors to the maxillary plane ($P < 0.05$). The Bass group showed minimal change in the inclination of the lower labial segment to the mandibular plane. The Bionator group demonstrated the greatest proclination of the lower labial segment (4.0 ± 3.6 degrees). Clinically important changes were measured in all the appliance groups when compared with the control group. Differences were also identified between the functional appliance groups. The Twin Block appliance and, to a lesser extent, the Bionator appeared the most effective in producing sagittal and vertical changes.

Introduction

The treatment of Class II malocclusions is frequently aimed at correcting or masking the skeletal discrepancy. Conflicting evidence exists as to the effectiveness of growth modification with functional appliances. Many retrospective studies have concluded that either fixed or removable functional appliances have a growth modifying influence on the mandible (Righellis, 1983; McNamara *et al*., 1985; Webster *et al*., 1996). Large inter-patient variation and small mean changes may mean that the differences in response may be more attributable to study design than treatment. Additionally, any dentofacial change may be due to normal growth and would have occurred irrespective of therapy. Tulloch *et al*. (1990) have been critical of past research and concluded that most studies are characterized by weak designs. As a result, it is not possible to come to any conclusions concerning the effects of functional appliances.

The Bass orthopaedic appliance system for correction of Class II malocclusion has been previously described (Bass, 1983a,b, 1987). Published studies regarding the efficacy of the appliance (Malmgren and Ömblus, 1985; Malmgren *et al*., 1987; Pancherz *et al*., 1989; Cura *et al*., 1996) demonstrate impressive results, although none have employed a control group for comparison.

The Bionator was first described by Balters in 1964. Most studies concerning this appliance have been retrospective in design or have not included untreated controls for comparison (Janson, 1977; Whitney and Sinclair, 1987; Op

Heij *et al*., 1989; Mamandras and Allen, 1990); others have wide ranges in treatment and observation periods between the groups being investigated (Bolmgren and Moshiri, 1986; Weinbach and Smith, 1992).

Developed by Clark in 1977, the Twin Block technique has generated a high level of interest. Of the scientific studies published (Clark, 1988; Trenouth, 1992), all data have been collected retrospectively or as consecutive cases, and suitably matched control groups, observing the effects of normal growth alone, have not been established.

No direct comparison of the Bass, Bionator, and Twin Block appliances has been reported. There is therefore a need to establish scientifically-based, prospective clinical trials with suitably matched control groups to substantiate the effects of these appliances. It is also necessary to consider all subjects treated regardless of compliance.

Aims of the study

1. To observe the initial skeletal and dentoalveolar changes produced by the Bass, Bionator and Twin Block functional appliances.
2. To compare these effects with the changes seen in the control group, produced by growth alone.

Subjects

The material used in this prospective clinical study comprised the lateral cephalometric radiographs, height measurements, and optical facial laser scans of 78 Class II division 1 adolescent children. All were considered suitable by a senior clinician for functional appliance therapy i.e. when the lower jaw was postured forwards into a Class I dental relationship, the soft tissue profile became orthodontically acceptable—a clinical indication that the Class II arch relationship was skeletal in nature.

The subjects fulfilled the following criteria:

1. Caucasian patients aged between 8–15 years of age.
2. A Class II division 1 malocclusion with a Class II molar relationship and an overjet greater than 7 mm.
3. Moderate Skeletal II base relationship (ANB > 6 degrees) with mandibular retrognathia.
4. No previous history of orthodontic therapy or permanent tooth extractions.
5. No significant or adverse medical history.

The first 58 patients who had been on the waiting list for the longest period were randomly allocated to one of three groups involving treatment with either a Bass appliance, a Bionator, or a Twin Block appliance. The control group comprised 20 patients satisfying the above criteria, but who had more recently been placed on the department's functional appliance waiting list. Hence, the average age of this group was slightly less than those of the treatment groups. All control subjects were offered treatment at a later date.

The investigation extended over a 9-month period, and all subjects and parents gave prior consent to their inclusion in the study. A lateral cephalogram, study models, clinical photographs, and a facial laser scan were taken at commencement of the study period and again after 9 months therapy/observation. The patients were allocated for treatment amongst postgraduate students of similar experience under the direction of an experienced supervisor committed to the respective technique. This was to eliminate variations in operator skills and experience.

The age, sex, and appliance distribution of the total sample is shown in Table 1. Eleven subjects (14 per cent) were excluded from the final sample. Five patients failed to return after initial records, four failed to attend after appliance fitting, one was unable to return for final records due to a change in family circumstances, and one was excluded due to initiation of steroid treatment during the study period. The final sample comprised 67 subjects. The breakdown of the latter is shown in Table 2.

Appliances

The design of the Bass appliance was as described by Bass (1987), but with the omission of the mandibular labial bumper (Figure 1). The

Table 1 Breakdown of the initial sample.

	Total	Bass	Bionator	Twin Block	Control
Initial Sample					
Total	78	18	21	19	20
Male	41	10	11	7	13
Female	37	8	10	12	7
Withdrawals					
Total	11	5	3	3	0
Male	6	3	2	1	0
Female	5	2	1	2	0
Final Sample					
Total	67	13	18	16	20
Male	35	7	9	6	13
Female	32	6	9	10	7

Table 2 Ages and sex distribution of the final sample.

Group	No.	Age (years)	
		Mean	SD
Bass			
Total	13	12.5	1.8
Male	7	12.5	1.9
Female	6	12.5	1.7
Bionator			
Total	18	11.8	1.5
Male	9	12.5	1.6
Female	9	11.2	1.1
Twin Block			
Total	16	11.5	1.5
Male	6	11.8	1.6
Female	10	11.3	1.5
Control			
Total	20	11.2	1.7
Male	13	11.7	1.8
Female	7	10.3	1.4

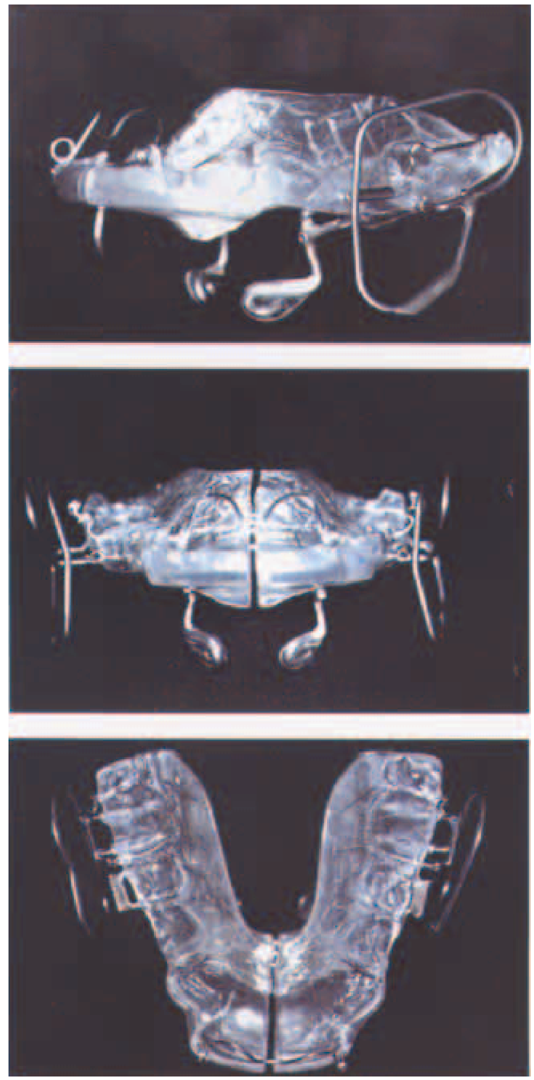

Figure 1 The Bass appliance.

lower lingual pads were constructed to a protrusive working bite, approximately 4 mm anterior to centric relation with 2–3 mm posterior bite opening. The pads were advanced by 2 mm every 6–8 weeks. Full time wear, except for eating and contact sports, was advised. Extra-oral orthopaedic forces of 1000–1500 g per side were applied by means of high pull safety headgear, for an average of 14 hours per day.

A modified Balter's Bionator which incorporated lower incisor capping was used (Figure 2). The working bite was taken with an edge to edge incisal relationship with 2–3 mm bite opening between the central incisors. In general, there was no occlusal coverage of the lower molars in order to allow unhindered vertical development of the lower buccal segments. The exception to this was in the very few high angle subjects

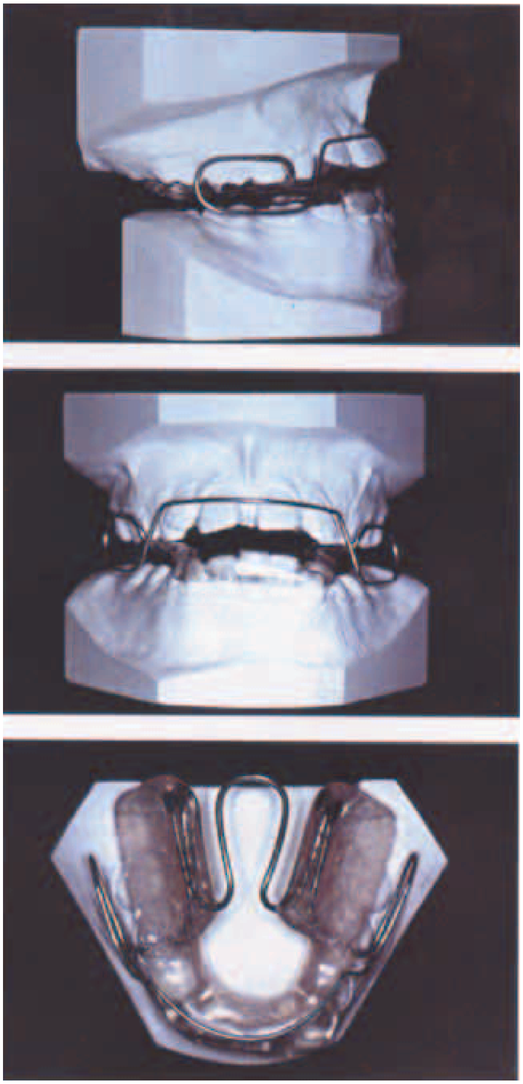

Figure 2 The modified Bionator.

where the appliance was constructed to an untrimmed design. Activation of the labial bow was avoided during treatment. Patients were instructed to wear the appliances on a full time basis except for meals and sports.

The design for the Twin Block appliance is shown in Figure 3 with the bite blocks interlocking at the steeper angle of 70 degrees (Clark, 1995) as opposed to the 45 degrees originally advocated by Clark (1982). Full time wear, including meals, but excluding sports, was encouraged. The bite registration was taken with the incisors in an edge to edge relationship where achievable, with 2–3 mm opening at the incisors. If this position was not attainable, then the working bite was recorded in a comfortable protrusive position and the blocks reactivated during treatment by the addition of cold-cure acrylic. In the small number of high angle cases, all first molars were cribbed and occlusal rests placed to hinder eruption of all the second molars.

Methods

For each patient, lateral cephalometric radiographs at the start and end of active treatment/observation were traced in sequence by two operators. All radiographs were traced on good quality acetate paper using a 4H pencil under optimum lighting conditions. The tracings were orientated to a horizontal 7 degrees below the sella–nasion line (Burstone *et al*., 1978) and a vertical reference plane drawn through sella. The points recorded are shown in Figure 4 and definitions not conforming to British standards (British Standards Institution, 1983) are indicated in the accompanying legend. Duplicate digitizations were made to a tolerance of 0.2 mm, from which 20 skeletal and 10 dental measurements were calculated (Tables 3 and 4). All measurements were corrected for radiographic enlargement (9.11 per cent in the median plane) and converted to life size.

Reproducibility and repeatability

Prior to the actual recording of the measurements, the reliability of the measurements was determined. Twenty-five randomly selected cephalograms were traced and digitized on three separate occasions by each of the two operators (H and D). The first two recordings (H1 and H2, D1 and D2) were carried out on the same day and the third recording (H3 and D3) performed 1 month later to eliminate any bias due to memory. New tracings were drawn by both operators for the 25 radiographs at each of the

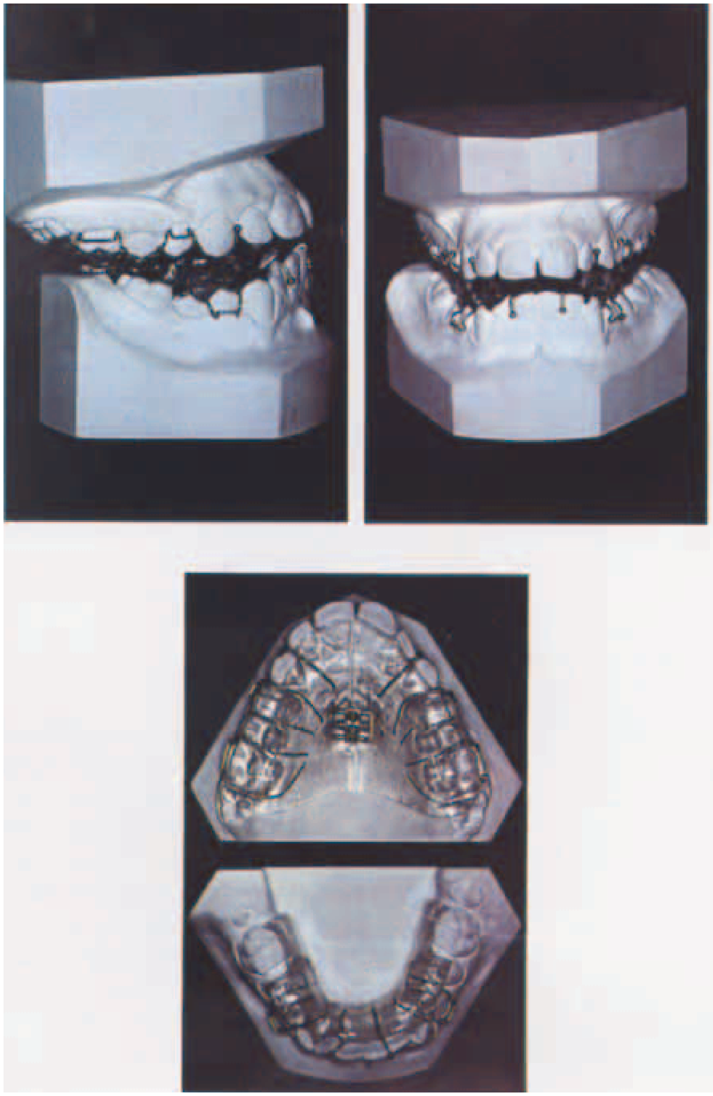

Figure 3 The Twin Block appliance.

three recordings in order to control random errors in landmark identification.

The method error was calculated by applying Dahlberg's formula (Dahlberg, 1940) and Midtgård's coefficient of reliability (Midtgård *et al*., 1974). This combination of error assessment has been suggested as the most satisfactory approach to the estimation of measurement error (Battagel, 1993). Two intra-operator comparisons were made to test the repeatability of the method with time (H1 versus H2) and (H1 versus H3), and one inter-operator comparison to test the reproducibility of the method (H1 versus D1). Dahlberg errors varied between 0.03 (LPFH per cent) and 0.47 (overbite) for linear variables, and from 0.04 (upper incisor tip to maxillary plane) to 0.58 (lower incisor tip to mandibular plane) for angular variables. The Midtgård values varied between 0.03 (LPFH per cent) and 16.33 per cent (lower incisor to A–Po line) for linear

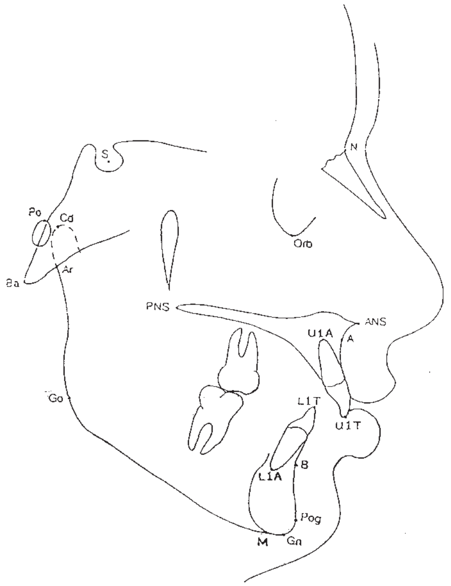

Figure 4 The cephalometric points recorded. Except where listed below, points, lines and planes conformed to British standard definitions (British Standard Institution, 1983). A, point A; ANS, anterior nasal spine; Ar, articulare; B, point B; Ba, basion; Cd, condylion; Go, gonion, the point where the bisector of the angle between the posterior and lower mandibular border tangents meets the mandibular angle; Gn, gnathion, the bisector of the angle formed by the lower mandibular border tangent and the vertical through pogonion; L1A, lower incisor apex; L1T, lower incisor tip; M, menton; the point of the intersection of the lower mandibular border and the symphyseal outline; N, nasion; Orb, orbitale; Po, porion; PNS, posterior nasal spine; Pog, pogonion; S, sella; U1A, upper incisor apex; U1T, upper incisor tip. Functional occlusal plane: a line drawn by eye between the tips of all fully erupted molar and premolar teeth. S Vertical, vertical reference plane perpendicular to horizontal plane at 7 degrees to S–N.

variables and between 1.85 (SNB) and 12.43 (lower incisor tip to mandibular plane) for angular variables.

Systematic errors were minimized by each author performing the digitizations of the cephalograms from all four groups in a blind and random sequence. The significance of the mean differences between the two recordings was evaluated by employing a paired *t*-test for each pair of replicate observations. None of the differences between the intra- and inter-operator linear or angular replicate recordings were statistically significant at the 0.05 level.

Statistical evaluation

The data were examined using SPSS PC+ (Norusis, 1986). Measurements were analysed separately for males and females, but where no significant differences were found between them, the data were pooled. Means and standard deviations were calculated. As the groups were found to conform to a normal distribution, comparative analysis of the four groups was undertaken using parametric two-way analysis of variance (ANOVA). All groups were tested for group differences at the start and end of treatment/observation and for the changes that occurred during the study period. Statistical significance was determined at the 0.05 level of confidence. Where the significance was $P < 0.05$, a one-way analysis of variance, Scheffé's method of multiple comparisons, was employed to test the significance of individual groups.

Results

The results are presented in Tables 3 and 4, and describe both the initial and final values for each group. The skeletal variables are examined in Table 3 and the dental variables are shown in Table 4. In a population of growing children, the effects of treatment are superimposed on those of growth. Linear cephalometric values will normally increase with age, but treatment may modify this effect. Angular variables, by contrast, remain relatively stable and therefore any significant alterations may be attributed more reliably to appliance therapy.

Two-way analysis of variance

Start observations. No linear or angular variables showed statistically significant differences between the four test groups. However, analysis of the linear variables showed differences between the sexes. These involved Ar–ANS, Ar–Gn, Ar–Pog, Cd–ANS, Cd–Gn, incisal tips to the maxillary and mandibular planes, and to S vertical and point A to S vertical. This is not unexpected as the linear dimensions of the male are generally greater than those of females for a population of similar age. None of the angular variables

Table 3 Before and after treatment/observation measurements. Significant differences found in the finish values were analysed by a one-way ANOVA and are denoted by asterisks. Where no differences between the sexes was found the data has been pooled; otherwise values for each sex are presented separately (skeletal measurements).

Skeletal measurements	Bass appliance				Bionator appliance				Twin Block appliance				Controls				Significance of finish variables
	Before treatment		After treatment		Before treatment		After treatment		Before treatment		After treatment		First observation		Second observation		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Maxilla																	
SNA degrees	83.3	3.9	84.2	4.3	83.1	5.1	82.5	4.7	80.7	3.2	79.3*	2.7	81.1	4.1	81.3	4.0	Twin Block from Bass
Art to ANS (male) mm	89.7	3.0	91.3	3.1	88.3	4.0	90.1	4.8	91.2	6.7	90.4	5.8	86.4	5.4	87.2	5.7	
Art to ANS (female) mm	87.5	5.9	87.2	4.5	82.6	4.7	82.1	5.9	83.7	5.2	85.0	5.0	83.2	4.3	82.4	4.5	
Cd to ANS (male) mm	91.5	3.3	92.9	2.9	89.0	4.3	91.7	5.7	92.3	6.8	92.4	5.7	88.2	5.7	88.9	6.2	
Cd to ANS (female) mm	89.3	6.2	88.4	4.1	83.9	5.0	83.7	6.7	85.4	5.3	86.7	5.2	84.9	5.3	85.1	5.2	
A to S vertical (male) mm	69.0	2.5	70.7	2.2	67.9	5.0	67.5	4.5	67.8	4.1	67.3	4.7	63.5	4.7	64.2	4.4	
A to S vertical (female) mm	62.5	4.6	62.7	4.7	62.0	4.4	62.6	4.5	61.9	4.8	61.4	4.5	62.5	4.6	63.5	4.7	
Max plane to SN	6.7	3.3	7.0	3.4	6.4	3.7	7.3	3.8	5.8	3.2	7.1	2.7	7.8	2.6	8.3	2.5	
Mandible																	
SNB degrees	76.8	3.0	77.7	3.5	76.9	4.6	77.5	4.9	73.9	2.7	74.7	2.8	72.4	3.7	74.1	3.9	
SN Pog degrees	78.1	3.4	79.0	3.8	78.3	4.4	78.7	4.8	75.6	3.0	76.2	3.2	75.4	3.8	75.3	4.1	
Mand plane to FOP (male) degrees	12.6	5.0	12.0	3.3	12.9	3.7	13.5	3.8	13.4	4.7	12.6	6.4	13.8	3.6	13.2	4.6	
Mand plane to FOP (female) degrees	15.4	3.6	14.3	4.7	15.7	3.8	17.8	2.3	15.4	3.6	13.2	3.8	15.8	4.9	15.4	4.9	
Art to Gn (male) mm	99.6	3.4	102.5	3.7	98.4	3.4	101.4	5.1	102.4	6.5	104.7	5.5	95.6	6.1	96.9	6.1	
Art to Gn (female) mm	96.4	4.7	98.1	4.7	93.3	7.1	96.8	6.0	93.9	7.2	97.6	6.7	91.3	5.1	91.7	4.7	
Cd to Gn (male)	105.1	2.4	107.6	2.7	103.3	3.4	107.6	5.6	108.5	6.8	113.0*	6.5	102.1	6.8	103.0	6.7	Twin Block from control
Cd to Gn (female)	103.0	6.4	103.7	3.3	98.2	6.4	101.6	6.5	100.3	6.5	103.5	6.7	97.1	6.0	99.1	5.2	
Art to Pog (male) mm	98.2	3.3	100.9	3.5	96.3	3.7	98.7	5.4	100.1	6.4	102.1	5.9	93.3	5.9	94.5	6.4	
Art to Pog (female) mm	93.5	3.7	95.6	4.3	91.2	6.8	94.7	5.5	92.3	7.0	95.7	6.5	89.5	4.8	89.9	4.2	
B to S vertical mm	56.1	5.6	57.5	6.9	55.7	7.4	56.7	7.9	51.9	6.2	53.7	6.8	51.3	6.1	51.4	6.5	
Pog to S vertical mm	57.2	6.5	58.8	7.8	57.0	8.2	58.0	8.7	53.1	7.4	54.9	8.1	51.7	6.9	52.0	7.4	
Intermaxillary																	
ANB degrees	6.5	2.2	6.5	1.9	6.2	2.2	5.0*	2.4	6.8	1.6	4.8**	1.8	6.9	2.2	7.3	2.1	Bionator and Twin Block from control
MM angle degrees	27.0	6.4	26.7	7.2	27.8	5.3	27.7	5.5	31.5	5.6	29.9	5.4	28.1	6.7	27.6	6.5	
Lower face height mm	55.3	4.5	57.2	3.8	55.5	5.7	57.6	4.8	57.2	4.7	59.9**	4.4	54.9	6.1	54.6	5.5	Twin Block from control
Upper face height mm	48.7	3.9	49.1	3.9	46.8	3.6	48.5	3.5	47.3	2.8	48.8	2.3	48.0	4.2	48.9	4.4	
Total face height (male) mm	104.2	4.8	106.8	3.4	104.0	2.9	108.2	5.1	109.7	6.0	113.5	6.4	105.2	8.5	105.7	8.5	
Total face height (female) mm	103.6	9.3	105.7	8.4	100.6	7.9	104.0	7.1	101.5	4.7	105.8	3.9	98.6	6.9	99.3	6.9	
LAFH %	53.0	2.1	53.8	2.0	54.0	2.9	54.4	2.0	54.4	1.5	55.1*	1.0	53.5	2.5	53.0	2.1	Twin Block from control
LPFH %	39.4	6.2	40.9	5.9	39.5	4.5	41.5	4.8	27.4	5.2	41.0	3.7	40.7	4.0	40.7	4.5	

* $P < 0.05$; ** $P < 0.01$.

Table 4 Before and after treatment/observation measurements. Significant differences found in the finish variables were examined by a one-way ANOVA and are denoted by asterisks. Where no differences between the sexes was found the data has been pooled; otherwise values for each sex are presented separately (dental measurements).

Dental measurements	Bass appliance				Bionator appliance				Twin Block appliance				Controls				Significance of finish variables
	Before treatment		After treatment		Before treatment		After treatment		Before treatment		After treatment		First observation		Second observation		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Maxilla																	
1|1 to max plane degrees	115.4	6.8	111.2	4.3	119.3	7.2	111.8	8.7	115.8	7.1	106.6**	8.3	118.7	7.5	116.8	8.5	Twin Block from control
1|1 tip to max plane (male) mm	26.6	3.2	26.6*	2.4	27.3	1.8	27.8	1.6	29.3	1.9	31.9	2.8	27.1	3.3	26.8*	3.2	Bass and control from Twin Block
1|1 tip to max plane (female) mm	26.1	2.4	27.2	4.0	24.7	3.9	25.9	3.6	25.4	1.9	27.3	1.3	23.5	3.4	23.8	3.5	
1|1 to S vertical (male) mm	74.5	3.7	73.9	3.3	73.4	5.8	70.4	6.4	74.0	3.8	71.3	3.7	68.4	6.0	68.2	6.6	
1|1 to S vertical (female) mm	67.4	3.9	65.3	4.8	69.1	6.6	67.4	7.9	66.1	6.8	62.5	7.3	69.0	4.8	70.4	4.2	
Mandible																	
1|1 to mand plane degrees	94.4	8.3	94.7	7.8	93.3	5.7	97.3	6.4	92.1	7.6	94.2	9.3	95.4	9.5	93.7	7.2	
1|1 tip to mand plane (male) mm	37.8	4.3	37.8	3.5	38.5	3.4	38.8	3.1	39.8	4.3	38.6	4.9	38.6	3.0	38.8	3.5	
1|1 tip to mand plane (female) mm	37.1	2.6	37.1	2.3	36.3	3.4	37.3	3.7	35.9	2.2	35.7	2.6	35.7	2.1	36.7	2.6	
1|1 to S vertical (male) mm	65.5	4.0	67.6*	3.9	64.2	6.4	66.3*	6.1	63.3	3.7	66.3	3.6	59.0	6.4	58.5	6.4	Bass and Bionator from control
1|1 to S vertical (female) mm	59.1	3.8	59.4	5.2	59.8	6.7	63.1	6.8	56.3	6.6	57.8	5.7	58.8	4.9	59.9	4.1	
1|1 to APo mm	–0.5	3.0	–0.2*	2.6	–0.4	2.7	2.4	1.8	–1.4	2.9	0.9	2.8	–0.3	2.5	–1**	2.6	Bass and control from Bionator
Intermaxillary																	
Overjet mm	9.3	2.6	5.9**	2.6	9.8	2.1	4.4**	2.1	10.2	2.1	4.5**	2.8	10.4	2.4	11.0	2.9	Bass, Bionator and Twin Block from control
Overbite (male) mm	6.2	1.9	4.3	1.5	6.6	1.8	4.3	2.7	4.7	1.6	3.2**	1.7	6.2	2.6	6.5	3.1	Twin Block from control
Overbite (female) mm	5.1	2.1	4.6	1.1	5.1	1.7	2.9	0.9	4.8	2.7	2.7	1.9	4.4	2.6	4.3	2.9	
Interincisal angle degrees	123.2	8.4	127.3	5.7	119.5	6.4	123.1	8.0	120.7	8.7	129.3	11.5	117.8	9.8	121.9	9.9	

* $P < 0.05$; ** $P < 0.01$.

showed statistically significant differences between males and females except for the mandibular plane to the functional occlusal plane.

Finish observations. The analysis of the linear variables demonstrated statistically significant differences between the four experimental groups. These involved the variables Ar–Gn, Ar–Pog, Cd–Gn, the upper incisor tip to the maxillary plane, overjet, overbite, lower incisor to A–Po, and lower face height. Five of the angular variables showed statistically significant differences between treatment types: SNA, SNB, ANB, upper incisors to maxillary plane, and the interincisal angle. These would all be expected outcomes of functional appliance therapy.

Change in start and finish observations. The ANOVA of the linear changes between the start and finish observations demonstrated statistically significant differences between the experimental groups. These changes involved the same variables as for the finish variables but were, in addition, statistically significant for lower incisal tip to S vertical, total face height, and percentage lower posterior face height. Angular variables involving SNA, ANB, and the inclinations of the incisors to their respective bases showed statistically significant differences at the $P < 0.01$ level. There were no statistically significant differences in angular or linear variables between the genders.

One-way analysis of variance

A one-way analysis of variance, Scheffé's method of multiple comparisons, was performed on those variables found in the two-way ANOVA to demonstrate statistical significance due to treatment type. This allowed the particular appliances causing the differences to be identified. P values were obtained for each variable. Where there were no differences due to gender, the male and female data were pooled, otherwise the data were analysed separately. The results are shown in Tables 3–6.

Start. At the start of therapy, no variables showed a difference between the treatment/control groups.

Finish (Tables 3 and 4). The one-way ANOVA demonstrated statistically significant differences in SNA between the Twin Block and Bass appliance groups. Both the Bionator and Twin Block showed statistically significant differences in ANB from the control group ($P < 0.01$ and $P < 0.05$, respectively). The finish values for LAFH per cent also differed between the Twin Block and control groups ($P < 0.05$).

For the dental variables, highly statistically significant differences ($P < 0.01$) in overjet were seen between all three appliance groups and the control group. Overbite reduction in the Twin Block group also showed differences ($P < 0.05$) from that of the control group. The Bionator showed statistically significant differences in the distance from the lower incisor tip to A–Po compared with the Bass appliance group, and highly statistically significant differences in this variable compared with the control group. Highly statistically significant differences were observed between the Twin Block and control groups in the linear distance from the upper incisors to the maxillary plane, suggesting some vertical development of the upper labial segment in the former group.

Differences between the sexes were also seen in some linear variables. Thus, the data were separated by sex and analysed (Tables 3 and 4). The male Twin Block sample showed statistically significant differences with the male control group in the variables Cd–Gn and lower face height. The male Twin Block sample showed statistically significant differences in the inclination of the upper incisors to the maxillary plane compared with the male Bass and control groups. Both the male Bass and male Bionator groups showed statistically significant differences from the control group in the distance of the lower incisor tip to S vertical.

Start–finish changes (Tables 5 and 6). With the male and female data again pooled, there was a statistically significant difference between the Twin Block and Bass samples with respect to their effect on SNA. Highly significant differences were seen for variable ANB between the Twin Block and Bass/control groups. In addition, the Bionator sample showed statistically significant

Table 5 Changes during treatment/observation and the significance of any differences between the four groups examined by a one-way analysis of variance. No differences between the sexes were found; therefore, data has been pooled (skeletal measurements).

Skeletal measurements	Bass appliance		Bionator appliance		Twin Block appliance		Control		Significance
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Maxilla									
SNA degrees	0.9*	1.9	0.9	1.9	–1.4	1.5	0.3	1.5	Bass from Twin Block
Art to ANS mm	0.7	2.7	0.6	3.0	0.5	2.3	0.3	2.2	
A to S vertical mm	1.0	2.5	0.1	1.6	–0.5	1.3	0.8	1.1	
Max plane to SN	0.3	1.2	0.9	2.4	1.4	1.5	0.6	1.7	
Mandible									
SNB degrees	0.9	0.8	0.6	2.1	0.8	1.3	–0.2	1.3	
SN Pog degrees	0.9	0.7	0.5	2.1	0.6	1.2	0.0	1.2	
Mand plane to FOP degrees	–0.9	2.6	1.3	3.3	–1.6	2.7	–0.5	3.5	
Art to Gn mm	2.4	1.4	3.6*	2.6	3.2*	2.1	1.0	1.5	Bionator and Twin Block from control
Cd–Gn mm	1.7	2.5	3.9	2.7	3.7	2.1	1.3	3.1	Bionator from control
Art to Pog mm	2.4	2.1	3.0	2.7	2.9	2.2	0.9	1.7	
B to S vertical mm	1.4	1.8	1.1	2.6	1.7	2.0	0.1	1.7	
Pog to S vertical mm	1.6	1.6	1.0	2.9	1.8	2.3	0.4	1.9	
Intermaxillary									
ANB degrees	0.0	1.9	–1.3*	2.2	–2.3**	1.3	0.4	1.2	Control from Bionator and Twin Block; Bass from Twin Block
MM angle degrees	–0.3	1.8	–0.8	2.5	–1.5	2.2	–0.4	1.8	
Lower face height mm	1.9**	1.6	2.1**	2.0	2.7**	1.7	–0.3	1.5	Bass, Bionator and Twin Block from control
Upper face height mm	0.4	0.6	1.6	2.1	1.5	1.5	0.9	1.5	
Total face height mm	2.3	1.6	3.8**	2.4	4.2**	1.7	0.5	1.7	Bionator and Twin Block from control
LAFH %	0.8*	0.7	0.4	1.2	0.7*	1.2	–0.5	1.0	Bass and Twin Block from control
LPFH %	1.5	1.8	2.0	2.8	3.6**	3.0	0.0	2.5	Twin Block from control

* $P < 0.05$; ** $P < 0.01$.

Table 6 Changes during treatment/observation and the significance of any differences between the four groups examined by a one-way analysis of variance. No differences between the sexes were found; therefore, data has been pooled (dental measurements).

Dental measurements	Bass appliance		Bionator appliance		Twin Block appliance		Control		Significance
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Maxilla									
1|1 to max plane degrees	–4.1	8.1	–7.6*	4.4	–9.1**	6.2	–1.9	4.1	Bionator and Twin Block from control
1|1 tip to max plane mm	0.5	1.8	0.8	1.6	2.1**	1.7	–0.1	1.7	Twin Block from control
1|1 to S vertical mm	–1.2	2.7	0.1**	1.6	–3.3**	2.5	0.4	1.9	Bionator and Twin Block from control
Mandible									
1|1 to mand plane degrees	0.3	5.1	4.0*	3.6	2.0	7.3	–1.7	5.4	Bionator from control
1|1 tip to mand plane mm	0.0	1.2	0.6	1.4	–0.6	2.8	0.5	1.2	
1|1 to S vertical mm	1.3	1.9	2.7**	2.4	2.1*	2.2	0.5	1.9	Bionator and Twin Block from control
1|1 to APo mm	0.3**	2.0	2.8**	1.9	2.3**	2.1	–0.7	1.5	Bionator and Twin Block from control; Bionator from Bass
Intermaxillary									
Overjet mm	–3.3**	2.8	–5.3**	3.2	–5.7**	3.3	0.7	1.5	Bass, Bionator and Twin Block from control
Overbite mm	–1.3	2.1	–2.2**	2.4	–1.8*	2.1	0.1	1.6	Bionator and Twin Block from control
Interincisal angle degrees	4.1	9.5	3.6	4.2	8.6	7.6	4.1	6.4	

* $P < 0.05$; ** $P < 0.01$.

differences from the control group for ANB. The Bionator and Twin Block groups showed significant differences in Ar–Gn from the control group. The former also demonstrated a difference in Cd–Gn compared with the control group, suggesting an increase in mandibular length. All three appliance groups demonstrated statistically significant differences from the control group in lower face height. The Twin Block and Bionator groups showed differences from the control group in total face height.

The Bionator and Twin Block groups both showed statistically significant differences with the control group ($P < 0.05$ and $P < 0.01$, respectively) in the inclination of the upper incisors to the maxillary plane. The Twin Block sample also showed statistically significant differences in the distance from upper incisor tip to maxillary plane, indicating some extrusion of the upper incisors as a result of therapy.

The Bionator group showed a difference with the control group in the inclination of the lower incisors to the mandibular plane ($P < 0.05$). The Bass group differed from the Bionator in its effect on the lower incisor to A–Po. The Twin Block and Bionator groups showed differences from the control group in overbite reduction, incisor tip to S vertical distance and from lower incisor to A–Po. All three appliance groups demonstrated statistically significant differences from the control group in overjet reduction.

Graphical presentation of the treatment changes (Figures 5–8)

The effects of treatment are depicted graphically in Figures 5–8. The solid lines indicate the mean start of treatment and the broken lines depict the mean end of treatment/observation. Each of the experimental groups are colour coded as follows; Black: Bass (Figure 5); Blue: Bionator (Figure 6); Green: Twin Block (Figure 7); Red: control (Figure 8). All plots were superimposed on S–N and registered at sella.

All three treatment groups showed a forward movement of point B with an increase in lower anterior face height. There was a downward and backward hinging of the mandible with the position of the temporomandibular joint

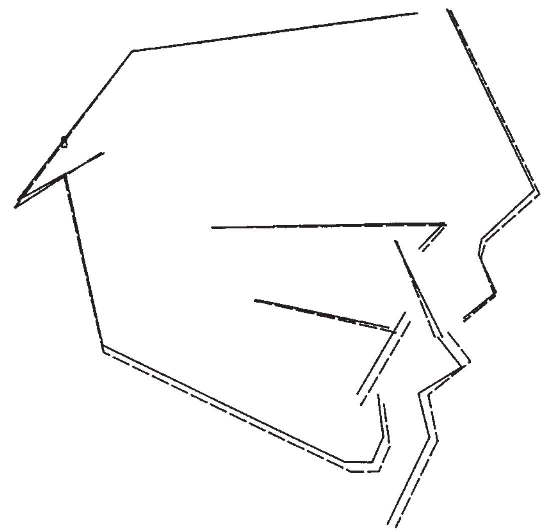

Figure 5 Mean facial diagrams, plotted from the averaged co-ordinates of selected points, for all Bass appliance subjects, superimposed on S–N, registered at S. Solid black line = start of treatment. Broken black line = after 9 months of active treatment.

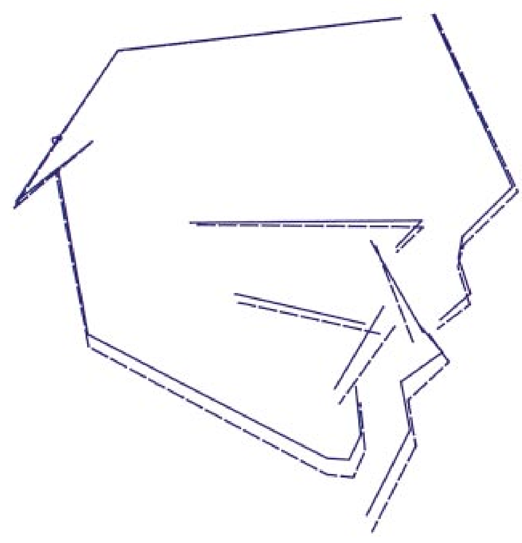

Figure 6 Mean facial diagrams, plotted from the averaged co-ordinates of selected points, for all Bionator subjects, superimposed on S–N, registered at S. Solid blue line = start of treatment. Broken blue line = after 9 months of active treatment.

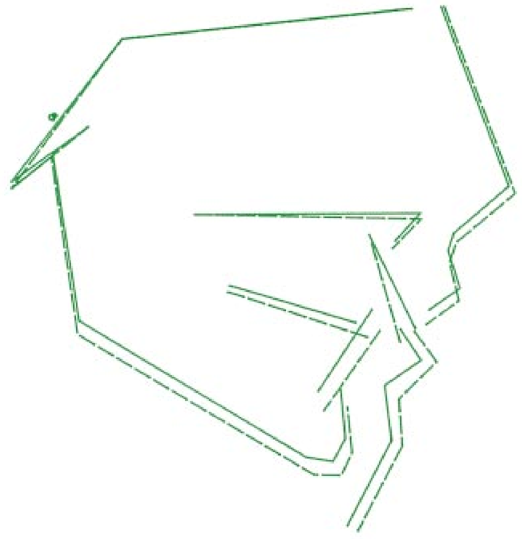

Figure 7 Mean facial diagrams, plotted from the averaged co-ordinates of selected points, for all Twin Block appliance subjects, superimposed on S–N, registered at S. Solid green line = start of treatment. Broken green line = after 9 months of active treatment.

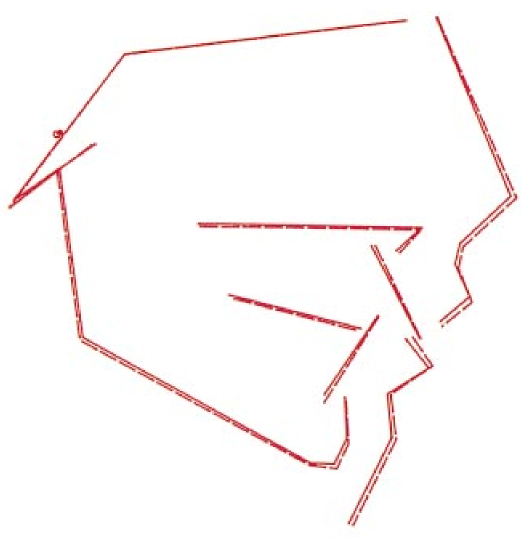

Figure 8 Mean facial diagrams, plotted from the averaged co-ordinates of selected points, for all control subjects, superimposed on S–N, registered at S. Solid red line = start of observation. Broken red line = after nine months of observation.

appearing unchanged. Forward movement of the tips of the lower incisors was seen in all the treatment groups. However, the inclination of the latter in the Bass group had not been altered to any visible extent. The greatest proclination of the lower incisors was seen in the Bionator sample. Point B appeared to have moved forward as a result of functional therapy in all treatment groups and to a lesser extent in the control group. The Bionator and the Twin Block samples depict a clockwise rotation of the maxillary plane. All treatment groups demonstrated a reduction in overjet and of the inclination of the upper incisors to the maxillary plane. This was greatest in the Twin Block and Bionator groups.

These effects are in contrast to the control group who showed minimal change over the experimental period. There was little forward repositioning of the mandible and only a slight increase in lower anterior face height. Slight reduction in the inclination of the incisors to their respective bases was observed, the uppers remaining outside lower lip control.

Discussion

General considerations

Despite the strict inclusion criteria for enrolment into the study, due to random allocation of the subjects, differences between groups will always exist. The sex distribution of the subjects was not equal between the control and Twin Block groups—this being entirely due to chance and without bias. Increasing the sample size would undoubtedly result in a more balanced ratio and would be advisable in view of the extremely variable treatment effects of functional appliance therapy.

In general, the males were older than the females, except in the Bass group where the ages were well matched. The Bass group was, however, a mean of 1.3 years older than the control group. This, although of no statistical significance at the start of treatment, may be clinically significant in terms of growth velocity. Younger children, exhibiting a smaller degree of change, will tend to underestimate the differences in a particular group. This is a justifiable criticism of the study caused by the fact that the control group comprised those subjects most recently placed on the waiting list. It was not considered ethical to defer the treatment of patients who had been on the waiting list longest.

This study compared the effects of the appliances and growth over a 9-month period and included all patients regardless of compliance or achievement of a Class I incisor relationship. Treatment was continued if the malocclusion was not fully corrected within the study period. As all mean changes were modest and frequently smaller than their associated standard deviations, this may have caused the significant differences to underestimate the true situation. From a clinical impression, the Twin Block appliance appeared to be the most readily tolerated and was advantageous in terms of rapidity of correction. The Bass appliance, however, appeared to be advantageous in terms of the effects on the lower incisors. It must be stressed that this study reports the initial effects and no conclusions can be drawn about stability.

The effects of the appliances

Each of the appliances was effective in producing either complete or partial correction of the Class II division 1 malocclusion. This appeared to be achieved by a combination of some skeletal, but mainly dentoalveolar changes, which were at variance with those of normal growth.

Maxilla. Changes in the value of ANB would suggest that the Twin Block appliance was the most effective in reducing the sagittal intermaxillary relationship, followed by the Bionator. The Bass and Bionator groups demonstrated a small mean increase in SNA as a result of therapy, in contrast to the Twin Block group which demonstrated a mean reduction. This suggests that forward movement of point A is restricted as a result of Twin Block therapy, which may be particularly effective due to intermittent forces being applied to the maxilla on a near full time basis. However, the tipping of the maxillary plane anteriorly will account for a downward and backward movement of point A, thus reducing SNA. Jakobsson (1967) reported this effect of functional appliance therapy as being due to the force vector acting well below the centre of resistance of the maxilla. This finding is confirmed by the changes in the angle of the maxillary plane to S–N, where the greatest increases in this variable were found in the Twin Block group. Birkebæk *et al*. (1984), using implants, also determined that the activator caused the maxilla to rotate in a downward and backward direction.

Point A is a deep alveolar point rather than a true skeletal landmark. Changes in the inclination of the teeth will alter the location of this landmark. The forward movement of point A, although slight with the Bass appliance, was an unexpected finding as the torquing spring and headgear were employed to limit the anterior movement of the apices of the central incisors. The results differ from those of Pancherz *et al*. (1989), who found a mean reduction, although minimal (-0.4 ± 1.0 degrees) in SNA, as did Cura *et al*. (1996) with -0.7 ± 1.8 degrees. Jakobsson and Paulin (1990) indicated that the basal areas of the maxilla are restrained in their normal forward development by functional appliance therapy, whilst Janson (1977) reported the skeletal effects of the Bionator to be insignificant (maximum 1 degree). The control group showed relatively little change in SNA over the observation period (0.25 ± 1.5 degrees).

Mandible. The findings suggest that functional appliance therapy results in an anterior relocation of point B and pogonion. Pancherz *et al*. (1989) also showed an increase in SNB in males with Bass therapy, albeit to a greater extent (1.6 ± 1.1 degrees). The control group, conversely, showed a mean reduction in SNB for both sexes, possibly due to a continued retroclining effect of the lower lip lying lingual to the upper incisors. The values of S–N–Pog and Pog to S vertical support these findings, demonstrating that the mandible had moved forward as a result of active therapy. The control group exhibited only a minimal increase in these variables as a result of growth alone.

Measurements of mandibular lengths from the points condylion and articulare to gnathion again demonstrated an increase in the treatment groups to a greater extent than in the control group. The greatest change was observed in the Bionator group (3.3 ± 2.6 mm), closely followed by the Twin Block group. The latter were statistically significant in comparison with the changes seen in the control group. The Bass appliance resulted in a smaller increase (2.4 ± 2.2 mm).

Vertical considerations. All four groups demonstrated a small mean reduction in the maxillary–mandibular planes angle (MMPA), the greatest being for the Twin Block group (–1.5 ± 1.5 degrees). This may be due to rotation of the maxillary plane with therapy which would tend to lower the value of this variable. Birkebæk *et al*. (1984) demonstrated different results to the above, reporting an increase in the MMPA of 2.5 degrees in their activator group. The control group, however, showed a similar slight decrease in this variable.

The control group also showed a slight mean reduction in the lower anterior face height (–0.3 ± 1.5 mm). The treatment group values increased considerably more and resulted in the most marked clinical change. The increase was greatest in the Twin Block group (2.7 ± 1.7 mm) followed by the Bionator (2.1 ± 2.0 mm) and Bass groups (1.9 ± 1.6 mm). Clark (1995) showed a significant increase in total vertical face height with Twin Block therapy, being 6.29 mm in males and 4.93 mm in females, over a 12-month period. Cura *et al*. (1996) showed an increase in total face height with Bass therapy of 3.4 ± 2.1 mm, and with the activator of 4.6 ± 1.8 mm.

The increase in upper face height was less in the Bass group than in the control group and much less than in the other appliance groups. This may be due to the headgear used with the Bass system limiting maxillary development. Combining this finding with the results of point A, it would appear that headgear is more effective at limiting the vertical rather than the anterior development of the maxilla.

In the treatment groups, a very small number of high angle subjects were included. The appliances for these subjects were designed to prevent further increase in facial height, i.e. use of an untrimmed Bionator to prevent eruption of the lower buccal segments; addition of occlusal rests to prevent eruption of second molars in Twin Block cases; posteriorly positioned high pull headgear in Bass therapy. Ideally, subjects in future studies should be selected with regard to their facial height, in addition to the current criteria.

Dentoalveolar changes. The differences between groups were most pronounced for dentoalveolar variables. All treatment groups demonstrated a mean reduction in the proclination of the upper incisors. This was greatest in the Twin Block group (–9.1 ± 6.2 degrees), followed by the Bionator (–7.7 ± 4.4 degrees) and Bass (–4.1 ± 8.1 degrees) groups. This is an expected treatment outcome of functional appliance therapy due to their Class II 'traction effect'. The decreased retraction of the upper incisors with the Bass appliance can be explained by either the anterior torquing spring preventing excessive palatal tipping of the teeth or by the fact that therapy was incomplete. Pancherz *et al*. (1989) also showed a reduction in the proclination of the upper incisors due to Bass therapy. The magnitude was not as great as for the current study (–1.8 ± 6.0 degrees); however, the incisors were less proclined at the commencement of their study. The findings support those of Clark (1982, 1988), in cases treated with the Twin Block, and those of Janson (1977), Hunt and Ellisdon (1985), Bolmgren and Moshiri (1986), and Op Heij *et al*. (1989), in cases treated with the Bionator.

The effect of appliance therapy on the position of the lower incisors varied between the appliance groups. The Bass appliance showed a negligible mean change in the position of the lower labial segment. This may be explained by the fact that these teeth are not subject to Class II traction forces by means of clasps or acrylic as with other appliances. Cura *et al*. (1996) found the Bass appliance to have little effect on the lower incisors (0.28 ± 3.26 degrees), whereas Pancherz *et al*. (1989) demonstrated more proclination of the lower incisors with the Bass appliance (2.2 ± 3.8 degrees).

The greatest proclination of the lower incisors was seen in the Bionator group (4.0 ± 3.6 degrees).

The Twin Block group showed an intermediate change (2.0 ± 7.3 degrees). Jakobsson (1967), Clark (1982, 1988), and Op Heij *et al.* (1989) reported a similar movement of the lower incisors during functional appliance therapy. The control group showed an overall mean retroclination of the lower incisors (–1.7 ± 5.4 degrees) due to the restraining effect of the lower lip.

As a result of therapy, the overjet decreased in all the appliance groups and increased slightly in the control group. The greatest reduction was observed in the Twin Block group, followed by the Bionator and Bass groups, respectively. As the Bass appliance showed the least retroclination of the upper incisors and minimal effect on the lower incisors, this would account for the incomplete reduction in overjet. It could be speculated that although, in this study, the Bass appliance did not show such rapid anteroposterior correction, the changes may be superior in terms of the effect on incisor inclination.

Conclusions

1. All the functional appliances included in this study produced a measurable change in the skeletal and dentoalveolar tissues, with the untreated sample showing minimal change due to growth alone.
2. The appliance groups all demonstrated a forward movement of pogonion and a more pronounced downward movement of menton in comparison with the control group. The anterior movement of the mandible was greatest in the Twin Block group, followed by the Bass and Bionator groups, respectively.
3. Highly statistically significant increases in lower anterior face height ($P < 0.01$) were found between all the appliance groups and the control group. This was the most marked facial change found in the study. The Twin Block and Bionator groups showed highly statistically significant increases in total face height ($P < 0.01$), suggesting that the Bass appliance, by incorporating headgear, is effective in limiting the vertical development of the maxilla.
4. The Twin Block group demonstrated statistically significant greater restriction of the anterior movement of point A than the Bass group ($P < 0.05$). The highly statistically significant reduction of ANB compared with the Bass and control groups ($P < 0.01$) may be attributed to the rotation of the maxillary plane observed in the Twin Block group.
5. The Twin Block and Bionator groups demonstrated a statistically significant reduction in the inclination of the upper incisors to the maxillary plane in comparison with the control group. The Bass appliance produced minimal change in the position of the lower labial segment, whilst the Bionator showed the greatest proclination of the lower labial segment.

Future study

1. It is proposed to continue the study and increase the sample sizes of the groups. In addition, the groups will be sub-divided according to facial height.
2. The cases will be followed over a longer time period to determine the stability of the changes observed.

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The references for this article will appear at the end of Part II which will be published in the next issue of the journal.