

A controlled clinical trial of the effects of the Twin Block and Dynamax appliances on the hard and soft tissues

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SUMMARY The aim of this controlled trial was to identify and quantify skeletal, soft tissue and dental changes during treatment, and immediately post-treatment with Twin Block (TB) or Dynamax appliance using the techniques of three-dimensional (3D) optical surface laser scanning, cephalometric, and clinical measurements.

Sixty-two Caucasian subjects, 36 males aged 11–14 years and 26 females aged 10–13 years were enrolled in the study. The patients were placed in two groups, matched for gender and age and subsequently allocated randomly for treatment with either a TB or Dynamax appliance. Active treatment lasted 9 months followed by 3 months' post-treatment observation. Laser scanning and clinical measurements were taken at 3-monthly intervals and final cephalometric records after 12 months. Statistical analysis was performed using Wilcoxon's matched-pairs signed-rank tests.

The non-compliance rates were the same for both groups (9 per cent), but a greater incidence of breakages was found in the Dynamax group. The TB was found to produce slightly more antero-posterior skeletal change, median ANB reduction, TB = 2 degrees, Dynamax 1.1 degree ($P = 0.006$), and similar forward movements of the chin and was associated with larger increases in the vertical facial dimension, median total anterior face height increase; TB = 3.2 mm, Dynamax = 2.8 mm ($P = 0.03$). The soft tissue vertical cephalometric increases were 3.6 mm with the TB, 2.0 mm with the Dynamax ($P = 0.036$), and with laser scanning 5.05 and 2.6 mm, respectively, a difference which is likely to be more clinically relevant. The median post-treatment changes in soft tissue pogonion were -0.65 mm in the TB and $+0.22$ mm in the Dynamax group.

The optical surface scanning mark and measure system is a valid method for quantifying soft tissue changes.

Introduction

The results of clinical trials generally confirm the ability of functional appliances to reduce overjets (Lund and Sandler, 1998; Gill and Lee, 2005). The relative contribution of skeletal and dental changes to overjet correction in growing patients treated with the Twin Block (TB) has been quantified as 73 and 27 per cent, respectively (O'Brien *et al.*, 2003b).

The TB was found to be the preferred functional appliance of over 75 per cent of members of the British Orthodontic Society (Chadwick *et al.*, 1998). This reflects the fact that the TB can rapidly reduce the overjet, is versatile, and allows early correction of the overjet. With maximal forward posture of the TB, there is the potential to eliminate unfavourable soft tissue factors from the outset. A disadvantage of the TB is its tendency to increase vertical face height (Illing *et al.*, 1998; Mills and McCulloch, 1998; Gill and Lee, 2005). This may be desirable in patients with deep bites, but it is contraindicated in those presenting with mandibular retrognathia and an increased vertical dimension, where a further increase in the vertical dimension is unfavourable for the soft tissues. The Dynamax appliance (Bass and Bass, 2003) is aimed at allowing gradual forward growth change of the mandible to occur, with less increase in the vertical dimension.

In addition, lower incisor proclination of 5.2 and 8.2 degrees have been shown by Mills and McCulloch (1998)

and Lund and Sandler (1998), respectively. This may increase the requirement for extractions and subsequent fixed appliance therapy, as proclined lower incisors have been shown to be susceptible to relapse (Hansen *et al.*, 1997; Tulloch *et al.*, 1998). The removable nature of the TB restricts the ability of the orthodontist to undertake concomitant fixed appliance therapy, whereas the Dynamax allows lower fixed appliance therapy concurrent with appliance wear, due to the introduction of a fixed mandibular component to oppose the upper removable appliance.

Soft tissue changes are most commonly assessed with lateral cephalometry. These changes are an inaccurate representation of three-dimensional (3D) changes and Adams *et al.* (2004) demonstrated on dry skulls that 3D measurements provided more accurate and precise measurements compared with conventional two-dimensional measurements, which significantly under or overestimate changes, particularly of bilateral structures.

The optical surface laser scanner provides a non-invasive system to regularly assess soft tissue changes during treatment, which is more accurate than conventional cephalometry and can be used regularly. Previous functional appliance studies have utilized superimposition of optical surface laser scans (Morris *et al.*, 1998; McDonagh *et al.*,

2001) providing a visual representation of change in the three dimensions.

A mark and measure system was introduced by Sharma and Lee (2005) which allows accurate dimensional measurements in three dimensions and statistical analysis.

The aims of the present study were as follows:

- 1 To compare the antero-posterior and vertical skeletal changes achieved in 9 months therapy with the TB and Dynamax appliances.
- 2 To assess the degree of dental movement achieved with both appliances.
- 3 To quantify the soft tissue profile changes cephalometrically in 1 year.
- 4 To assess the soft tissue changes during and after appliance therapy with optical surface laser scanning.

Subjects and methods

A prospective controlled clinical trial was undertaken within the Orthodontic Department of the Royal London Hospital, London, UK. Prior to commencing the trial, ethical approval was obtained from the East London and City Local Research Committee.

Participants

All subjects recruited into the study fulfilled the following selection criteria: Class II division 1 malocclusion, minimum overjet of 7 mm, mandibular retrognathia contributing to the Skeletal II pattern as assessed clinically, male Caucasians aged 11–14 years, female Caucasians aged 10–13 years, no previous orthodontic treatment or extraction of permanent teeth.

Clinical protocol and appliances

All patients wore the appliances full time for 9 months (active phase). The appliances were then withdrawn and no treatment was undertaken for 3 months (observation phase). Cephalometric measurements were taken at the outset of treatment and at 12 months. Laser scanning, overjet and reversed overjet, and statural height measurements were taken at 3-monthly intervals.

Lateral cephalograms

Lateral cephalograms were taken after patient allocation at the outset of treatment. Records were obtained with the teeth in centric occlusion with the lips in a relaxed position as described by Hillesund *et al.* (1978). Similarly, the laser scanning measurements were taken with the teeth in occlusion and the lips in a relaxed position.

The hard and soft tissue cephalometric points recorded are shown in Figure 1a,b, respectively.

The horizontal cephalometric measurements for the hard and soft tissues points were calculated with reference to a

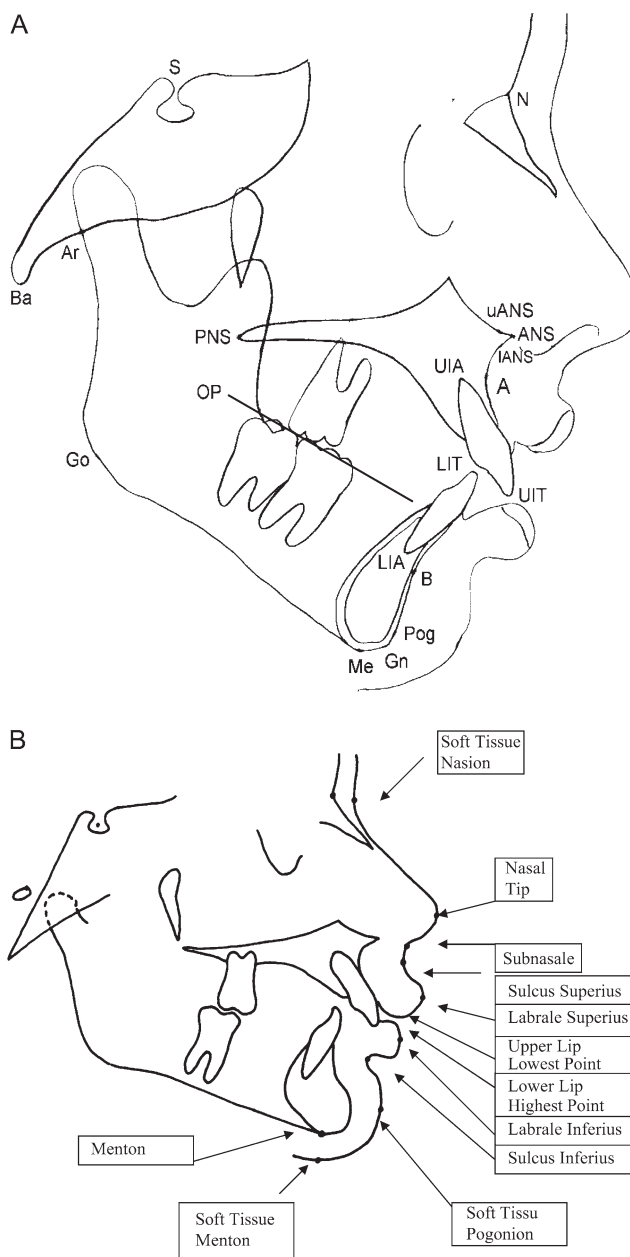


Figure 1 The hard (A) and soft (B) tissue cephalometric points recorded. Except where listed below, points, lines, and planes conform to the British standard definitions (British Standards Institute, 1983). A, point A; ANS, anterior nasal spine; uANS, point on the upper shadow of the ANS where the spine is 3 mm thick; IANS, point on the lower shadow of the ANS where the spine is 3 mm thick; Ar, articulare; B, point B; Ba, basion; Go, gonion, the point where the bisector of the angle between the posterior and lower mandibular border tangents meet the mandibular angle; Gn, gnathion, the bisector of the angle formed by the lower mandibular border tangent and the vertical through pogonion; M, menton, the point of the intersection of the lower mandibular border and the symphyseal outline; N, nasion; PNS, posterior nasal spine; Pog, pogonion; S, sella; UIA, upper incisor apex; UIT, upper incisor tip. Functional occlusal plane (OP): 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.

line vertical to the constructed horizontal line at 7 degrees to the SN plane as used in previous studies by Illing *et al.* (1998) and Gill and Lee (2005).

Optical surface laser scan

The technique of optical surface laser scanning has been previously described by Moss *et al.* (1994). Landmarking the edited scans was undertaken using the Windows compatible Cloud© program (University College, London, UK). This program allows accurate placement of landmarks using horizontal and vertical profile guidelines which aid in the location of the 3D landmarks. The landmarks are identified as the point of intersection of the two profile guidelines. Following placement of all the appropriate landmarks, a set reference landmark is chosen by clicking on the landmark of choice with the aid of a mouse. The computer is then able to calculate the inter-landmark distances from the set reference landmark to all the landmarks identified. The inter-landmark distance of interest is saved, and this process is repeated for each individual landmark as required.

The computed dimensions can be of two types: the shortest distance between any two points, as used in this study, or the distance between points following a path over the surface. The chosen landmarks are comparable with anthropometric points. The landmarks chosen are illustrated in Figure 2a,b.

Cephalometric error study

Twenty radiographs were selected at random, retraced and redigitized by one operator (GJM) at least 2 weeks later in order to determine the error. Three different tests were performed: mean-square error, the coefficient of reliability, and paired *t*-tests. This allowed random and systematic errors to be evaluated. The mean-square error test values were greater than 1.0 per cent for lower incisor inclination and nasolabial and labiomental angles.

Optical surface laser scan error study

Twenty subjects from the study sample were scanned twice at two different time intervals within 2 weeks. Unlike the cephalometric error study, the laser scans were taken twice which enabled errors in both projection and landmark registration to be analysed. The patients' files were renamed with numerical file numbers with the same landmarks placed, and inter-landmark calculations obtained. Analogous to the cephalometric error study, the same tests were performed, i.e. mean-square error, the coefficient of reliability, and paired *t*-tests.

The laser scan error study showed high mean-square error test values greater than 1.0 per cent for posterior face height and gonial width measurements. Although gonion is relatively easy to locate clinically by manual palpation, when viewed on the laser scans it appears as a flat surface and is therefore difficult to accurately locate.

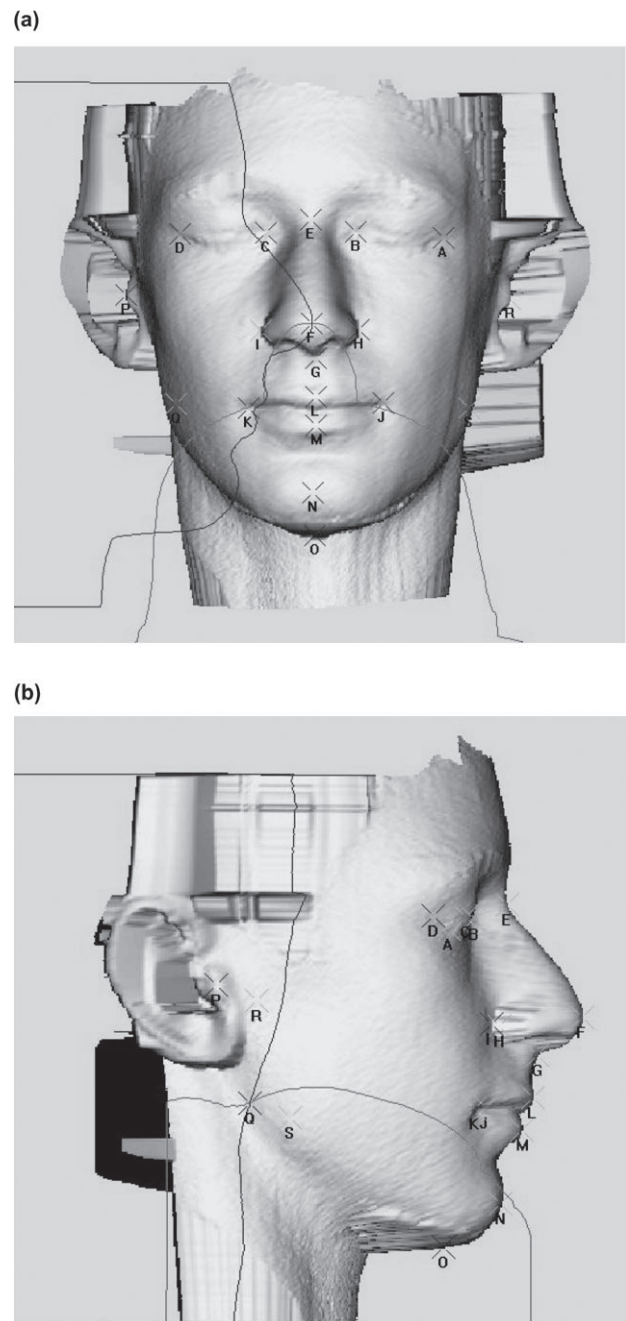


Figure 2 Optical surface laser scan landmarks as viewed from a frontal (a) and sagittal (b) aspect.

Clinical measurements

Standing height measurements were recorded to the nearest millimetre at 3-month intervals using a Harpenden stadiometer (Harpenden, Hertfordshire, UK). The stretched position was used in order to minimize the effects of diurnal variation (Tanner, 1962). This was undertaken to assess the comparability of growth between the groups.

Overjet and reversed overjet were recorded to the nearest tenth of a millimetre at each visit using a digital calliper

gauge (Mitutoyo Ltd, Andover, Hampshire, UK). The Frankfort plane was orientated horizontally and the measurement was recorded from the midpoint of the maxillary incisal edges to the labial surface of the lower incisors.

All the clinical measurements of height, overjet, and reversed overjet were repeated three times and the mean was calculated in order to reduce errors. The measurement of the reversed overjet was incorporated into the protocol as it has been advocated as a more reliable clinical guide to treatment progress (Petit and Chateau, 1984). The use of this system is also more likely to increase the reliability of the overjet measurement by identifying postural variations. The reversed overjet was recorded from the same area of the labial surface of the upper and lower incisors and the patient was asked to maximally protract the mandible.

Design of appliances

The design of the TB appliance used in the trial is shown in Figure 3. An upper labial bow was not incorporated and the blocks were designed to interlock at an inclination of approximately 70 degrees. The upper bite block overlaid both premolars and permanent molars, with the lower bite block covering both premolars. These bite blocks were not trimmed during treatment. Retention was provided by Adams' clasps on the first permanent molars and premolars for both the upper and lower appliances along with ball-ended clasps at the distal contact points of both lower central incisors. The construction bite was taken using an Exacto bite stick (Forestadent, Milton Keynes, Buckinghamshire, UK). The patient was instructed to bite in as near an edge-to-edge bite as possible. This provided 4 mm of anterior separation of the incisors with variable degrees of posterior bite opening.

The Dynamax appliance used in the trial is illustrated in Figure 4. The design of the appliance allows gradual forward movement of the mandible with minimal increase in the vertical facial dimension. The lower appliance is a fixed lingual arch with 3 mm shoulders soldered on to bands on the first permanent molars. The shoulders were positioned to contact vertical spring projections from the upper removable appliance which consisted of a prefabricated module of vertical spring projections of 14 mm. The prefabricated module allows expansion of the upper removable appliance which is retained on the first molars and second premolars. The acrylic base plate covers the occlusal surfaces of all the maxillary dentition with minimal acrylic thickness to minimize vertical opening. Additionally, the appliance incorporates a torquing spring in contact with the upper maxillary central incisors which was not activated during the trial.

At insertion, the vertical spring projections of the upper appliance contact the shoulders of the lower lingual arch and produce 3 mm of forward protrusion of the mandible. Further 2 mm forward activations of the appliance were undertaken at the 3- and 6-month appointments using a standardized jig to ensure these changes were 2 mm on either side.

Sample

Sixty-two patients were identified from a waiting list, matched for gender and age, and then randomly allocated to an appliance group by a non-clinician. As the intention was to provide treatment to those in the early pubertal growth spurt, the gender distribution was 28 males aged 12–14.7 years and 34 females aged 10.6–13.7 years.

Statistical method

The necessary sample to fulfil the requirement for this study was 32 subjects in each group. The power of the test was set at 80 per cent and the level of significance 5 per cent ($P < 0.05$). Since the variance of the outcome variable was not known, the size of the sample was calculated to identify a difference between the appliance groups of 1 standard deviation (SD). The limitation of this assumption is that if the SD is large, the study will identify only large differences (Altman, 1991).

The Statistical Package for the Social Sciences for Windows (SPSS Inc., Chicago, Illinois, USA) was used. Wilcoxon's matched-pairs signed-rank test was used to analyse the data between the two appliance groups. The groups were not considered to be normally distributed and

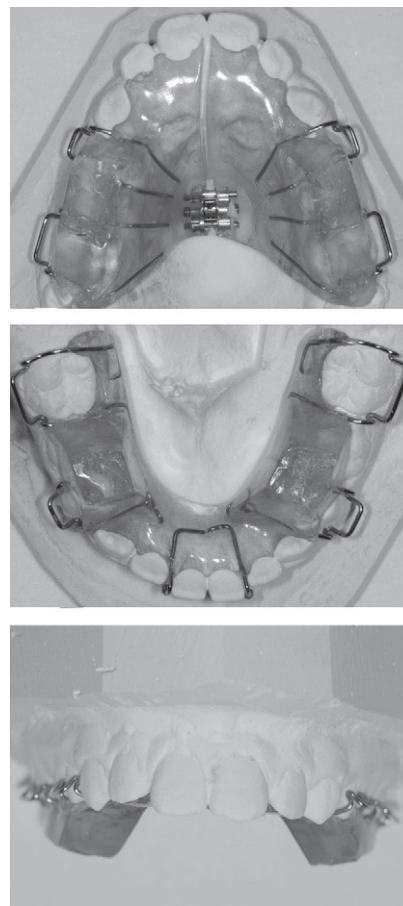


Figure 3 The Twin Block appliance used.

non-parametric tests were therefore undertaken, with the median and interquartile ranges being used, with the median as a measure of central tendency. A value of $P < 0.05$ was determined to be of statistical significance.

Results

Six patients failed to complete the 12-month protocol. No patients were excluded from the trial on the grounds of poor treatment response, and when poor compliance was suspected, the trial protocol was adhered to and final radiographs were taken on an intention-to-treat basis.

Figure 5 shows the flow of patients through the trial. The age and clinical cephalometric values at the start of treatment are given in Table 1 and the changes in the hard and soft tissues in Tables 2 and 3, respectively.

The optical surface laser scan results are shown at different time intervals with changes at 6 months (Table 4), after 9 months treatment (Table 5), and post-treatment changes, 9–12 months (Table 6). The overall changes over the 12-month period are shown in Table 7.

The clinical measurements of overjet and reversed overjet at different stages of the trial are shown in Table 8.

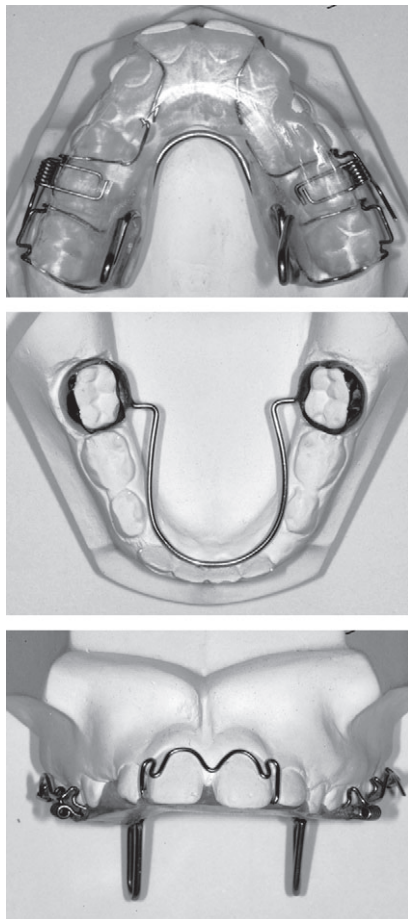


Figure 4 The Dynamax appliance.

Clinical measurements

Although there were considerable variations in the increase in statural height measurements, as represented by the range of the minimum and maximum figures, there were no statistically significant differences in the growth changes recorded between the treatment groups.

Although the TB was slightly more effective in reducing the overjet than the Dynamax (median reductions of 6 and 5 mm, respectively), the difference was not statistically significant.

The median increases in the reversed overjet measurements were 5 and 4 mm for the TB and Dynamax, respectively. The greater increase in reversed overjet in the TB group was statistically significant ($P = 0.04$) at 9 months when compared with the Dynamax group. However, this difference was not evident at 12 months.

Both groups experienced a similar degree of overjet and reversed overjet relapse (1 mm) between the withdrawal of the appliance (9 months) and the final collection of records (12 months).

Cephalometric hard tissue measurements

The cranial base growth changes were similar for each group and no statistically significant differences were found for the parameters measured. The median increase in the

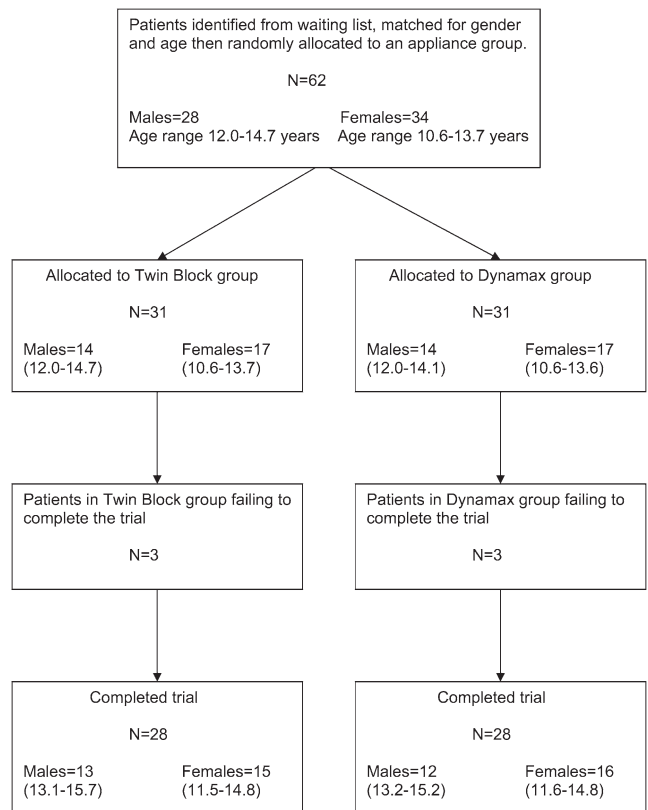


Figure 5 Flow of patients.

Table 1 Age and clinical and hard tissue cephalometric values at the start of treatment.

	Twin Block, <i>n</i> = 28			Dynamax, <i>n</i> = 28		
	Interquartile range			Interquartile range		
	Median	25th	75th	Median	25th	75th
Age (years)	12.5	12.0	13.3	11.7	12.4	13.1
Height (mm)	1518	1486	1605	1503	1429	1582
Overjet (mm)	10	9	11.5	9.5	8	12
Reverse overjet (mm)	0	-1	1	0.5	0	1
S-N (mm)	65.4	64.4	67.2	65.5	63.4	66.6
ANB (°)	5.9	5.1	7.2	6.2	4.7	7.5
A-S vertical (mm)	63.6	58.3	66.5	60.2	56.9	62.7
Pog-S vertical (mm)	51.9	47.6	60.5	49.7	46.4	50.9
Art-Pog (mm)	91.9	88.3	94.3	86.8	83.5	90.3
Total anterior face height (mm)	102.5	100.7	105.3	102.1	97.6	109.0
U1-maxillary plane (°)	120.1	114.1	125.6	116.4	111.5	121.9
L1-mandibular plane (°)	98.8	93.3	104.3	98.2	93.3	104.3

Table 2 Dental and skeletal changes compared between the groups (0–12 months).

	Twin Block, <i>n</i> = 28			Dynamax, <i>n</i> = 28			Wilcoxon
	Interquartile range			Interquartile range			<i>P</i> value
	Median	25th	75th	Median	25th	75th	
Height (mm)	67	45	84	58	42	94	0.88
Overjet (mm)	-6	-4	-7.5	-5	-4	-7	0.20
Reverse overjet (mm)	5.5	4.0	6.5	4.5	3	6	0.04
S-N (mm)	0.6	0.2	1.2	0.4	0.1	0.9	0.35
ANB (°)	-2.0	-2.4	-1.0	-1.1	-1.6	0.1	0.006*
A-S vertical (mm)	0.1	-0.9	1.0	0.4	-0.5	0.8	0.77
Pog-S vertical (mm)	2.1	1.1	4.7	2.0	0.5	3.5	0.19
Art-Pog (mm)	4.8	3.6	6.4	2.9	0.6	5.2	0.004*
Total anterior face height (mm)	3.2	2.8	4.4	2.8	1.2	4.6	0.03*
U1-maxillary plane (°)	-3.2	-5.1	0.9	-1.7	-5.2	0.6	0.96
L1-mandibular plane (°)	2.3	-1.0	4.4	2.3	-0.5	6.2	0.41

P* < 0.05.Table 3** Soft tissue cephalometric changes for males and females combined: 0–12 months.

Variables	Twin Block, <i>n</i> = 28			Dynamax, <i>n</i> = 28			Wilcoxon
	Interquartile range			Interquartile range			<i>P</i> value
	Median	25th	75th	Median	25th	75th	
0–12 months							
S vertical to Sulcus superius	1.22	0.63	2.45	1.34	-0.54	2.33	0.835
S vertical to Sulcus inferius	3.92	1.71	6.01	2.09	-1.8	3.49	0.052
S vertical to soft tissue Pog	3.71	1.4	5.74	1.63	-1.19	3.65	0.089
Labiomental angle	10.71	3.54	17.8	2.01	-6.54	13.94	0.078
Soft tissue total anterior face height	3.61	1.23	6.14	1.98	0.72	3.45	0.036*
Soft tissue lower anterior face height	2.35	0.82	6.0	0.88	-0.9	3.8	0.033*
Upper lip length	0.77	-1.1	2.14	0.02	-0.56	1.41	0.684
Lower lip length	2.96	1.12	5.1	0.98	0.25	3.33	0.013*
Upper lip to E-line	-1.46	-3.01	1.97	-0.48	-1.21	0.23	0.042*
Lower lip to E-line	0.14	-1.82	1.3	0.08	-1.39	0.89	0.645

**P* < 0.05.

Table 4 Optical surface laser scan changes for males and females combined: 0–6 months (option 1).

Variables	Twin Block, <i>n</i> = 28			Dynamax, <i>n</i> = 28			Wilcoxon
	Interquartile range			Interquartile range			<i>P</i> value
	Median	25th	75th	Median	25th	75th	
0–6 months							
Commissural width	1.64	1.0	2.0	1.15	0.24	2.2	0.311
Soft tissue total anterior face height	2.31	0.84	4.1	0.4	–1.2	1.96	0.043*
Soft tissue lower anterior face height	4.19	1.2	6.8	1.26	0.12	2.98	0.023*
Upper lip length	1.38	0.98	2.12	0.62	0.01	1.77	0.438
Lower lip length	0.91	–0.63	2.67	2.22	0.47	3.78	0.069
Tragus to soft tissue Pog	3.8	2.13	7.96	3.86	2.4	6.17	0.741

P* < 0.05.Table 5** Optical surface laser scan changes for males and females combined: 0–9 months.

Variables	Twin Block, <i>n</i> = 28			Dynamax, <i>n</i> = 28			Wilcoxon
	Interquartile range			Interquartile range			<i>P</i> value
	Median	25th	75th	Median	25th	75th	
0–9 months							
Commissural width	2.88	1.22	5.98	0.75	–1.02	1.96	0.007*
Soft tissue total anterior face height	4.04	1.58	8.01	2.52	0.12	4.6	0.026*
Soft tissue lower anterior face height	4.83	2.19	6.91	2.14	1.4	3.04	0.001*
Upper lip length	1.45	0.94	2.31	0.05	–0.21	1.47	0.013*
Lower lip length	2.03	1.15	5.21	1.72	1.03	4.72	0.686
Tragus to soft tissue Pog	5.11	3.47	8.33	4.17	2.7	6.85	0.196

P* < 0.05.Table 6** Optical surface laser scan changes for males and females combined: post-treatment changes 9–12 months.

Variables	Twin Block, <i>n</i> = 28			Dynamax, <i>n</i> = 28			Wilcoxon
	Interquartile range			Interquartile range			<i>P</i> value
	Median	25th	75th	Median	25th	75th	
9–12 months							
Commissural width	–0.71	–1.87	0.95	–0.96	–1.58	1.1	0.772
Soft tissue total anterior face height	–0.38	–1.23	1.94	–0.26	–1.83	1.56	0.860
Soft tissue lower anterior face height	0.18	–1.38	1.98	0.44	–1.32	1.12	0.725
Upper lip length	–0.21	–1.45	0.97	0.78	–0.86	1.74	0.099
Lower lip length	–0.19	–1.32	1.45	–0.65	–1.23	1.41	0.102
Tragus to soft tissue Pog	–0.65	–1.98	1.44	0.22	–0.25	2.4	0.359

linear measurement of SN was found to be in the region of 0.5 mm for each group. There were no significant differences for maxillary base measurements.

The results indicated that the TB produced similar advancement of the chin at pogonion to the Dynamax of 2.1 mm compared with 2.0 mm. The measurement of the mandibular unit length (Art–Pog) increased significantly more in the TB group, 4.8 mm compared with 2.9 mm. The TB also produced a significantly greater reduction in ANB of 1 degree at a significance level of *P* = 0.006.

The increase in the vertical dimension was slightly greater with the TB 3.2 mm than with the Dynamax, 2.8 mm, which is unlikely to be clinically significant, but was found to be statistically significant (*P* = 0.03).

The soft tissue cephalometric results, however, showed larger differences, with the vertical changes of soft tissue total anterior face height (St TAFH) and soft tissue lower anterior face height (St LAFH) increasing significantly more with the TB appliance. Increases for St TAFH were 3.61 and 1.98 mm, respectively, for the TB and Dynamax

Table 7 Optical surface laser scan changes for males and females combined: 0–12 months.

Variables	Twin Block, <i>n</i> = 28			Dynamax, <i>n</i> = 28			Wilcoxon
	Interquartile range			Interquartile range			<i>P</i> value
	Median	25th	75th	Median	25th	75th	
0–12 months							
Commissural width	3.24	1.42	5.9	0.41	−0.89	3.62	0.019*
Soft tissue total anterior face height	3.89	2.68	6.9	2.84	1.25	4.76	0.096
Soft tissue lower anterior face height	5.05	2.86	7.65	2.57	1.33	3.15	0.000*
Upper lip length	1.29	0.71	2.48	0.74	−0.24	2.22	0.358
Lower lip length	1.51	0.8	5.4	1.23	0.49	2.58	0.001*
Tragus to soft tissue Pog	6.99	3.7	8.0	6.31	3.75	7.72	0.263

**P* < 0.05.

Table 8 Median overjet (OJ) and reverse overjet changes (ROJ) in mm between 0–9 and 9–12 months and significance of changes between the groups.

	Twin Block		Dynamax		Wilcoxon's test	
	0–9 m	9–12 m	0–9 m	9–12 m	TB (0–9) versus Dynamax (0–9)	TB (9–12) versus Dynamax (9–12)
	OJ change	6	1	5	1	<i>P</i> = 0.20
Minimum	1	1	1	1		
Maximum	11	2	9	3		
ROJ change	5	1	4	1	<i>P</i> = 0.04*	<i>P</i> = 0.12
Minimum	1	3	0	0		
Maximum	13	4	9.5	2		

**P* < 0.05.

appliances, with St LAFH being 2.35 mm (TB) and 0.88 mm (Dynamax), *P* = 0.03.

Similarly, lower lip length significantly increased by 2.96 mm (TB) and 0.98 mm (Dynamax). All these values were statistically significant (Table 9).

Optical surface laser scan results

The results demonstrated a statistically significant difference in the increase in St LAFH (*P* = 0.02) and St TAFH (*P* = 0.04) during the first 6 months of treatment (Table 4), with increases of 4.19 mm (TB) and 1.26 mm (Dynamax). After 9 months of full-time appliance wear, the differences were maintained 4.83 mm TB, 2.14 mm Dynamax, with additional changes for commissural width (2.8 mm TB, 0.75 mm Dynamax) and upper lip length 1.45 mm TB and 0.05 mm Dynamax.

During the final 3 months (9–12 months) of the study, with no appliance wear, the changes were of reduced magnitude with negative changes in some of the measurements (Table 6).

The results over the 12-month period demonstrated significantly greater increases in the measurements of St LAFH, lower lip length, and commissural width with the TB than with the Dynamax.

Appliance breakages

A higher percentage of subjects were found to present with appliance breakages in the Dynamax (55 per cent) than in the TB group (35 per cent). The breakages recorded for the TB appliance included fractures of the Adams' clasps that did not necessarily require repair. The vertical component of the Dynamax appliance was found to be more susceptible to fracture. Such a breakage inevitably required laboratory repair and involved an interruption in treatment.

Discussion

General considerations

The recruitment of 62 subjects allowed the creation of 31 matched pairs who were subsequently randomly allocated. This was the minimum number of patients required to satisfy the statistical power calculation. The patients were analysed using non-parametric tests, which are conservative, but the most appropriate for samples of this size.

Six patients failed to complete treatment and were not included in the analysis. This did not affect the balance of gender and age and therefore both groups had similar amounts of growth during the observation. As an

Table 9 Soft tissue cephalometric changes for males and females combined: 0–12 months.

Variables	Twin Block, <i>n</i> = 28			Dynamax, <i>n</i> = 28			Wilcoxon
	Interquartile range			Interquartile range			<i>P</i> value
	Median	25th	75th	Median	25th	75th	
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S vertical to Sulcus superius	1.22	0.63	2.45	1.34	-0.54	2.33	0.835
S vertical to Sulcus inferius	3.92	1.71	6.01	2.09	-1.8	3.49	0.052
S vertical to soft tissue Pog	3.71	1.4	5.74	1.63	-1.19	3.65	0.089
Labiomental angle	10.71	3.54	17.8	2.01	-6.54	13.94	0.078
Soft tissue total anterior face height	3.61	1.23	6.14	1.98	0.72	3.45	0.036*
Soft tissue lower anterior face height	2.35	0.82	6.0	0.88	-0.9	3.8	0.033*
Upper lip length	0.77	-1.1	2.14	0.02	-0.56	1.41	0.684
Lower lip length	2.96	1.12	5.1	0.98	0.25	3.33	0.013*
Upper lip to E-line	-1.46	-3.01	1.97	-0.48	-1.21	0.23	0.042*
Lower lip to E-line	-0.14	-1.82	1.3	0.08	-1.39	0.89	0.645

**P* < 0.05.

intention-to-treat analysis was applied, a number of the patients included in the analysis did not have clinically successful results, which inevitably reduced the impact of the appliances. A failure to complete treatment of 9 per cent was low, with the Dynamax being tolerated to a similar extent to the TB. Previous reports have reported discontinuation rates with the TB of 28 per cent (Illing *et al.*, 1998), 43 per cent (McDonagh *et al.*, 2001), 33 per cent (O'Brien *et al.*, 2003a), and 30 per cent (Banks *et al.*, 2004). As all patients were treated in the same department, it was possible to report on 91 per cent of the original sample which compares favourably with a multicentred trial comparing two functional appliances, with only 130 of 215 subjects being included in the pre- and post-treatment cephalometric analysis (O'Brien *et al.*, 2003a).

Appliance design

The TB appliance was designed specifically to incorporate all of the lower dentition and only the upper buccal segments. This was to ensure that traction was not applied by the lower arch to the whole of the upper arch. The effect should be from the whole of the lower arch to the upper buccal segments, and thereby limit movements of the upper and lower incisors, as occurred in this study.

The Dynamax appliance had a torquing spring which is less obtrusive than the previous spring of the Bass appliance. This spur was not activated and was intended to limit tipping movements of the upper incisors which was minimal at -1.7 degrees.

Skeletal changes

There was minimal forward movement of point A of 0.1 mm with the TB and 0.4 mm with the Dynamax. This is slightly less than the 0.6 mm reported by Lund and Sandler (1998) and Mills and McCulloch (1998) for the TB appliance. O'Brien *et al.* (2003b), over a 15-month period,

with a younger age group, similarly reported a mean advancement of point A by 0.6 mm in comparison with a control group of 1.5 mm. There may, therefore, be an element of maxillary restraint with both appliances.

The horizontal changes in the mandible are best identified at pogonion, and the median changes for the TB and Dynamax were 2.1 and 2.0 mm, respectively. This is not dissimilar to the 3.5 mm found by O'Brien *et al.* (2003b) over a 15-month period and the 3.87 mm by Mills and McCulloch (1998) over 14 months in a retrospective trial.

Changes in mandibular length have an element of vertical change and the increase of 4.9 mm with the TB was significantly greater than the 2.5 mm with the Dynamax (*P* = 0.003). Similar studies on mandibular length by Mills and McCulloch (1998) and Toth and McNamara (1999) reported an increase in mandibular length of 6.5 and 6.1 mm, respectively.

The vertical changes in total anterior face height (TAFH) were statistically significantly different (*P* = 0.03) but of small magnitude at 3.1 mm TB and 2.8 mm Dynamax. The differences were more marked, however, in the soft tissue cephalometric and the laser scanning analyses. The magnitude of skeletal change, however, was more vertical than antero-posterior, particularly with the TB appliance.

Soft tissue changes

Cephalometric analysis indicated that forward movement of the soft tissues was greater with the TB, 3.9 mm at the sulcus and 3.7 mm at the chin, compared with 2.1 and 1.6 mm, respectively, with the Dynamax. This cephalometric soft tissue change confirms slightly more movement at the sulcus than at the chin as found in the study of Illing *et al.* (1998) who reported forward movement at the sulcus of 3.6 mm and at the chin of 2.6 mm, while 4.1 mm forward movement at the sulcus and 4 mm at the chin was found by Sharma and Lee (2005).

Using a finite element scaling analysis, Singh and Clark (2003) reported that the labiomental groove increased by 25 per cent, with the chin area reducing by 5 per cent in males, indicating that the TB is associated with more forward movement at the sulcus than at the chin.

The vertical soft tissue changes were greater with the TB and statistically significant, with an increase of 3.6 mm (TB) and 2.0 mm (Dynamax) in TAFH ($P = 0.036$). Lower lip length increased by an equivalent amount to the increase in the anterior soft tissue vertical dimension. The flattening of the labiomental angle with sulcus inferius becoming more anteriorly positioned will appear to improve the facial profile and balance, even if soft tissue pogonion does not advance in relative proportion. The lower lip will tend to unfurl with an increase in lip competence as the lower lip length increases.

Dental changes

The upper incisors were found to have minimal retroclination -3.2 degrees (TB) compared with -1.7 degrees (Dynamax), slightly less than that reported by Sharma and Lee (2005) of -5 degrees with the TB.

In studies using a labial bow on TB's, a retraction of the maxillary incisal tip by -2.3 mm (O'Brien *et al.*, 2003b) and -11 degrees by Lund and Sandler (1998) was found, which is equivalent to -2.9 mm of incisal tip retraction. This would suggest that the addition of a labial bow produces a significant clinical retraction effect on the upper incisors.

Movement of the lower incisors has been reported as proclination of 8.2 degrees by Lund and Sandler (1998) and 1.4 mm by O'Brien *et al.* (2003b). These are greater than the 2.3 degrees found with both the TB and Dynamax in this study. This may be related to the appliance design, with any traction to the lower arch being from the upper buccal segments to the whole of the lower dentition. The appliance design of Mills and McCulloch (2000) showed an increased lower incisor proclination of 5.2 degrees, with the lower appliance not incorporating clasps on the lower posterior teeth, and therefore forces being delivered to the lower anterior teeth only from the upper posterior teeth.

Treatment duration and relapse

The laser scans allowed assessment of treatment progress and the immediate post-treatment changes. During the first 6 months of treatment, soft tissue pogonion advanced, on average, by 4 mm with both appliances. This advancement was substantially less over the following 3 months with an average increase of 1.5 mm, and during the post-treatment phase, individual response tended to be negative, with both appliances showing slowing down, which is illustrated in Figure 6a,b.

In both treatment groups, the post-treatment changes in many patients showed a relapse, as growth cannot occur in a negative direction. These changes are similar to those reported by Sharma and Lee (2005) with soft tissue pogonion

relapsing by -1.1 mm with the TB and this study showing a slightly smaller relapse at -0.65 mm in the 3-month post-treatment. The Dynamax, however, was not associated with relapse and this could be related to the more gradual forward advancement of the mandible.

Optical surface laser scanning compared with cephalometry

The changes in the vertical dimension were of similar magnitude when measured with either cephalometry or laser scanning, with statistically significant changes in St LAFH observed with both systems. The laser scanning

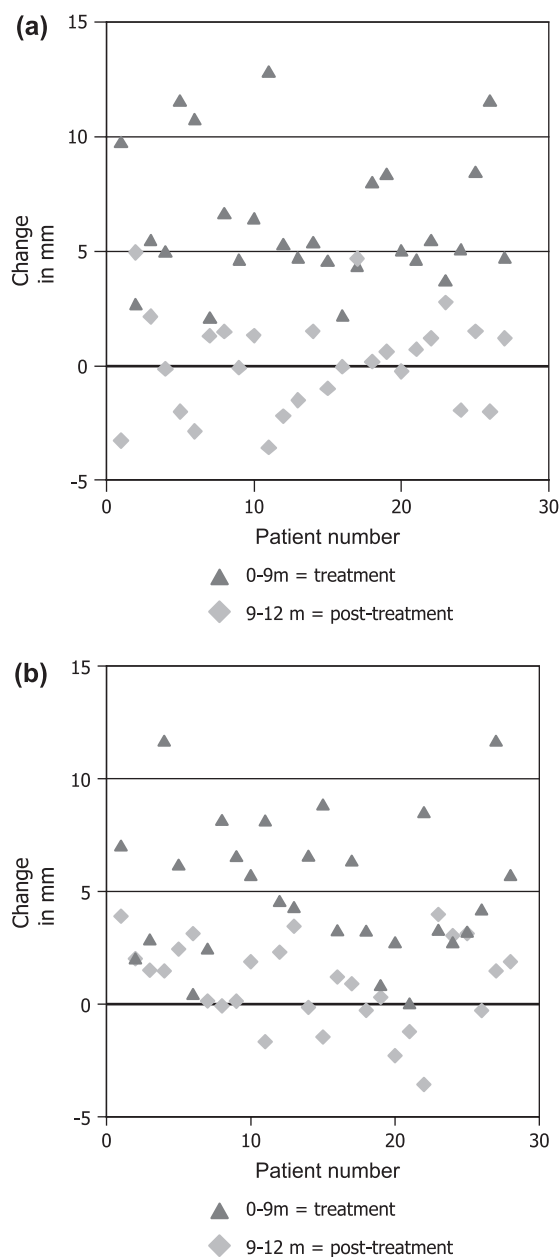


Figure 6 A comparison of the change in soft tissue pogonion in the Twin Block (a) and Dynamax (b) appliance groups between 0–9 months and 9–12 months recorded by laser scans.

measurement is more likely to be accurate, however, as a laser scan repeated and digitized again, showed similar measurement errors to a cephalometric radiograph digitized twice. The optical surface laser scanner is able to assess the face from four different angles, frontal, above, below, and left and right sagittal views. In addition, a particular area of interest can be magnified to aid in measurement.

Conclusions

- 1 Forward movement of the chin and pogonion was similar cephalometrically with the TB at 2.1 mm and the Dynamax 2.0 mm.
- 2 There was a slightly greater increase in the skeletal vertical dimension with the TB (3.2 mm) than the Dynamax (2.8 mm) which was statistically significant, $P = 0.03$, but of small magnitude.
- 3 St TAFH increases were more with the TB, 3.6 mm, than the Dynamax 2.0 mm ($P = 0.036$).
- 4 The soft tissue changes in lower lip length were similar to the face height changes, and forward movement of lower sulcus slightly more than that at the chin.
- 5 The absence of a labial bow on the TB and the use of a torquing spring on the Dynamax reduced tipping of the upper incisors.
- 6 Both appliances produced the greatest rate of change during the first 6 months of treatment and withdrawal of the appliances was associated with relapse, particularly with the TB.
- 7 Considerable individual variation was found with all appliances, and further investigation into the ideal duration of treatment is required.

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