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

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SUMMARY A prospective clinical study with a random allocation of 47 patients to three different functional appliance groups was established and compared with a slightly younger control group over a 9-month period. The cephalometric hard tissue changes were assessed in relation to the soft tissue changes produced and the patients were also assessed by three-dimensional (3D) laser scanning of the facial soft tissues. Each 'averaged' appliance group scan was compared with the 'averaged' control group face.

Statistically and clinically significant changes occurred in the group treated with the Twin Block appliance, and to a lesser extent in the group treated with the Bionator appliance. No statistically significant facial soft tissue changes could be demonstrated in the Bass appliance group. Upper lip position remained stable despite the significant overjet reduction attained in the three appliance groups. Lower lip protrusion (up to 3.8 mm), lower lip length (up to 4.0 mm), and soft tissue lower and total face height increased significantly in all appliance groups by varying amounts. The long-term effect of these changes needs to be fully evaluated.

The laser scanning system was found to be a sensitive and accurate method of quantitatively assessing small changes in the soft tissue facial form. Significant changes of the facial tissues in the transverse plane were highlighted by this technique.

Introduction

Despite the wealth of studies in the literature investigating the mechanism and treatment effects of various functional appliances, the vast majority have tended to concentrate on the measurable skeletal and dental changes induced (Calvert, 1982; Cohen, 1983; McNamara *et al.*, 1985; Vargervik and Harvold, 1985), and have ignored the effects on the patient's facial soft tissues. There is, at present, a paucity of longitudinal data available relating to the soft tissue changes induced by functional appliances. The relative lack of published work on this topic may be because there is still a question as to how stable and reproducible a relaxed lip position is for meaningful cephalometric measurements (Hillesund *et al.,* 1978).

Much of the clinical data available on the effects of functional appliance therapy has come from analysis of pre- and post-treatment results on biased successful cases. Previous workers have often failed to include an untreated control group in their study design, while others have used patients either of a dissimilar age (Calvert, 1982), from unsuccessful cases (Ahlgren and Laurin, 1976), or those undergoing an alternative form of orthodontic therapy (Cohen, 1983).

The Bass orthopaedic appliance system for the correction of moderate to severe Class II malocclusions has been previously described (Bass, 1983a,b). A few clinical studies based on this appliance (Malmgren and Ömblus, 1985; Malmgren *et al.*, 1987; Pancherz *et al.*, 1989; Cura *et al.,* 1996; Ömblus *et al.,* 1997) have been published. Four of these investigations were for 6-month observation periods only, while Cura *et al.*'s (1996) study had a mean treatment duration of 6.9 years. None of the studies included a suitable control group for comparison and only that by Malmgren *et al.* (1987) reported on the effect of the appliance on the soft tissue profile.

There have been a few, mainly retrospective, clinical studies based on the Bionator appliance. The majority have major flaws in their design by either not including an untreated control group for comparison (Whitney and Sinclair, 1987; Op Heij *et al.*, 1989; Mamandras and Allen, 1990) or having a large range of treatment and observation periods between the groups being investigated (Bolmgren and Moshiri, 1986; Weinbach and Smith, 1992). There is, however, a total lack of any soft tissue analysis of the treated and control cases presented in all these studies.

As yet, no clinical investigation has been published into the effect of the Twin Block appliance on the facial soft tissue profile. Information concerning this aspect of Twin Block therapy would help to determine and quantify the claimed improvement in facial balance that has reportedly been achieved in these patients (Clark, 1988).

Traditional cephalometric appraisals depend on linear and/or angular measurements spanning specific datum points. Measurement of changes in the position of these points as a result of growth or treatment may be frustrating as bilateral ill-defined areas on a three-dimensional object are projected onto a single flat median plane and the measurement error often approximates to that of the individual changes. Soft tissue facial profile changes, however, may not be confined to specific datum points and so may not be amenable to traditional cephalometric appraisal. The ability to measure soft tissue variations has, in the past, been confined to changes in the midline profile only and limited to a two-dimensional (2D) assessment of a three-dimensional (3D) change measured from lateral skull radiographs (Subtelny, 1959). The frontal cephalogram has rarely been used as the information it supplies is insufficient for assessing the facial soft tissue proportions and measuring any changes that have occurred through growth or treatment. Such criticisms have stimulated research into alternative methods of evaluation, such as finite element analysis techniques (Lavelle and Carvalho, 1989), Moiré and contour photography (Kamonji, 1980), stereophotogrammetry (Kobayashi *et al.,* 1990) and, more recently, optical surface laser scanning techniques (Moss *et al.,* 1989).

The aims of the present study were:

1. To quantitatively assess, cephalometrically and by the use of a 3D facial laser scanning technique, the treatment changes of the facial soft tissue profile and form produced by three different functional appliances.
2. To compare the effect of each appliance with the facial changes resulting from natural growth alone.
3. To evaluate the potential of the laser scanning technique in measuring and detecting facial soft tissue profile changes and thus examine its possible role in future serial longitudinal studies of facial soft tissue growth.

Subjects and methods

The inclusion criteria for this prospective study has been previously described in Part I of this article (Illing *et al.,* 1998). The patient sample, appliance design, and clinical techniques used in this study were all identical to that described in the earlier article.

Standing height measurements

These were recorded for each subject at 3-monthly intervals using the same stadiometer. All height measurements were carried out solely by one author (DM) using the standardized technique described by Tanner (1962).

Cephalometric analysis

The analysis method used for the radiographic data has been described earlier (Illing *et al.,* 1998). Of particular importance for this part of the investigation was the interpretation of the patient's soft tissue posture at rest. Patients were instructed to bite gently into centric occlusion with their lips and facial soft tissues relaxed during the radiographic exposure. Any radiographs with evidence of mandibular posturing or unrelaxed soft tissue outline were discarded and retaken.

Seventeen skeletal, dental and soft tissue points were identified by inspection. The points recorded are shown in Figure 1. The majority of

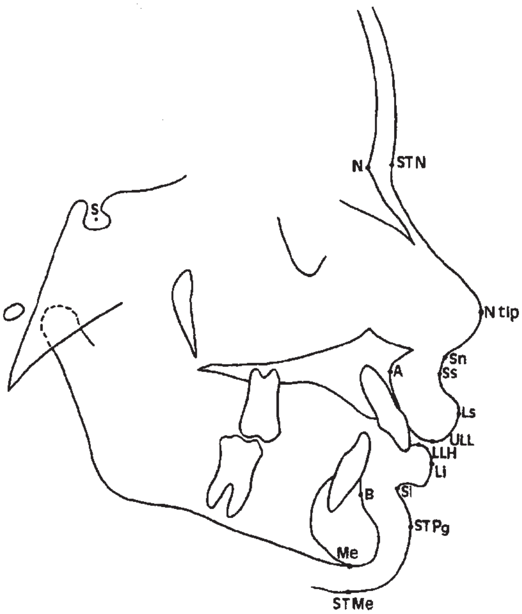

Figure 1 The cephalometric points recorded. Except where listed below, points, lines, and planes conformed to British Standard definitions (British Standard Institution, 1983). Hard tissue: A, point A; B, point B; N, nasion; S, sella. Soft tissue: ST N, soft tissue nasion, the point of greatest concavity between the nose and forehead in the midline; N tip, nasal tip, the most anterior point on the soft tissue outline of the nose; Sn, subnasale, the point where the lower margin of the columella meets the upper lip in the midline; Ss, sulcus superioris, the most concave point on the soft tissue outline of the upper lip; Ls, labrale superioris, the most prominent point on the soft tissue outline of the upper lip; ULL, upper lip lowest point, the most inferior point on the upper lip in the midline; LLH, lower lip highest point, the most superior point on the lower lip in the midline; Li, labrale inferioris, the most prominent point on the soft tissue outline of the lower lip; Si, sulcus inferius, the most concave point on the soft tissue outline of the lower lip, ST Pg, soft tissue pogonion, the most prominent or anterior point on the chin in the midsagittal plane; ST Me, soft tissue menton, the point at which a vertical line from bony menton crosses the soft tissue outline of the chin.

the points used conformed to British Standard definitions (British Standard Institution, 1983) except where indicated on the accompanying legend. Duplicate tracings were digitized to a tolerance of 0.2 mm, from which 21 soft tissue measurements (17 linear and four angular) were calculated (Table 1).

Reproducibility and repeatability

The method error study has been previously described (Illing *et al.,* 1998). Dahlberg errors ranged from 0.12 degrees ('H' angle) to 1.41 degrees (labiomental fold) for angular variables, and from 0.10 (lower lip thickness) to 0.60 mm (upper lip thickness) for linear variables. Midtgård *et al.*'s (1974) values varied between 0.42 ('H' angle) and 8.35 per cent (nasolabial angle) for angular variables, and from 0.23 (Li to E plane) to 18.9 per cent (ST Pg to St Nasion) for linear variables.

No systematic errors were detected for the angular variables. The paired *t*-test was significant for only one of the linear variables (ST Pg to ST nasion: $P = 0.033$).

Statistical method

The statistical software package used for all the analyses in this study was SPSS/PC+ (Norusis, 1986). All the variables were tested for group differences with respect to their start values (before treatment), finish values, and the changes (differences) that occurred during the study period (Tables 2 and 3). When a significant *F*-ratio of <0.05 was observed, a one-way analysis of variance (ANOVA) technique was employed using Scheffé's method of multiple comparisons to test the significance of individual groups.

Laser scan technique

Facial laser scans of each of the 67 subjects were taken at the start and finish of the study period. All scan recordings, registration, landmarking, and their subsequent analysis were carried out solely by one author (DM). Calibration of the laser scanning equipment to check the alignment of the mirrors and the laser beam was undertaken at regular weekly intervals throughout the study period.

The 3D data used were obtained by optical surface laser scanning the face of each subject using a system comprehensively described by Moss *et al.* (1989). The patient was rotated under computer control and approximately 220 profiles of the face were recorded at every 2.8 degrees of rotation, except over the central portion of the

Table 1 Angular and linear measurements (soft tissue)

Variable	Definition
Angular (degrees)	
Facial convexity	The angle formed between soft tissue pogonion—nasal tip-soft tissue nasion
Nasolabial angle	The angle formed between the nasal tip-subnasale-labrale superioris
Labiomental fold	The angle formed between labrale inferioris-sulcus inferioris-soft tissue pogonion
Holdaway's harmony ('H') angle	The angle formed between soft tissue nasion-soft tissue pogonion-labrale superioris
Linear (mm)	
Upper lip thickness	The distance from labrale superioris to point A
Lower lip thickness	The distance from labrale inferioris to point B
Soft tissue upper face height (ST UFH)	The distance from soft tissue nasion to subnasale
Soft tissue lower face height (ST LFH)	The distance from subnasale to soft tissue menton
Soft tissue total face height (ST TFH)	The distance from soft tissue nasion to soft tissue menton
Soft tissue lower face (ST LFH %age)	The distance between subnasale and soft tissue menton expressed as a percentage of the total face height
Upper lip (Ls) to E-line	The distance from labrale superioris to a line joining the nasal tip and soft tissue pogonion
Lower lip (Li) to E-line	The distance from labrale inferioris to a line joining the nasal tip and soft tissue pogonion
Upper lip length (ULL)	The distance from subnasale to the lowest point of the upper lip
Lower lip length (LLL)	The distance from soft tissue menton to the highest point of the lower lip

face where it was recorded at every 1.4 degrees. Three-dimensional coordinates of 300 datum points along each profile line were collected and stored. Each scan included data just posterior to both ears. Each patient was instructed to bite gently on their back teeth, to relax their lips and facial muscles, and close their eyes while the 10-second recording was being made. The correct relaxed lip posture and position was visually assessed in all subjects by one author (DM) immediately prior to each laser scan recording. It is acknowledged, however, that without surface recording it was not possible to establish the precise muscle activity. Scans were repeated if subject movement occurred during data collection—seen as a lack of spatial continuity of the screened image. A few children required a number of scans, due to the effects of movement, before a successful one was obtained.

The data for each subject were displayed by faceting and Gouraud shading. Scans of patients were averaged using a landmark-based technique (McCance *et al.,* 1992). Five landmarks across the eyes and nose were chosen:

1. left lateral canthus;
2. left medial canthus;
3. soft tissue nasion: the point of maximum concavity on the vertical plane and maximum convexity on the transverse plane profile;
4. right medial canthus;
5. right lateral canthus.

To these five points were added a further five mathematically constructed points across the forehead. As the scaling of the scans for the production of an 'average' was dependent on the landmarks chosen, further landmarks spread over as large an area of the face as possible were added. This permitted radial data to be sampled from the whole face and gave equal weighting to all parts of the scan.

The following five additional points were identified and registered:

11. the left alar base: the most inferior and lateral points on the alar base;
12. the base of the nose in the midline: the point of maximum concavity on the vertical profile

Table 2 Before and after treatment/observation measurements. Significant differences found in the finish variables were examined by a one-way ANOVA and are denoted by an asterisk. Where no significant differences between the sexes were found, data have been pooled; otherwise values for each sex are presented separately (soft tissue measurements).

Variable	Bass appliance				Bionator appliance				Twin Block appliance				Controls			
	Before treatment		After treatment		Before treatment		After treatment		Before treatment		After treatment		First observation		Second observation	
Soft tissue measurements	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Angular (degrees)																
Facial convexity	130.7	4.8	131.2	4.5	132.1	5.4	133.2	5.1	134.6	5.8	135.4*	6.1	131.5	5.7	129.8	6.1
Nasolabial angle	117.4	10.7	122.4	7.0	126.7	8.0	128.1	10.2	124.3	9.9	128.2	9.7	123.6	9.7	123.5	8.5
Labiomental fold	108.7	17.1	116.7	17.8	115.5	15.7	124.6	17.3	120.4	16.6	132.5	19.2	119.3	17.5	118.7	15.3
'H' angle	26.8	3.3	24.8	4.2	25.8	4.3	23.0*	4.2	22.1*	4.6	20.0**	4.7	27.1	4.7	27.5	4.1
Linear (mm)																
ST Pg to ST nasion	99.2	5.1	99.7	4.7	96.3	6.1	100.1	5.8	101.0	5.6	102.2	6.7	97.8	7.9	98.1	7.4
Sn to S vertical (male)	84.1	3.3	85.5	2.4	82.6	5.0	83.5	5.6	81.5	5.0	83.0	5.0	78.6	4.3	78.9	4.9
Sn to S vertical (female)	76.5	5.5	77.3	5.9	77.8	4.6	77.4	4.7	75.4	4.5	75.5	4.8	76.9	3.7	78.1	4.0
Ss to S vertical (male)	83.6	3.2	84.5	2.0	81.8	5.3	81.9	6.2	80.8	4.6	81.9	4.4	77.1	4.5	77.6	5.0
Ss to S vertical (female)	75.6	5.4	75.9	5.5	77.0	4.7	76.5	5.2	73.6	5.6	73.9	5.4	76.2	3.7	77.5	4.0
Ls to S vertical (male)	87.5	3.4	88.1	2.6	84.5	6.0	84.6	5.6	84.0	3.9	85.2	4.4	80.5	5.3	80.6	6.1
Ls to S vertical (female)	79.6	4.7	78.7	5.2	79.9	5.7	79.5	6.6	76.4	6.8	75.6	6.4	79.5	4.1	80.7	3.9
Li to S vertical (male)	78.5	3.4	82.2**	3.5	79.3	6.4	79.7*	6.3	76.7	6.0	81.0*	4.5	70.5	6.7	71.1	6.3
Li to S vertical (female)	72.2	4.7	72.8	5.6	72.3	7.0	74.8	7.4	66.7	8.3	70.2	6.9	71.0	3.9	72.1	4.7
Si to S vertical	65.5	5.5	67.9	6.9	66.1	8.4	67.8	8.3	62.1	7.2	65.6	7.3	61.1	6.5	61.8	6.6
ST Pg to S vertical	67.9	6.7	70.0	7.6	68.4	9.2	69.7	9.5	63.9	8.4	66.6	9.0	62.1	6.6	63.1	7.3
Upper lip thickness	17.8	2.4	16.7	1.5	17.2	2.2	17.0	2.3	15.1*	1.7	15.6	3.4	17.0	1.5	16.7	1.8
Lower lip thickness	19.5	3.2	20.4	2.6	20.1	2.8	20.5	2.6	18.5	4.5	20.6	3.4	19.4	4.2	20.1	3.3
ST upper face height	53.4	4.6	53.6	4.9	51.5	4.2	53.5	3.9	52.6	2.3	54.9	3.3	52.5	4.9	53.6	4.6
ST lower face height	60.7	4.4	62.4	4.1	60.3	6.0	62.3	5.7	61.3	4.9	63.4	5.5	59.4	4.4	58.9	5.0
ST total face height	114.1	5.2	116.0	5.6	111.7	7.0	115.7	7.3	113.8	7.2	118.3	7.9	111.9	7.7	112.5	8.2
ST lower face height %age	53.2	3.2	53.8	3.1	53.9	3.2	53.8	2.7	53.8	1.7	53.6	1.8	53.1	2.4	52.4	2.2
Ls to E-line (male)	1.5	2.2	0.3	3.6	1.0	1.7	0.1	2.5	0.7	3.4	–0.4	4.1	1.6	2.3	1.3	2.4
Ls to E-line (female)	1.0	2.1	–1.2*	1.9	0.7	2.8	–1.1*	2.2	–0.9	3.0	–2.5**	2.5	2.7	2.5	2.6	1.8
Li to E-line	–0.6	3.5	0.3	3.7	0.1	3.1	0.0	2.7	–1.6	4.6	–0.5	3.9	0.7	3.5	0.0	3.0
Upper lip length	18.2	2.8	18.5	3.0	19.4	2.2	19.4	2.3	18.0	2.8	19.1	1.9	18.3	1.8	18.4	2.6
Lower lip length	38.0	2.5	41.3	2.7	39.5	4.6	41.5	4.9	38.6	4.8	42.6*	5.0	37.1	3.3	37.9	3.2

$^{*}P < 0.05$; $^{**}P < 0.01$.

Table 3 Changes during treatment /observation and the significance of any differences between the four groups examined by a one-way analysis of variance. No significant differences between the sexes were found so data have been pooled (soft tissue measurements).

	Bass appliance		Bionator appliance		Twin Block appliance		Controls		
Soft tissue measurements	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Significance
Angular (degrees)									
Facial convexity	0.5	1.2	1.0*	4.1	0.8	2.3	–1.7	1.8	Bionator from control
Nasolabial angle	5.0	7.8	1.4	9.1	3.8	10.3	–0.1	6.0	None
Labiomental fold	8.1	8.3	9.1	13.9	12.1	15.4	–0.6	20.8	None
'H' angle	–2.1	2.4	–2.8*	3.1	–2.1	3.5	0.4	3.0	Bionator from control
Linear (mm)									
ST Pg to ST Nasion	0.5	1.9	3.8*	3.2	1.2	3.9	0.3	4.0	Bionator from control
Sn to S vertical	1.1	1.8	0.2	1.8	0.6	1.8	0.6	1.3	None
Ss to S vertical	0.6	1.9	–0.2	1.8	0.6	1.8	0.8	1.5	None
Ls to S vertical	–0.1	2.3	–0.1	2.1	0.0	2.3	0.5	2.3	None
Li to S vertical	2.3	3.2	1.5	2.7	3.8*	3.4	0.8	4.0	Twin Block from control
Si to S vertical	2.4	2.4	1.7	2.8	3.6**	2.0	0.7	2.6	Twin Block from control
ST Pg to S vertical	2.1	2.1	1.3	3.4	2.7	2.3	1.0	2.7	None
Upper lip thickness	–1.1	2.4	–0.2	2.0	0.5	1.8	–0.3	2.0	None
Lower lip thickness	0.9	2.1	0.4	1.5	2.1	2.8	0.6	3.6	None
ST upper face height	0.2	1.1	2.0*	1.6	2.3**	1.2	1.0	1.7	Bionator and Twin Block from Bass
ST lower face height	1.7	1.8	2.0*	2.6	2.2**	2.0	–0.5	2.3	Twin block and Bionator from control
ST total face height	1.9	1.8	4.0**	2.4	4.5**	1.9	0.6	2.4	Bionator from control; Twin Block from Bass and control
ST lower face height %age	0.6	1.0	–0.1	1.6	–0.2	1.1	–0.7	1.5	None
Ls to E-line	–1.7	1.5	–1.3	1.5	–1.4	2.2	–0.2	2.0	None
Li to E-line	–0.4	2.0	–0.1	1.5	1.0	3.1	–0.7	3.0	None
Upper lip length	0.3	1.6	0.0	1.8	1.1	1.8	0.1	1.6	None
Lower lip length	3.3	2.6	1.9	2.4	4.0*	3.2	0.8	2.6	Twin Block from control

$^{*}P < 0.05$; $^{**}P < 0.01$.

and the point of maximum convexity on the horizontal profile;
13. the right alar base;
14. the most anterior point in the midline of the upper lip;
15. the most anterior point in the midline of the lower lip.

These latter two points were defined as: 'the point of maximum convexity in both the horizontal and vertical profiles'.

The software program produced an 'average face' from all the scans in a particular group (directory). For the purpose of this study, male and female subjects were kept separate for each of the three appliance groups and the control group. An 'average' scan was produced for each of the eight sub-groups (Bass male and female, Bionator male and female, Twin Block male and female, and control male and female) at the start and end of the study period.

Each 'averaged' appliance group was then compared with the 'average' control group face by a superimposition method that matched 10 landmarks across the eyes and forehead of each scan. The 'best fit' match of the landmarks was calculated using a least-means-squared procedure with a root means-squared error of less than 0.5 mm. A check was performed on the landmark points and the program displayed the distances between these points. Any pair of points with a difference of more than 0.5 mm was edited and altered so as to reduce the error between the two sets of figures to <0.5 mm. Once the landmarks were accurately registered, the software program aligned the scans by superimposing the scan on the left of the monitor screen with that on the right side.

The differences in areas of change between two facial scans were demonstrated using a registration program with a colour millimetre scale that differentiates between various degrees of movement in much the same way that a geographical atlas uses bands of colour to display the differences in height between the surface of the earth and sea level. In this study, the 'height' being measured was the radial distance from the centre of rotation of the scanning chair. 'Warm' colours (yellow-orange-red) represent positive growth, while 'cold' colours (green-blue-purple) represent negative changes (Figure 2). Areas where there has been no change retain the original colour of the laser scan (neutral brown). For the purpose of this research, the scans were assessed from both the frontal and right profile aspects. The frontal view enabled appreciation of any transverse facial changes, while the profile view allowed direct comparison with the cephalometric findings. In this way, both the area and amount of movement could be visualized.

Figure 2 Laser scan colour scale (mm) chart. Areas of no change retain the original laser scan colour.

The colour scale shown in Figure 2 represents the difference in millimetres between each appliance group facial scan and that of the corresponding control group. In these comparisons, the 'control' scan is situated on the right side of the figure with the 'appliance' scan on the left. Thus, if the 'appliance' image displayed shows positive 'warm' colours, then there has been positive forward movement compared with the control scan—which conversely will show negative 'cold' colour changes. The left- and right-hand images shown within each figure can therefore be regarded as negatives of each other.

Laser scan method error (landmark identification)

Ten non-growing individuals had laser scans performed on three separate occasions during the same day. Landmarks were sited on each scanned image by one author (DM) on two separate occasions with a time interval of 4 weeks. Both groups of scans were then averaged by the method described earlier. Differences between

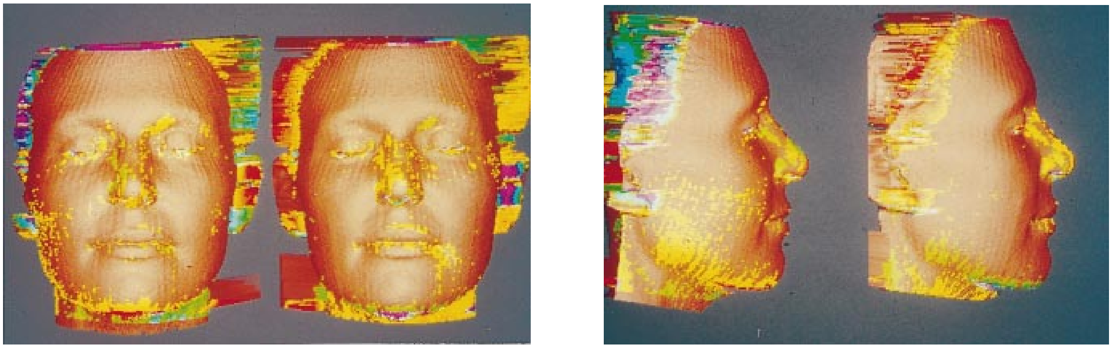

Figure 3 (a) Laser scan measurement error study—frontal view. (b) Laser scan measurement error study—profile view.

the two sets of laser scans were revealed by using the standard superimposition technique and are shown in Figure 3a and b.

Minimal bilateral patchy changes were observed on the lateral aspects of the nose. These differences represent the effects of nasal breathing on the position of the nasal tissues during scan acquisition. Minor changes were also seen associated with the soft tissues of the neck and under the body of the mandible. These areas are subject to change with successive scans due to variations in the degree of tension of these tissues caused by alterations in the positioning of the subject's head in the vertical plane. In areas where there was <1.0 mm of difference, the original colour of the laser scan (neutral brown) remained. For the purposes of this study, however, the areas of interest (i.e. the lips, tip of nose, philtrum, chin, and cheek regions) were found to be unaffected by the method error of the scanning procedure. The facial landmarks used in this study were consistently located with a mean difference between the two locations of each landmark of ≤0.9 mm. These differences are small and of little clinical significance.

Results

Comparison of groups before treatment

Cephalometric findings. Means and standard deviation values for each pre-treatment soft tissue cephalometric variable in all four groups are depicted in Table 2. The groups were generally well matched in their soft tissue pattern. Analysis of variance of the pre-treatment measurements revealed that only two variables exhibited significant differences ($P < 0.05$) between the groups. The 'H' angle variable in the Twin Block group was found to be significantly smaller (by 5 degrees) than both the control and Bass groups with no sex difference within the groups. The Twin Block group also had slightly thinner upper lips than both the other two appliance groups but with no sex difference observed.

Significant sex differences in all groups existed for some of the linear variables, particularly the measurements recording antero-posterior distances from the sella vertical reference line. The control group sex differences were not as marked as for the three appliance groups, which may be a reflection of the age gap between the groups. The males showed higher values for the horizontal linear measurements than the females. These differences were mainly concentrated in the maxillary region of the face, i.e. point A, Sn, Ss, and Ls, indicating that the boys were more protrusive in this region of the face. This illustrates the importance of separating the male and female cephalometric data in a study of this type, as pooling the results may either mask or exaggerate significant findings. Angular measurements did not demonstrate any significant male-female variability. Overall, the control group was cephalometrically well-matched with the three appliance groups.

Laser scan findings. To help the reader with the interpretation of these superimposed scans, Figure 8a and b will be used as an example. These particular scans illustrate that the male Twin Block group started the study period with slightly more retrusive lips, a greater soft tissue facial height and a wider nose than their control counterparts. When these same two groups are compared at the end of the study period (Figure 14a and b), marked changes can be seen to have occurred in the lower face region of the Twin Block male group while their noses remained wider and shorter. The upper lip position stayed constant, in contrast to the generalized 3–5 mm increase in the width and length of the face. Similar positive (i.e. forward) changes in the lower lip and mentalis region can also be seen.

Both intra-group and appliance:control group comparisons of the same sex were carried out; but only the latter are reported in this article. In each illustrated case, the positive changes that have occurred within each appliance group are 'mirrored' by the corresponding 'negative' colours on the control group scan.

The 'start' comparisons for each appliance group's 'average' face compared with the control group are illustrated in Figures 4–9.

Bass male start and control male start (Figure 4a and b)

The Bass male group exhibited a slightly shorter upper lip with a more advanced chin position. The nasal dimensions were larger in both an antero-posterior and transverse direction with a more prominent forehead region. Their 'average' face was, however, narrower than the control males, especially in the zygomatic region.

Bass female start and control female start (Figure 5a and b)

These two groups had a 2-year mean age difference which explains the more dramatic differences found in the colour shading of these two particular scans. The female Bass faces were wider and longer with a more prominent lower chin point and longer nose. The lips were only slightly more protrusive. The different outline of the philtrum and paranasal region indicates that differences here are only just within the 1-mm cut-off point of the colour scale chart.

Bionator male start and control male start (Figure 6a and b)

Less obvious differences between these two sub-groups existed. The main feature was of a relative circumoral retrusiveness in the Bionator group. The body of the mandible region was also wider and longer vertically than the control 'average'.

Bionator female start and control female start (Figure 7a and b)

The Bionator group had a slightly more retrusive upper lip. This is in contrast with the cephalometric findings which showed the upper lip variables to be of similar values in the sagittal direction for both groups. The dimensions of the noses in the two groups were very similar. The relative prominence of the lower lip and chin region in the Bionator group agrees with the radiographic findings. Of most significance, was the large (up to 5 mm) increase in width of the face which extended from the chin region, and radiated upwards and backwards to the buccinator/masseteric region.

Twin block male start and control male start (Figure 8a and b)

Some differences in the upper lip and stomion region were present. Cephalometrically, the control group's labrale superioris position was approximately 1 mm further forward, which agrees with the laser scan findings. Soft tissue facial height was greater for the Twin Block group with relative downward and forward movement of the chin region. The nares region was less prominent vertically, but the width of the nose was greater. The soft tissues covering the mandibular ramus region were thicker.

Twin Block female start and control female start (Figure 9a and b)

Patchy, unequal coloured areas in the lip region indicate a slight relative retrusion of the upper lip in the Twin Block sample. This group also had

Figures 4–9 Laser scan superimpositions comparing the start 'average' faces.

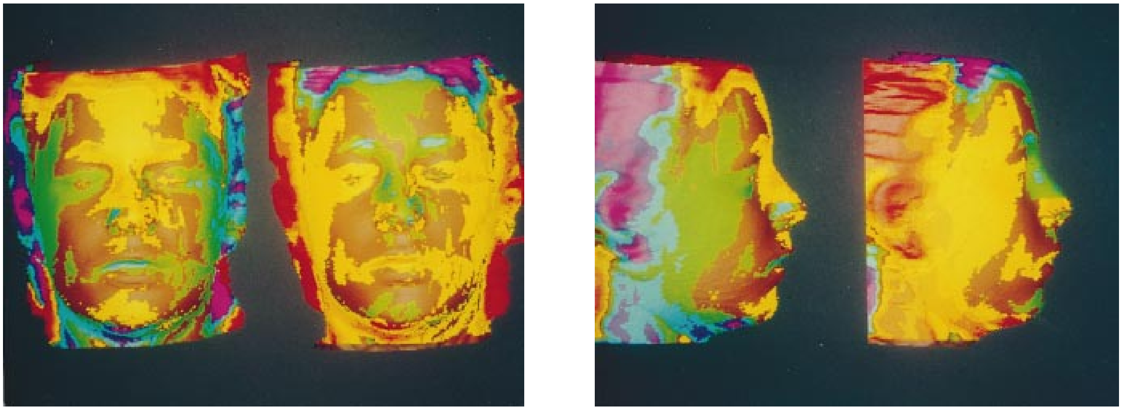

Figure 4 (a) Bass versus control (male) 'start' superimposition—frontal view. (b) Bass versus control (male) 'start' superimposition—profile view.

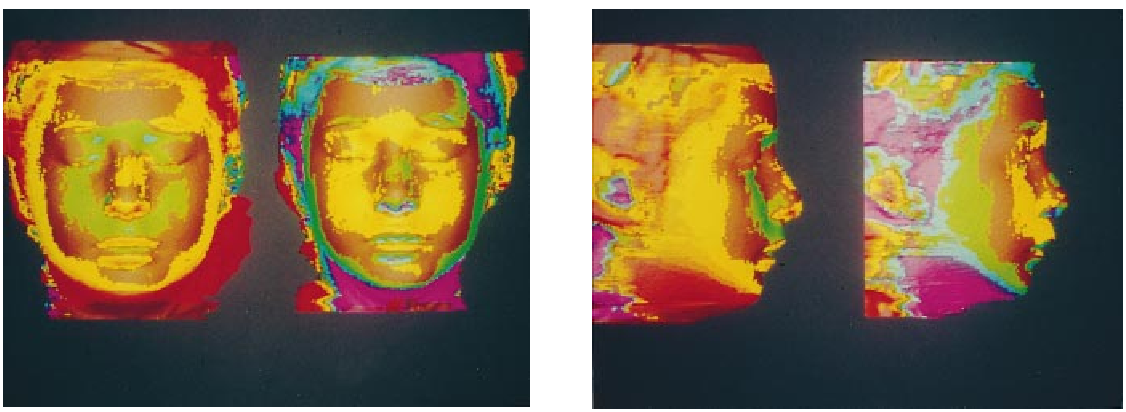

Figure 5 (a) Bass versus control (female) 'start' superimposition—frontal view. (b) Bass versus control (female) 'start' superimposition—profile view.

a relatively increased height and width of the mandible. The Twin Block face was significantly wider over the majority of the lateral facial surface. The actual chin area colour difference was distributed asymmetrically which may indicate why the laser scan finding for this area does not correspond to the soft tissue pogonion and sulcus inferioris 2D radiographic results. Nasal dimensions were similar for both groups.

Changes during active treatment/observation

Cephalometric findings (Tables 2 and 3). The mean changes (and their standard deviation) that occurred in the soft tissue variables during the study period were tabulated. Analysis of variance results are shown to illustrate significant changes for each group. No sex differences were found to be associated with these results

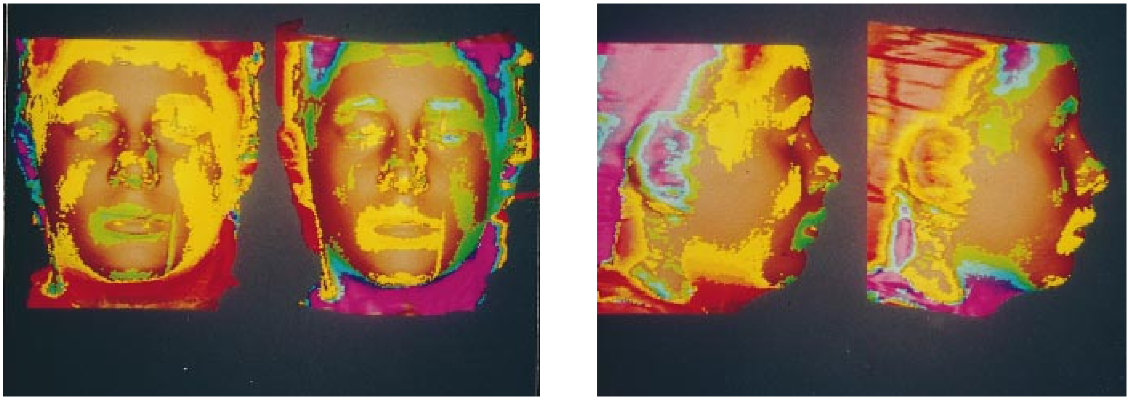

Figure 6 (a) Bionator versus control (male) 'start' superimposition—frontal view. (b) Bionator versus control (male) 'start' superimposition—profile view.

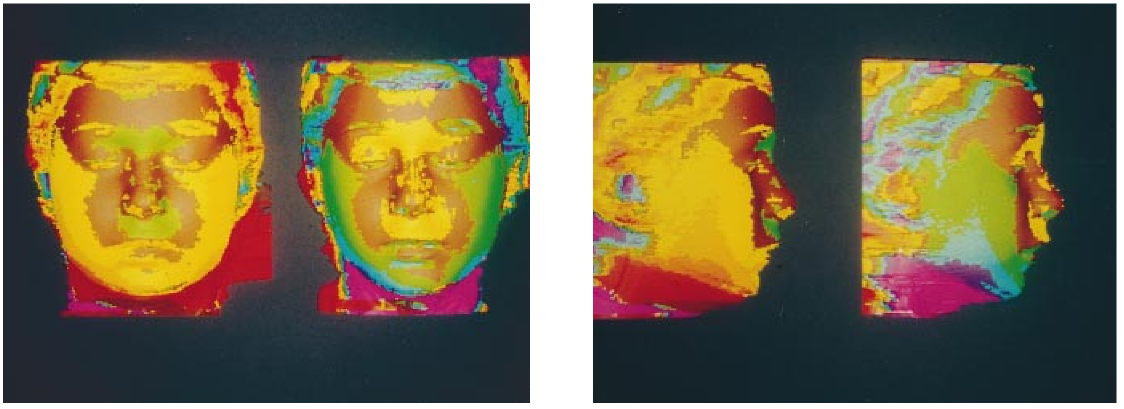

Figure 7 (a) Bionator versus control (female) 'start' superimposition—frontal view. (b) Bionator versus control (female) 'start' superimposition—profile view.

Figure 8 (a) Twin block versus control (male) 'start' superimposition—frontal view. (b) Twin Block versus control (male) 'start' superimposition—profile view.

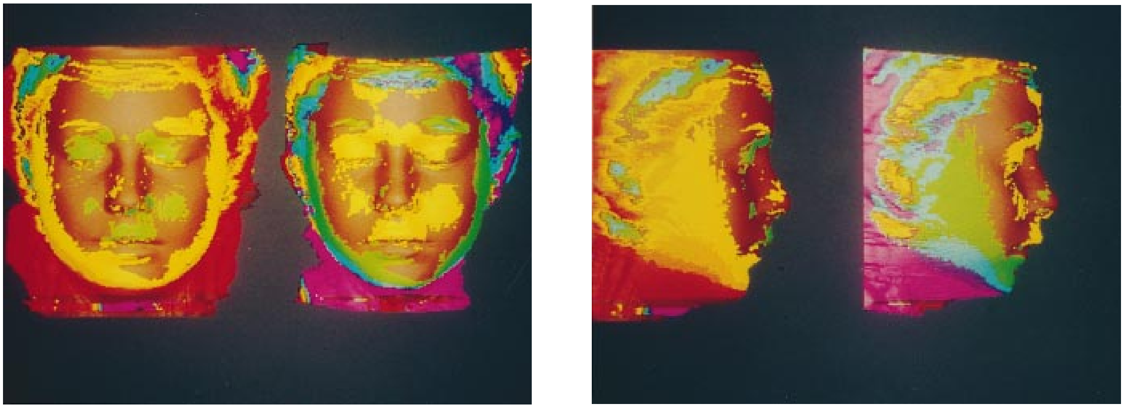

Figure 9 (a) Twin Block versus control (female) 'start' superimposition—frontal view. (b) Twin Block versus control (female) 'start' superimposition—profile view.

and so any comments will refer to the 'pooled' group combining male and female subjects.

Significant differences were found for the angular variables of facial convexity and the 'H' angle. Facial convexity significantly reduced with the Bionator compared with the controls where growth made the profile more convex. The 'H' angle decreased significantly more for the Bionator group (–2.8 degrees) in comparison with the control sample, where it increased very slightly. The other two appliance groups showed the same trend, but their differences did not reach statistical significance.

The ST Nasion-ST Pog variable showed a more significant increase for the Bionator (3.8 mm) than the control group. In view of the problems found with accurate measurement of this linear variable during the error study, the actual relevance of this finding has to be regarded as questionable. This increase was, however, 2 mm more than that achieved by any of the other two appliance groups.

The only significant findings among the horizontal linear measurements to the sella vertical reference line were those of labrale inferioris (Li) and sulcus inferioris (Si) in the Twin Block group. Anterior movement of the lower lip point in this latter group (3.6 mm) was greater than the 0.7 mm observed in the control group ($P < 0.01$). The lower lip prominence point (Li) showed a similar disparity between these two groups. A significant increase in the lower lip length was demonstrated in the Twin Block group (4.0 mm). The labiomental fold also opened up by over 12 degrees—the highest value achieved by any group. Statistical significance was not found to support the numerical differences seen in this variable. The Bass group also showed a non-significant but reasonable increase in lower lip length.

Upper and lower soft tissue face heights showed highly significant increases ($P < 0.01$) for the Twin Block subjects and a significant increase ($P < 0.05$) for the Bionator group when compared with the negligible growth changes seen in the control group. The Bass patients exhibited relative stability of their soft tissue upper face height compared with the increase of the Bionator (2.0 mm) and Twin Block groups (2.3 mm). The total soft tissue facial height values showed highly significant increases for both the Twin Block and Bionator groups when compared with the controls, and a significant difference between the Twin Block and the Bass subjects.

Laser scan findings. The 'finish' (end of the study period) comparisons (Figures 10–15) are demonstrated in the same format as the previous 'start' comparisons. When comparing the 'finish' views, attention should be paid to the colour changes

Figures 10–16 Laser scan superimpositions comparing the finish 'average' faces.

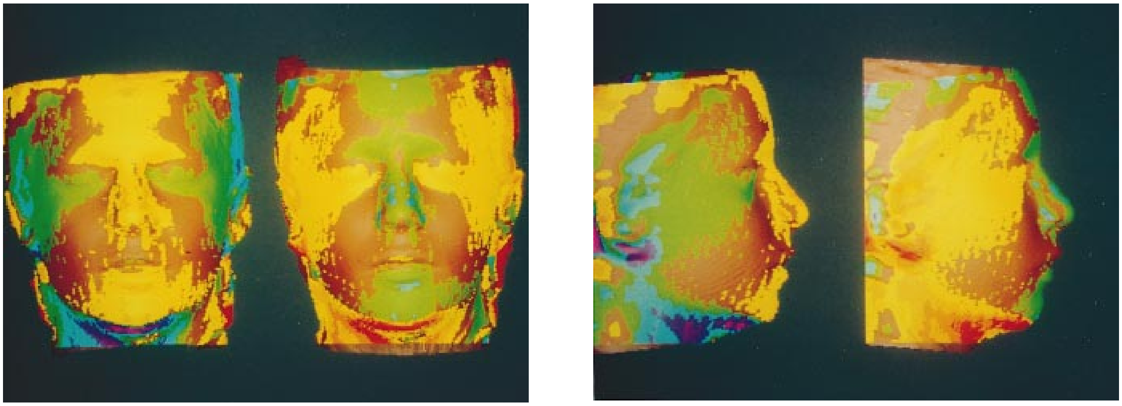

Figure 10 (a) Bass versus control (male) 'finish' superimposition—frontal view. (b) Bass versus control (male) 'finish' superimposition—profile view.

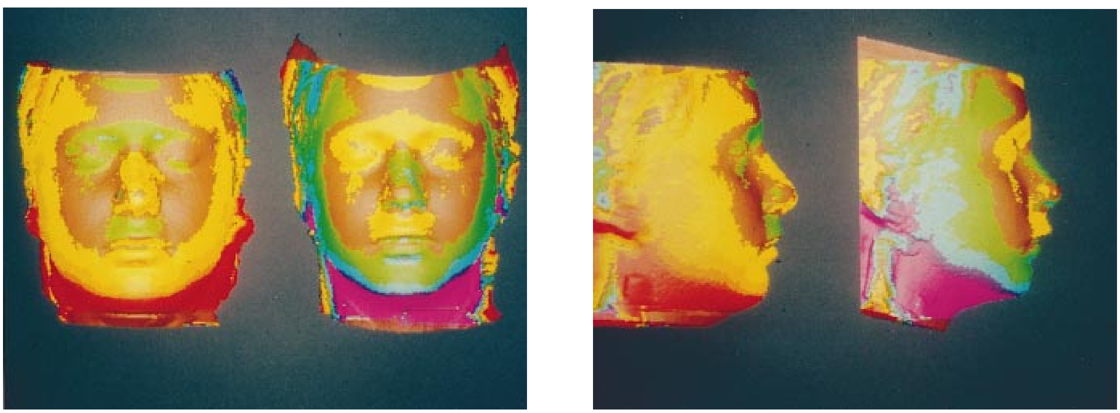

Figure 11 (a) Bass versus control (female) 'finish' superimposition—frontal view. (b) Bass versus control (female) 'finish' superimposition—profile view.

that have occurred within the particular group during the study period by referring to the original 'start' scans. Intra-group superimpositions were carried out, but are not illustrated here.

Bass male finish and control male finish (Figure 10a and b)

The Bass group showed some improvement in the area of the lips, especially the lower one. The philtrum region remained stable. The mandible remained vertically shorter than for the control group. No significant facial width changes occurred. A small amount (up to 3 mm) of antero-posterior improvement of the chin position has occurred to improve the original mandibular retrusion. Nasal dimensions remained unaltered. These findings match the cephalometric changes described earlier.

Bass female finish and control female finish (Figure 11a and b)

The female Bass patients showed slightly more definitive changes than the corresponding male group. All colour changes remained within the

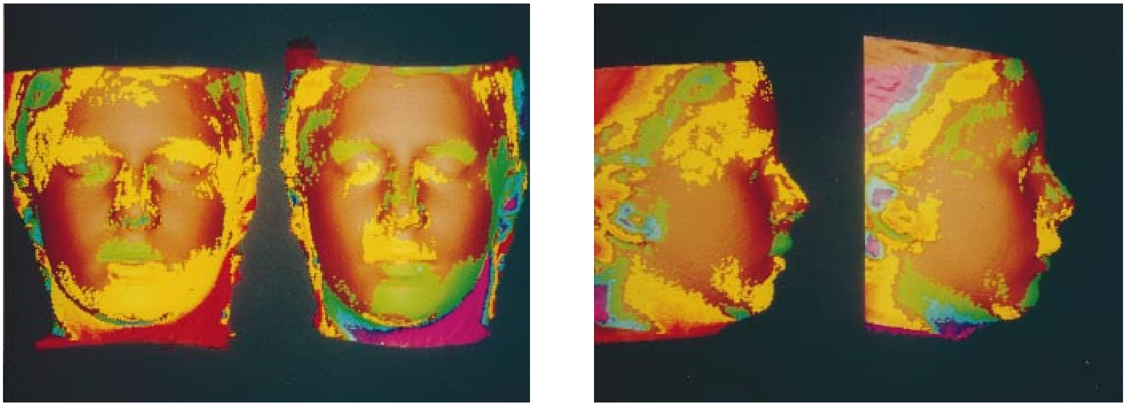

Figure 12 (a) Bionator versus control (male) 'finish' superimposition—frontal view. (b) Bionator versus control (male) 'finish' superimposition—profile view.

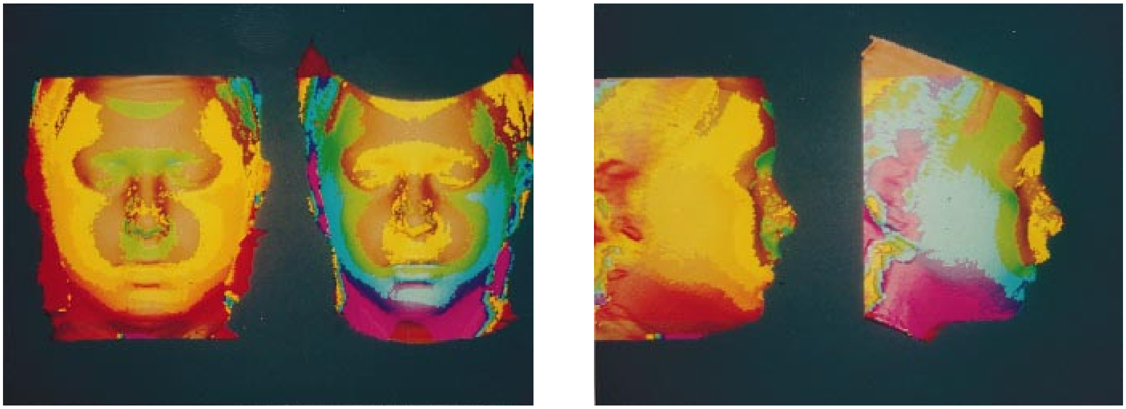

Figure 13 (a) Bionator versus control (female)'finish' superimposition—frontal view. (b) Bionator versus control (female) 'finish' superimposition—profile view.

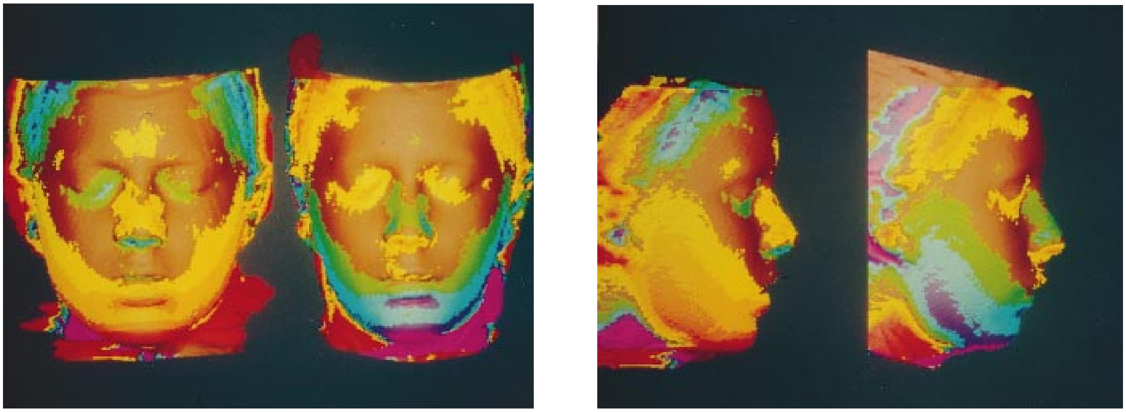

Figure 14 (a) Twin Block versus control (male) 'finish' superimposition—frontal view. (b) Twin Block versus control (male) 'finish' superimposition—profile view.

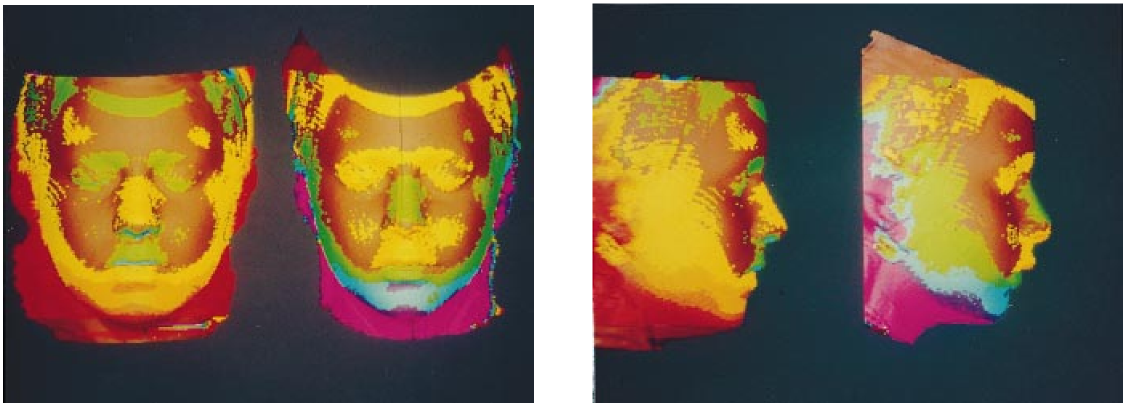

Figure 15 (a) Twin Block versus control (female) 'finish' superimposition—frontal view. (b) Twin Block versus control (female) 'finish' superimposition—profile view.

1.1–2.9 mm range. There was some improvement in downward facial growth with a concurrent increase in facial width over the majority of the lateral surface of the face. Upper lip position was minimally retruded within the lowest colour band. A similar amount of forward positioning of the lower aspect of the chin was also achieved.

Bionator male finish and control male finish (Figure 12a and b)

Prominence of the cheekbones reduced bilaterally in the Bionator group. There was no increase in the width of the face and no evidence of masseteric hypertrophy. The Bionator appliance seemed to have a slight retrusive effect on the upper lip and maxilla region. The lower facial height increased by a small amount. The lower lip became more protrusive and positive 1–3 mm colour changes occurred in the chin and labiomental fold region. These findings are mirrored by the cephalometric results.

Bionator female finish and control female finish (Figure 13a and b)

No detectable changes occurred in the upper lip and alar base region and they remained retrusive in comparison with the control females. A significant increase in lower facial height was recorded with a similar 3.0 mm forward movement of the mandibular tissues. These scans resembled those of the male Twin Block group, in the way that the resultant lower facial soft tissue changes are so well-delineated and symmetrical in nature. Moderate changes were seen in the transverse dimension due to masseteric enlargement.

Twin Block male finish and control male finish (Figure 14a and b)

As with the cephalometric data, there is no doubt that the Twin Block groups demonstrated the most significant changes during the study period. The nose remained wider and shorter, and the upper lip position stayed constant, while marked changes occurred in the lower facial region. These differences took the form of 3–5 mm forward movement of the sulcus inferioris area and lower lip, thus reducing the prominence of the labiomental fold. There was also a significant increase, in the range of 3 mm, for the lower face height and a generalized forward and downward movement of the chin. The mandible increased in length by a distance of 1.1–2.9 mm. A marked increase in facial width, particularly in the mandibular area (3–5 mm) occurred, probably as a result of appliance-induced masseteric hypertrophy.

Twin Block female finish and control female finish (Figure 15a and b)

The females reacted to the Twin Blocks in a similar manner to their male counterparts, i.e. no significant upper lip changes occurred but the lower lip and labiomental region came forwards 3.1–4.9 mm. The scans bore a similarity to the Bionator group. Less masseteric response was seen in the female Twin Block subjects, but changes were still appreciable at the inferior region of the mandibular ramus. Nasal width growth was significant during this period. The mandibular area moved downwards and forwards with colours changing to the next band on the scale, i.e. yellow to orange, indicating 2–3 mm increments of improvement. The lower face height increased by a similar amount.

The start and finish comparison laser scans of the control group males and females agreed three-dimensionally with the two-dimensional cephalometric findings; namely, that little significant facial growth occurred in these individuals during the study period. This is demonstrated by the 'patchy' asymmetric distribution of the yellow/green shading of the scans in Figure 16.

Discussion

General considerations

The results shown closely reflect the clinical impression of treatment progress throughout the study period. One of the biggest problems in functional appliance treatment is patient compliance. In general, patients found the Twin Block appliance easier to tolerate. The overall discontinuation rate during the study period was 14 per cent, which compares favourably with the 25 per cent quoted by Hunt and Ellisdon (1985) and the mean rate of 15.2–21.9 per cent reported by Haynes (1991) in the 10–14-year-old age group. The Bass appliance group numbers in this study fell by 28 per cent—a similar discontinuation rate as experienced by Malmgren *et al.* (1987). The relative compliance rates of functional appliances are an important clinical and economic consideration.

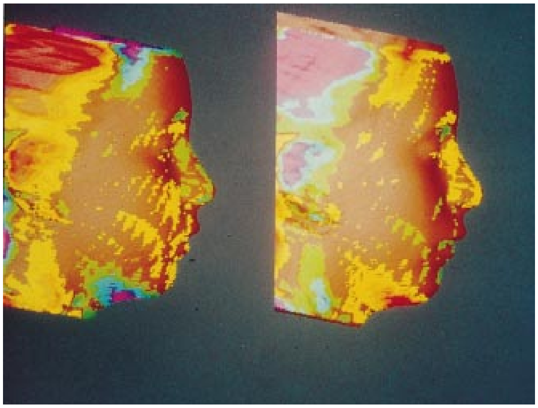

Figure 16 Control male 'start' versus 'finish' superimposition—profile view.

The soft tissue changes

It would seem that Twin Block therapy had the soft tissue effect of bringing the lower lip forwards and upwards, as the overjet reduced. Similar soft tissue changes were observed by Talass *et al.* (1987) with their Edgewise subjects. They found that an increase in the lower lip length was the major component accounting for the increase in soft tissue facial height. They, similarly, found a non-significant increase of the nasolabial angle. This was, however, associated with significant upper lip retraction due to the fixed appliance mechanics, a feature not found in this study. Clark (1988) claimed that a statistically significant reduction in the facial convexity occurs with the Twin Block, along with an increase in facial height in deep overbite cases. In the present study, a minor numerical reduction in facial convexity occurred but this did not reach a statistically significant level.

The faces of the treatment groups became less convex with opening up of the nasolabial angle and labiomental fold compared with the controls. This agrees with the findings of Battagel (1990) on the Fränkel appliance, and Looi and Mills (1986) with the activator. The large inherent individual variability and lower measurement accuracy associated with these two angular variables makes statistical significance unlikely to ever be achieved.

The 'H' angle values reduced in each of these three groups with almost no change occurring in the control subjects. Statistically significant reduction was only achieved by the Bionator group. All groups exhibit values for this soft tissue angle well above Holdaway's (1983) quoted range of 7–9 degrees. This, as suggested by Holdaway, is to be expected in Class II subjects because of their increased ANB values and marked facial convexity.

Each appliance group showed more negative changes in the upper lip (Ls) to E-line relationship than the controls. Upper lip landmarks and point A changed little throughout the study period, and were of similar values for all four groups. Despite the overjet reduction achieved in the appliance groups (Illing *et al.*, 1998), this did not result in any proportional changes in upper lip thickness as reported by Wisth (1974). This is in contrast to findings with the Fränkel appliance (Haynes, 1986) which caused significant retraction (3–3.5 mm) of the labrale superioris and point A. Similarly, Battagel (1989) found that the Fränkel appliance produced a more ideal relationship of the lips to the aesthetic plane when compared with the more concave profile produced in an Edgewise group, some of whom had undergone extraction of premolar units. Retraction of maxillary incisors by more than 6.7 mm has been found to lead to concomitant retraction of the upper lip, an increase in lower lip length and in the nasolabial angle (Talass *et al.,* 1987).

Lower lip points, as well as soft tissue pogonion and point B, advanced, with the trend between the groups being Twin Block > Bass > Bionator. Only the Twin Block produced a mean positive forward movement of the lower lip in front of the E-line. The increase in chin prominence seen in the Twin Block group (2.7 ± 2.3 mm) was similar to that found by Forsberg and Odenrick (1981) in their activator study (3.1 ± 2.6 mm) over a mean 2-year observation period. Malmgren *et al.* (1987) reported a significant forward movement of the lower lip (1.4 ± 1.5 mm) during Bass appliance therapy. The Bass group in this study produced similar values for lower lip movement.

Overall, little significant soft tissue changes, associated with a less complete overjet reduction, were seen in the Bass group. This can be accounted for by the combined factors of a relatively small sample of subjects with a reduced general growth trend, a limited study period and the more variable compliance experienced with this appliance.

Minimal growth changes were seen in the control subjects during the study period with a total of only three soft tissue variables changing by one degree/millimetre. This lack of significant facial growth in the control subjects could be due to the relatively short observation time.

Consistently more antero-posterior changes occurred for the lower lip landmarks in all treatment groups compared with their relative stability in the control subjects. These figures only reached statistical significance for the Twin Block appliance group. Mean soft tissue changes were generally small with large standard deviation values indicating high individual variability within the group (Looi and Mills, 1986). Significant differences between the Twin Block appliance group and the other two appliances were seen in the soft tissue profile. This is contrary to the findings of Remmer *et al.* (1985) in their retrospective study based on activator, fixed appliance and Fränkel treatment groups. They found that apart from a 1.8-mm difference in the horizontal position of the upper lip between the Fränkel and the fixed appliance groups, there were no significant differences between the profiles of the three treatment groups. Forsberg and Odenrick (1981) compared 47 patients successfully treated with an activator with 31 untreated control subjects over a 2-year period. They found that lip retrusion and forward movement of soft tissue pogonion were significantly greater in the treated group.

Looi and Mills (1986) found a wide variation in individual response of the soft tissues in patients treated with the Andresen activator, by the Begg appliance with extractions, and in an untreated control group. However, their observation period for each of the groups varied by up to a year, with the control group being reviewed for the longest period. In addition, the control group exhibited a significantly less severe Class II malocclusion, males and females were not analysed separately, and the radiographs used were taken in a number of different centres. Mamandras *et al.*

(1989) found that the effect of the activator on maxillary growth appears to be neutral, whilst all mandibular soft tissue points advanced significantly more than the control sample.

The inherent limitations of cephalometrics needs to be considered when assessing the observed differences as a result of therapy. Statistically significant changes were observed for many of the cephalometric variables measured. However, the majority of the standard deviations reported (Table 3) are larger than the corresponding mean values. In view of this, the clinical value of these findings should be interpreted with caution, despite most of the trends found in this study corroborating those reported previously. This paper should not be used as a clinical rationale for selecting a particular functional appliance due to the relatively small mean changes and high individual variation within each appliance group.

Assessment of laser scan technique

The laser scanning method described relies on a more objective method of identifying landmarks on the human face and profile, leading to a useful quantitative description of the facial features. It has been found to be sensitive to small changes on the facial surface. The technique is safe, non-invasive and can be repeated *ad infinitum* at any time interval required by the clinician. The scanned image is rapidly acquired (within 15 seconds), is immediately available, and can be viewed from various directions. The image can also be stored and then retrieved for superimposition purposes.

At the present time, there are no alternative methods to facial laser scanning that will allow for a direct comparison to be made. Accuracy of the laser scanning method is also dependent upon the care and attention paid during the scan acquisition procedure and to the placement of the landmarks. It is important that the same operator performs all these tasks on a collection of scans.

The laser scanner has been shown to reproduce 3D measurements to an accuracy of 0.9 mm over the entire facial surface, with a resolution of <0.5 mm for individual data points (Moss *et al.*, 1989). McCance *et al.* (1992, 1997) have previously reported the method errors of identifying these landmarks on the face using the same laser scanner set-up. Method errors were reported numerically as the mean difference and the standard deviation of the x, y and z co-ordinates. The mean difference in each co-ordinate was found to be <0.5 mm for all variables in all three planes of space. Coward *et al.* (1997) found that mean differences of the same co-ordinates ranged from 0 to 0.85 mm, and 3D mean differences of each landmark were found to range between 1 and 2.5 mm. However, the majority of the landmarks used in their study were based on measurements of the ear and are therefore not directly comparable.

The automated method inherent in the laser scanning technique, combined with the vertical and horizontal profile markers present on the screen during the landmarking procedure, markedly reduce the subjectivity inherent in the process of landmark determination. As a result, subsequent quantitative analysis has a high level of repeatability. Exact comparison with other work is not possible since no other functional appliance study has used a laser scanning technique to evaluate treatment effects. The ultimate goal of complete objectivity with regard to landmark identification and placement has recently been demonstrated with mathematically-derived landmarks from curvature analysis and scale space filtering techniques (Moss *et al.*, 1992). This future modification to the present system may answer the concerns of critics with regard to the reproducibility of the laser scanning method and enable inter-centre scientific investigations to be carried out. The reproducibility (inter-operator variability) of the laser scanning technique was not within the remit of this study but this aspect would benefit from further investigation in the future (Coward *et al.,* 1997).

Standing height changes

Harvold and Vargervik (1971) suggested that close association between facial growth and standing height change is of importance for the successful outcome of treatment with functional appliances. Interestingly, increases in standing

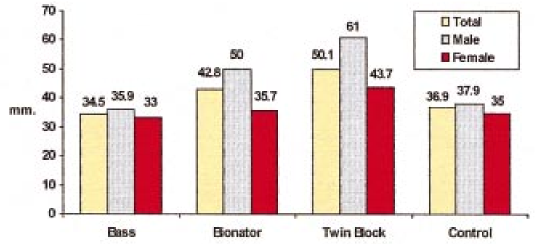

Figure 17 Standing height measurements during the study period.

height measurements (Figure 17) during the study period revealed a similar trend between the groups (both male and female), as had been found for the soft tissue parameters. These show the Twin Block and Bionator groups to have grown in stature the most (mean 50 mm and 42 mm respectively), while the Bass (mean 34 mm) and control group (mean 36 mm) had recorded less of a height increase. A wide range of height changes and standard deviations was observed for each group. This chance effect may have contributed to the relatively greater success of the former appliances. Whether this finding is coincidental or of actual clinical relevance is open to debate and would require more long-term data collection.

Further research

This study has provided some baseline data on the facial soft tissue changes that occur to varying extents with the use of functional appliances. It should, however, be considered a pilot study. Further longitudinal studies are undoubtedly necessary to corroborate and extend these initial findings. The subjects in this investigation will be followed up as they progress through their second phase of fixed appliance therapy. This will enable more substantial long-term soft tissue changes (including treatment stability and relapse) to be assessed and compared with the initial findings presented in this article. The addition of further subjects, as they are referred for treatment, would help to increase the individual group numbers and thus the statistical power of the study.

Larger sample sizes would offer a better chance of attaining a level of statistical significance, as relatively small changes are being demonstrated in the presence of wide individual variation. This would provide reasonable assurance that a clinically meaningful ‘difference’ was not being overlooked as small sample sizes often confer insufficient power for the statistical test employed (Freiman *et al.*, 1978; Tulloch *et al.*, 1990).

In order to discern minor treatment effects, the statistical management of multiple comparisons requires larger samples than would be the case for *t*-tests comparing the means of two samples. A larger sample is required when: the difference between treatment responses in the groups is smaller, the variability of the data increases, the significance level (*P*-value) decreases and the power of the statistical test employed is increased. The methodologically correct approach of sub-dividing the study sample into smaller homogenous groups, matched for age and gender, has the serious drawback of reducing statistical power.

Further analysis of the cephalometric data collected in the present study was performed in order to estimate the required sample size when comparing four treatment groups by analysis of variance. Statistical power calculations were carried out retrospectively for each hard and soft tissue cephalometric variable to estimate the sample size required to provide a minimum 80 per cent power to detect a difference between the groups at the 5 per cent level of significance (Day and Graham, 1989). This revealed that certain linear (Art to ANS, B to S vertical, Pog to S vertical, Sn/Ss/Ls/ST Pg to S vertical, Ls/Li to E-line and upper lip length) and angular cephalometric variables (max plane to SN, SN Pog, MM angle, interincisal angle, nasolabial, and labiomental fold angles) are relatively insensitive measurements of treatment changes and would require individual groups of between 40 and 72 subjects to detect a clinically significant difference of 2 degrees or millimetres between them. Most of these variables are associated with large standard deviations and wide individual variation, which makes it more difficult for conclusive and statistically significant findings to be made. It would therefore be prudent for researchers to be aware of the cephalometric measurements that are less reliable and more variable with respect to the sample size available. Single centre studies often suffer from this drawback of inadequate or finite sample size. Increasing the number of subjects, by employing a multi-centre study design, often means sacrificing close control of other important variables, e.g. number of operators involved, technique/equipment differences and appliance design/construction variation.

Conclusions

Within the limitations of this study, the results suggest that:

1. Growth was associated with only minimal changes in the soft tissue facial profile and form during the study period.
2. Each of the three functional appliance groups produced further changes in the soft tissue profile and form than would otherwise have been expected. Greater antero-posterior changes occurred in the male treatment groups. Upper lip landmarks showed no significant changes in any of the appliance groups despite the significant overjet reduction achieved in each appliance group.
3. The quality and quantity of soft tissue change varied between the three appliance groups and seemed to be directly related to the clinical impression of patient co-operation. Individual variation within each group was also wide.
4. The Twin Block appliance group (male and female) achieved greater changes in their facial soft tissues in comparison with the other two functional appliances. The most significant effect found was the advancement and lengthening of the lower lip combined with some forward movement of the chin point and increase in all the face height parameters.
5. The most significant soft tissue effect in the Bionator appliance group was an increase in the face height values. The Bionator was the only appliance group to achieve statistically significant reductions in both the 'H' angle and facial convexity values.
6. No statistically significant facial soft tissue findings could be demonstrated in the Bass appliance group. Similar, but smaller, increases in lower lip length, chin protrusion, and facial height were, however, detected.
7. The facial laser scanning technique proved to be a simple, non-invasive method of measuring three-dimensionally and provided accurate information comparable with the cephalometric data. It also enabled a more thorough, quantitative assessment of the soft tissue changes seen within the groups. The superimpositions were of particular value in demonstrating the transverse facial changes that occurred to varying degrees in the appliance groups.
8. The long-term significance and ultimate stability of these changes must be considered with caution. Further investigation based on these initial findings is planned at the end of active treatment.

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