European Journal of Orthodontics 26 (2004) 515–522
European Journal of Orthodontics vol. 26 no. 5

Adaptive condylar growth and mandibular remodelling changes with bionator therapy—an implant study

Adriano M. Araujo*, Peter H. Buschang** and Ana Claudia M. Melo*

*Department of Orthodontics, Araraquara School of Dentistry, São Paulo, Brazil and **Department of Orthodontics, Baylor College of Dentistry, Texas A&M University System Health Science Center, Dallas, Texas, USA

SUMMARY The purpose of this study was to describe condylar growth and mandibular remodelling changes associated with bionator therapy. Twenty-five patients (15 males and 10 females) between 6.9 and 11.2 years of age with Class II division 1 malocclusions were randomly allocated to either control (*n* = 11) or treatment (*n* = 14; bionator only) groups and followed longitudinally for approximately 1 year. Treatment consisted of a bionator only, constructed to clear the buccal dentition by 2 mm and to position the mandible into an edge-to-edge incisor relationship. Using metallic implants for superimposition, mandibular growth, displacement, and true rotation were evaluated cephalometrically.

The results showed significant changes in the direction (more posterior) but not in the overall amount of condylar growth. The bionator appliance produced greater than expected posterior drift of landmarks in the condylar and gonial regions. Cranial base superimposition showed greater than expected anterior mandibular displacement, but little or no true mandibular forward rotation with bionator therapy. The bionator appliance alone produced changes in condylar growth direction and remodelling changes associated with mandibular rotation and displacement.

Introduction

Changes in mandibular position might be expected to produce or be associated with changes in condylar growth and mandibular remodelling. Animal studies have shown that an altered mandibular position produces adapative changes in condylar growth and mandibular remodelling (Petrovic *et al.*, 1975; Woodside *et al.*, 1983; McNamara and Bryan, 1987). The clinical application of functional appliances is based on the notion that the condyles adapt to the altered mandibular position (Williams and Melsen, 1982a; Op Heij *et al.*, 1989; Jakobsson and Paulin, 1990; Paulsen, 1997; Pancherz *et al.*, 1998; Croft *et al.*, 1999, Ruf *et al.*, 2001).

While it is generally accepted that functional appliances alter mandibular growth, the actual changes produced at the condyle and along the surfaces of the mandible remain poorly understood. Most studies have evaluated angular and dimensional changes between landmarks; they report increases in the overall mandibular length (Op Heij *et al.*, 1989; McNamara *et al.*, 1990; Mills, 1991; Nelson *et al.*, 1993; Illing *et al.*, 1998; Ghafari *et al.*, 1998; Keeling *et al.*, 1998; Toth and McNamara, 1999; Almeida *et al.*, 2002) and increases in anterior face height (Nielsen, 1984; Almeida *et al.*, 2002). Reports suggesting increased growth with functional appliances are based primarily on mandibular length changes rather than actual condylar growth (Op Heij *et al.*, 1989; McNamara *et al.*, 1990; Mills, 1991; Nelson *et al.*, 1993; Illing *et al.*, 1998; Ghafari *et al.*, 1998; Keeling *et al.*, 1998; Toth and McNamara, 1999; Almeida *et al.*, 2002). While mandibular length represents an important measure of therapeutic outcome, it can be misleading because its increase could be due to changes in the amount of condylar growth, changes in condylar growth direction, some combination of the two, or remodelling of the mandibular symphysis.

Studies superimposing on natural mandibular reference structures show consistent changes in condylar growth direction, but remain controversial concerning treatment changes in the total amount, that is both horizontal and vertical, of condylar growth. Several studies clearly show that functional appliances redirect condylar growth in a more posterior direction (Hultgren *et al.*, 1978; Jakobsson and Paulin, 1990; Pancherz *et al.*, 1998; Croft *et al.*, 1999, Ruf *et al.*, 2001; Baltromejus *et al.*, 2002). It has been demonstrated that there are increases in both posterior and superior condylar growth with the Herbst and activator appliances (Pancherz and Hägg, 1985; Pancherz *et al.*, 1998; Ruf and Pancherz, 1998a, b; Ruf *et al.*, 2001; Baltromejus *et al.*, 2002). However, it has also been reported that functional appliances do not increase total condylar growth (Jakobsson and Paulin, 1990). Long-term follow-up studies of Herbst treatment show changes in condylar growth direction, but no increase in the total amount of condylar growth (Pancherz *et al.*, 1998; Croft *et al.*, 1999).

Mandibular implants provide the most accurate and reliable reference structures; they serve as the gold standard for evaluating condylar growth, mandibular remodelling, and changes in mandibular position and rotation (Björk, 1969; Sarnat, 1986; Baumrind *et al.*, 1992a). Although the differences between implant and natural structure references are small, systematic differences have been described (Baumrind *et al.*, 1992b). To date, only two studies have evaluated the effects of functional appliance therapy using implants. Williams and Melsen (1982a, b) described the effects of activator therapy in 19 patients, but were not able to differentiate the effects of therapy due to a lack of untreated controls. Birkebæk *et al.* (1984) reported an increase in the amount and direction of condylar growth with a Harvold-type activator, but their controls may have been subject to selection bias. Neither study evaluated mandibular remodelling changes associated with functional appliance treatment.

The purpose of this implant study was to provide a more complete, unbiased, description of condylar growth and mandibular remodelling changes associated with bionator therapy. To enhance internal validity, the control subjects were randomly allocated prior to the trial.

Subjects and methods

The sample comprised 25 patients (15 males and 10 females) between 6.9 and 11.2 years of age (Table 1) with Class II division 1 malocclusions, erupted upper and lower incisors, little or no crowding (less than 1.5 mm) and no crossbites. Using a random number table, the subjects were randomly allocated to either a control (n = 11) or treatment (n = 14) group and followed for approximately 1 year (range 0.8–1.2 years). The control group was treated after the follow-up period. Treatment consisted of a bionator only (Figure 1), as described by Ascher (1977). All bionators were constructed to lie approximately 2 mm away from the buccal dentition, and to position the mandible forward into an edge-to-edge incisor relationship. Using the techniques described by Björk and Skieller (1972), each subject had three metallic implants placed in the mandible prior to treatment. The three implants included an anterior implant in the midline of the symphysis and two posterior bilateral implants placed as far as possible proximal and inferior to the first permanent molar. The stability of all implants over time was checked and verified. Informed consent was obtained from all subjects.

Lateral cephalograms were obtained at the beginning of treatment (T1) and at the follow-up appointment (T2). The cephalograms were taken with the head positioned according to the Frankfort horizontal at standardized source–subject and subject–film distances. The analyses pertained to 12 mandibular landmarks (Figure 2) defined using operational definitions (Table 2). All cephalograms were traced and digitized by the same person (AMA), who was blind to group affiliation. To increase reliability, each radiograph was evaluated twice and the averages computed for each measurement. Error analyses of 15 replicates showed no systematic error and method errors (Dahlberg, 1940) ranged between 0.13 and 0.87 mm.

To describe condylar growth and mandibular remodelling, each subject's radiographs were superimposed

Table 1 Pre-treatment (T1) and follow-up (T2) ages (years) of the treated (bionator) and untreated (control) Class II division 1 subjects.

Group	n	Sex	T1 Mean age (range)	T2 Mean age (range)	T1–T2 Mean age (range)
Control	11	6 males, 5 females	8.9 (6.9–10.6)	9.9 (7.8–11.6)	1.0 (0.8–1.2)
Bionator	14	9 males, 5 females	9.5 (7.3–11.2)	10.5 (8.2–12.3)	1.0 (0.9–1.2)
Total	25	15 males, 10 females	9.2 (6.9–11.2)	10.2 (7.8–12.3)	1.0 (0.8–1.2)

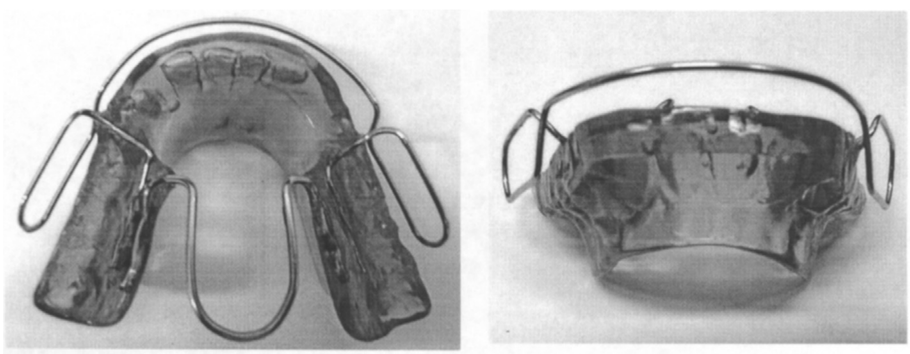

Figure 1 Occlusal and frontal views of the bionator used in the experimental group.

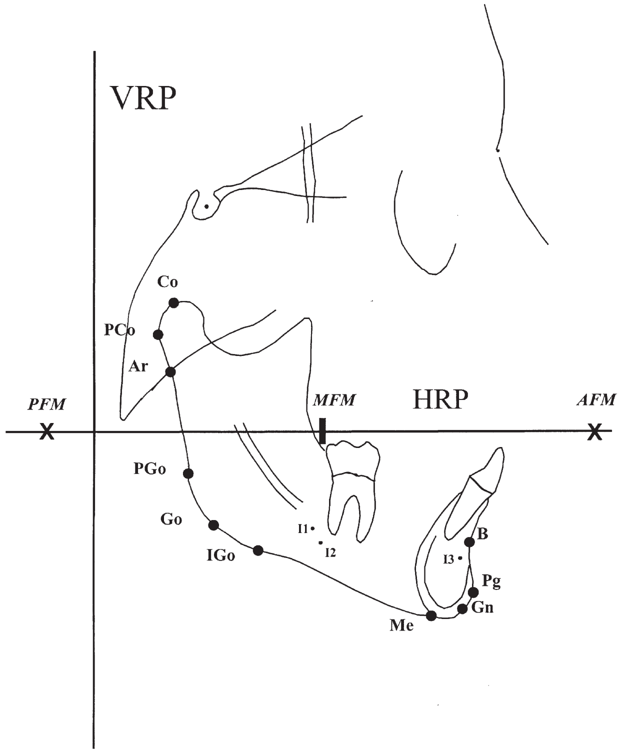

Figure 2 A schematic representation of the landmarks (see Table 2), three implants (I1, I2, I3), three fiducial markers (anterior: AFM; midpoint: MFM; posterior: PFM) and reference planes orientated parallel (HRP) and perpendicular (VRP) to the inferior occlusal plane.

using the three metallic implants. First, two fiducial landmarks, orientated along the mandibular functional occlusal plane (based on first molar and premolars), were marked in front of and behind the mandible on the T1 tracing. These two fiducial landmarks defined the horizontal reference plane (HRP). Next, the T2 tracing was superimposed on the T1 tracing based on the best fit of the three mandibular implants and the two fiducial landmarks were transferred to the T2 tracing. Rectangular (X, Y) co-ordinates were used to describe each landmark's horizontal and vertical positions, relative to the posterior fiducial landmark (i.e. the origin). Changes in landmark position were evaluated relative to a HRP and a vertical reference plane (VRP), defined perpendicular to the HRP (Figure 2). For example, the horizontal change in the position of pogonion was measured parallel to the HRP and the vertical change was measured parallel to the VRP. The total change for each landmark was: $\sqrt{(\text{horizontal change}^2 + \text{vertical change}^2)}$.

True mandibular rotation (Solow and Houston, 1988) was defined as the angular change of the HRP relative to the sella–nasion plane, which was transferred from the T1 tracing to the T2 tracing following cranial base superimposition (Björk and Skieller, 1972). The horizontal and vertical displacements of the mandible were described by positional changes of the anterior and posterior fiducial landmarks delimiting the HRP and their midpoint.

Statistical analyses

The distributions of the variables were judged to be normal based on skewness and kurtosis statistics. Means and standard deviations were used to describe central tendencies and dispersion. Due to the small sample

Table 2 Landmarks, definitions and horizontal/vertical method error.

Landmark	Abbreviation	Definition	Horizontal/vertical method error (mm)
Condylion	Co	Superior tangent on the mandibular condyle determined by a perpendicular tangent from the ramal plane.	0.28/0.18
Posterior condylion	PCo	Point on the posterior contour of the condyle defined by the superior tangent of the ramal plane.	0.20/0.22
Articulare	Ar	Intersection point of the inferior cranial base surface and the averaged posterior surfaces of the mandibular condyles.	0.13/0.20
Posterior gonion	PGo	Intersection point between the posterior contour of the mandibular ramus and its inferior tangent.	0.32/0.49
Gonion	Go	Point on the contour of the mandible determined by bisecting the angle formed by the mandibular plane and ramal plane.	0.57/0.87
Inferior gonion	IGo	Intersection point between the inferior contour of the mandibular corpus and its posterior tangent.	0.63/0.27
Menton	Me	Intersection point of the posterior symphyseal contour and the inferior contour of the corpus.	0.18/0.27
Gnathion	Gn	Point between menton and pogonion determined by bisecting the angle formed by the mandibular plane and its perpendicular tangent to pogonion.	0.36/0.18
Pogonion	Pg	Most anterior point on the contour of the chin, determined by a perpendicular tangent to the mandibular plane.	0.23/0.35
Point B	B	Point most posterior to a line from the infradentale to pogonion on the anterior surface of the symphyseal outline.	0.19/0.26

size, non-parametric procedures were used to compare changes over time within groups (Wilcoxon signed rank) and to evaluate group differences (Mann–Whitney *U*).

Results

While the bionator group was older than the control group at the start of treatment, the differences were not statistically significant. There were also no statistically significant gender differences in condylar growth, mandibular remodelling, mandibular displacement, and true mandibular rotation.

Significant ($P < 0.05$) horizontal growth and remodelling changes were observed within (T1–T2) and between the control and bionator groups (Table 3). The anterior corpus landmarks showed no significant horizontal changes in position. Both groups displayed posterior drift of bone in the gonial region (Figure 3a). The bionator group also showed significant posterior growth in the condylar region (Figure 3b). Posterior growth changes were greatest for the landmarks located in the gonial region. The bionator group showed significantly greater posterior growth for posterior gonion and condylion.

Both groups also displayed significant vertical growth changes in the gonial and condylar regions. The changes in the condylar region were consistently greater for the control than for the bionator group, while the changes in the gonial region were greater for the bionator group. None of the group differences was statistically significant.

All of the landmarks showed statistically significant total changes in position. The control group showed greater total changes in the condylar region, with group differences approaching significant levels. The bionator group showed greater changes in the gonial region; the group difference was statistically significant for posterior gonion ($P = 0.03$). Total changes for landmarks

Table 3 Mandibular growth and remodelling changes (mm) of the control and bionator samples.

	Control		Bionator		Group difference	
Point	Mean	SD	Mean	SD	Difference	*P* value
Horizontal						
B	0.29	0.65	0.16	0.71	0.13	0.622
Pg	0.24	0.40	–0.14	0.62	0.38	0.118
Gn	0.37	1.17	0.12	0.80	0.25	0.273
Me	0.08	1.72	0.13	1.55	0.07	0.681
IGo	–1.62*	1.33	–2.42*	2.53	0.79	0.187
Go	–1.41*	1.29	–2.33*	1.58	0.92	0.139
PGo	–0.73	1.57	–2.34*	1.24	1.61	0.018
Ar	0.30	1.60	–1.09*	1.13	0.78	0.351
PCo	0.16	2.54	–0.99*	1.33	1.15	0.112
Co	0.81	3.08	–0.90*	1.45	1.71	0.025
Vertical						
B	–0.36	1.32	0.14	0.69	0.50	0.426
Pg	–0.69	1.57	–0.28	0.98	0.41	0.338
Gn	–0.17	0.87	–0.13	0.99	0.04	0.701
Me	–0.57*	0.74	–0.41*	0.53	0.16	0.297
IGo	1.00	1.74	1.44*	1.28	0.44	0.427
Go	1.56*	1.67	1.82*	1.82	0.25	0.529
PGo	1.79	2.90	2.42*	2.44	0.62	0.396
Ar	3.12*	1.92	1.96*	1.91	1.16	0.147
PCo	3.43*	2.04	2.47*	1.81	0.95	0.239
Co	3.41*	2.44	2.46*	1.82	0.95	0.311
Total						
B	1.29*	0.76	0.88*	0.45	0.42	0.189
Pg	1.43*	0.99	0.99*	0.64	0.43	0.250
Gn	1.33*	0.62	1.09*	0.59	0.24	0.262
Me	1.71*	0.83	1.38*	0.91	0.32	0.262
IGo	2.37*	1.61	3.40*	2.05	1.03	0.273
Go	2.44*	1.68	3.49*	1.45	1.05	0.090
PGo	2.90*	2.40	3.95*	1.71	1.05	0.033
Ar	3.64*	1.58	2.75*	1.49	0.89	0.119
PCo	4.27*	1.88	3.02*	1.71	1.26	0.080
Co	4.62*	2.35	3.02*	1.73	1.60	0.080

See Table 2 for definitions.
*Significant ($P < 0.05$).
A minus sign signifies posterior and inferior change.
SD, standard deviation.

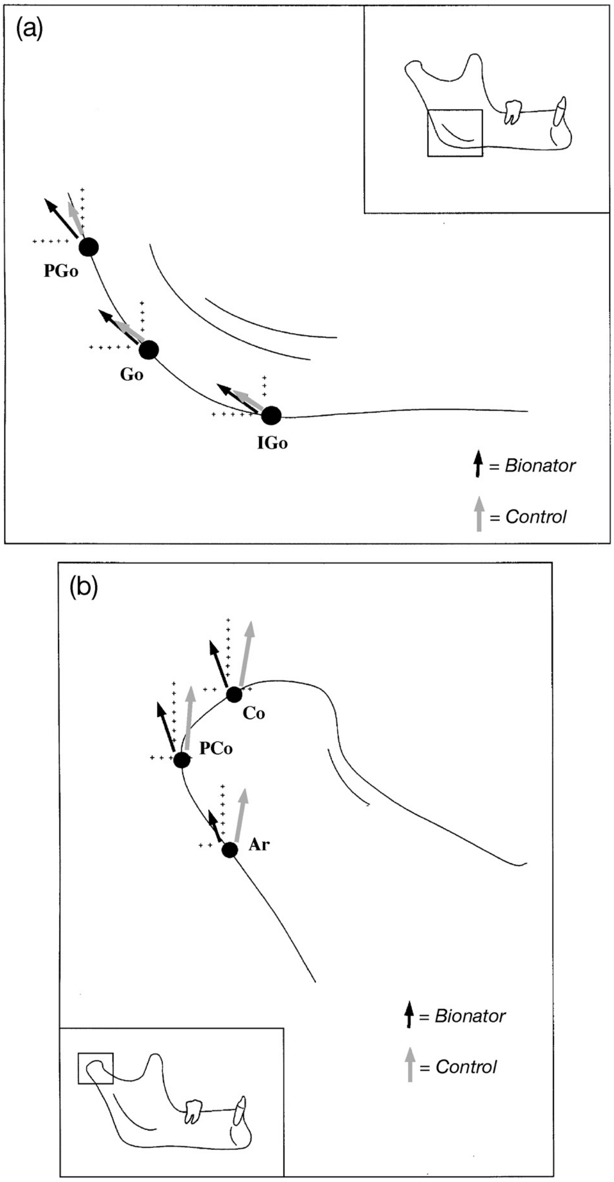

Figure 3 (a) Mandibular remodelling and (b) condylar growth after 1 year for the treated and untreated children with Class II malocclusions (+ = 0.5 mm).

located in the anterior corpus ranged between 0.9 and 1.7 mm, with no significant group differences.

Table 4 shows significant ($P < 0.05$) group differences in mandibular displacement and true rotation. The bionator group displayed significant ($P < 0.01$) anterior displacement; the control mandible showed slight posterior displacement of the fiducial landmarks. Group differences in horizontal displacement were statistically significant ($P < 0.01$) for all three fiducial landmarks. Both groups displayed significant inferior mandibular displacement; the bionator group showed significantly greater inferior displacement of the anterior fiducial landmark. Whereas the untreated control group showed significant forward mandibular true rotation, the bionator group displayed no rotational changes (Figure 4a, b).

Discussion

The control group in this study showed expected growth and remodelling patterns for most of the measurements. The mandible was displaced downward more than forward (Birkebæk *et al.*, 1984; Vargervik and Harvold, 1985; Spady *et al.*, 1992; Buschang and Gandini, 2002) and it underwent true forward rotation due to greater inferior displacement of its posterior aspect (Björk and Skieller, 1972; Mathews and Ware, 1978; Baumrind *et al.*,1992a; Buschang and Gandini, 2002). The condylar region displayed predominately superior growth (Enlow and Harris, 1964; Ødegaard, 1970a, b; Björk and Skieller, 1972; Mathews and Ware, 1978; Pancherz and Hägg, 1985; Baumrind *et al.*, 1992a; Buschang and Santos-Pinto, 1998; Buschang *et al*, 1999; Croft *et al.*, 1999; Ruf *et al.*, 2001; Buschang and Gandini, 2002), the gonial region showed apposition along the posterior border and resorption along the inferior border (Enlow and Harris, 1964; Björk and Skieller, 1972; Mathews and Ware, 1978; Baumrind *et al.*, 1992a; Croft *et al.*, 1999; Buschang and Gandini, 2002), and the anterior lower border of the mandible showed some apposition (Enlow and Harris, 1964; Björk and Skieller, 1972; Mathews and Ware, 1978; Baumrind *et al.*, 1992a; Buschang and Gandini, 2002).

These results suggest little or no change in the horizontal position of the condyle for untreated Class II subjects. Slight but definite posterior condylar growth changes have been previously reported for untreated subjects (Mathews and Ware, 1978; Pancherz and Hägg, 1985; Baumrind *et al.*, 1992a; Buschang and Santos-Pinto, 1998; Buschang and Gandini, 2002). Jakobsson and Paulin (1990) described a slight anterior condylar growth direction for 60 untreated Class II children. Differences between studies could be due to the methods used to quantify condylar growth direction. For example, the present study used the functional occlusal plane, while others have used the sella–nasion plane, which might be expected to produce a systematic difference. Moreover, the horizontal changes observed were small and highly variable, which may explain why they were not statistically significant. Greater variability in horizontal growth has been previously described for the condylar region (Björk and Skieller, 1972; Birkbæk *et al.*, 1984; Baumrind *et al.*, 1992a; Ruf *et al.*, 2001; Buschang and Gandini, 2002). Buschang and Gandini (2002) suggested that variability may be linked with response potential to biomechanical stimuli.

The results showed that functional appliance therapy changes the direction of condylar growth but does not increase the overall amount of condylar growth. Posterior redirection of condylar growth with functional

Table 4 Displacement (mm) at the fiducial landmarks (anterior, midpoint and posterior) and true mandibular rotation (degree) in the control and bionator samples.

	Control		Bionator		Group difference	
	Mean	SD	Mean	SD	Difference	*P* value
Horizontal displacement						
Anterior	–1.13	2.16	1.97*	3.20	3.11	0.010
Midpoint	–1.27	2.21	2.00*	3.12	3.28	0.006
Posterior	–1.42	2.27	2.03*	3.07	3.45	0.004
Vertical displacement						
Anterior	0.64	1.77	2.68*	1.60	2.03	0.012
Midpoint	1.88*	1.49	2.72*	1.70	0.84	0.338
Posterior	3.11*	1.61	2.76*	2.43	0.35	0.324
True rotation	–2.53	1.58	–0.17	2.27	2.36	0.014

*Significant ($P < 0.05$).
Negative values signify posterior and superior movements, and forward rotation.
SD, standard deviation.

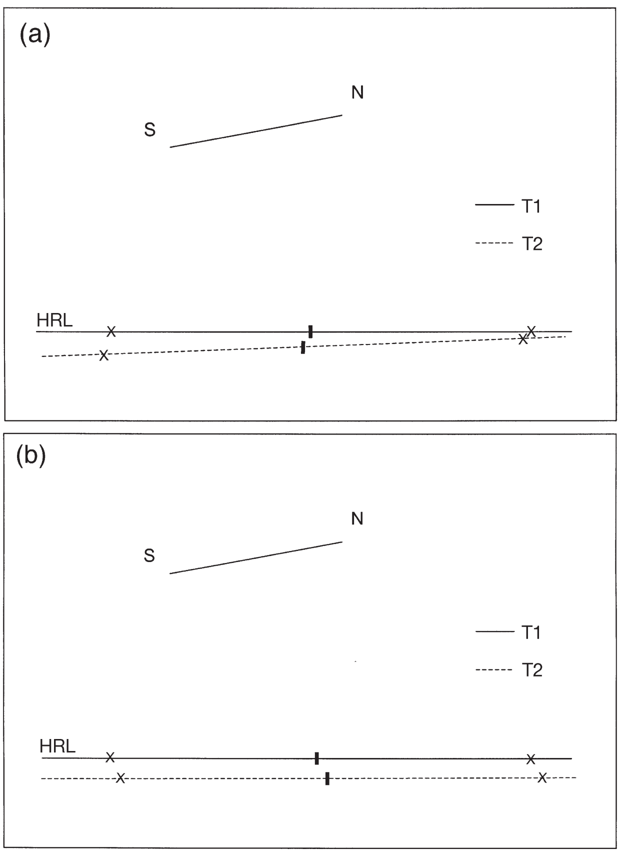

Figure 4 Displacement and rotation of the three fiducial landmarks (anterior, midpoint, posterior) for (a) the control group and (b) the bionator group (T1 = pre-treatment; T2 = follow-up).

appliances is well established for humans (Hultgren *et al.*, 1978; Williams and Melsen, 1982b; Birkebæk *et al.*, 1984; Vargervik and Harvold, 1985; Pancherz and Hägg, 1985; Op Heij *et al.*, 1989; Jakobsson and Paulin, 1990; Paulsen, 1997; Pancherz *et al.*, 1998; Croft *et al.*, 1999; Ruf *et al.*, 2001) and experimental animals (Petrovic *et al.*, 1975; Woodside *et al.*, 1983; McNamara and Bryan, 1987). Because posterior growth increased and superior growth decreased slightly, overall condylar growth was not significantly different from the controls. Jakobsson and Paulin (1990) also showed no differences in overall condylar growth with the Andresen appliance. Interestingly, untreated subjects who undergo less forward mandibular rotation and more posteriorly directed condylar growth also display less overall condylar growth (Björk, 1969; Ødegaard, 1970a, b; Lavergne and Gasson, 1976; Dibbets, 1990; Spady *et al.*, 1992; Baumrind *et al.*, 1992a; Buschang and Gandini, 2002), suggesting that the lack of rotation associated with functional appliances may have an inhibitory effect on the amount of growth.

To put the observed condylar growth changes into perspective, it is important to distinguish between actual condylar growth and overall mandibular growth. The former is site specific and requires a mandibular superimposition; the latter pertains to increases in mandibular length '*in toto*'. There is substantial literature reporting statistically significant increases in overall mandibular growth associated with functional appliances (Op Heij *et al.*, 1989; McNamara *et al.*, 1990; Mills, 1991; Nelson *et al.*, 1993; Illing *et al.*, 1998; Ghafari *et al.*, 1998; Keeling *et al.*, 1998; Toth and McNamara, 1999; Almeida *et al.*, 2002). Even though mandibular length increases more with functional appliances, it does not mean that actual condylar growth is increased. A more posteriorly directed condylar growth will necessarily increase overall mandibular growth even though actual condylar growth remains unchanged. Changes in mandibular length should not be interpreted as growth increases without an evaluation of condylar growth amount and direction.

Associated with posterior condylar growth redirection, there was less true forward mandibular rotation for the treated patients than for controls in the present study. The relationship between condylar growth direction and mandibular rotation is well established for untreated subjects (Björk, 1969; Ødegaard, 1970a, b; Lavergne and Gasson, 1976; Dibbets, 1990; Spady *et al.*, 1992; Baumrind *et al.*, 1992a; Buschang and Gandini, 2002). From the vertical perspective, the bionator group showed relatively more displacement anteriorly and less displacement posteriorly. In other words, the bionator postures the mandible forward, and also rotates the mandible. This suggests that the bionator prevents or interferes with the normal rotational changes, as previously suggested (Hultegren *et al.*, 1978; Birkebæk *et al.*, 1984). Greater than expected increases in lower face height have been consistently reported with functional appliances (Righellis, 1983; Nielsen, 1984; Pancherz and Hägg, 1985; McNamara *et al.*, 1990; Mills, 1991; Croft *et al.*, 1999). Increased anterior lower face height without compensatory forward mandibular rotation produces relative mandibular retrusion (McNamara, 1984; Toth and McNamara, 1999), which could, overtime, obviate the positive effects of functional appliance therapy.

The remodelling changes and group differences observed in the gonial region can also be related to the displacement patterns observed. Increased posterior growth in the gonial region, representing compensations for forward mandibular repositioning, might be expected to occur in both treated and untreated subjects (Mojdehi *et al.*, 2001; Buschang and Gandini, 2002). The present results support the notion that a repositioned mandible will undergo predictable remodelling changes.

Further studies are necessary to verify these results. Due to the small sample sizes, it is possible that the differences in the age and sex distributions at T1 could have biased the results. While the groups were randomly allocated, the bionator group was marginally older and with a slightly higher proportion of males than the control group (64 versus 55 per cent).

Conclusions

Based on this randomized clinical implant study of 25 patients followed longitudinally for 1 year, it is concluded that bionator therapy:

1. Alters the direction (greater posterior) but not the amount of condylar growth.
2. Produces greater than expected posterior drift of bone in the condylar and gonial region.
3. Displaces the mandible anteriorly but limits the amount of true mandibular forward rotation that would normally occur.

Address for correspondence

P. H. Buschang
Department of Orthodontics
Baylor College of Dentistry
Texas A&M University System Health Science Center
3302 Gaston Avenue
Dallas TX 75246
USA

Acknowledgement

This research was supported by CAPES—Brazil.

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