Original Article

Use of the Clark Twin Block functional appliance with and without an upper labial bow: a randomized controlled trial

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ABSTRACT

Objectives: To compare dentoalveolar and skeletal changes in two groups of Class II division 1 patients treated with different designs of Clark's Twin Block (CTB), with (Group 1) or without (Group 2) an upper labial bow.

Materials and Methods: A randomized controlled trial was conducted in the Department of Orthodontics at the East Kent Hospitals University NHS Foundation Trust, UK. Sixty-two white subjects (aged 10–14 years at the start of treatment, minimum overjet $>$ 6 mm, molar relationship at least ½ unit Class II) were recruited. Subjects were divided into age- and sex-matched pairs, were randomly allocated to treatment with either appliance design, and were treated for 12 months, at which time additional data were collected.

Results: Sixty participants were available for final data collection. The two groups were well matched with respect to age (mean 12.5 years in Group 1; 12.3 years in Group 2). No statistical difference was noted between groups for any dentoalveolar or skeletal variables measured. Both groups experienced a reduction in overjet as a result of maxillary incisor retroclination, mandibular incisor proclination, and forward positioning of the pogonion. Maxillary molar distalization, mandibular molar mesialization, and ANB reduction also occurred in both groups.

Conclusions: The addition of a maxillary labial bow to the CTB has no influence on dentoalveolar or skeletal changes, or on rate of overjet reduction, in relation to appliance therapy. (*Angle Orthod.* 2012;82:363–369.)

KEY WORDS: Clark Twin Block; Labial bow; RCT; Effectiveness

INTRODUCTION

Functional appliances contribute to Class II correction in growing patients through a combination of dentoalveolar and skeletal effects. Skeletal change has been shown to account for approximately one-third of the decrease in overjet that is seen in successful cases, with the remainder predominantly maxillary incisor retroclination.[1]

Anterior repositioning of pogonion is desirable when mandibular retrognathia contributes to a Class II malocclusion;[2] however, excessive dentoalveolar and rotational changes may limit this anterior translation of the mandible. The original design of the Clark Twin Block (CTB) appliance incorporated a maxillary labial bow.[3] However, in an attempt to reduce incisor retroclination and to maximize skeletal effects of the appliance, many clinicians choose to omit this component. Alternative modifications have been investigated in an attempt to promote skeletal change and limit dentoalveolar movements, including torquing spurs on the upper incisors,[4] Southend clasps,[5] and the addition of headgear.[6]

To date, no direct investigations have explored the overall effects of the upper labial bow on the outcome of CTB therapy. Although it does contribute to retention, the labial bow is unesthetic, and in the absence of clear advantages, it could be eliminated from the basic appliance design. Indeed, the presence

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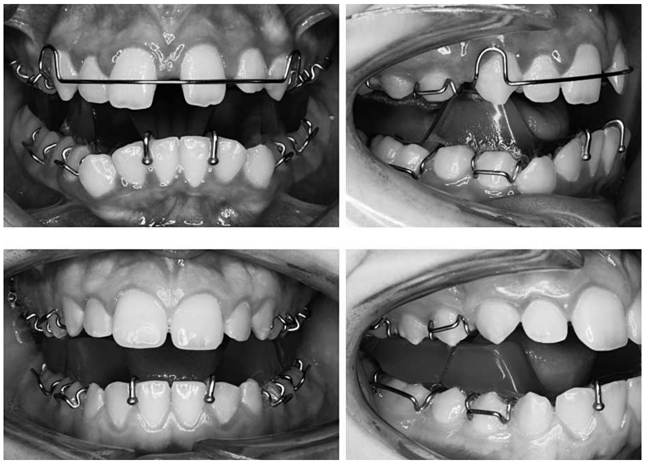

Figure 1. Subjects were allocated for treatment with a CTB-LB (upper panels) or a CTB-NLB (lower panels).

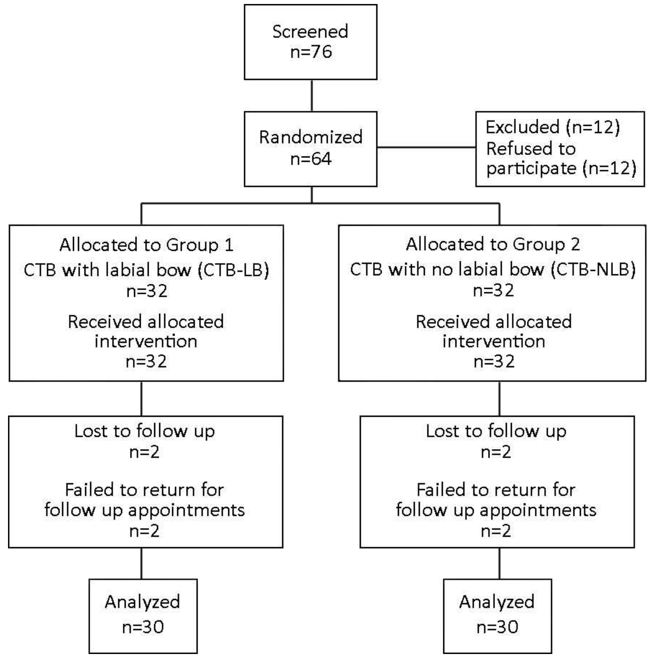

Figure 2. CONSORT flow diagram of subjects through each stage of the study.

of excessive maxillary incisor retroclination at the expense of skeletal change would, in most cases, be regarded as a disadvantage. The aims of this study were to investigate whether the addition of a maxillary labial bow has any effect on the inclination of the maxillary incisors and the magnitude of skeletal change that can be achieved in relation to conventional CTB appliance therapy.

MATERIALS AND METHODS

This study was a randomized controlled trial carried out in the Orthodontic Department at Kent and Canterbury Hospital. Ethical approval was obtained from the East Kent Research Ethics Committee (08/H1103/66). Subjects included in the study satisfied the following criteria:

- Class II division 1 incisor relationship (British Standards Institute).
- Overjet greater than 6 mm.
- Aged 10–14 years at the start of treatment.
- Molar relationship at least a half unit Angle Class II.
- White ethnic origin.
- No previous history of orthodontic therapy or permanent tooth extraction.
- No significant or adverse medical history or craniofacial syndrome.

Participants who met these inclusion criteria were recruited from the orthodontic functional appliance treatment waiting list and were provided with information describing the purpose of the study. Written consent was obtained from both patients and parents.

Sample Size

Based on previous research and statistical analysis, a minimum of 52 subjects were required (26 in each group) for the study to have a power of 0.95 to detect a significant difference of 5 degrees in upper incisor retroclination at the 5% significance level. To compensate for attrition of the sample, 64 subjects were recruited overall. Power calculations were performed on G*Power 3 (Institute for Experimental Psychology, Dusseldorf, Germany).

Randomization Procedure

A stratified allocation sequence was generated using an electronic computer program. Patients were stratified according to age and gender. All patients were placed into age- (±2 mo) and gender-matched pairs. Pairs of patients were matched according to age and sex, with one patient from each pair randomly selected and allocated to either treatment group (using www.random.org). The prescribed appliance for Group 1 incorporated a passive upper labial bow (CTB-LB); for Group 2, the appliance was constructed with no labial bow (CTB-NLB) (Figure 1). The treating clinician was blinded from the randomization procedure, but because of clear differences in appliance design, blinding was not possible during the treatment period. A CONSORT diagram showing the flow of patients through the trial is provided in Figure 2. Sixty-four participants were recruited from a cohort of 76 who were screened, with 12 declining to participate. Among these, 32 were allocated to each treatment group. A total of 60 (30 in each group) were available for final data collection, and 4 (2 from each group) dropped out as they failed to attend their follow-up appointments.

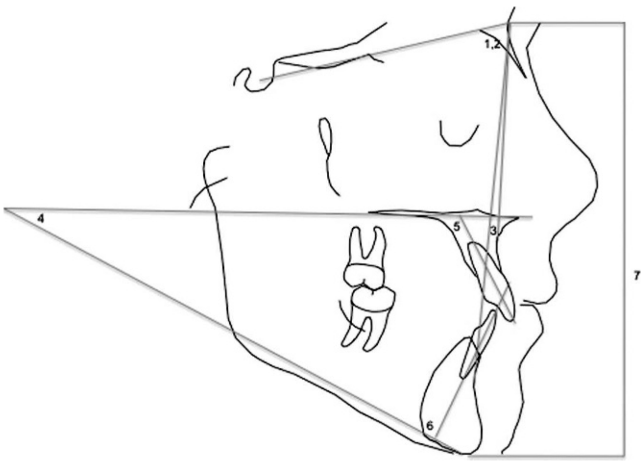

Figure 3. Eastman analysis. (1) Sella-nasion-A point (SNA). (2) Sella-nasion-B point (SNB). (3) A point-nasion-B point (ANB). (4) Maxillary-mandibular planes angle (MMPA). (5) Upper incisor-maxillary plane (UI). (6) Lower incisor-mandibular plane (LI). (7) Nasion-menton anterior face height (AFH).

Appliance Design and Clinical Management

All appliances were constructed by senior orthodontic technicians at the Kent and Canterbury Hospital orthodontic laboratory using self-curing acrylic. The general design of the modified CTB involved the following:

- Adams clasps on first permanent molars and premolars in both arches (0.7 mm stainless steel).
- A midline screw that was turned once per week.
- Ball-ended clasps on the mandibular incisors (0.7 mm stainless steel).
- Upper and lower acrylic blocks with inclined planes at 70 degrees to the occlusal plane.
- For those in Group 1, the CTB-LB incorporated a passive upper labial bow extending from canine to canine tooth and constructed from 0.7 mm stainless steel.

All treatment was carried out by one operator under the supervision of a senior clinician with 15 years' experience in use of the CTB. The functional bite for both appliance designs was taken with the patient biting forward in the maximum protrusion that was comfortable. This allowed an overjet of up to 10 mm to be corrected with a single advancement. If full overjet correction was not possible with initial advancement, the appliance was reactivated in treatment by adding cold-cured acrylic to the upper blocks. Participants were instructed to wear the CTB full time, removing the appliance for cleaning twice daily and during contact sporting activities. The upper midline expansion screw was turned 0.2 mm once a week, until the necessary transverse expansion was achieved. Each participant was reviewed at intervals of 8 weeks over the 12 months of active appliance therapy. The period of wear was standardized at 12 months to optimize skeletal change, reduce relapse, and avoid the need to annualize growth from radiographs taken at different time periods.

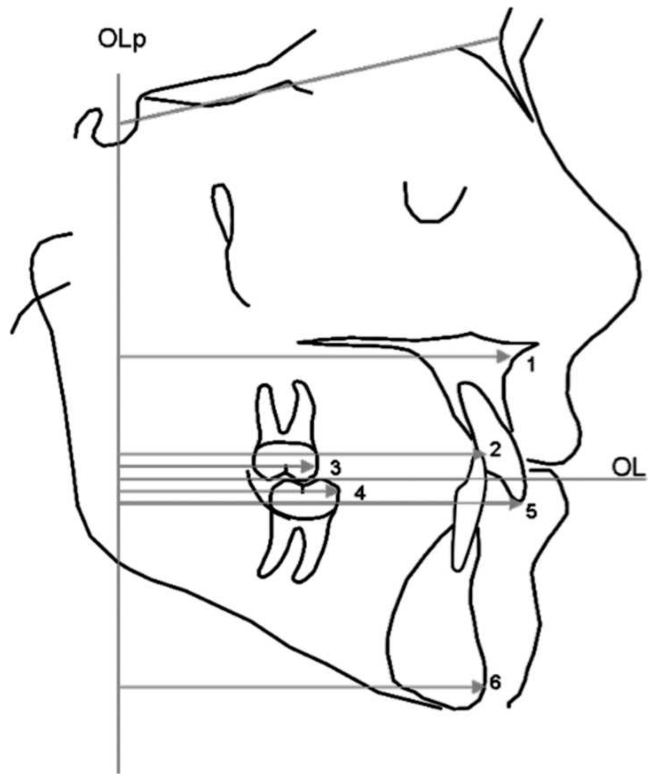

Figure 4. Pancherz analysis. OL: line drawn tangent to disto-buccal cusp of maxillary first permanent molar and bisecting the incisal vertical overbite. OLp: a line perpendicular to OL through sella. Sp: (subspinale) deepest point on the anterior contour of the maxillary alveolar projection by tangent perpendicular to OL. Ii (incision inferius): the incisal tip of the most prominent mandibular central incisor. Is (incision superius): the incisal tip of the most prominent maxillary central incisor. Ms (molar superius): the mesial contact point of the maxillary permanent first molar determined by a tangent to OL. Mi (molar inferius): the mesial contact point of the mandibular permanent first molar determined by a tangent perpendicular to OL. Pg (pogonion): the most prominent point on the bony chin determined by a tangent perpendicular to OL. (1) Sp/OLp. (2) Li/OLp. (3) Ms/OLp. (4) Mi/OLp. (5) Pg/OLp.

Data Collection

Data obtained included routine pretreatment study models, photographs, and radiographs (cephalometric lateral skull and dental panoramic tomography) (T1). An additional set of routine posttreatment study models, photographs, and radiographs were taken after 12 months of active appliance therapy (T2).

Pretreatment and posttreatment cephalometric lateral skull radiographs were corrected for magnification and underwent a modified Eastman and Pancherz

Table 1. Error Analysis

Variable	Difference: Average (SD)	(95% Limits of Agreement)	Correlation Between Difference and Mean
Ii/OLp, mm	0.150 (0.671)	(−1.165, 1.465)	0.353
Is/OLp, mm	0.100 (0.718)	(−1.308, 1.508)	−0.263
Mi/OLp, mm	0.100 (0.788)	(−1.445, 1.645)	0.282
Ms/OLp, mm	0.100 (0.553)	(−0.983, 1.183)	−0.004
Sp/OLp, mm	−0.200 (1.005)	(−2.170, 1.770)	0.181
Pg/OLp, mm	0.100 (0.852)	(−1.570, 1.770)	0.262
ANB, degrees	−0.100 (0.641)	(−1.356, 1.156)	−0.479
UI, degrees	0.000 (0.562)	(−1.101, 1.101)	0.051
LI, degrees	−0.050 (0.686)	(−1.395, 1.295)	−0.021
MMPA, degrees	−0.150 (0.366)	(−0.868, 0.568)	−0.272
AFH, mm	−0.250 (0.786)	(−1.791, 1.291)	−0.579

analysis[7,8] (Figures 3 and 4, respectively). Tracings were carried out in a blind manner by one researcher. Twenty cephalometric tracings were repeated after a period of 2 weeks to assess method error. This confirmed good agreement between the two sets of cephalometric measurements for all outcomes examined (Table 1).

Statistical Analysis

Initially, measurements were analyzed separately for males and females. No significant gender-related differences were detected; therefore, the data were combined. Descriptive statistics, including means and standard deviations for demographic and clinical characteristics, were calculated.

Graphical observation of the data suggested that they conformed to a normal distribution. The influence of the addition of the labial bow on the outcomes of interest was assessed by analysis of variance (ANOVA). Additionally, linear regression was used to calculate the rate of change in overjet over the 12-month period at intervals of 3 months; an unpaired *t*-test was used to compare the two groups. All groups were tested for group differences at the start and the end of the treatment period. Statistical significance was prespecified at $P < .05$.

RESULTS

The groups were well matched with respect to age, with a mean age of 12.5 years (range, 10.5–13.5 y) in Group 1 and 12.3 years (range, 10.8–13.2 y) in Group 2. Unpaired *t*-tests confirmed no significant differences between groups with respect to pretreatment cephalometric baseline values (Table 2).

Results of the cephalometric analyses carried out on both groups are shown in Table 3. The maxillary incisors retroclined by more than 10 degrees among participants treated with the CTB-LB in Group 1; the corresponding value was 2.4 degrees less for those treated with the CTB-NLB in Group 2. However, ANOVA confirmed that no statistical difference was noted between the presence of an upper labial bow and maxillary incisor inclination change during treatment ($P = .94$). Anterior face height increased by 5.83 mm (SD = 5.51 mm) in Group 1 and by 5.53 mm (SD = 3.99 mm) in Group 2; however, no statistically significant difference was observed between appliances. The maxillary-mandibular planes angle (MMPA) increased by 0.63 degrees (SD = 1.83 degrees) in Group 1, in contrast to 0.37 degrees (SD = 2.22 degrees) in Group 2. Again, no statistical difference between groups was noted. The ANB angle decreased by 2.83 degrees (SD = 2.12 degrees) in Group 1 and

Table 2. Baseline Cephalometric Variables

Variable	CTB-LB (Group 1), Mean (SD)	CTB-NLB (Group 2), Mean (SD)	Difference, Mean (95% CI)	*P* Value
Ii/OLp, mm	77.3 (4.1)	75.0 (5.4)	2.3 (−0.2, 4.8)	.07
Is/OLp, mm	88.0 (4.6)	86.5 (5.0)	1.6 (−0.9, 4.0)	.21
Mi/OLp, mm	52.3 (4.1)	50.6 (5.3)	1.7 (−0.7, 4.1)	.17
Ms/OLp, mm	53.9 (4.5)	52.2 (4.1)	1.7 (−0.6, 3.9)	.14
Sp/OLp, mm	79.8 (4.3)	77.8 (5.5)	2.0 (−0.5, 4.6)	.12
Pg/OLp, mm	77.5 (4.8)	76.9 (6.2)	0.6 (−2.3, 3.4)	.68
ANB, degrees	6.9 (2.5)	6.0 (1.6)	0.9 (−0.2, 2.0)	.10
UI, degrees	121.9 (5.9)	121.2 (7.5)	0.7 (−2.8, 4.2)	.71
LI, degrees	93.3 (5.4)	92.1 (4.7)	1.2 (−0.6, 4.9)	.20
MMPA, degrees	24.4 (5.5)	25.4 (5.3)	−1.0 (−3.9, 1.9)	.49
AFH, mm	111.3 (6.8)	111.8 (5.6)	−0.5 (−3.7, 2.8)	.77

Table 3. Effects of Appliance on Cephalometric Measurements

Variable	CTB Design	Mean	SD	*t*	Significance Test
ii/OLp	CTB-LB	6.30 mm	3.26	1.42	*P* = .92
	CTB-NLB	7.30 mm	2.30		
is/OLp	CTB-LB	2.07 mm	3.63	0.98	*P* = .83
	CTB-NLB	1.17 mm	3.50		
mi/OLp	CTB-LB	5.40 mm	3.07	1.67	*P* = .95
	CTB-NLB	6.63 mm	2.63		
ms/OLp	CTB-LB	−0.40 mm	3.11	0.15	*P* = .44
	CTB-NLB	−0.53 mm	3.85		
sp/OLp	CTB-LB	1.30 mm	4.61	0.46	*P* = .68
	CTB-NLB	1.77 mm	3.08		
pg/OLp	CTB-LB	4.50 mm	3.94	1.50	*P* = .93
	CTB-NLB	6.00 mm	3.81		
SNA	CTB-LB	−1.03 degrees	2.72	1.39	*P* = .92
	CTB-NLB	−0.03 degrees	3.19		
SNB	CTB-LB	1.83 degrees	2.39	1.08	*P* = .86
	CTB-NLB	2.63 degrees	3.29		
ANB	CTB-LB	−2.83 degrees	2.12	0.49	*P* = .31
	CTB-NLB	−3.07 degrees	1.51		
UI	CTB-LB	−10.13 degrees	5.99	1.54	*P* = .94
	CTB-NLB	−7.73 degrees	6.12		
LI	CTB-LB	4.63 degrees	3.60	0.67	*P* = .75
	CTB-NLB	5.33 degrees	4.44		
MMPA	CTB-LB	0.63 degrees	1.83	0.51	*P* = .69
	CTB-NLB	0.37 degrees	2.22		
AFH	CTB-LB	5.83 mm	5.51	0.24	*P* = .41
	CTB-NLB	5.53 mm	3.99		

by 3.07 degrees (SD = 1.51 degrees) in Group 2, reflecting a slightly greater decrease in SNA in Group 1 (SD = 1.03 degrees) and an SNA value that was almost unchanged in Group 2. Conversely, SNB increased slightly more in Group 2, although this difference failed to reach statistical significance (*P* = .86). The mandibular incisors were proclined relative to the mandibular plane in both groups. The amount of proclination increased by 4.63 degrees (SD = 3.6 degrees) in Group 1 and by 5.33 degrees (SD = 4.44 degrees) in Group 2. Mandibular first molars moved anteriorly by 5.40 mm (SD = 3.07 mm) and 6.63 mm (SD = 2.63 mm) in Groups 1 and 2, respectively. Maxillary molars were distalized slightly in both groups (range, 0.4–0.53 mm). Pogonion moved forward by 4.5–6 mm in both groups, with 1.5 mm more forward movement arising in Group 2. However, the intergroup difference also failed to reach statistical significance (*P* = .93).

Differences in the rate of overjet reduction are shown in Table 4. Results demonstrate no significant differences between groups in terms of any overjet variable. The two groups were not found to differ at baseline, at 12 months, or in terms of rate of change of overjet values during the study (Figure 5).

DISCUSSION

The overall effects of CTB appliance therapy have been the subject of several investigations.[1,4–6,9–12] The main aim of this study was to compare the effect on treatment response of incorporating a maxillary labial bow in the core CTB appliance design in a matched sample of Class II division 1 subjects. Both appliance designs were effective in producing complete or partial correction of the overjet during the period of observation. This correction was achieved by a combination of dentoalveolar and, to a lesser extent, skeletal change.

Table 4. Rate of Overjet Reduction Between Groups

Measurement	CTB-LB (Group 1), Mean (SD)	CTB-NLB (Group 2), Mean (SD)	Mean Difference (95% CI)	*P* Value
Baseline	10.0 (1.4)	10.4 (1.6)	−0.4 (−1.2, 0.3)	.23
3 months	6.0 (2.2)	5.8 (2.0)	0.2	.67
6 months	3.3 (2.0)	4.1 (2.1)	−0.8	.14
9 months	2.4 (1.5)	2.9 (1.9)	−0.5	.30
12 months	2.0 (1.3)	2.2 (1.4)	−0.2 (−2.8, 0.6)	.71
Rate of change	−0.65 (0.16)	−0.65 (0.14)	0.0 (−0.08, 0.08)	.98

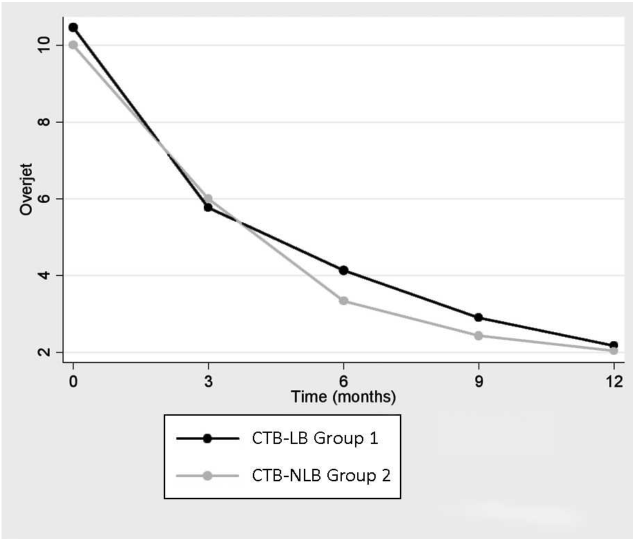

Figure 5. Rate of overjet reduction between groups during the study.

Dentoalveolar changes included retroclination of the maxillary incisors, proclination of the mandibular incisors, mesial movement of the mandibular buccal segments, and distal movement of maxillary buccal segments. These findings were in broad agreement with those of previous authors.[1,8,9,11,13] A limitation of this study is that it analyzed only short-term effects of the CTB appliance. Long-term follow-up will be required to ascertain whether the reported changes are permanent.

No previous study has prospectively and randomly compared treatment effects with CTB functional appliances constructed with or without a labial bow. Evidence from previous studies suggests that use of an upper labial bow with a CTB will produce some retroclination of the maxillary incisors; however, the use of spurs or, indeed, the absence of a labial bow can also produce this effect (Table 5).

Therefore, the presence or absence of a labial bow appears to have a variable and unpredictable influence on dentoalveolar changes arising during CTB therapy. This study reinforces these findings; no statistically significant differences in dentoalveolar or skeletal outcome were noted between groups treated with the CTB-LB or the CTB-NLB. Advocates of incorporating a labial bow within the core design of a CTB argue that it can aid retention, facilitate retroclination of a proclined upper labial segment, and maximize overjet reduction. Opponents suggest that the labial bow compromises esthetics and can result in overcorrection of the incisors, increasing the interincisal angle, deepening the overbite, maximizing dentoalveolar change, and compromising potential skeletal change. These effects are particularly relevant in relation to the anterior movement of the pogonion, as greater dentoalveolar change has been reported to result with greater skeletal rotation and downward and backward repositioning of the pogonion, which is usually undesirable and is termed the *activator effect.*[14] This effect has similarly been reported for the use of headgear in Class II correction. In this study, forward positioning of the pogonion measured for both appliance designs compares favorably with that reported from a previous study investigating the effects of a CTB-LB design using the Pancherz analysis.[15]

Table 5. Incisor Retroclination Using the Twin Block

Investigation	CTB Design	UI Retroclination
Harradine and Gale, 2000	Labial bow	8.4
Harradine and Gale, 2000	Spurs	7.6
Gill and Lee, 2005	No labial bow	8.0
Gill and Lee, 2005	Spurs	4
O'Brien et al., 2003	No labial bow	3.11
Parkin et al., 2001	Labial bow	11
Parkin et al., 2001	Spurs	6.9
Trenouth, 2000	Labial bow	7.2
Mills and McCulloch, 1998[20]	No labial bow	5.6
Illing et al., 1998	No labial bow	5.7
Lund and Sandler, 1998	Labial bow	10.8

Comparison with other studies is more difficult because different cephalometric analyses have been used, and although this study hinted that there was greater anterior positioning of the pogonion without the labial bow, and therefore less backward rotation or "headgear effect," this finding was not statistically significant. It has been argued that in most cases a labial bow is not necessary, with the edge-to-edge construction bite encouraging a lip seal as the appliance is worn, and resulting lip pressure acting to retract the upper incisors without the need for a labial bow.[16] This investigation suggests that both of these arguments are true.

The potential disadvantage of compromised retention associated with lack of a labial bow was not seen in this study. One of the main problems with removable functional appliances is poor patient cooperation, with discontinuation rates between different appliances primarily reflecting design. One of the main advantages of the CTB is the fact that it is well tolerated and has a low discontinuation rate, which varies between 9% and 33%[4,10] and compares favorably with that of other functional appliances, including the Bass appliance (28%),[10] the bionator (25%),[17,18] and the functional regulator (up to 42%).[19] In this study, the overall discontinuation rate was 6.25%. It is therefore reasonable to assume that the inclusion of a labial bow in terms of esthetics or retention had no effect on a patient's willingness or ability to wear the appliance. Compliance during treatment was assessed clinically by the reduction in overjet, the change in the molar relationship, the patient's speech with the appliance in situ, and the general wear and tear of the appliance.

When compliance was deemed inadequate, reinstruction and encouragement were given. Compliance overall in this study compares favorably with that in previous studies, and although it is difficult to ascertain why this is so, it is probably, at least in part, due to careful clinical management, the experience of the supervising clinician (Dr DiBiase) with the appliance, and possibly the fact that the patients knew they were in a study.

Overall, the results of this investigation would suggest that in white children with a moderate Class II division 1 malocclusion, the CTB performs similarly in terms of dentoalveolar and skeletal change when designed with or without a labial bow.

CONCLUSION

Children with a Class II division 1 malocclusion treated with a CTB designed with or without a maxillary labial bow show the following:

- No statistically significant differences in maxillary incisor retroclination.
- No statistically significant differences in the amount of skeletal change.
- No statistically significant differences in the rate of overjet reduction.
- An upper labial bow can be excluded from the design of a CTB with no detrimental treatment effect.

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