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The effect of an anterior biteplate on dental and skeletal Class II correction using headgears: a cephalometric study

Structured Abstract

Authors – Thurman MM, King GJ, Ramsay DS, Wheeler TT, Phillips, C **Objective** – To test the hypothesis that there are significant differences in skeletal and/or dental changes between Class II subjects treated with headgear (HG) compared with those treated with HG plus maxillary acrylic biteplate (BP) discluding teeth.

Setting and Sample Population – Secondary analysis performed in Department of Orthodontics at the University of Washington. Fifty pre-adolescent Class II subjects were treated with HG as part of a randomized clinical trial (RCT) at the University of North Carolina/Chapel Hill, and 81 similar subjects were treated with HG plus a flatplane maxillary anterior BP for occlusal separation and anterior labial bow at the University of Florida as part of a separate RCT.

Material and Methods – This retrospective cohort study examined anteroposterior (AP) and vertical cephalometric changes in two cohorts of Class II subjects. Pre- and post-treatment cephalometric radiographs for each group were obtained from the two centers and measured for dental and skeletal changes. These data were adjusted for differences in magnification and compared using ANCOVA, controlling for important cohort and protocol differences between the two centers.

Results – Overbite and maxillary incisor inclinations were reduced significantly more in the HG/BP group. All other vertical and AP changes were not statistically significantly different between the groups.

Conclusion – The maxillary anterior BP with labial bow is an effective appliance for reducing overbite and retracting incisors but provides no additional AP dental or skeletal benefit over HG treatment.

Key words: biteplate; cephalometric; Class II malocclusion; headgear

Introduction

Class II malocclusions present with multiple combinations of dental, skeletal, and esthetic problems, each with its own set of solutions. Orthodontists have used a variety of mechanical approaches for Class II correction, including headgear (HG), functional appliances (1, 2), tissue, and implant-supported intra-arch molar distalization (3–5), and intermaxillary traction (6). Yet, the comparative effectiveness of these various treatment approaches remains incomplete. One method for improving

anteroposterior (AP) skeletal discrepancies in Class II malocclusions applies posteriorly directed extraoral forces to the maxilla during a time of facial growth (1, 2). Consequently, the HG appliance has been studied extensively and has gained widespread acceptance as an effective mean for correcting AP discrepancies. Nevertheless, the role that the dental occlusion may play in this type of correction remains unclear.

Previous studies have shown that during adolescence, the mandible grows more than the maxillary complex in an AP direction, and this mandibular growth continues for a longer period than other parts of the craniofacial complex (7). Consequently, the mandible becomes positioned more anteriorly relative to the maxilla, and the facial profile becomes less convex. Yet, Class II malocclusions usually do not self-correct but persist despite these favorable skeletal growth changes (8). This begs the question: if the skeletal base discrepancy in Class II malocclusions decreases with age, why do the dental relations not follow suit? Recent studies (9) suggest that dentoalveolar compensation mediated through intercuspation of the dentition may contribute to the maintenance of these malocclusions despite this favorable growth trend.

As dentoalveolar compensations clearly exist in untreated growing patients (9), it seems reasonable that separating the dentition during Class II treatment may prevent these adaptations and thereby permit more efficient Class II dental correction. Although there are multiple rationales for and against the use of a biteplate (BP) in conjunction with a HG in Class II corrections, including reduction in excessive tooth wear, need for greater patient compliance, speech concerns, changes in appliance 'fit' as primary teeth are shed, laboratory costs, and esthetics; many clinicians also prescribe a BP with the objective of avoiding dentoalveolar impediments to the full expression of differential jaw growth. The hypothesis of this study is that Class II patients treated with the HG/BP combination will experience better AP corrections than those treated with HG alone. Therefore, the purpose of this cephalometric analysis of two treatment approaches evaluated in separate randomized clinical trials was to determine whether there are significant differences in skeletal and/or dental changes between Class II subjects treated with HG alone compared to those treated with HG plus a maxillary acrylic BP designed to disclude the posterior teeth.

Materials and methods Sample

The HG/BP group consisted of 81 subjects treated at the University of Florida as part of a randomized Controlled trial (RCT) (2). The original inclusion criteria for these patients were as follows: bilateral end-end Class II molar relationship or greater (judged clinically), fully erupted first permanent molars, presence of not more than three permanent cuspids or bicuspids, positive overbite and overjet, good oral health, and a willingness to participate in the study. If required, some patients received preparatory incisor alignment with a partial fixed appliance (2×4) to produce over equal to or greater than the molar discrepancy prior to HG/BP treatment. Following this pre-treatment phase, these fixed appliances were removed and baseline (T1) records were taken. Thus, the pre-treatment phase was not included in the total treatment time. The mandibular plane angle (MPA; Figure 2, angle 6) was used to determine the type of headgear used. Patients received either cervical pull HG (MPA <40°) or a highpull HG (MPA $> 40^{\circ}$), and a flatplane anterior maxillary acrylic BP with labial bow and molar circumferential clasps designed to disclude posterior teeth. There was a median time of 26.6 months between the T1 and post-HG treatment (T2) cephalograms. These subjects were instructed to wear the BP full time, removing it for eating, brushing, and contact sports, and told to wear the HG 14 h each day. The headgears were adjusted at each appointment to deliver 16 ounces of force per side, and BPs were adjusted to prevent posterior dental occlusal contacts. T1 cephalograms were taken immediately before HG treatment began and T2 radiographs at the completion of phase 1 HG/BP therapy. The protocol mandated stopping HG/BP treatment when a Class I molar relationship was achieved or after 24 months. T2 records were taken on all patients who remained in the study, and all of these cephalometric radiographs were included in the current sample regardless of the success or failure with achieving a Class I molar relationship. An 'intent to treat' analysis was reported and found not to impact the original randomization on any of the important variables (10). Digital copies of these cephalograms were obtained from the study PI (TW).

The HG group consisted of 50 subjects treated with a combination HG only at the University of North

Carolina in conjunction with another RCT (1). The original inclusion criteria for this group were as follows: presence of an overjet of 7 mm or greater (determined clinically), mixed dentition, developmentally at least a year before peak pubertal growth, having received no previous orthodontic treatment, and a willingness to participate in the study. A moderate range of vertical problems was included, but children with extreme vertical disproportions (>2 standard deviations from published norms) were excluded. The patients were instructed to wear the combination HG at night, which was designed to deliver between 8 and 10 ounces of force from the head cap and sufficient force from the neck strap to prevent buccal flaring of the maxillary molars. The median time period between the T1 and T2 cephalograms was 15 months. Digital copies of these cephalograms were obtained from the study PI (CP).

Cephalometric protocol

The digital copies of all original cephalograms were imported and digitized using Dolphin Imaging software (Dolphin Imaging and Management Solutions, Chatsworth, CA, USA). One examiner (MT) determined the locations of all cephalometric landmarks. The linear and angular cephalometric measurements are represented in Figs 1 and 2, respectively. Masking was not possible between centers because of the presence of a millimeter calibration ruler in the HG group; however,



Fig. 1. Linear cephalometric measurements. 1. Overbite; 2. Overjet; 3. Mandibular length (Ar-Gn); 4. Maxillary first molar MB cusp to H Perpendicular; 5. Maxillary first molar MB cusp to palatal plane; 6. Mandibular first molar to H perpendicular; 7. Mandibular first molar MB cusp to lower border of mandible.



Fig. 2. Angular cephalometric measurements. 1. SNA; 2. SNB; 3. ANB; 4. Mx incisor to NA; 5. Mn incisor to mandibular plane; 6. Mandibular plane angle to SN. SNA = sella-nasion-A point angle; SNB = sella-nasion-B point angle; ANB = A point-nasion-B point.

the examiner was masked to T1 and T2 time points. To assess intra-operator error of landmark localization and the digitizing procedure, 10 randomly selected radiographs were retraced and remeasured after an interval of 1 month. Measurement error was assessed using Dahlbergs's formula (11). The errors ranged from 0.1 to 0.6 mm for the linear measurements and 0.1° to 0.8° for angular measurements. These were considered to be acceptable.

Magnification adjustments

There were slight magnification differences between the two sets of cephalograms because of the differences in the original settings of the cephalometers and differences in the scanning and cropping procedures used in the transformation of the cephalograms into a digital format at the two centers. A millimeter ruler, which could be used to adjust for these differences, was not present on all the films. These differences could be easily identified and adjusted a priori because the anterior cranial base is known to be stable during the treatment intervals of both studies (12). We maintain that adjusting for magnification differences in all cephalograms would be a more direct approach than including them in the statistical model. Therefore, 15 T1 cephalograms from each center were randomly selected, and the linear distance between the cranial base landmarks, sella and nasion, was measured. The mean (SD) S–N distance for the HG/BP and HG groups were 94.4 mm (3.1 mm) and 85.8 mm (3.6 mm), respectively. Using these values, a magnification proportion of 1.1 was calculated and used to adjust all linear measurements prior to the calculation of the change from T1 to T2. Angular measurements were not adjusted. We assumed that the S–N distance would yield the most stable adjustment because of the similarity in T1 subject ages at the two centers and because this measure does not change dramatically during adolescent growth (13).

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS; SPSS Inc., Chicago, IL, USA). Medians and interquartile ranges (IQR) were calculated. Ages at baseline and treatment time for the two groups were compared using Wilcoxon rank sum. The baseline cephalometric values between the groups were compared using Mann-Whitney U tests. The outcome of interest for each cephalometric measure was the change from T1 to T2. Analysis of covariance (ANCOVA) was used to assess whether the average change in each measure from T1 to T2 was the same for the two treatment groups. In this model, the center, number of months in treatment, and the adjusted T1 values were included as the covariates. 99% confidence intervals for the difference between the two groups in the change values were calculated after controlling for the covariates. Significance was set at $p \leq 0.01$ to control the type I error.

Results

The median ages at baseline of the two groups were not significantly different, but the median treatment time was longer in the HG/BP group (Table 1). There were no statistically significant differences between the two treatment groups in the distributions of the baseline values for any of the vertical cephalometric characteristics (Table 2). With respect to AP baseline measurements, the upper incisors were more proclined and overjet was significantly greater in the HG group.

Table 1. Comparison of baseline characteristics of the two treatment approaches

	HG/BP (n = 81)	HG (n = 50)	р
Age: years	9.7 (0.9)	9.4 (1.0)	0.1
Median (IQR)			
Tx time: months	26.6 (14.2)	15.0 (0.0)	<0.0005
Median (IQR)			
Gender (% male)	56%	50%	-

BP, biteplate; HG, headgear; IQR, interquartile range.

Group differences in age and treatment time were compared using Wilcoxon rank sum.

Table 2. Comparison of baseline cephalometric variables

	HG/BP Median (IQR)	HG Median (IQR)	<i>p</i> value
Vertical			
Overbite	3.15 (2.16)	3.40(2.23)	0.93
U6-PP	15.75(2.25	16.91(2.09)	0.27
L6-MP	21.15(3.96)	21.87(2.46)	0.98
MnPlane-SN	34.7(8.4)	33.45(6.38)	0.73
AP			
Overjet	5.22(2.52)	7.53(2.56)	<0.0005
U1-NA	21.5(8.8)	25.45(8.05)	<0.001
L1-MP	92.9(9.1)	93.1(6.4)	0.64
U6-HPerp	34.83(7.02)	35.43(4.74)	0.75
L6-HPerp	32.76(7.29)	33.42(5.69)	0.60
SNA	82.1(6.1)	84.15(4.43)	<0.0005
SNB	76.6(5.0)	77.05(4.92)	0.59
ANB	5.0(2.4)	6.3(2.25)	<0.0005

AP, anteroposterior; BP, biteplate; HG, headgear; IQR, interquartile range.

Group differences were compared using Wilcoxon rank sum.

Skeletally, the HG group also had a greater median SNA value and ANB angle.

The overall (T2–T1) changes for the vertical measures for each treatment group and the 99% confidence interval for the differences between the two groups are presented in Table 3. Overbite was the only vertical measurement that showed a statistically significant change difference from T1 to T2. All other vertical changes were not statistically different between the two treatments, although mandibular plane angle showed a strong trend toward greater increase in the HG/BP group (p = 0.02).

Table 3. Descriptive statistics for the total vertical change from T1 to T2 for each treatment group

				99% CI for	
	HG/BP	HG	Difference	the HG-HG/	
	Mean (SD)	Mean (SD)	(HG-HG/BP)	BP difference	p value
Overbite (mm)	-1.0 (0.1)	0.1 (0.2)	1.1	0.6, 1.8	<0.001
U6-PP (mm)	1.1 (0.1)	0.8 (0.2)	-0.3	-1.2, 0.6	0.2
L6-MP (mm)	1.2 (0.2)	0.8 (0.2)	-0.4	-1.3, 0.5	0.2
MP-SN (°)	1.2 (0.1)	0.1 (0.3)	-1.1	-2.1, 0.01	0.02

BP, biteplate; HG, headgear.

The comparison of interest, i.e., whether the change observed in the two groups is the same, is indicated by the 99% CI of the difference between the two groups in the change observed.

Table 4.	Descriptive	statistics f	for the t	otal antero	posterior	change	from T	'1 to	T2 for	each	treatment	grou	p

	HG/BP	HG	Difference			
	(SD)	(SD)	(HG-HG/BP)	99% CI	<i>p</i> value	
Overjet (mm)	-2.0 (0.2)	-1.6 (0.3)	0.4	-0.3, 1.1	0.2	
U1-NA (°)	-2.4 (0.5)	1.1 (0.7)	3.5	1.5, 5.4	0.001	
L1-MP (°)	-0.01 (0.4)	0.3 (0.6)	0.3	-1.2, 1.9	0.6	
U6-Hperp (mm)	-1.3 (0.4)	-0.8 (0.4)	0.5	-0.5, 1.6	0.3	
L6-Hperp (mm)	1.4 (0.3)	1.7 (0.4)	0.3	-0.8, 1.4	0.5	
SNA (°)	-0.7 (0.3)	-0.9 (0.4)	-0.2	-1.0, 0.8	0.6	
SNB (°)	-0.01 (0.2)	0.5 (0.3)	0.5	-0.2, 1.3	0.2	
ANB (°)	-0.7 (0.2)	-1.3 (0.2)	-0.6	-1.2, 0.03	0.04	

BP, biteplate; HG, headgear.

The comparison of interest, i.e., whether the change observed in the two groups is the same, is indicated by the 99% CI of the difference between the two groups in the change observed.

The AP skeletal changes are presented in Table 4. None of the AP skeletal changes were statistically different between the two treatments, but there was a strong trend in favor of greater correction in the HG group for ANB angle (p = 0.04). The AP dental changes are also presented in Table 4. The only significant difference in this dimension was a greater reduction in the inclination of the upper incisor (U1-NA) in the HG/BP group. Lower incisor inclination, overjet, AP upper and lower molar positions, SNA, and SNB changes all showed no statistically significant difference from T1 to T2 between the two treatments.

Discussion

In this study, we have used RCT data, which were previously published by both centers separately, but have never been combined to examine this new issue. We are aware of a Cochrane Collaboration report (14) that examined data from these two trials, but that systematic review focused on another question - the effectiveness of orthodontic treatment of maxillary protrusion-and did not make direct comparisons between the two trials. The differences in inclusion/exclusion criteria, protocol and baseline measures between these two RCTs do present with some analytical challenges. With the potential pitfalls of combining cohorts from two different studies in mind, we have adopted analytical approaches that take possible confounders into consideration. Recognizing these limitations, the opportunity to compare these two cohorts, with and without disclusion, offers a unique opportunity to address a new question using these valuable samples.

The purpose of this analysis was to determine whether there were significant skeletal and/or dental differences in the changes from T1 to T2 between Class II subjects treated with HG alone and those treated with HG plus a BP. Perhaps, the most universally accepted HG effect is the restriction of downward and forward translation of the midface during active growth (9). Some clinicians believe that a posteriorly directed HG force to the maxilla can be transferred from the occlusion to the mandibular dentition, thereby inhibiting Class II dental correction (15). This is the rationale for some orthodontists electing to disclude the dentition during HG treatment. Despite the persistence of the belief that 'unlocking' the occlusion will facilitate Class II correction during HG treatment, there are no studies that directly test this hypothesis. The fortuitous difference in appliance choices between two RCT's designed to examine the effectiveness of early Class II treatment aimed at growth modification (1, 2), provided the unique opportunity to directly test this hypothesis with large sample sizes because one RCT used HG alone and the other used it in combination with a BP to disclude the posterior teeth. However, interpreting the results from these two cohorts of patients should be approached with some caution because of the potential for introducing bias because of the differences in protocols and cephalometric magnifications between the two centers. Bias owing to magnification differences was conveniently and reasonably managed for linear measures by adjustments based on cranial base landmarks and was not an issue for the angular measures. ANCOVA was used as the statistical test for the primary outcomes (i.e., the changes that occurred during Phase I treatment) to statistically control for potential biases because of protocol differences. In each model, the center, number of months in treatment, and the T1 values were included as the covariates and the comparisons of the two treatments were adjusted for these factors. Although a new RCT would be the ideal experimental design to definitively answer this question, it seems unlikely that the question would be considered central enough to comparative effectiveness of orthodontic treatment to warrant the funding and resources required to launch such a study. Instead, cohort studies can serve to clarify these econdary questions on orthodontic treatment as long as the potential sources of bias are recognized and appropriately minimized. Results from such cohort studies would also serve to justify the further examination of this and related questions using RCT methodology.

The main finding of this study is that the BP provides no additional benefit when using a HG for Class II treatment aimed at modifying AP growth. Changes in SNA, SNB, ANB, and mandibular length were not statistically significantly different between the groups (Table 4). In fact, contrary to a predicted benefit from the BP, the ANB angle showed a trend toward greater average correction in the HG group (p = 0.04). With regard to this point, it seems noteworthy to recognize that the HG patients had significantly greater ANB angles at baseline and therefore would have had more opportunity for correction than did the HG/BP. Also, this trend was likely related to another revealed in the vertical plane, which showed that mandibular plane angle tended to open more in the HG/BP group. Clockwise rotation of the mandible during treatment is recognized as having the potential to inhibit Class II corrections (7).

The maxillary first molars moved posteriorly approximately the same average amount in both groups, and there was no difference in the amount of forward movement by the mandibular first molars. If occlusal contacts impact the AP dental movements, one would expect the mandibular first molar to have less forward translation in the group without the BP.

Table 4 indicates that there was no difference in the average lower incisor inclination relative to mandibular plane, but the maxillary incisors were significantly retroclined in the HG/BP group compared with the HG group. The latter difference can be attributed to the labial bow, providing an active retraction force to the maxillary anterior teeth.

The most significant difference between the two cohorts was actually in the vertical plane – greater overbite reduction in the HG/BP patients. This finding confirms previous work that has shown anterior BPs to be effective in reducing deep overbites (16).

The lack of group differences between maxillary first molars relative to palatal plane and the mandibular first molars to mandibular plane was surprising because one would expect that chronic disclusion of these teeth would have resulted in greater eruption in the HG/BP group, especially with the downward traction on the maxillary molars caused by the headgears. However, these findings were also consistent with the failure to find a significant difference between the treatment groups in mandibular plane angle change. Despite this, the latter did show a strong trend toward greater opening in the HG/BP group (p = 0.02), suggesting that the combined maxillary and mandibular vertical changes may have had some influence on rotation of the mandible. Long-term records to determine the stability of this vertical change were not considered in the present study.

With the exception of change in overbite and upper incisor inclination, none of the other cephalometric changes were statistically different. Owing to the majority of non-statistically significant differences between the two early treatment approaches, one may ask whether this study had sufficient statistical power to minimize type II error. The considerations with respect to setting a significance value for decision making relative to a null hypothesis are multiple: controlling type I error and the relative 'cost' of a type I and II error. *p* values often imply therapeutic decisions not just statistical conclusions. Given the limitations of this analysis with respect to the differences in study protocols and cephalometers, the 'cost' of a type I error in the sense of implying a clinical difference when there is not one is substantial. However, our sample was collected from two separate RCTs that based their respective sample sizes on a priori power calculations. As our sample was derived from these previous RCTs that were powered to detect AP changes, we considered the likelihood of detecting false-negative findings in the current study to be fairly low. Also, our 99% confidence intervals were small enough to suggest a low likelihood of insufficient power.

The increased overjet and upper incisor inclinations in the HG group at baseline (Table 2) were likely because of the differences in the original inclusion criteria between the centers, with patients being included in the HG group based on initial overjet (≥ 7 mm). The initial occlusal inclusion criteria for the HG/BP group were based on an end-end molar relationship or greater. Owing to these differences, there was likely an increased prevalence of milder Class II malocclusions in this group. Conversely, as none of the patients in the HG group received any treatment prior to HG, it is likely that some may have had an increased overjet with normal molar relationships because of maxillary dental spacing. Skeletally, the HG group also showed greater mean SNA and ANB angles. This can also be attributed to the different original inclusion criteria, with the HG/BP group likely having more orthognathic patients because they included subjects with end-to-end molar relationships. The differences in treatment length between the two groups also arose from the differing protocols in the two original studies. In an effort to minimize the impact of these protocol differences, the groups were compared using an ANCOVA model that controlled for center, treatment time, and T1 differences as covariates.

Despite this, differences in treatment time may have indirectly affected our results because patient compliance may have differed between the groups, as it has been well documented that compliance tends to diminish as patients are asked to wear appliances for longer periods (17). Although the HG/BP patients were asked to wear their appliances for a longer period of time, the average time these patients actually wore the appliances may have been much less. Both centers tried to develop methods to objectively assess compliance, but the technology at the time was not mature enough to ultimately be successful. Instead, both had to rely on self-reports, assessments by clinicians, and indirect measures that are recognized as being unreliable (18, 19). Therefore, we could not assess compliance-related effects in this study. Furthermore, different teams of orthodontists treated the two cohorts, and it is possible that the motivational effectiveness on patient compliance may have differed between the centers.

There are numerous studies in the literature using cephalometric (20, 21) and finite element modeling (22), suggesting that variations in HG biomechanics may lead to different craniofacial changes. Also, there is one report on 200 consecutively treated patients, showing that cephalometric changes related to HG biomechanics are quite variable and statistically nonsignificant (23). It is clear that the two centers, providing cephalometric radiographs for this study, used different HG biomechanics and these could have been confounders in the result. However, it bears repeating in this context that the ANCOVA model used in this study adjusts for possibly important confounders influencing the treatment changes. The specific model adjusted for the effects of differences in protocol between the centers, baseline cephalometric values, and treatment times on the total change between the two groups. Therefore, differences in HG protocols would have been accounted for in the 'center' covariate of the model.

The previous finding that dentoalveolar compensations occur in untreated populations as a result of occlusal contacts (9) may not be contradicted by this study because the occlusal changes produced by orthodontic or orthopedic treatment may also minimize occlusal contacts. It is plausible that the extrusive movement of the maxillary first molar because of HG forces provides enough occlusal disruption to mitigate the forces transmitted through the occlusion. As it has been established that maximum intercuspation is a tooth-determined position (24), tooth movement of any kind may disrupt this functional position and allow the mandible and mandibular dentition to assume an altered position. This modified occlusal relationship may reduce the forces that are transmitted through the occlusion so that the 'bite' no longer provides the force necessary to compensate the dentition during active mandibular growth.

In conclusion, the addition of a maxillary anterior BP with labial bow to a HG does not provide additional AP dental or skeletal benefit over HG alone for growing patients with Class II malocclusions. The occlusal separation provided by the BP does not permit greater mandibular growth or greater forward translation of the mandibular dentition. However, adding an anterior BP with labial bow to the HG in these patients is an effective way to reduce overbites and retract incisors by uprighting proclined maxillary incisors.

Clinical relevance

Dentoalveolar compensations occur during the adolescent growth years in untreated populations. These adaptations may work to maintain Class II occlusal relationships despite favorable AP skeletal growth changes. With this in mind, many orthodontists believe that eliminating occlusal contacts during Class II corrections with headgears provides a better AP skeletal result with less dentoalveolar compensation. Often, this is cited as a rationale for prescribing a BP in conjunction with traditional HG appliances. However, the effectiveness of discluding posterior teeth with a HG/BP combination during growth modification treatment of Class II patients has never been compared with HG alone.

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