ORIGINAL ARTICLE

Timing of Class II treatment: Skeletal changes comparing 1-phase and 2-phase treatment

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Introduction: Previous studies reported small but significant skeletal changes as a result of early treatment of Class II malocclusion with headgear and functional appliances. In this study, we report on the skeletal changes for 1-phase and 2-phase treatment of Class II malocclusion. **Methods:** This was a prospective randomized clinical trial conducted sy the Department of Orthodontics at the University of Florida between 1990 and 2000. A total of 261 subjects demonstrating at least a one half-cusp Class II molar relationship and meeting the inclusion criteria were enrolled in the study and had at least 1 follow-up visit. During phase 1, 86 subjects were treated with a bionator, 95 were treated with a headgear/biteplane, and 80 served as the observation group. For phase 2, all subjects were then treated with full orthodontics appliances. Skeletal changes were monitored with cephalograms taken at baseline, at the end of early Class II treatment or observation baseline, at the beginning of fixed appliances, and at end of orthodontic treatment. **Results:** Overall skeletal changes at the end of phase 1 treatment were as follows: (1) SNA angle increased in the bionator (0.51) and the observation groups (0.67), whereas it decreased (–0.50) in the headgear/biteplane group; (2) SNB angle increased in the bionator (1.36) and the observation groups (0.84), whereas it remained unchanged (0.19) in the headgear/biteplane group; (3) ANB angle decreased in the bionator (–0.85) and the headgear/biteplane groups (–0.72), and was unchanged in the observation group; and (4) the mandibular plane angle increased (1.30) only in the headgear/biteplane group. By the end of full orthodontic treatment, the skeletal differences in all measurements for all 3 groups were within 1°. Linear regression models showed that, during phase 1, baseline value and treatment group were significant. However, when the entire treatment period was considered, treatment group had no effect. **Conclusions:** There is temporary skeletal change as a result of phase I treatment with both appliances but no detectible skeletal difference between 1-phase and 2-phase treatment of Class II malocclusion by the end of full orthodontic treatment. (Am J Orthod Dentofacial Orthop 2007;132:481-9)

The best timing for treatment of Class II malocclusion has been controversial. The question is whether early treatment, which is initiated during the mixed dentition, is more effective and efficient than treatment started in the permanent dentition.[1] Can early treatment provide superior skeletal, dental, or esthetic results?

Reviews of Class II treatment studies before 1989 concluded that, because of their inadequate designs, it was not yet known whether early treatment provided enough benefits to justify it.[2,3] Recently, data have become available from 2 randomized clinical trials that addressed this question.[4-6] Although the studies examined anteroposterior changes in different ways (one used the "pitchfork" analysis of Johnston,[7] which assesses anteroposterior changes in relation to the occlusal plane, and the other used cranial base as a reference), both reported similar results. Irrespective of which appliance was used, both reduced the severity of the Class II skeletal discrepancy at the end of phase 1. Also, both studies reported a reduction in peer assessment rating scores as a result of phase 1 treatment.[8,9] Not surprisingly, phase 1 treatment resulted in more subjects in the bionator and headgear/biteplane groups having a Class I molar relationship than in the observation group, although this was related to initial molar severity.[10]

Results from the end of phase 2 treatment in these studies are beginning to be reported. It appears that many differences between treatment groups that are evident at the end of phase 1 are no longer present by the end of phase 2.[9,8] Subjects who receive treatment in

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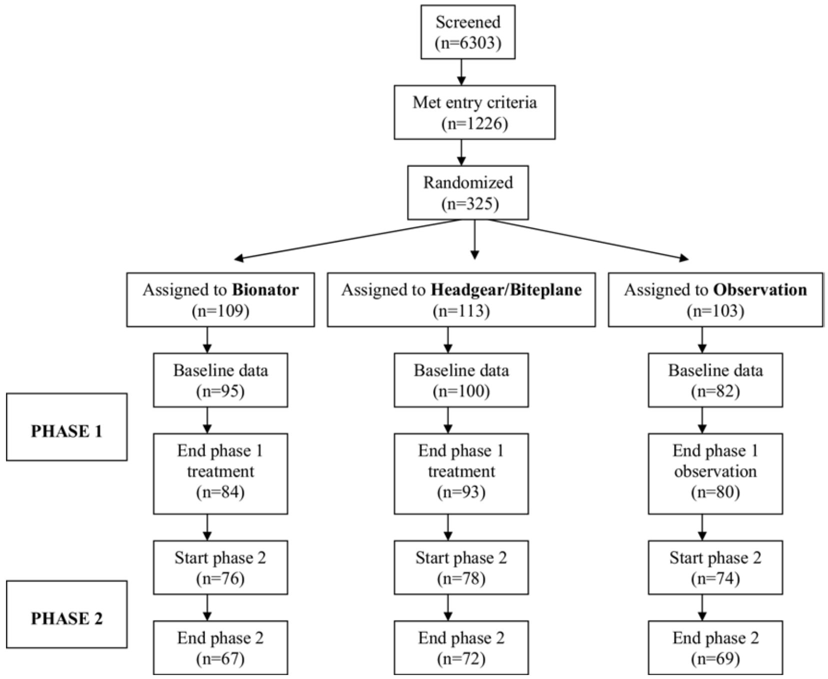


Fig 1. Flowchart depicts the study participants screening, randomization, and treatment.

2 phases, with the first aimed at orthopedic correction in the mixed dentition and the second detailing the permanent dentition, do not have significant skeletal or dental differences from those who receive 1 phase of treatment in the permanent dentition.

In this study, we report on the skeletal changes from phases 1 and 2, using the complete cephalometric data set from 1 clinical trial. In addition, linear regression models were used to examine the impact of baseline covariates on the cephalometric values at the end of phase 1 and the end of phase 2.

MATERIAL AND METHODS

The study was a prospective, randomized clinical trial with 2 treatment groups and an observation group. During phase 1, the subjects were treated with either a bionator or headgear/biteplane. An equal number of subjects were followed in the observation group. Assignment into a group was done by stratification block randomization based on molar class severity, mandibular plane angle, need for preparatory treatment, race, and sex. This ensured a balance of these factors in the treated and observation groups. After phase 1 treatment and a 12-month observation period, all subjects received the most appropriate phase 2 finishing orthodontic treatment, usually involving full fixed orthodontic appliances.

Details of the study were previously published.[6] Briefly, 6303 third and fourth grade public school (Alachua County, Fla) children were screened at school, 1226 of the students qualified to participate in the study, 325 were randomized, 277 began the study, 261 had baseline and at least 1 follow-up data collection visit, and 208 subjects completed orthodontic treatment (Fig 1). The inclusion criteria consisted of positive overbite and overjet, intact mixed dentition (>3 deciduous molars), bilateral (>one half cusp) Class II molar relationship, all permanent first molars, less than 3 permanent canines or premolars, and good general health. The exclusion criteria included periodontal problems or dental decay, unwillingness to be randomly assigned to a treatment group, and failure to sign informed consent.

Each subject for phase 1 treatment was randomized into 1 of 3 groups: bionator, headgear/biteplane, and observation. Phase 1 treatment lasted until 2 project orthodontists independently agreed that a bilateral Class I molar relationship was achieved or 2 years had elapsed from the start of treatment.[6] After phase 1 treatment, half of the subjects in the bionator and headgear/biteplane groups were randomly assigned to 6 months of retention. This consisted of wearing the bionator only at night or wearing the headgear/biteplane every other night. This was followed by 6 months of no retention; the other half of the subjects had no retention for a year. All subjects were then given the most appropriate orthodontic treatment. Phase 2 treatment was determined as follows: orthodontic records at the end of phase 1 were made into videos and sent randomly to orthodontists selected from the American Association of Orthodontists' directory. In general, each patient was reviewed by an average of 4 orthodontists, and there was 72% overall agreement of the entire treatment plan (ie, treatment need, approach, and extraction need) that they proposed.[11] Based on their responses, a consensus treatment plan was formulated for phase 2 treatment. Of the 261 subjects, 20% of the observation, 12% of the headgear/biteplane, and 8% of the bionator groups had some premolars extracted ($P =$ .07). During phase 2 treatment, headgear was used more often (42%) in the observation group than in the headgear/biteplane (15%) or bionator (23%) group ($P = .0001$). We report on the following data collection (DC) points: DC1, baseline; DC3, end of early Class II treatment or observation; DC7, beginning of fixed appliances; and DCF, end of orthodontic treatment.

All lateral cephalograms were made on a cephalostat with a standard cathode-to-ear rod distance of 60 in and an ear rod-to-film distance of 15 cm by using Kodak Lanex X-D 600 speed film with X-O MATIC intensifying screens (Eastman Kodak, Rochester, NY). These were exposed for 1 second at 80 to 85 kVP and 15mA.

All lateral cephalograms were traced and digitized; 60 points were identified. Only the following points were used for analysis: nasion (N), sella (S), A-point, B-point, orbitale, porion, anterior nasal spine, posterior nasal spine, gonion, and gnathion.

Statistical analysis

Descriptive statistics were used to examine the data. Baseline differences by treatment group were assessed by using chi-square tests for categorical variables and analysis of variance (ANOVA) for continuous variables. These tests were also used to compare those who completed the study with those who did not. For key cephalometric variables, analysis of repeated measures by using mixed models was performed.[12] For each model, the cephalometric measure at the 3 follow-up points was modeled as a function of baseline value, treatment group, time point, and interaction between treatment group and time point. Pearson correlation coefficient estimates were used to describe the relationship between changes in the cephalometric variables. Linear regression models were used to examine the impact of a standard set of covariates (age at baseline, treatment group, sex, initial cephalometric values, and initial molar class severity) on cephalometric measures at the end of phase 1 and the end of treatment. For each model, regression parameter estimates were obtained, and their magnitude and significance were assessed. All analyses were made with software (SAS, Cary, NC; Insightful Corporation, Seattle, Wash). A P value less than .05 was considered statistically significant.

RESULTS

Three hundred twenty-five subjects were randomized, and 277 subjects began the study, with 261 having a baseline visit and at least 1 follow-up DC visit. Of those who completed phase 1, 84 were treated with a bionator, 93 were treated with a headgear/biteplane, and 80 were the observation group. The dropout rates were 7% for phase 1, 11% during the retention phase, and 9% for phase 2. There were no significant differences initially in the number of subjects in each treatment group for stratification and demographic variables (Table I). The mean ages at the start of treatment were similar for the 3 groups. Similar numbers of subjects in the bionator (49%) and headgear/biteplane (51%) groups had some pretreatment orthodontic treatment. This usually involved alignment of maxillary incisors with fixed 2×4 appliances. Pretreatment orthodontics were done in 12% of the observation group. More boys entered the study than girls, and more subjects were classified with high molar class severity, and few patients had a high mandibular plane angle. Cephalometric values representing horizontal and vertical skeletal points also were not significantly different at baseline (Table II).

As shown in Figure 2, SNA angle decreased 0.50° during phase 1 treatment in the headgear/biteplane group but relapsed to its original value during retention/observation before the start of phase 2 treatment. In the bionator and observation groups, SNA angle increased (0.51° and 0.67°, respectively) during phase 1 and until the start of phase 2. SNA angle in these groups decreased during phase 2 treatment. The mixed-model analysis for SNA angle (*insert* in Fig 2) indicated significant effects from baseline value ($P < .0001$), treatment group ($P < .0001$), and DC time ($P < .0001$), but no interaction between treatment group and time point was found ($P = 0.10$).

At the end of DC3, the greatest increase in SNB angle was in the bionator group (1.36°) (Fig 3). The observation group had greater changes in SNB angle than the headgear/biteplane group (0.84° and 0.19°, respectively). Between the end of phase 1 and the beginning of phase 2, SNB angle increased significantly in the headgear/biteplane group, so that it became similar to the observation group. During phase 2

Table I. Subjects in each treatment group and demographics for subjects

Variable	*Treatment* Bionator	Observation	Headgear	P *value*
Age at baseline (mean, range) (y)	9.6 (6.9-12.9)	9.5 (8.1-12.6)	9.7 (7.3-11.6)	.65
Total subjects (n)	86	80	95	
Variables (n, %)				
Sex				.86
Male	52 (60)	51 (64)	57 (60)	
Female	34 (40)	29 (36)	38 (40)	
Race				.37
White	75 (87)	74 (92)	88 (93)	
Nonwhite	11 (13)	6 (8)	7 (7)	
Initial molar class severity				.99
High	39 (45)	37 (46)	44 (46)	
Mild	23 (27)	20 (25)	22 (23)	
Low	23 (28)	23 (29)	29 (31)	
SN-MP				.90
>40°	8 (10)	6 (8)	6 (6)	
30° ≤ x ≥ 40°	57 (66)	56 (70)	63 (66)	
<30°	21 (24)	18 (22)	26 (28)	
Pretreatment				
No	44 (51)	70 (88)	47 (49)	B vs H
Yes	42 (49)	10 (12)	48 (51)	.82
Retention				
No	45 (52)	80 (100)	49 (52)	B vs H
Yes	41 (48)	0 (0)	46 (48)	.92

All differences were determined by chi-square tests, except for age at baseline, when ANOVA was used. *B vs H* indicates comparison of bionator with headgear/biteplane subjects only, because observation subjects were treated differently per study design.

Table II. Baseline cephalometric variables

Variable	*Treatment (mean ± SD)* Bionator	Observation	Headgear	P
SNA angle (°)	79.4 (3.5)	79.5 (3.1)	79.8 (3.9)	.80
SNB angle (°)	74.6 (3.2)	74.9 (3.1)	75.2 (3.5)	.56
ANB angle (°)	4.8 (2.0)	4.6 (2.1)	4.6 (1.8)	.79
SN-MP angle (°)	35.7 (5.6)	36.0 (4.7)	36.1 (5.1)	.90

treatment, there were few changes in SNB angle in all treatment groups. The mixed-model analysis for SNB angle (*insert* in Fig 3) was similar to SNA angle, except that there was an interaction between treatment group and time point ($P = .0019$).

Although ANB angle decreased in both the bionator and the headgear/biteplane groups during the study (Fig 4), the observation group changed little until phase 2 treatment. At the end of phase 2, there was little difference in ANB angle between the 3 groups. The mixed-model analysis for ANB angle (*insert* in Fig 4) indicated significant effects from baseline value ($P < .0001$), treatment group ($P = .0021$), and DC time ($P < .0001$), and between treatment group and time point ($P = .0005$).

The skeletal changes in the vertical dimension were assessed by examining the mandibular plane (MP) angle in relation to the S-N line (SN-MP angle) and the Frankfort horizontal. Since both measurements behaved similarly, only data for the SN-MP angle will be presented (Fig 5). In the observation and bionator groups, SN-MP angle decreased until phase 2 treatment. Phase 1 treatment resulted in an increase in SN-MP angle in the headgear/biteplane group (1.30°); it relapsed before phase 2 treatment. Phase 2 treatment resulted in a slight increase in SN-MP angle in all 3 groups. The mixed-model analysis for SN-MP angle (*insert* in Fig 5) indicated significant effects due to baseline value, treatment group, and DC time. No interaction between treatment group and time point was detected ($P = .08$) in SN-MP angle.

The 3 groups were categorized as unfavorable if ANB angle increased more than 0.5°, no change if ANB angle changed ± 0.5°, favorable if ANB angle decreased 0.5° to 1.5°, and highly favorable if ANB angle decreased more than 1.5°[5] (Fig 6, *A*). By the end of phase 1 treatment, there were significant differences in the numbers of subjects in each category ($P < .0001$). In general, the percentages of subjects in each of the 4 categories at the end of phase 1 were similar regardless

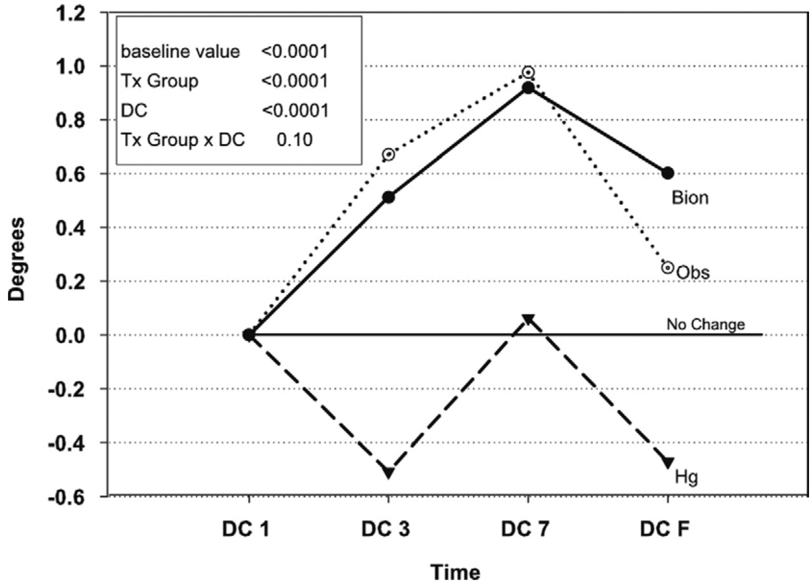


Fig 2. Changes in SNA angle (°) throughout the study period. *Inset* shows the results from the mixed-models analysis.

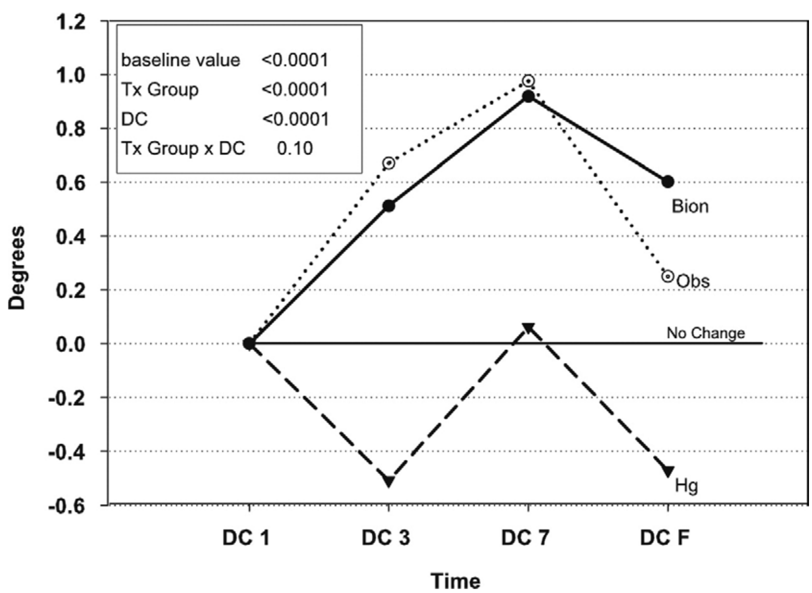


Fig 3. Changes in SNB angle (°) throughout the study period. *Inset* shows the results from the mixed-models analysis.

of whether a bionator or headgear/biteplane was used. In both treatment groups, about 90% of the subjects were equally divided between highly favorable, favorable, and no change. Six percent of the subjects in the bionator group and 14% of those in the headgear/biteplane group were classified as having an unfavorable response, whereas 27% of the observation group fell in that category. Only 8% of the subjects were categorized as having a highly favorable response by the end of phase 1. By the end of phase 2 (Fig 6, *B*), the percentages of subjects in each of the 4 categories were similar for the 3 groups (P = .14).

To examine the impact of additional factors on growth to the end of phase 1 and the end of treatment, additional linear regression models were fitted, by using a standard set of covariates; baseline cephalomet-

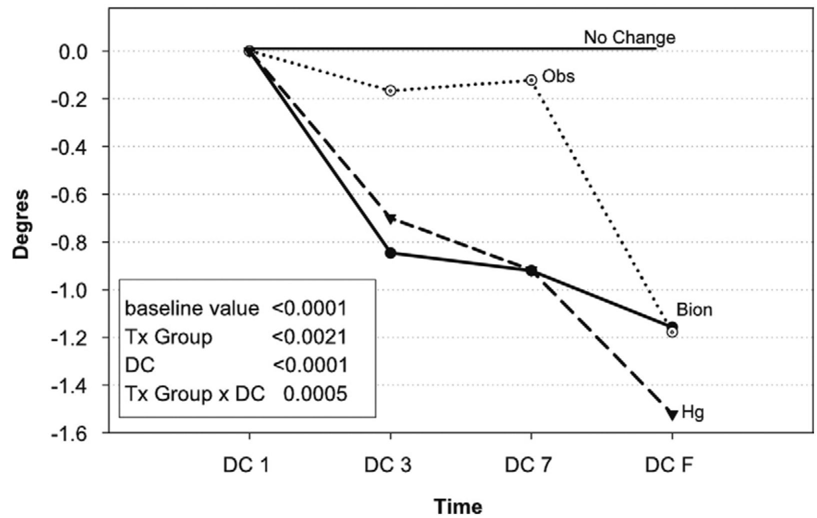


Fig 4. Changes in ANB angle (°) throughout the study period. *Inset* shows the results from the mixed-models analysis.

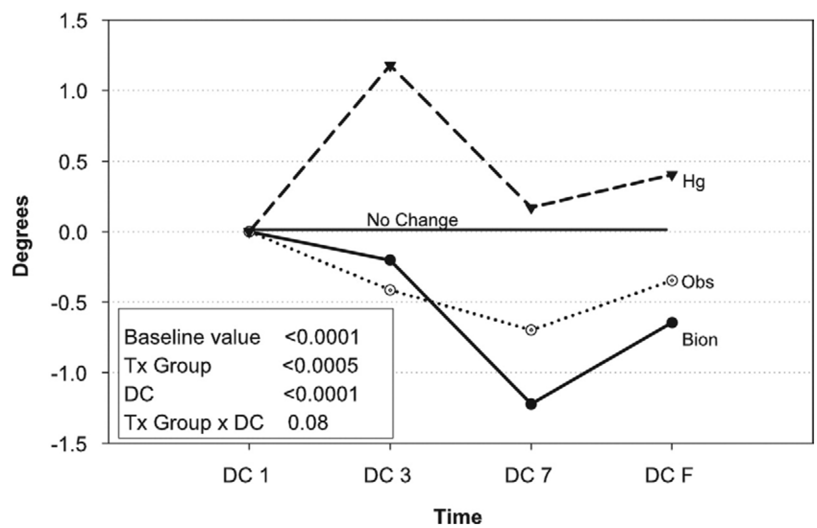
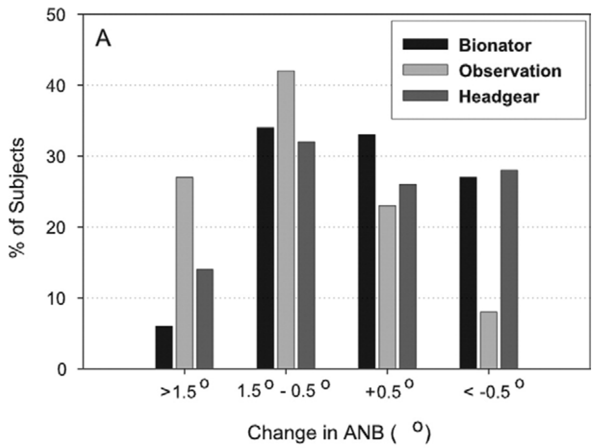


Fig 5. Changes in SN-MP angle (°) throughout the study period. *Inset* shows the results from the mixed-models analysis.

ric value, treatment group, sex, initial molar class, and age at baseline were used to predict values for cephalometric variables at various time points. The magnitude and significance of the estimated coefficients (Tables III and IV) illustrate the role of these factors. For the variables bionator, headgear, male, severe mild, and severe high, the coefficient was added, if the factor was present, to calculate the predicted value for a subject. For baseline value and age at DC1, the coefficient was multiplied by the actual value of the variable for a subject and then added to obtain the predicted value. To illustrate, considering SNA angle at end of phase 1 (Table III), if all other variables were the same, the predicted value for a bionator subject would be 0.16 less than an observation subject's predicted value, and the predicted value for a headgear/biteplane subject would be 1.16 less than an observation subject's predicted value.

Because of the length of the study, it was inevitable that some subjects would be lost. Consequently, we examined the baseline characteristics of those who were randomized but did not finish the study (n = 117) and those who completed (n = 208). The groups appear similar (Table V) with regard to sex, initial molar class



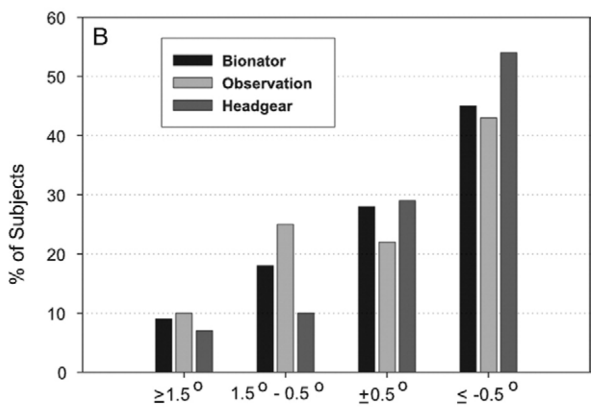


Fig 6. A, Percentages (%) of subjects according to total change in ANB angle at end of phase 1. *Unfavorable* if ANB angle increased >0.5°, *no change* if ANB angle changed ± 0.5°, *favorable* if ANB angle decreased 0.5°-1.5°, and *highly favorable* if ANB angle decreased >1.5°. **B,** Percentages (%) of subjects according to total change in ANB angle from DC1 to DCF. *Unfavorable* if ANB angle increased >0.5°, *no change* if ANB angle changed ± 0.5°, *favorable* if ANB angle decreased 0.5°-1.5°, and *highly favorable* if ANB angle decreased >1.5°.

severity, initial mandibular plane angle, pretreatment, postphase 1 retention, and treatment group. Differences were found for race, with a higher percentage of nonwhite subjects (21%) among those who did not complete the study compared with those that did (7% nonwhite).

DISCUSSION

Using a prospective randomized clinical trial design in preadolescent children with Class II malocclusion, we set out to determine whether 2-phase orthodontic treatment, which starts in the mixed dentition, produces different outcomes from 1-phase treatment, which begins in the permanent dentition. The total dropout rate from DC1 through DCF was 25%. Some reasons given for not entering phase 2 were as follows: felt no need for treatment, inconvenient to make monthly appointments, moved out of town, and did not want to participate further. According to the baseline stratification and demographics of the initial cohort with the 208 subjects who completed the study, the groups remained balanced (Table V). The only exception was that more nonwhite subjects failed to finish. Despite significant improvements in important cephalometric variables at the end of phase 1, these differences vanished by the end of phase 2. These results, in general, apply to white subjects because only 10% of our subjects were not white.

The skeletal changes we observed are similar to what was reported previously.[4-6] Specifically, the changes were in a few variables and typically of small magnitude. Changes that were significant at the end of phase 1 were no longer different by the end of phase 2.[13] This was observed regardless of whether standard cephalometric analyses or other types of analyses were used.[14] Direct comparison among similar studies is sometimes difficult because different analyses are used[15,16] or annualized changes are reported.[4] As a result, the focus should be on the direction of change rather than an exact number comparisons. The results from this study for the end of phase 1 treatment are comparable with those of Tulloch et al[4]: SNA angle increased in the bionator and observation groups and decreased in the headgear group, whereas SNB angle increased in all 3 groups. ANB angle remained unchanged in the observation group until the start of phase 2 treatment and then decreased in all treatment groups.

The final ANB-angle values in our 3 groups also were similar to the previously reported findings.[4,5,13] We found ANB-angle values at the end of treatment to be 3.7°, 3.5°, and 3.4° for the bionator, observation, and headgear/biteplane groups, respectively. Similarly, the results from a previous Class II study reported ANB-angle values of 3.8°, 4.4°, and 4.0° for bionator, observation, and headgear, respectively. In general, in that study, the better overall responses (in ANB angle) were observed even though the initial ANB angle was greater than in our study (about 6° vs about 4.6°). Although both studies had similar inclusion and exclusion criteria, we used molar classification whereas the previous study used overjet. This might account for the slight discrepancies in ANB-angle data between them.

The vertical changes that we report follow those of others.[17-19] Headgear treatment caused an increase in MP angle, which then relapsed to its initial value.

Table III. Coefficient estimates of linear models of selected cephalometric values, with end of phase 1 values modeled as function of listed covariates

Variable	Baseline value	Bionator	Headgear	Male	Severe mild	Severe high	Age at DC1	Model R^2
SNA angle (°)	0.94*	−0.16	−1.16*	0.31	0.18	−0.14	0.05	0.89
SNB angle (°)	0.94*	0.52*	−0.60*	0.18	0.26	0.13	−0.09	0.87
SN-MP angle (°)	0.99*	0.19	1.57*	−0.29	−0.42	−0.04	−0.22	0.88
ANB angle (°)	0.90*	−0.67*	−0.56*	0.12	−0.66	−0.22	0.13	0.75

*$P < .05$.

Table IV. Coefficient estimates of linear models of selected cephalometric values, with end of treatment values modeled as function of listed covariates

Variable	Baseline value	Bionator	Headgear	Male	Severe mild	Severe high	Age at DC1	Model R^2
SNA angle (°)	0.88*	0.33	−0.66	0.41	−0.11	−0.26	0.00	0.74
SNB angle (°)	0.96*	0.33	−0.30	0.50	0.19	0.40	−0.14	0.69
SN-MP angle (°)	1.04*	−0.28	0.73	−0.59	−0.84	−0.38	−0.53	0.77
ANB angle (°)	0.79*	0.03	−0.35	−0.10	−0.28	−0.50	0.11	0.54

*$P < .05$.

Table V. Comparison of those who completed DCF with those who did not

	No DCF	DCF	P value
Age at baseline (mean ± SD) (y)	9.80 (0.93)	9.55 (0.89)	.053
Total subjects (n)	117	208	
Variables (n, %)			
Sex			.91
Male	69 (59)	124 (60)	
Female	48 (41)	84 (40)	
Race			.002
White	93 (79)	194 (93)	
Nonwhite	24 (21)	14 (7)	
Initial molar class severity			.93
High	54 (46)	100 (48)	
Moderate	29 (25)	48 (23)	
Mild	34 (29)	30 (29)	
SN-MP			.39
>40°	11 (9)	12 (6)	
30° ≤ × ≥ 40°	75 (64)	145 (70)	
<30°	31 (27)	51 (25)	
Pretreatment			.95
Yes	46 (39)	81 (39)	
No	71 (61)	127 (61)	
Postphase 1 retention			.90
Yes	38 (32)	69 (33)	
No	79 (68)	139 (67)	
Treatment group			.70
Bionator	42 (36)	67 (32)	
Observation	34 (29)	69 (33)	
Headgear/biteplane	41 (35)	72 (35)	

The other early treatment Class II study reported that, by the end of phase 1, about 50% of the subjects from each group were categorized as having no response (ANB angle change, ± 0.5°).[5] In our study, 34% of the bionator, 32% of the headgear/biteplane, and 42% of the observation groups were classified as having no change. These differences can be attributed to slightly different inclusion criteria or protocols in the 2 studies. In this study, a cervical-pull headgear and biteplane (in case of a high MP angle, high-pull headgear) were used, whereas the former study used combination headgear. More importantly, at the University of North Carolina, the authors took phase 1 records at the end of 15 months, whereas, at the University of Florida, we took records when a Class I molar relationship was achieved or at a maximum of 24 months. Interestingly, about the same percentages of the observation groups experienced unfavorable and favorable changes (27% and 23%, respectively). Figure 6, *B*, shows additional evidence that supports a conclusion of minimal skeletal differences between 1-phase and 2-phase treatment. By the end of phase 2, the percentages of subjects categorized as having highly favorable to unfavorable responses in ANB angle were similar for the 3 groups.

The use of mixed models for repeated measures allows for the simultaneous assessment of the impact of baseline value, treatment group, time point, and treatment group by time point interaction. In all models, the baseline values were highly significant. There was a high degree of correlation between baseline and follow-up measurements for each variable with higher correlations between measurements closer in time. The mixed-model approach allows for the incorporation of this structure in the specification of the model. Of particular interest is the treatment-group by time-point interaction. When this is significant, it indicates that the pattern of change differs over time depending on treatment group. Additional linear regression models were developed to examine the impact of a uniform set of covariates (baseline value, treatment group, sex, initial molar class severity, and age at beginning of study) on growth shown on cephalograms between DC1 and DC3, and between DC1 and DCF. During phase 1, baseline value and treatment group were significant in all models. The impact of treatment group was not detected when the growth shown on cephalograms during the entire time period was considered. For both time periods, sex, initial molar class severity, and age had little effect. Our mixed-model results are supported by the results of O'Brien et al,[16] who also found that baseline data correlated with the outcome of treatment.

The following possibilities have been suggested as possible effects of functional appliances on mandibular growth: (1) "increased" beyond its genetic potential; (2) "accelerated" when there is an increase in the growth rate during treatment, followed by a period of slow growth, thereby achieving the expected growth; or (3) anterior mandibular positioning with adaptation as further growth occurs.[20] Our data suggest that there is no growth beyond the genetic potential, thus eliminating the first possibility. From Figure 3, both the second and third possibilities are plausible.

CONCLUSIONS

1. Phase 1 treatment with either a bionator or headgear/biteplane results in a decrease in ANB angle.
2. Headgear/biteplane results in an increase in SN-MP at the end of phase 1.
3. Early intervention had no effect on the skeletal pattern at the end of all treatment compared with treatment in 1 phase at adolescence.
4. Using linear regression analysis, we demonstrated that treatment group had no effect on the final cephalometric values.

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