Dental and skeletal effects associated with the Carriere distalizer appliance

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ABSTRACT

Objective: The overall objectives of this study were to compare pre-treatment (T0), post-distalization (T1), and post-treatment (T2) lateral cephalograms of patients who wore the Carriere distalizer appliance in terms of the dental and skeletal components of anteroposterior changes between three time-points.

Materials & Methods: The study evaluated 33 adolescent patients (mean age 13.3 ± 1.5 months) with pre-treatment Class II molar relationships of at least 2 mm. Subjects were categorized into groups by amount of Class II relationship: Group A, 2.0-3.0 mm, and Group B, 3.1-7.0 mm. Lateral cephalograms were traced and analyzed using Johnston's pitchfork analysis to determine the dental and skeletal components of anteroposterior change across the three time-points.

Results: Treatment with the Carriere distalizer appliance lasted 5.2 months, while overall treatment time lasted 20.4 months for Group A and 24.6 months for Group B. Group A had 2.8 mm and Group B had 4.4 mm of molar relationship correction from T0-T1. Following comprehensive treatment, Group A had 1.8 mm and Group B had 3.3 mm of overall molar relationship correction from T0-T2. In group A from T0-T2, 77% of the correction was due to dental change, whereas in Group B 91% of the correction was due to dental change.

Conclusions: The distalization achieved from T0-T1 was completely lost during the remaining orthodontic treatment for mild Class II relationships (2.0-3.0 mm), while only

63% of the distalization achieved in moderate-severe Class II relationships (3.1-7.0 mm) was lost at the end of treatment. Total (T0-T2) molar relationship correction was 1.8 mm for mild Class II relationships and 3.3 mm for moderate-severe Class II relationships. There were no statistically significant differences detected between gender or between groups by CVM at any of the three time intervals.

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I. Introduction

A. Background & Significance

Class II malocclusion is a common presentation in the orthodontic office, and accordingly several appliances have been developed to correct it. Distalization of Class II maxillary molars into a Class I relationship (Figure 1), i.e., using orthodontic forces to move the maxillary teeth posteriorly into an ideal occlusal position, has been achieved with appliances ranging from extraoral headgear to removable appliances to sliding jigs.[1]

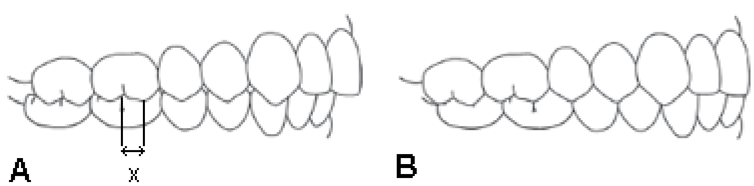

Figure 1. Classifications of malocclusion by molar position: (A) Class II molar relationship by x mm. For the 2 groups of Class II molar relationships in this study, x = 2.0-3.0.5 mm or 3.6-7 mm. (B) Class I molar relationship following maxillary molar distalization and orthodontic treatment.

In the early 2000s the Carriere distalizer appliance (Figure 2) was introduced and described as an effective way to distalize maxillary first molars into a Class I relationship.[2] Since its introduction, the appliance has gained popularity among orthodontic clinicians, but most of the articles that have been published until recently were case series and reports of clinical management of the appliance.[3-6]

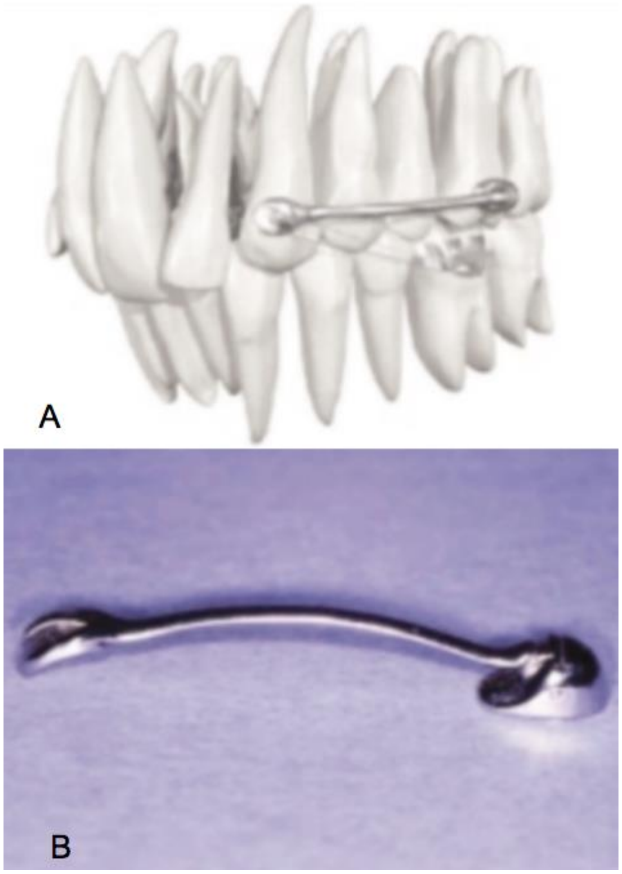

Figure 2. (A) Illustration of Carriere distalizer appliance bonded to maxillary canine and first molar with an intermaxillary elastic worn from the maxillary canine to a hook on the mandibular first molar.[2] (B) The appliance is made of mold-injected stainless steel and consists of a canine pad with an arm that runs posteriorly to the ball and socket joint in the molar pad.[2]

A recent study found that the Carriere distalizer appliance efficiently corrects Class II molar relationships, primarily via dentoalveolar change, but also found that some skeletal change of the anteroposterior position of the maxilla occurred.[7] Another recent study compared the treatment effects of the Carriere distalizer appliance with those of intermaxillary Class II elastics and the Forsus appliance, and found that the Carriere distalizer appliance is no more effective or efficient than the alternatives for Class II malocclusion correction.[8] Furthermore, this study found no statistically significant skeletal change associated with the Carriere distalizer appliance. The present study aimed to supplement the recent studies by reporting the dental and skeletal effects of treatment with the Carriere distalizer appliance using a cephalometric analysis that separates the dental and skeletal components of anteroposterior change.

In 1996 Johnston proposed a cephalometric analysis that separated the skeletal and dental components of anteroposterior change.[9] The method utilized a pitchfork diagram (Figure 3) that quantified skeletal movements and changes in upper (U1) and lower (L1) incisors (overjet) and maxillary (U6) and mandibular (L6) molar relationships using cephalometric superimpositions.

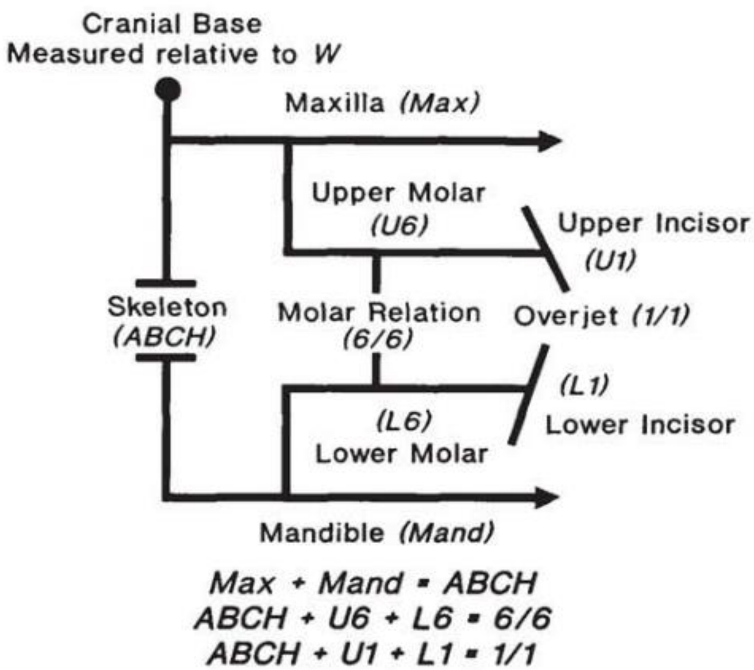

Figure 3. The ‘pitch-fork’ diagram represents anteroposterior maxillary (Max) and mandibular (Mand) skeletal displacement relative to the cranial base, summed as apical base change (ABCH), and anteroposterior change in upper (U) and lower (L) molar (6) and incisor (1) position relative to the basal bone. Changes in overjet (1/1) and molar relationship (6/6) are measured by combining the total skeletal and dental changes. Wing point (W) is the point at which the averaged outline of the greater wings of the sphenoid bone cross the planum sphenoidale, and it represents the cranial base in the pitch-fork diagram.[9]

The four anteroposterior components were displacement of the maxilla relative to cranial base (Max), displacement of maxillary teeth relative to the maxilla, displacement of mandible relative to cranial base (Mand), and displacement of mandibular teeth relative to the mandible. The sum of maxillary and mandibular translatory movement relative to the cranial base was termed ‘apical base change’ (ABCH = Max + Mand), and often represented the amount that the mandible had outgrown the maxilla. ABCH was added to total maxillary and mandibular molar or incisor movement relative to basal bone, equaling the changes in molar relationship (6/6) and overjet (1/1), respectively.

The pitch-fork analysis proposed by Johnston allowed for simplified measurement of dental and skeletal components of anteroposterior change in molar relationship and overjet correction. Importantly, previous studies relating to maxillary molar distalization appliances have used heterogeneous methods with varying cephalometric analyses to measure the skeletal and dental effects.[1,7,8,10-15] This makes comparison of results between studies difficult to interpret, and indicates the need for a cephalometric analysis that focuses on anteroposterior change and separates the dental and skeletal components of molar relationship correction when evaluating the dental and skeletal effects of a maxillary molar distalization orthodontic appliance.

Another important factor to consider in evaluating orthodontic treatment effects in adolescent subjects is developmental stage. One method used to evaluate developmental stage is cervical vertebral maturation (CVM) analysis, which uses lateral cephalograms to identify the shapes of cervical vertebrae and categorize subjects into six different classification stages (CS1-CS6).[16] Generally, CS1-2 are prepubertal, CS3-4 are circumpubertal, and CS5-6 are post-pubertal. Determining developmental stage yields information about the skeletal growth potential of the maxilla and mandible and is particularly important in the case of growing patients with skeletal Class II relationships, in which the anteroposterior position of the mandible is retrognathic compared to the maxilla. Subjects with remaining growth potential are expected to have relatively more mandibular growth than maxillary growth, which represents the skeletal component to molar relationship correction, termed ABCH in the pitch-fork analysis. The current study used conventional cephalometric skeletal landmarks (Figure 4), hand-traced dental landmarks, and the method outlined in Johnston's pitchfork analysis to quantify skeletal and dental anteroposterior change in Class II patients treated with the Carriere distalizer appliance.

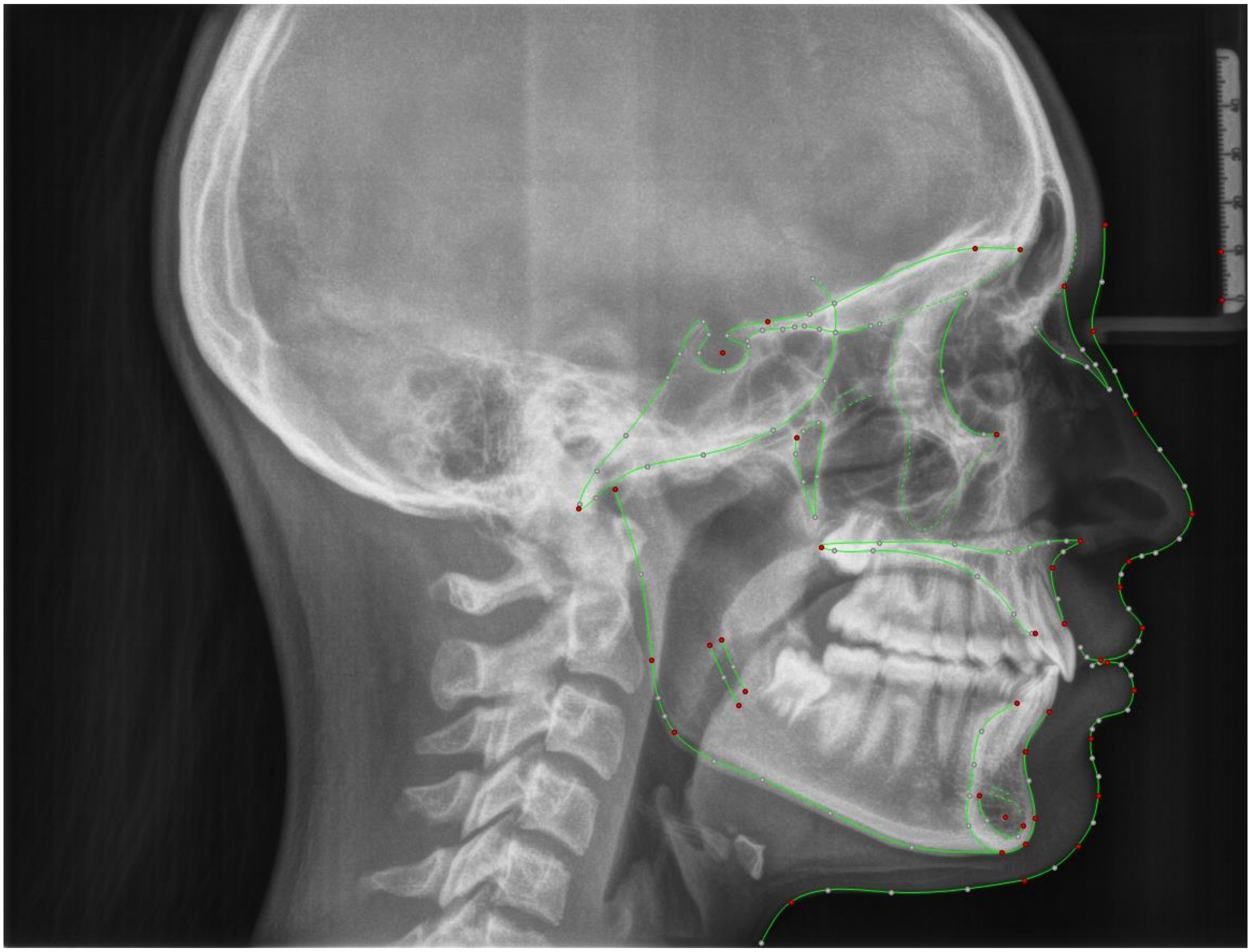

Figure 4. Cephalograms at three time-points for each subject were traced digitally with Dolphin Imaging Software to identify the following skeletal structures: basion, developing third molar (when appropriate), inferior alveolar canal, internal symphysis, key ridge, mandible, maxilla, nasion, pterygomaxillary fissure, roof of orbit, sella, soft tissue profile, and supplementary bony anatomy within the cranial base and symphysis.

B. Specific Aims

The overall objectives of this study were to compare pre-treatment (T0), post-distalization (T1), and post-treatment (T2) lateral cephalograms of patients who wore the Carriere distalizer appliance in terms of the dental and skeletal components of anteroposterior changes between three time-points.

Specifically, the aims were to measure and compare anteroposterior change in position (mm) of the maxilla (MX), mandible (MN), and first molars (MX6, MN6) from:

1. Pre-treatment to post-distalization (ΔT1-T0) between 2 groups of Class II relationships at T0 (A) 2.0-3.0 mm, B) 3.1-7.0 mm), 2 groups of CVM classification at T0 (≤CS3, ≥CS4) and 2 genders (female, male).
2. Post-distalization to post-treatment to (ΔT2-T1) between 2 groups of Class II relationships at T0 (A, B), 2 groups of CVM classification at T0 (≤CS3, ≥CS4) and 2 genders (female, male).
3. Pre- to post-treatment (ΔT2-T0) between 2 groups of Class II relationships at T0 (A, B), 2 groups of CVM classification at T0 (≤CS3, ≥CS4) and 2 genders (female, male).

II. Materials & Methods

A. Sample

The sample used in this pilot study was a convenience sample of 33 consecutively treated cases assigned to two groups determined by amount of Class II relationship: 2.0-3.0 mm (Group A) and 3.1-7.0 mm (Group B). The sample was composed of two groups of CVM classification (≤CS3, ≥CS4), and two genders (female, male), with efforts made to have the groups as balanced as possible.

Inclusion Criteria

1. the patient was growing (CVM ≤ CS5) at the beginning of treatment

2. the patient had a bilateral average Class II relationship of at least 2 mm at T0
3. the patient was treated with Carriere distalizer appliance
4. the patient was treated without extraction of permanent teeth (excluding third molars)
5. the patient was reasonably compliant during treatment (as evidenced by chart notes)
6. good quality pre-treatment (within 4 months of start of treatment), post-distalization (immediately upon appliance removal), and post-treatment (immediately upon completion of treatment) cephalograms and digital dental models were available

Exclusion Criteria

1. any cases that did not meet the inclusion criteria
2. changes were made in molar posterior-transverse occlusal relationships (e.g. correction of a posterior crossbite)
3. patients with cleft palate or craniofacial conditions

B. Protocol

The digitized records of 50 subjects with Class II malocclusions consecutively treated with the Carriere distalizer appliance in one private orthodontic office were de-identified and evaluated. After excluding the subjects who met the exclusion criteria, 33 subjects met the inclusion criteria. Lateral cephalograms from one machine were exposed at three time-points: within four months prior to the beginning of orthodontic treatment (T0), immediately upon removal of the distalization appliance (T1), and immediately upon removal of all orthodontic appliances at the end of treatment (T2). Cephalometric tracing and analysis were performed using a combination of specialized software (Dolphin, Dolphin Imaging & Management Solutions Chatsworth, California) and hand-tracing with acetate paper in the Oregon Health & Science University Orthodontic Department. The cephalometric analysis used was Johnston's pitchfork analysis,[9] which separates the dental and skeletal components of anteroposterior change.

Cephalometric identification of skeletal structures allowed for measurement of anteroposterior skeletal change via overall and regional superimpositions. Cranial base reference landmarks included basion, cribriform plate, ethmoid crest, greater wings of the sphenoid bone, internal outline of frontal bone, nasion, roof of orbit, sella turcica, supplementary bony anatomy within the cranial base, and wing point (W), the point at which the averaged outline of the greater wings of the sphenoid bone cross the planum sphenoidale (Figure 5).

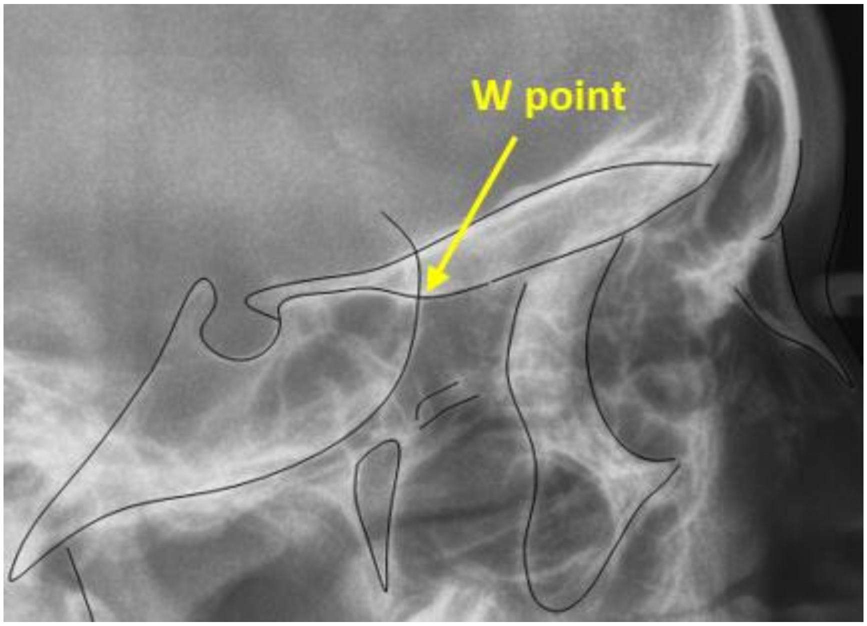

Figure 5. Wing point (W), the point at which the averaged outline of the greater wings of the sphenoid bone intersect the planum sphenoidale.

Maxillary skeletal reference landmarks included the zygomatic processes, the lateral contours of the orbit, the anterior nasal spine (ANS), the posterior nasal spine (PNS), the inferior and superior surfaces of the posterior hard palate, and the pterygomaxillary fissure. Mandibular skeletal reference landmarks included the internal and external borders of the symphysis, the inferior alveolar canal, the third molar tooth buds, the inferior and posterior borders of the mandible, supplementary bony anatomy within the symphysis, and the constructed ‘D-point’ (D), the center of the bony symphysis by inspection (Figure 6). The D-point was constructed by visually identifying the center of the symphysis and marking the point for transfer onto the remaining two time-points by tracing with mandibular regional superimposition. Bilateral skeletal structures such as sphenoid wings and zygomatic ridges were bisected.

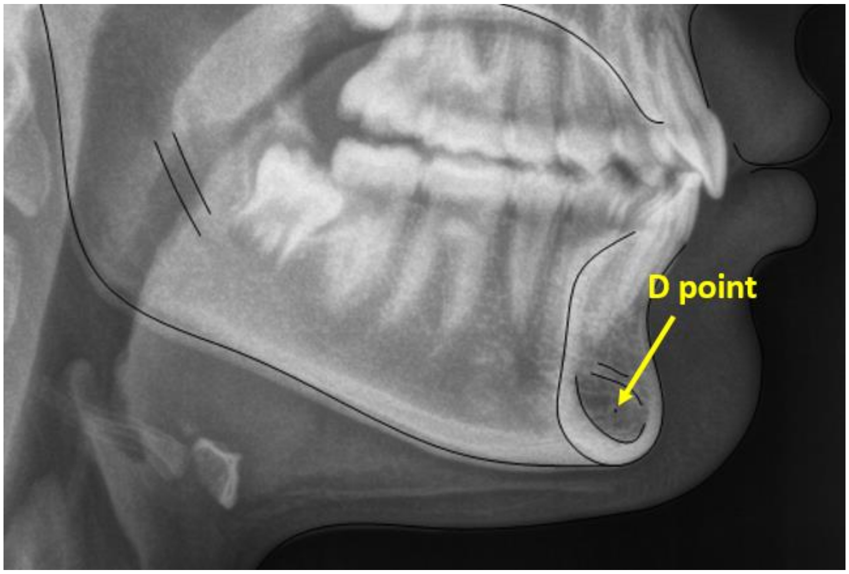

Figure 6. The constructed ‘D-point’ (D), the center of the bony symphysis by inspection.

Due to the complex nature of the pitchfork cephalometric analysis and limitations of the tracing software, complete cephalometric analysis using the pitchfork analysis within Dolphin Imaging Software was infeasible. Therefore, a combination of digital tracing and hand-tracing of printed cephalograms was utilized. Digital identification of skeletal structures allowed for improved accuracy due to the ability to digitally alter contrast, brightness, and sharpness of the images to improve visualization of landmarks. All skeletal structures were digitally traced on the clearest cephalogram of the three time-points, and then the traced structures were digitally transferred to the other two time-points and altered as needed for best fit. Cephalograms from all three time-points with digitally traced skeletal structures were printed for the remainder of the pitchfork analysis to be performed with hand-tracing on acetate paper.

Acetate paper was fixated onto each of the printed cephalograms from the three time-points, and digitally traced skeletal structures were transferred to the acetate paper using sharpened colored pencils, with a different color used for each time-point. An acetate template for different sizes and shapes of molars and incisors (Figure 7) was used to trace maxillary and mandibular first molars and incisors in order to maintain consistent tooth size within one set of traced cephalograms.

Figure 7. The template used to assist in tracing different shapes and sizes of maxillary incisors, mandibular incisors, maxillary molars, and mandibular molars.

Similar to the skeletal structures, when molars were identified bilaterally, they were bisected and traced accordingly. Once skeletal and dental structures were traced onto acetate paper, the functional occlusal plane (FOP) was hand-traced onto T0 and T2 time-points by visualizing the plane that passes through the occlusal surfaces of maxillary and mandibular first molars, premolars, and canines, but not the incisors. The fixated acetate paper was then removed from the printed digital cephalograms.

Three fiducial markers for each of the superimpositions were constructed on the T0 time-point by drawing 40 mm lines with 20 mm hash marks with arbitrary position and angulation (Figure 8).

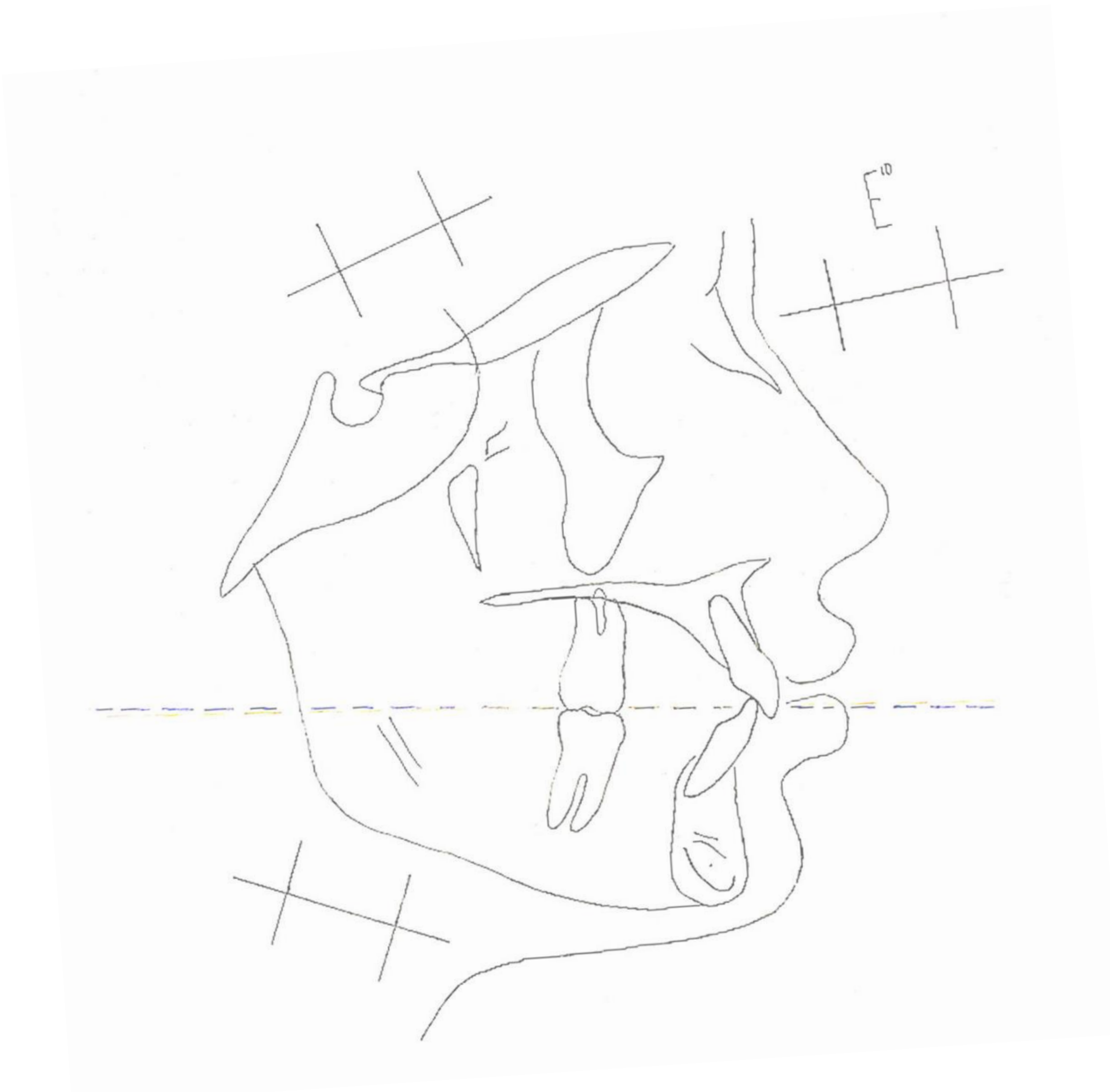

Figure 8. T0 time-point traced with FOP (yellow) and MFOP (purple) and fiducial markers to be used for superimposition of the cranial base, the maxilla, and the mandible. A 10 mm scale based on the cephalometer's calibration ruler was included for reference.

The fiducial markers were traced onto the T1 and T2 time-points using cranial base superimposition and regional maxillary and mandibular superimpositions. The superimposition techniques utilized were based on the methods outlined by Johnston,[9] as well as the standard superimposition techniques outlined by the American Board of Orthodontics. Cranial base superimposition utilized the anterior wall of sella turcica, the ethmoid crest, and the greater wings of the sphenoid as primary anatomical structures, with the roof of orbit and planum sphenoidale as secondary anatomical structures. Maxillary regional superimposition utilized the anterior surface of the zygomatic process and the orbital and nasal floors as the primary anatomical structure, and the maxillo-zygomatico temporal sulcus as the secondary structure. Mandibular regional superimposition utilized the internal contours of the symphysis and the inferior alveolar canal as the primary anatomical structures, and inferior surface of the developing third molar bud (only when no root development had begun) as the secondary anatomical structures. Transferring fiducial marks to all time-points using these careful superimposition techniques allowed for quick, reproducible superimposition when performing the pitchfork analysis to evaluate change between time-points.

Once all three fiducial markers were traced onto all three time-points using the relevant regional or overall superimposition techniques, the FOPs from the T0 and T2 time-points were visually averaged with the two time-points superimposed via maxillary regional superimposition to generate the mean functional occlusal plane (MFOP). MFOP was used as the horizontal reference plane perpendicular to which all anteroposterior changes were measured (Figure 9).

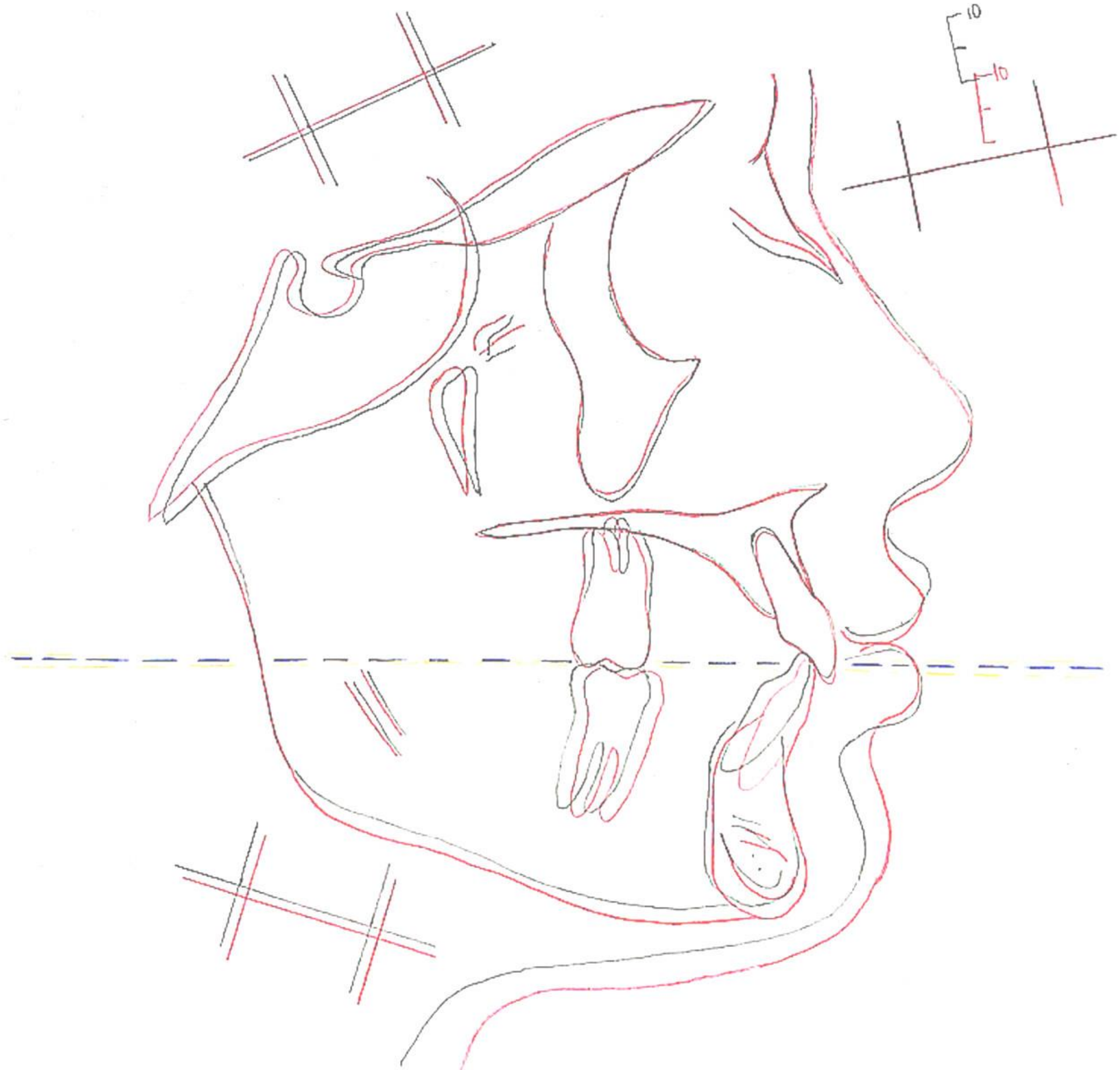

Figure 9. T0 (black) and T2 (red) time-points superimposed with maxillary regional superimposition. The functional occlusal plane (FOP) was traced as a yellow dashed line on each time-point, and these were averaged visually to generate the constructed mean functional occlusal plane (MFOP) seen as a purple dashed line. MFOP was traced onto all three time-points using the fiducial markers constructed with maxillary regional superimposition.

Furthermore, mandibular regional superimpositions were used to transfer D point from T0 to the remaining time-points (Figure 10).

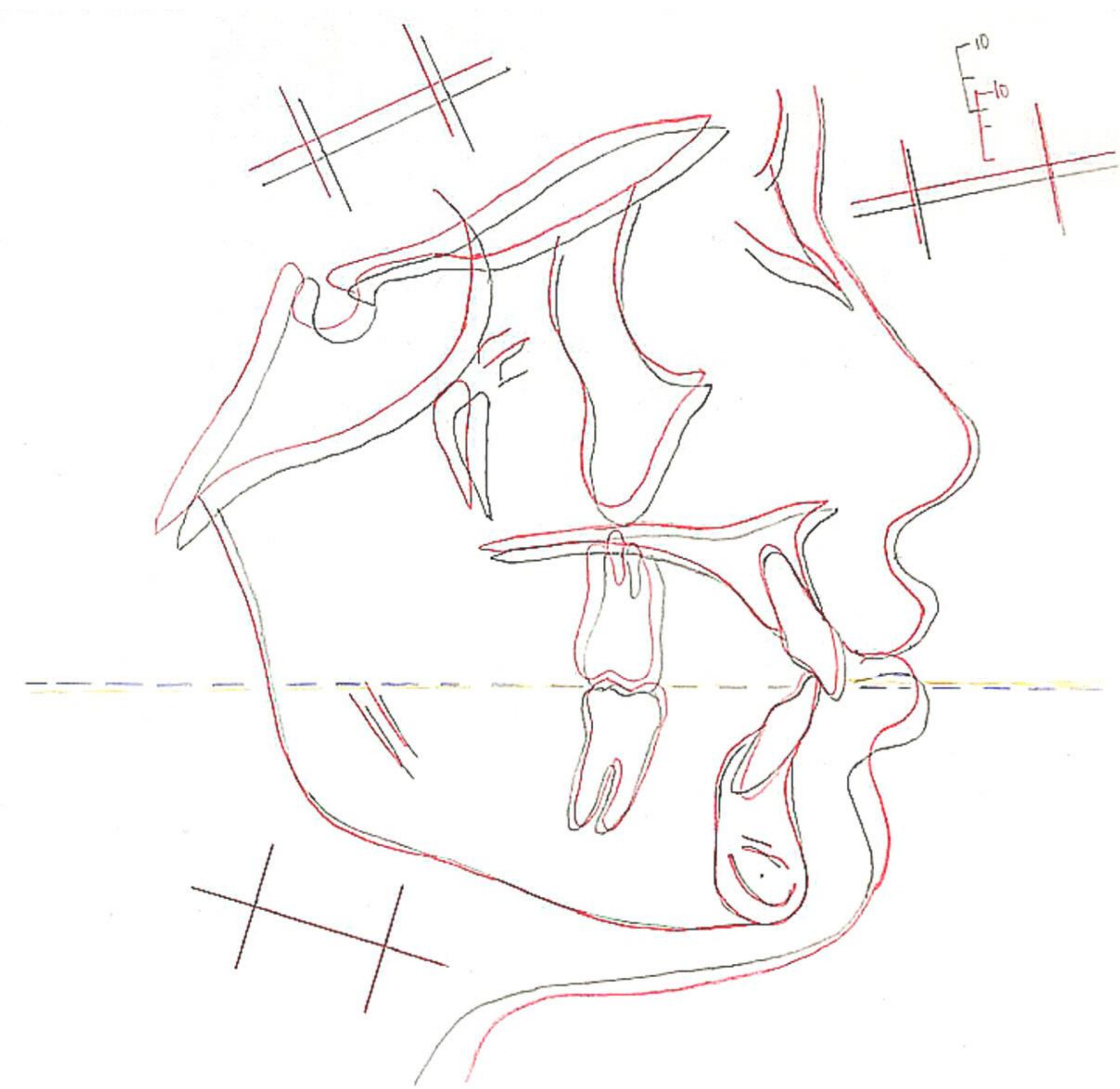

Figure 10. T0 (black) and T2 (red) time-points superimposed with mandibular regional superimposition. The constructed D-point was transferred from T0 to the T1 and T2 time-points using mandibular regional superimposition.

With MFOP, constructed D point, W point, and all other skeletal and dental structures hand-traced onto acetate for all three time-points T0-T2, the pitchfork analysis was used to evaluate the skeletal and dental components of anteroposterior change. Graph paper with a one-millimeter regular grid and a digital calipers were used to measure all changes to the nearest 0.5 millimeter (mm). Per the convention outlined in Johnston's pitchfork analysis, all measurements were given positive (+) signs when the displacement represented a change from a Class II to a more Class I occlusal relationship (e.g., anterior displacement of the mandible or mandibular molar, or posterior displacement of the maxilla or maxillary molar). Similarly, measurements were given negative (-) signs when the displacement represented a change towards a more Class II relationship (e.g., anterior displacement of the maxilla or maxillary molar, or posterior displacement of the mandible or mandibular molar).

Maxillary regional superimposition of T0 and T1 time-points and the T1 and T2 time-points allowed for measurement of anteroposterior displacement of the maxilla, the mandible, and the maxillary molar, all measured parallel to MFOP (Figure 11).

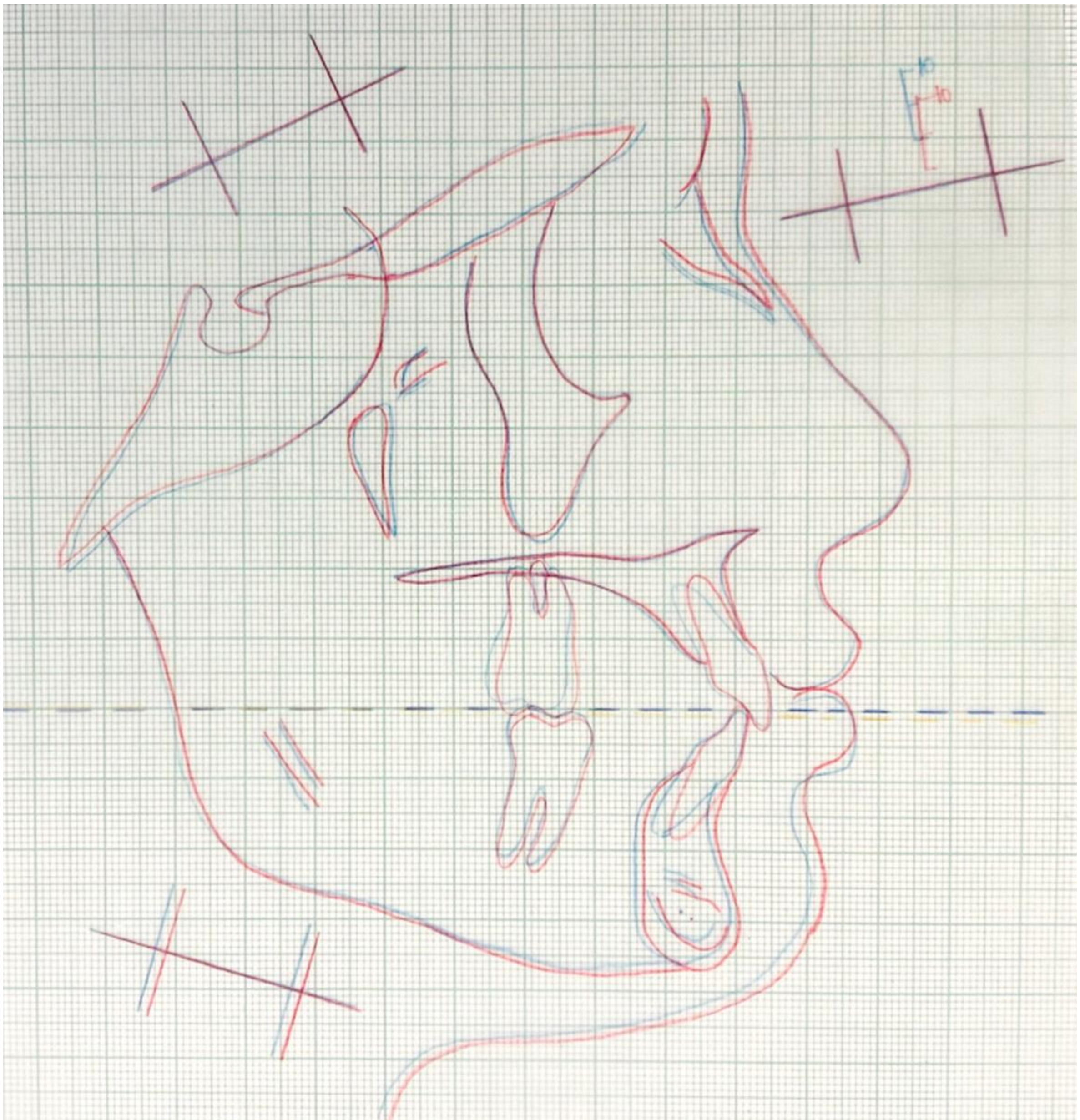

Figure 11. T1 (blue) and T2 (red) time-points superimposed with maxillary regional superimposition. Maxillary skeletal change was measured by the anteroposterior displacement of wing point, or the intersection of the greater wing of the sphenoid with planum sphenoidale. Mandibular skeletal change was measured by the anteroposterior displacement of D point. Maxillary molar change was measured by the anteroposterior displacement of the most convex point on the mesial surface of the maxillary molar outline.

Maxillary skeletal change was measured by the anteroposterior displacement of wing point in mm and termed ΔMX. Because of the downward and forward growth pattern of the maxilla relative to the cranial base, the wing point at the later time-point was either posterior to or unchanged relative to the wing point at the earlier time-point on maxillary regional superimposition. For all 33 subjects, ΔMX was either negative, indicating anterior displacement of the maxilla relative to the cranial base, or zero, indicating no anteroposterior change.

Mandibular skeletal change was measured by the anteroposterior displacement of D point in mm relative to the maxilla and termed ΔMN. Generally, the D point of the later time-point was anterior to the D point of the earlier time-point on maxillary superimposition, indicating that the mandible had been displaced anteriorly relative to the maxilla. However, the D point of the later time-point was in some cases located posterior to the D point of the earlier time-point, indicating a possible downward and backward mandibular displacement relative to the maxilla. For this reason, ΔMN was generally a positive value, indicating anterior mandibular displacement relative to the maxilla, but was in some cases negative, indicating posterior mandibular displacement relative to the maxilla.

Notably, the mandibular skeletal change in the pitchfork analysis is measured relative to the maxilla rather than the cranial base, due to the ease with which anteroposterior skeletal change can be measured from only one reproducible superimposition. To determine the mandibular skeletal change relative to the cranial base, the ΔMX and ΔMN values can be summed to yield the apical base change in mm (ABCH), or the amount that the mandible outgrew the maxilla ($\Delta MX + \Delta MN = ABCH$).

Positive values for ABCH represent more anterior displacement of the mandible relative to the cranial base than anterior displacement of the maxilla relative to the cranial base. Negative values for ABCH represent more anterior displacement of the maxilla relative to the cranial base than anterior displacement of the mandible relative to the cranial base.

Maxillary molar change was measured by the anteroposterior displacement of the most convex point on the mesial surface of the maxillary molar outline in mm relative to the maxilla and termed ΔMX6. Because a distalizing appliance was used between T0 and T1, the maxillary molar generally moved posteriorly between these time-points, leading to a positive value for ΔMX6. However, because the molar position moved anteriorly during the rest of orthodontic treatment, the ΔMX6 value was generally negative from T1 to T2, indicating maxillary molar relapse towards a more Class II relationship following distalization.

The measurement of mandibular molar anteroposterior change utilized a different superimposition technique than the previous measurements. Maintaining the MFOP of both time-points parallel to each other, the tracing of one time-point was slid horizontally until the D-points of both time-points were aligned in a vertical line perpendicular to the MFOP (Figure 12).

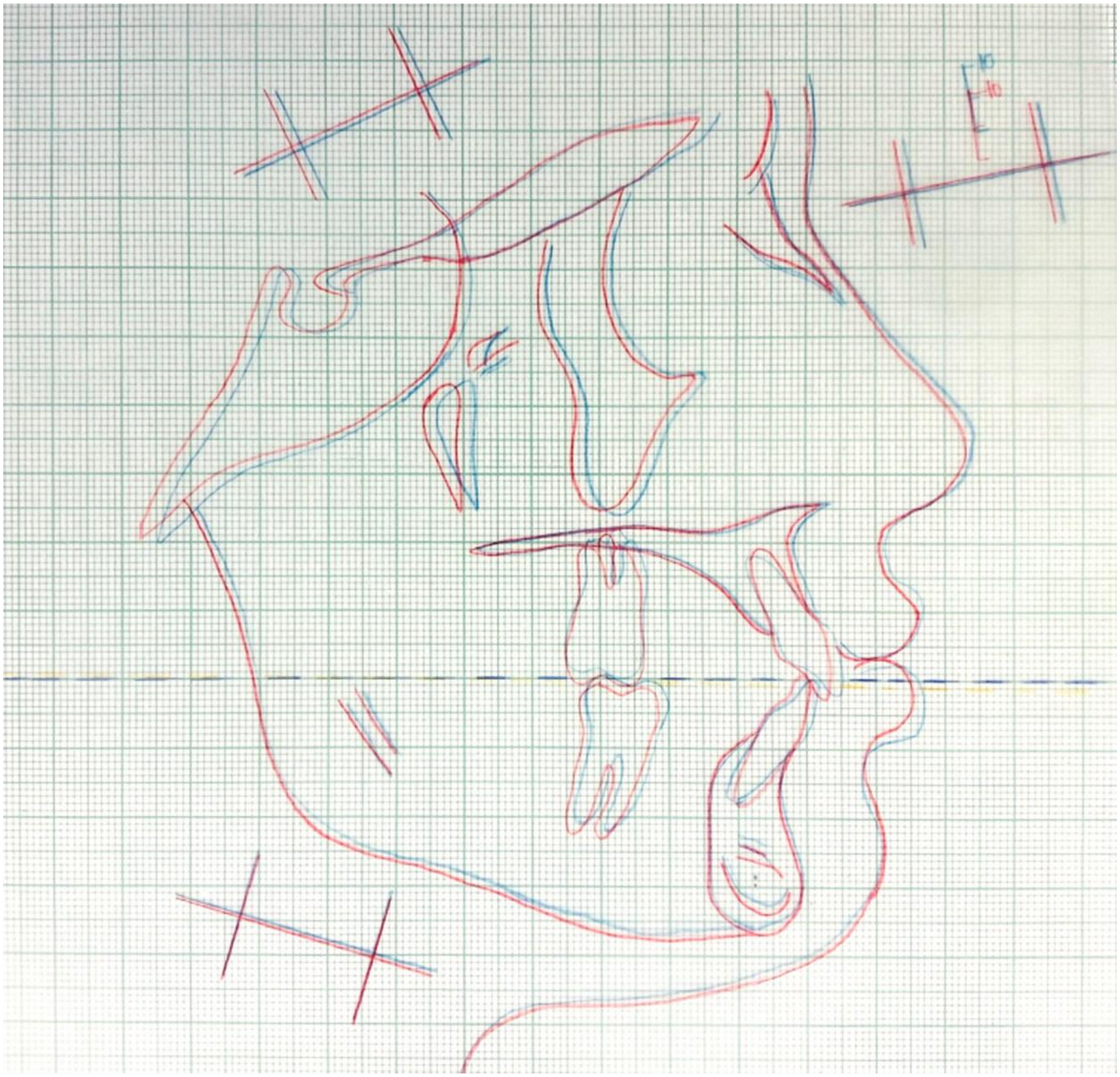

Figure 12. T1 (blue) and T2 (red) time-points superimposed for measurement of mandibular molar change. Mandibular molar change was measured by sliding the acetate tracing of one time-point horizontally, maintaining both MFOP tracings parallel with each other, until the D points from both time-points were aligned vertically perpendicular to MFOP. From this position, mandibular molar change was measured by the anteroposterior displacement of the most convex point on the mesial surface of the mandibular molar outline.

From this superimposition, the anteroposterior displacement of the most convex point of the mesial surface of the mandibular molar was measured in mm relative to the mandible and termed ΔMN6. In general, as is often the case with correction of Class II molar relationships, the mandibular molar appeared to move anteriorly between all time-points. Once all skeletal and dental measurements were made, the pitchfork analysis was used to calculate the skeletal and dental components of molar relationship change.

Anteroposterior skeletal change was calculated by summing ΔMX and ΔMN to yield ABCH. The overall anteroposterior molar relationship change was calculated by summing the skeletal change, ABCH, with the dental change, ΔMX6 and ΔMN6. This value (ABCH + ΔMX6 + ΔMN6) represents the total molar relationship correction in mm between two time-points. A positive value of ABCH + ΔMX6 + ΔMN6 represents correction of a Class II molar relationship towards a more Class I relationship, while a negative value of ABCH + ΔMX6 + ΔMN6 represents a change towards a more Class II relationship.

In addition to measuring cephalograms, digital dental models were used in order to categorize subjects according to T0 Class II molar relationship. Digital models in commercially available software (OrthoCAD, Cadent, San Jose CA) were used to determine Class II molar relationship. In order to ensure that the software viewer was oriented parallel to the buccal segment, the line formed by the central grooves of the posterior teeth was used as a reference perpendicular to which the viewer was to be oriented in order to best assess the Class II relationship from the direct buccal aspect. Measurements were made in the software to the nearest tenth of a millimeter between the maxillary first molar mesiobuccal cusp tip and the mandibular first molar buccal groove to quantify molar relationship.

C. Data and Analyses

Data from each qualified case included: digitized cephalograms from digital models at three time-points, gender (female, male), pre-treatment age (years), and dates of start (T0), end of distalization (T1) and end of treatment (T2). Measurements from the cephalometric analyses included: anteroposterior maxillary and mandibular skeletal growth relative to the cranial base, summed as apical base change (ABCH), and anteroposterior change in maxillary (MX) and mandibular (MN) molar (6) positions relative to the basal bone, summed as changes in molar relationships (6/6 = ABCH + MX6 + MN6). Measurements from the digital models were measured in tenths of a millimeter, measurements from cephalograms were measured within a half millimeter, and means and standard deviations were reported with two decimal places. Measurements for each subject at each of the three time-point intervals can be seen in Appendix A. Data for all measurements are reported as means ± standard deviations in Appendix B.

In this study, the main dependent variables were ABCH and 6/6 changes measured between the time-points (ΔT0-T1, ΔT1-T2, and ΔT0-T2). The independent variables were amount of Class II relationship (2.0-3.0 mm or 3.1-7.0 mm) at T0, CVM (≤CS3: greater potential for growth, ≥CS4: lesser potential for growth) at T0, and gender (female, male).

One case was randomly selected to test reliability of measurements. Cephalometric tracing, measurements, and superimpositions were performed between two time-points by the same operator once per week for 5 weeks to calculate intra-operator reliability with coefficients of variance for cephalometric landmark identification.

Statistical analyses used were analysis of variance with Tukey post-hoc tests where indicated and significance defined by $P \leq 0.05$.

III. Results

A. Sample description

The sample used in this study was comprised of 33 subjects all treated with the Carriere distalizer appliance. Subjects were categorized into two groups based on amount of Cl II molar relationship in mm at the pre-treatment time-point (T0): 2.0-3.0 mm (Group A) and 3.1-7.0 mm (Group B). Group A had a mean pre-treatment Class II molar relationship of -2.5 ± 0.3 mm, while Group B had a mean pre-treatment Class II molar relationship of -4.1 ± 0.8 mm (Table 1). Group A had 16 subjects (females=10, males=6), and Group B had 17 subjects (females=8, males=9). The mean age at T0 was 13.4 ± 1.7 years for Group A and 13.2 ± 1.4 years for Group B. Group A had 10 subjects with CVM ≤ CS3 and 10 subjects with CVM ≥ CS4, while Group B had 9 subjects with CVM ≤ CS3 and 4 subjects with CVM ≥ CS4.

Group (T0 Class II in mm)	Treatment Phase	Start Phase Molar Class II (mm)	Δ MX	Δ MN	ABCH	Δ MX6	Δ MN6	ABCH + ΔMX6 + ΔMN6	End Phase Molar Class II (mm)	Time (months)
A (2-3) N=16	T0-T1	-2.5 ± 0.3	-0.5 ± 0.6	0.8 ± 1.4	0.2 ± 1.7	1.2 ± 1.1	*1.4 ± 0.7	*2.8 ± 1.2	1.2 ± 0.9	4.9 ± 1.1
	T1-T2	1.2 ± 0.9	*-0.6 ± 0.7	0.8 ± 1.1	0.2 ± 1.3	-1.6 ± 1.4	0.4 ± 1.3	-1.1 ± 0.6	0.1 ± 0.6	15.5 ± 6.1
	T0-T2	-2.5 ± 0.3	-1.1 ± 1.1	1.5 ± 1.6	0.4 ± 1.8	*-0.4 ± 1.4	1.8 ± 1.0	1.8 ± 1.2	0.1 ± 0.6	*20.4 ± 6.1
B (3.1-7) N=17	T0-T1	-4.1 ± 0.8	-0.4 ± 0.6	0.7 ± 1.2	0.3 ± 1.3	2.2 ± 1.2	*1.8 ± 1.1	*4.4 ± 1.0	1.0 ± 0.7	5.4 ± 2.0
	T1-T2	1.0 ± 0.7	*-0.9 ± 0.9	0.8 ± 1.3	-0.1 ± 1.6	-1.4 ± 2.1	0.2 ± 1.6	-1.1 ± 1.0	-0.0 ± 0.9	19.2 ± 8.4
	T0-T2	-4.1 ± 0.8	-1.3 ± 1.0	1.6 ± 1.9	0.3 ± 2.2	*0.8 ± 1.5	2.1 ± 1.5	3.3 ± 1.6	-0.0 ± 0.9	*24.6 ± 8.6

Table 1. Skeletal and dental anteroposterior changes and treatment durations associated with the distalization and post-distalization treatments by amount of Class II molar relationship at T0. Group A (2.0-3.0 mm) had 16 subjects, Group B (3.1-7 mm) had 17 subjects. Data are shown as mean ± standard deviation. Positive values indicate change towards a more Class I occlusal relationship (e.g., relative anterior displacement of mandible), while negative values indicate change towards a more Class II occlusal relationship (e.g., relative anterior displacement of maxilla). Significant differences between groups for same time-points are indicated by * where P ≤ 0.05.

B. Treatment Duration

The distalization treatment phase (T0-T1) lasted 5.2 ± 1.8 months in Group A and 5.2 ± 1.2 months in Group B (Table 1; Figure 13), while the post-distalization treatment phase (T1-T2) lasted 15.5 ± 6.1 in Group A and 19.2 ± 8.4 months in Group B (Table 1; Figure 13) and these between-group comparisons were not significantly different. The overall treatment duration (T0-T2) lasted 20.4 ± 6.1 months in Group A and was significantly shorter than the 24.6 ± 8.6 months in Group B (Table 1; Figure 13).

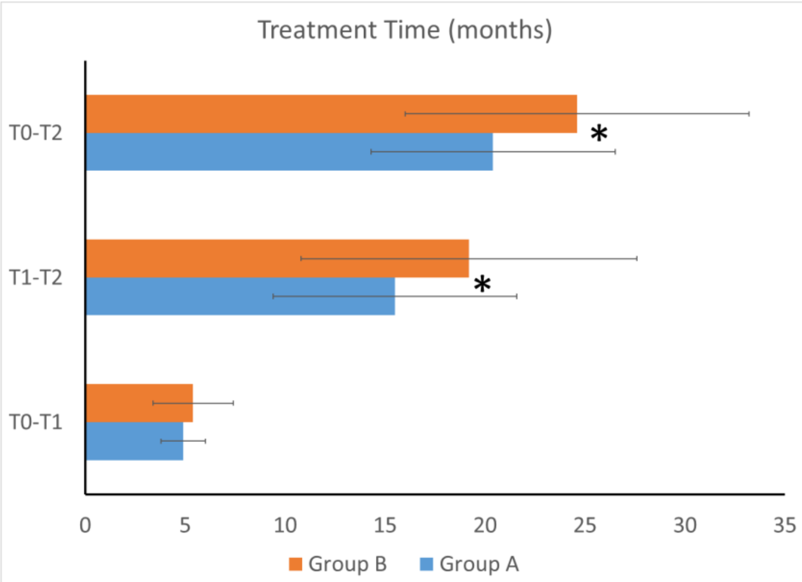

Figure 13. Treatment time in months shown by pre-treatment T0 Class II molar relationship: Group A (2.1-3.0 mm) and Group B (3.1-7.0 mm). Significant differences between groups for same time-points are indicated by * where P ≤ 0.05.

C. Skeletal Change

During the distalization treatment phase (T0-T1), both groups showed anterior displacement of the maxilla and mandible relative to cranial base (Table 1). In Group A from T0-T1, maxillary anterior displacement was -0.5± 0.6 mm, and the overall mandibular anterior displacement was 0.8 ± 1.5 mm (Figure 14). The ABCH for Group A was 0.2 ± 1.7 mm, indicating that on average the mandible very slightly outgrew the maxilla during the overall treatment period (Figure 15). In Group B, the overall maxillary anterior displacement was -0.4± 0.6 mm, and the overall mandibular anterior displacement was 0.7 ± 1.2 mm (Figure 14). The ABCH for Group B was 0.3 ± 1.3 mm, indicating that on average the mandible very slightly outgrew the maxilla during the overall treatment period (Figure 15).

During the post-distalization treatment phase (T1-T2), both groups showed anterior displacement of the maxilla and mandible relative to cranial base (Table 1). In Group A from T1-T2, maxillary anterior displacement was -0.6± 0.7 mm, and the overall mandibular anterior displacement was 0.8 ± 1.1 mm (Figure 14). The ABCH for Group A was 0.2 ± 1.3 mm, indicating that on average the mandible very slightly outgrew the maxilla during the overall treatment period (Figure 15). In Group B, the overall maxillary anterior displacement was -0.9 ± 0.9 mm from T1-T2, and the overall mandibular anterior displacement was 0.8 ± 1.3 mm (Figure 14). The ABCH for Group B was -0.1 ± 1.6 mm, indicating that on average the maxilla very slightly outgrew the mandible during the overall treatment period (Figure 15).

Subjects in Groups A and B experienced anterior displacement of both the maxilla and mandible relative to the cranial base during the overall treatment period (T0-T2; Table 1). In Group A, the overall maxillary anterior displacement from T0-T2 was -1.1 ± 1.1 mm, and the overall mandibular anterior displacement was 1.5 ± 1.6 mm (Figure 14). The T0-T2 ABCH for Group A was 0.4 ± 1.8 mm, indicating that on average the mandible slightly outgrew the maxilla during the overall treatment period (Figure 15). In Group B, the overall maxillary anterior displacement was -1.3 ± 1.0 mm, and the overall mandibular anterior displacement was 1.6 ± 1.9 mm (Figure 14). The ABCH for Group B was 0.3 ± 2.2 mm, indicating again that on average the maxilla very slightly outgrew the mandible during the overall treatment period (Figure 15).

The only statistically significant difference ($P \leq 0.05$) between groups A and B with respect to skeletal change was found in maxillary anterior displacement from T1-

T2, in which Group B showed significantly more maxillary anterior displacement. (Table 1; Figure 14).

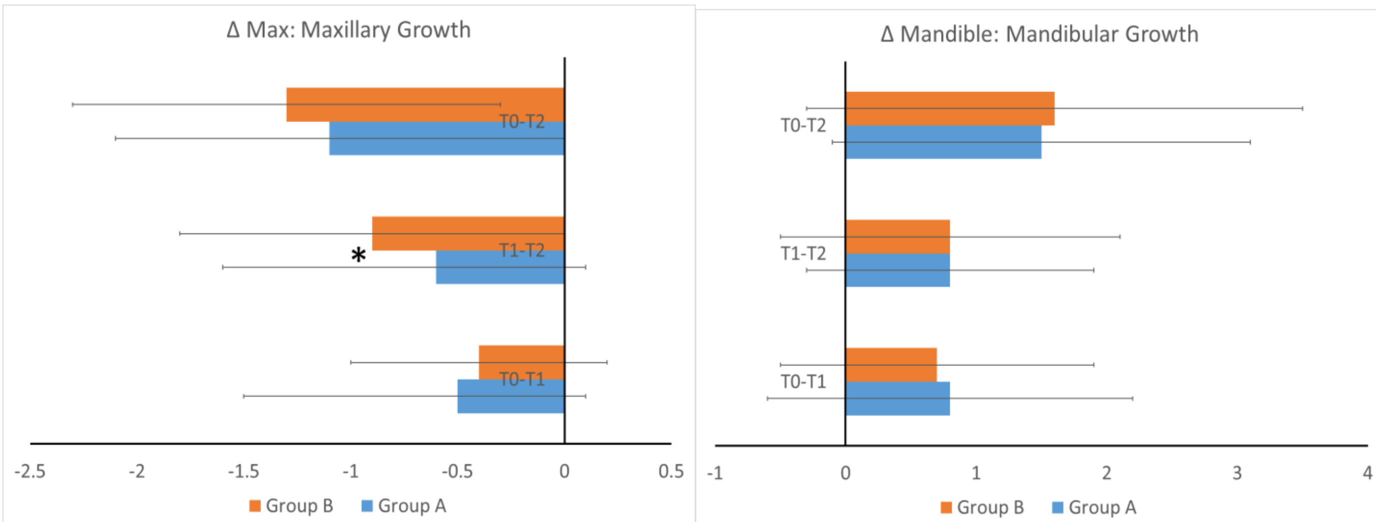

Figure 14. Differences in mandibular and maxillary skeletal change in mm between groups by pre-treatment T0 Class II molar relationship: Group A (2.1-3.0 mm) and Group B (3.1-7.0 mm). Significant differences between groups for same time-points are indicated by * where $P \leq 0.05$.

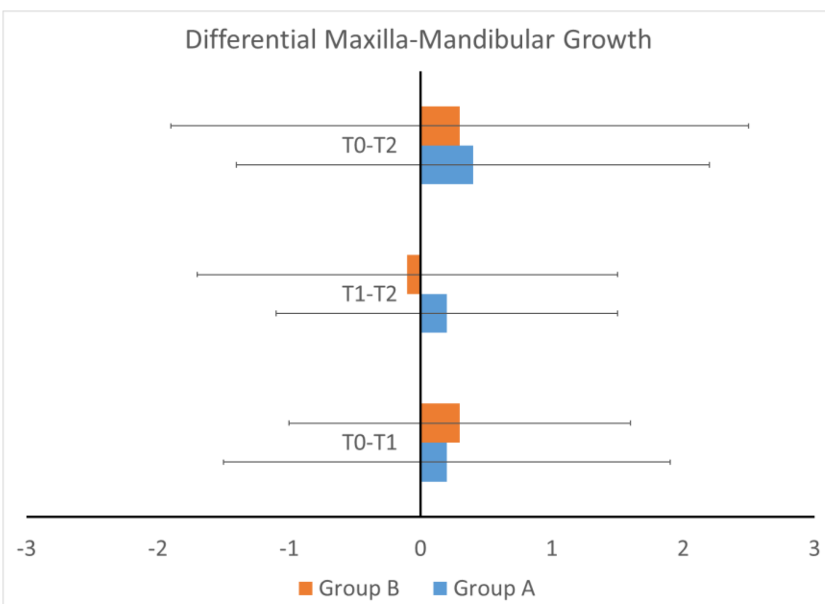

Figure 15. Differences in mandibular and maxillary skeletal growth in mm between groups by pre-treatment T0 Class II molar relationship: Group A (2.1-3.0 mm) and Group B (3.1-7.0 mm). Negative values represent the amount that the maxilla outgrew the mandible over a given time interval. Significant differences between groups for same time-points are indicated by * where P ≤ 0.05.

D. Dental Change

Subjects in Groups A and B experienced distal movement of the maxillary molar and mesial movement of the mandibular molar during the distalization phase (T0-T1; Table 1). In Group A, the maxillary molar moved distally 1.2 ± 1.1 mm and the mandibular molar moved mesially 1.4 ± 0.7 mm (Figure 16). In Group B, the maxillary molar moved distally 2.2 ± 1.2 mm and the mandibular molar moved mesially 1.8 ± 1.1 mm. These changes resulted in overcorrection of initial Class II molar relationships in both groups. At T1, Group A had a 1.2 ± 0.9 mm Class III molar relationship and Group B had a 1.0 ± 0.7 mm Class III molar relationship.

In the post-distalization phase (T1-T2), subjects in both Groups A and B showed relapse of the maxillary molar distalization achieved during the distalization phase as well as further mesial movement of the mandibular molar (Table 1). In Group A from T1-T2, the maxillary molar moved mesially -1.6 ± 1.4 mm and the mandibular molar moved mesially 0.4 ± 1.3 mm (Figure 16). In Group B, the maxillary molar moved mesially -1.4 ± 2.1 mm and the mandibular molar moved mesially 0.2 ± 1.6 mm (Figure 16). Though in both groups the maxillary molar relapsed during the post-distalization treatment phase, the final (T2) molar relationships in both groups were within 0.2 mm of a Class I molar relationship.

During the overall treatment period (T0-T2), for Group A the maxillary molar moved mesially by -0.4 ± 1.4 mm and the mandibular molar moved mesially by 1.8 ± 1.0 mm (Figure 16). For Group B, the maxillary molar moved distally by 0.8 ± 1.5 mm and the mandibular molar moved mesially by 2.1 ± 1.5 mm (Figure 16).

Statistically significant differences ($P \le 0.05$) between groups A and B with respect to dental change were found in maxillary molar displacement from T0-T2, in which Group B showed significantly more maxillary molar distalization, and in mandibular molar displacement from T1-T2, in which Group B showed significantly more mandibular molar mesial movement (Table 1; Figure 16).

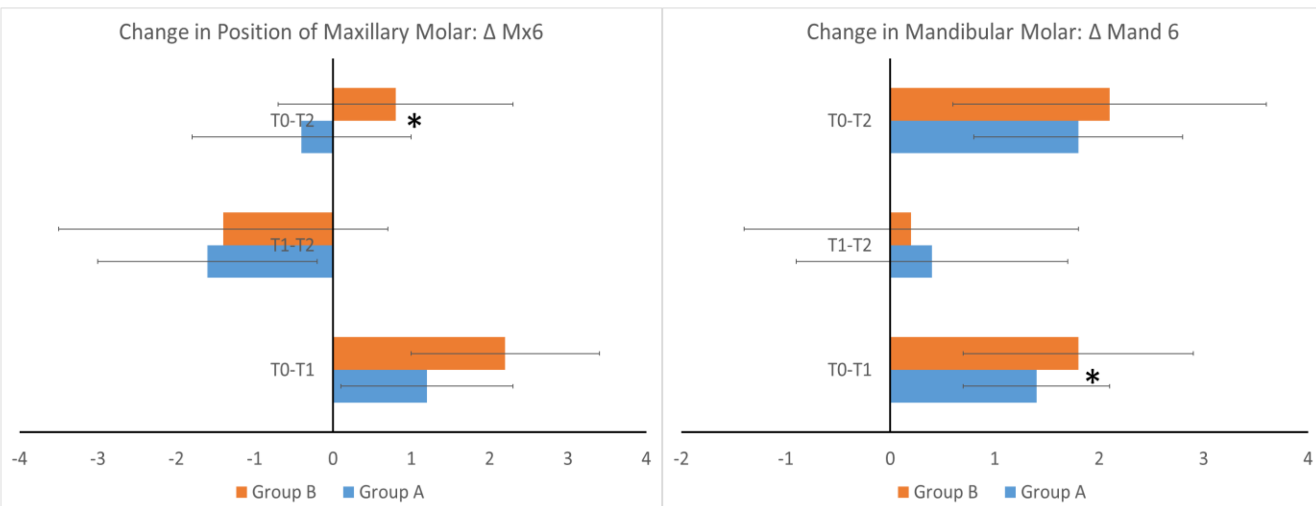

Figure 16. Differences in mandibular and maxillary molar change in mm between groups by pre-treatment T0 Class II molar relationship: Group A (2.1-3.0 mm) and Group B (3.1-7.0 mm). Significant differences between groups for same time-points are indicated by * where $P \le 0.05$.

E. Molar Relationship

Group A had a mean pre-treatment (T0) Class II molar relationship of -2.5 ± 0.3 mm. The average total molar change for Group A as measured by the pitchfork analysis during T0-T1 was a 2.8 ± 1.2 mm improvement towards Class I molar relationship (Table 1; Figure 17). However, the molar relationships as measured by digital models at the post-distalization time-point (T1) were 1.2 ± 0.9 mm Class III, indicating a 3.7 mm change in molar relationship. Similarly, the average molar relationship change for Group A as measured by the pitchfork analysis during T0-T2 was a 1.8 ± 1.2 mm improvement towards Class I molar relationship (Figure 17). However, the molar relationships as measured by digital models at the end of treatment (T2) were 0.1 ± 0.6 mm Class III, which based on the starting Class II molar relationship of -2.5 ± 0.3 mm indicates a 2.6 mm T0-T2 molar relationship change.

Group B had a mean pre-treatment (T0) Class II molar relationship of -4.1± 0.8 mm. The total molar change for Group B measured by the pitchfork analysis during T0-T1 was a 4.4 ± 1.0 mm improvement towards Class I molar relationship (Table 1; Figure 17). However, digital model molar relationship at T1 was 1.0 ± 0.7 mm Class III, indicating a 5.1 mm molar relationship correction. Similarly, the average molar relationship change from T0-T2 for Group B as measured by the pitchfork analysis was a 3.3 ± 1.6 mm improvement towards Class I molar relationship (Figure 17). However, the molar relationships as measured by digital models at the end of treatment (T2) were -0.0 ± 0.9 mm Class II (virtually Class I), which based on the starting Class II molar relationship of -4.1 ± 0.8 mm indicates a 4.1 mm T0-T2 molar relationship change.

The only statistically significant difference (P ≤ 0.05) between groups A and B with respect to molar relationship change were found in from T0-T1, in which Group B showed significantly great molar relationship change than Group A (Table 1; Figure 17).

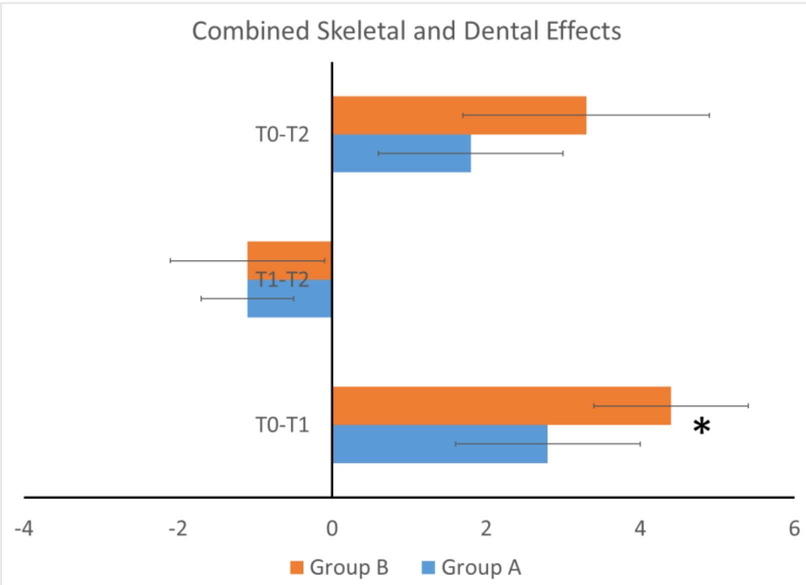

Figure 17. Differences in total molar relationship change in mm between groups by pre-treatment T0 Class II molar relationship: Group A (2.1-3.0 mm) and Group B (3.1-7.0 mm). Significant differences between groups for same time-points are indicated by * where P ≤ 0.05.

F. Clear Aligners vs. Fixed orthodontic appliances

While the primary categorization of subjects was based on starting Class II molar relationship, the results were also analyzed based on which of two orthodontic treatment modalities were utilized in the subjects: clear aligner therapy (CAT) and fixed orthodontic appliances (FOA). The groups were not well-balanced, with 27 of the 33 subjects receiving CAT and only 6 of the 33 subjects receiving FOA. No statistically significant differences were detected for any dental measurements across the three time-points between groups by appliance type. While these results may not be sufficiently powered to demonstrate statistical significance, the mean pre-treatment Class II molar relationship was -3.4 ± 1.1 mm for the CAT group and -3.2 ± 0.8 mm for the FOA group. Total molar relationship change from T0-T2 was 2.7 ± 1.6 mm for the CAT group and 1.7 ± 1.5 mm for the FOA group and was not significantly different (Table 2). The distalization phase (T0-T1) lasted 5.2 ± 1.6 months for the CAT group and 4.7 ± 1.6 months for the FOA group and was not significantly different. The post-distalization orthodontic treatment phase (T1-T2) lasted 16.3 ± 5.8 months for the CAT group and 22.6 ± 12.1 months for the FOA group. Total treatment duration (T0-T2) was 21.5 ± 6.4 months for the CAT group and 27.3 ± 11.6 months for the FOA group.

Several statistically significant differences ($P \leq 0.05$) between CAT and FOA groups were found. With respect to treatment duration, the FOA group had a significantly longer treatment than the CAT group at the T0-T2 and T1-T2 intervals. With respect to skeletal change, the FOA group had significantly more maxillary anterior displacement from T1-T2, the CAT group had significantly more mandibular anterior displacement from T0-T2, and the CAT group had a significantly larger ABCH for T0-T2 and T1-T2 (Table 2).

Group (CAT vs. FOA)	**Treatment Phase**	**Start Phase Molar Class II (mm)**	**Δ MX**	**Δ MN**	**ABCH**	**Δ MX6**	**Δ MN6**	**ABCH + ΔMX6 + ΔMN6**	**End Phase Molar Class II (mm)**	**Time (months)**
CAT	T0-T1	-3.4 ± 1.1	-0.5 ± 0.6	0.8 ± 1.3	0.3 ± 1.5	1.8 ± 1.3	1.6 ± 0.8	3.7 ± 1.3	1.2 ± 0.8	5.2 ± 1.6
N=27	T1-T2	1.2 ± 0.8	*-0.6 ± 0.7	1.0 ± 0.9	*0.4 ± 0.9	-1.5 ± 1.5	0.2 ± 1.4	-1.0 ± 0.7	0.1 ± 0.8	*16.3 ± 5.8
	T0-T2	-3.4 ± 1.1	-1.1 ± 0.9	*1.8 ± 1.3	*0.7 ± 1.3	0.3 ± 1.3	1.7 ± 1.2	2.7 ± 1.6	0.1 ± 0.8	*21.5 ± 6.4
FOA	T0-T1	-3.2 ± 0.8	-0.4 ± 0.7	0.4 ± 1.4	0.0 ± 1.5	1.4 ± 0.9	1.8 ± 1.6	3.3 ± 1.4	0.6 ± 0.5	4.7 ± 1.6
N=6	T1-T2	0.6 ± 0.5	*-1.3 ± 0.9	-0.2 ± 1.9	*-1.5 ± 2.5	-1.3 ± 2.9	0.9 ± 1.7	-1.6 ± 1.4	-0.1 ± 0.9	*22.6 ± 12.1
	T0-T2	-3.2 ± 0.8	-1.8 ± 1.1	*0.3 ± 2.8	*-1.5 ± 3.5	0.1 ± 2.6	2.8 ± 1.5	1.7 ± 1.5	-0.1 ± 0.9	*27.3 ± 11.6

Table 2. Skeletal and dental anteroposterior changes and treatment durations associated with the distalization and post-distalization treatments by orthodontic appliance used. Clear aligner therapy (CAT) was utilized in 27 subjects, while fixed orthodontic appliances (FOA) were used in 6 subjects. Data are shown as mean ± standard deviation. Positive values indicate change towards a more Class I occlusal relationship (e.g., relative anterior displacement of mandible), while negative values indicate change towards a more Class II occlusal relationship (e.g., relative anterior displacement of maxilla). Significant differences between groups for same time-points are indicated by * where $P \leq 0.05$.

G. CVM and Gender Differences

There were no statistically significant differences for any of the dependent variables between groups by gender and groups by T0 CVM.

H. Intra-operator Reliability Assessment

One case was randomly selected to test reliability of measurements. The methods of cephalometric tracing, measurements, and superimpositions described above were performed between by the same operator once per week for 5 weeks to calculate intra-operator reliability for cephalometric landmark identification. The intra-class correlational coefficients of variation (COV) for each dependent variable were evaluated based on these definitions: COV<0.50 was indicative of poor reliability, 0.50<COV<0.75 indicated moderate reliability, 0.75<COV<0.90 indicated good reliability, and COV>0.90 indicated excellent reliability. Four of the six dependent variables showed poor reliability (COV≤0.42) – ΔMX, ΔMN, ΔMX6, and ABCH+MX6+MN6, while ΔABCH showed good reliability (COV=0.62) and ΔMN6 showed excellent reliability (COV=1.00) (Table 3).

IV. Discussion

A. Treatment Duration

The average duration of the distalization phase of treatment (T0-T1), approximately 5 months, is similar to previous findings in the literature of 5 months.[7,8] The second phase of treatment lasted 15 months in Group A and 19 months in Group B and the difference was not significant. However, in terms of treatment duration from T0-T2, Group A at 20.4 months was significantly shorter than Group B at 24.6 months. This finding may be explained by the fact that subjects in Group A started with a less severe Class II malocclusion, leading to a more efficient molar correction and total treatment time. Similarly, the more severe Class II malocclusions in subjects in Group B may have had underlying differences in vertical and or anteroposterior growth patterns, which could have affected the efficiency of treatment and lead to an increase in overall treatment time in Group B compared to Group A.

There were also statistically significant differences between groups by appliance type for the T1-T2 interval and the T0-T2 interval. The 6 subjects in the FOA group were treated for approximately 6 months longer in the post-distalization treatment phase (T1-T2), leading to approximately 6 months more of total orthodontic treatment (T0-T2). While this difference did meet statistical significance, it should be noted that effect size was small and a larger sample would be needed in the FOA group to achieve sufficient power. In addition to the imbalance in sample size, the difference in treatment durations between the CAT group and the FOA group may be due to differences in case difficulty unrelated to the amount of T0 molar Class II relationship, such as crowding, spacing, vertical facial morphology, or other factors influencing treatment that this study did not evaluate. Furthermore, this study only evaluated the records of one orthodontist, which may reflect the preferences of the clinician rather than a generally applicable clinical difference in treatment duration between clear aligners and fixed appliances.

B. Skeletal change

The maxilla showed very slight anterior displacement from T0-T1, on average 0.5 mm in Group A and 0.4 mm in Group B. The mandible in both groups was displaced anteriorly on average by 0.8 mm and 0.7 mm, respectively. The average T0-T1 changes yielded ABCH values of 0.2 mm in Group A and 0.3 mm in Group B. In Group A, a positive average ABCH of 0.2 mm was also seen from T1-T2, where the mandible continued to outgrow the maxilla. However, in Group B, the maxilla outgrew the mandible on average by 0.1 mm from T1-T2. Furthermore, the average T0-T2 ABCH in Group A was 0.4 mm, while the average T0-T2 ABCH in Group B was 0.3 mm.

The T1-T2 ΔMX difference between groups by Class II molar relationship was found to be statistically significant, with -0.6 mm of maxillary anterior displacement in Group A, and -0.9 mm of maxillary anterior displacement in Group B. However, this difference had a statistically small effect size, and may not have been sufficiently powered to be clinically useful information. Furthermore, it should be noted that the statistical significance shown here may not be of clinical significance, as previous authors investigating anteroposterior cephalometric change over time have suggested that clinical significance can be seen in measures ≥ 2.0 mm.[7,17]

In addition to the statistically significant difference between groups by T0 Class II molar relationship, there were several statistically significant differences between groups by appliance type. These included differences in ΔMX values from T1-T2, in which the FOA group showed more maxillary anterior displacement, and ΔMN values from T0-T2, in which the CAT group showed more mandibular anterior displacement, and ABCH values from T1-T2 and T0-T2, in which the CAT group showed more mandibular anterior displacement than maxillary by 0.7 mm overall (T0-T2), and the FOA group showed more maxillary anterior displacement than mandibular by 1.5 mm overall (T0-T2). As mentioned previously, these differences were of small effect size and while statistically significant, may not represent clinically significant differences between subjects treated with clear aligner therapy and fixed orthodontic appliances. Nonetheless, a possible reason for these differences may be posterior mandibular rotation during the treatment period in the FOA group. The effects of remodeling and growth on the rotational position of the mandible during adolescent development have been described in the literature,[18-23] and it is possible that subjects in the FOA group may have had differing vertical skeletal morphologies than those in the CAT group, which previous studies have shown to contribute to directional differences in mandibular growth.[24-26] Indeed, one recent study noted similar posterior changes in mandibular position following treatment with the Carriere distalizer appliance, and an increase in the vertical dimensions following treatment has been postulated as a possible contributing factor.[7] Because anteroposterior and vertical skeletal patterns were not measured and compared in this study, future studies comparing pre-treatment skeletal morphologies would be needed to determine whether or not the differences in anteroposterior positions in the maxilla and mandible across the time-points were due to differences in vertical or anteroposterior skeletal growth patterns of the maxillo-mandibular complex relative to the cranial base.

C. Dental change

The dental changes in both groups by T0 Class II molar relationship showed a distal movement of the maxillary molar and mesial movement of the mandibular molar from T0-T1. The higher values for both maxillary and mandibular molar movement in Group B compared to Group A may be attributed to the higher pre-treatment Class II molar relationship values in Group B and the clinical protocol, in which the use of the Carriere distalizer appliance was terminated once a Class I or super Class I molar relationship was achieved. This protocol is consistent with those of several studies of maxillary molar distalization previously reported in the literature.[1,3-6,12-15] Interestingly, the amounts of distal maxillary molar movement from T0-T1 found in this study, 1.2 mm for Group A and 2.2 mm for Group B, were less than the 2.8-6.1 mm of maxillary molar distalization previously reported by Chiu et al and Caprioglio et al.[14,15] This difference may be due to varying methods of cephalometric analysis or smaller sample size in the current study.

Furthermore, while mesial mandibular movement was present in both groups from T0-T1, there was a statistically significant difference between groups detected for this measurement. For Group A from T0-T1, the mandibular molar moved mesially by 1.4 mm, while for Group B it moved mesially by 1.8 mm. This difference may be due to differences in the active clear aligners being worn by the subjects in the mandibular arch during distalization with the Carriere distalizer appliance. However, it should be noted that the statistical significance shown here may not be of clinical significance, as this discrepancy is 0.4 mm and may be insufficient for clinical relevance.[7,17]

The dental changes observed in both groups from T1-T2 reflect a relapse of the maxillary molar movement achieved during the distalization treatment phase as well as further mesial mandibular molar movement. In Group A, all of the distalization (100%) was lost during the second phase of treatment, whereas in Group B, only 1.4 mm of the initial 2.2 mm of molar distalization (63%) relapsed. These findings corroborate those of previous reports, in which the amount of maxillary molar distalization relapse was found to be 43-91%.[12,14,15] Mesial mandibular molar movement was similar between both groups from T1-T2.

Total dental change from T0-T2 in Group A showed a net mesial maxillary molar movement of 0.4 mm despite the distalization achieved from T0-T1 while Group B showed a net distal movement of the maxillary molar of 0.8 mm from T0-T2, representing a statistically significant difference in groups by T0 Class II molar relationship. These findings are similar to those of Burkhardt et al.,[12] who found 0.8 mm of maxillary molar distalization during the comprehensive orthodontic treatment of patients treated with the Pendulum appliance. Importantly, similar to previous studies on maxillary molar distalization appliances,[12-15] the dental measurements in the present study evaluated the dental component of molar relationship correction with the Carriere distalizer appliance, while more recent studies[7,8] have not separately quantified the dental and skeletal components of overall molar relationship correction.

D. Molar Relationship

The change in molar relationship summed as ABCH + ΔMX6 + ΔMN6 was statistically significantly different between the two groups. From T0-T1, Group A showed a total molar relationship correction of 2.8 mm, while Group B showed 4.4 mm of correction. The statistically significant difference between these values is consistent with overcorrection of the pre-treatment Class II molar relationships for Group A and Group B, which were 2.5 mm and 4.1 mm, respectively. The molar relationship correction achieved during the distalization phase of treatment was similar to those reported previously, which ranged from 2.8-6.4 mm from pre-treatment to post-distalization (T0-T1) with the Pendulum and distal jet appliances.[12,14,15] Furthermore, molar relationship change from T1-T2 showed 1.1 mm of relapse in both groups. These values are similar to the 1.0-3.5 mm of molar relationship relapse following use of distalizer appliances described in the literature.[7,14,15]

The methods used in the current study allowed for measuring change in molar relationship both on digital study models as well as via cephalometric analysis. As mentioned previously, T0-T1 molar relationship change measured with cephalometric analysis was 2.8 mm and 4.4 mm for Groups A and B, respectively, but when measured with digital models, T0-T1 molar relationship change was 3.7 mm and 5.1 mm. Similarly, T0-T2 molar relationship change measured with cephalometric analysis was 1.8 mm and 3.3 mm for Groups A and B, respectively, but when measured with digital models, the changes were 2.6 mm and 4.1 mm. The discrepancy between the findings using these two methods of measurement indicate the need in a future study to determine the most accurate way to measure molar relationship change over time. This discrepancy may be due to operator errors in the method of cephalometric analysis such as difficulty visualizing dental and skeletal landmarks. However, this may also be caused by inaccurate bite registration within the digital model software, which would alter the molar relationships at the various time-points.

Finally, overall molar relationship change during the distalization and comprehensive treatment phases from T0-T2 was 1.8 mm for Group A and 3.3 mm for Group B. These findings are consistent with those reported for the distal jet and pendulum appliances, which ranged from 2.9-3.6 mm,[14,15] and for the Carriere distalizer appliance, which were reported at 3.3-3.5 mm (Figure 18).[7,8] While these findings indicate that significant Class II molar relationship correction occurred in patients treated with this appliance, the results do not indicate that the appliance was more effective than other Class II correctors, and no comparison was made to show differences in molar relationship correction between patients treated with the Carriere distalizer appliance and an untreated control group. Furthermore, the 1.4-1.6 mm of maxillary molar mesial movement that occurs during the post-distalization orthodontic treatment from T1-T2 indicates the possibility that anchorage, such as skeletal anchorage with mini-implants or extraoral anchorage, may reduce this mesial movement and improve the efficiency of Class II molar correction. Thus, the current study shows the importance of knowing the dental and skeletal component contributions affecting the molar relationship changes and the phase of treatment when these occur.

Notably, the cephalometric analysis used in this study allowed for separation of the skeletal and dental components of anteroposterior change that contributed to the overall molar relationship correction. Skeletal change can be estimated by taking the

ABCH as a fraction of total molar change (ABCH / (ABCH+ΔMX6+ΔMN6)), and dental change can be estimated by subtracting this fraction from 1. In Group A, approximately 77% of the total (T0-T2) molar relationship correction was attributable to dental change, whereas in Group B, 91% of the total molar relationship correction was attributable to anteroposterior dental changes. The difference in skeletal and dental contributions to molar relationship change between Group A and Group B may be due to differences in anteroposterior and vertical growth patterns. Importantly, the pitchfork cephalometric analysis does not differentiate between anteroposterior changes due to growth and those that occur as an effect of orthodontic treatment. These findings indicate that while some skeletal change may occur, the change in molar relationship in patients treated with the Carriere distalizer appliance are due primarily to dental rather than skeletal change.

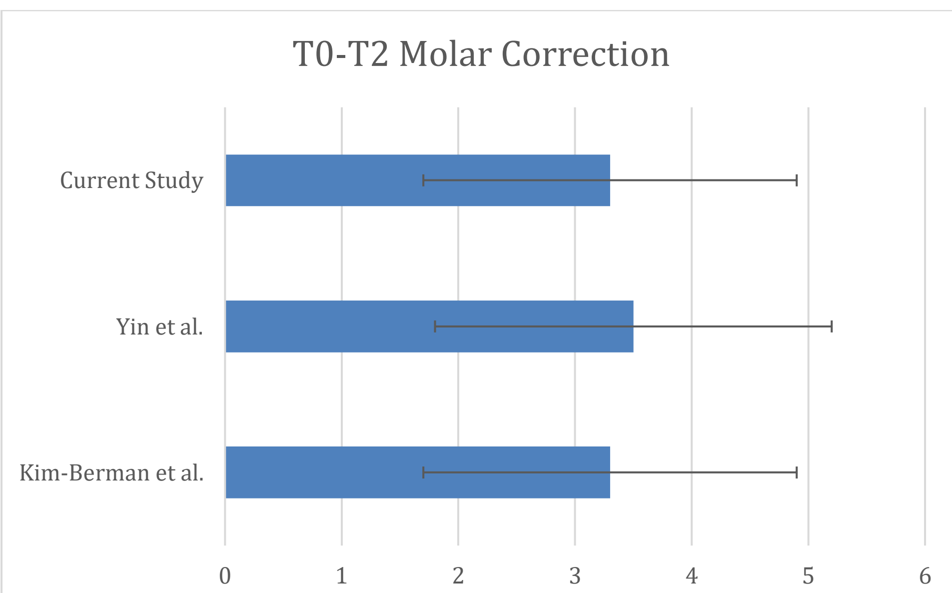

Figure 18. Comparison of total Class II molar relationship correction in mm from T0-T2 between group B from the current study and groups treated with the Carriere distalizer appliance in previous studies[7,8].

E. CVM and Gender

No statistically significant differences were detected for any of the dependent variables in groups by gender or by pre-treatment CVM. This may indicate that the effects of the Carriere distalizer appliance are not different in patients depending on gender or stage of development. The relatively small sample size in this study may have influenced whether any statistically significant differences were detected among genders or different levels of maturation.

F. Intra-operator Reliability Assessment

One case was randomly selected to test reliability of measurements. The methods of cephalometric tracing, measurements, and superimpositions described above were performed between by the same operator once per week for 5 weeks to calculate intra-operator reliability for cephalometric landmark identification. The coefficients of variation (Table 3) reflect a poor reliability in the measurements of one operator across 5 weeks. These low values for intra-rater reliability may be due to the fact that measurements were all made rounded to the nearest 0.5 mm, and the values of the variables generally ranged from -3 mm to +3 mm, causing a decrease in reliability whenever there were slight differences in measurements across time-points.

	Intra-class Correlational Coefficients of Variance with one rater
Δ Max	-0.41
Δ Mand	-0.22
ABCH	0.62
Δ MX6	0.40
Δ MD6	1.00
ABCH + MX6 + MN6	-0.30

Table 3. Intra-class correlational coefficients of variance (COV) for one operator measuring the same case one week apart for 5 weeks. COV<0.50 was indicated poor reliability, 0.50<COV<0.75 indicated moderate reliability, 0.75<COV<0.90 indicated good reliability, and COV>0.90 indicated excellent reliability.

G. Limitations

There were several limitations to the present study. The methods used for cephalometric tracing involved digital landmarks as well as hand tracing, and difficulty in identifying accurate dental and skeletal landmarks as well as variation in dental and skeletal anatomy may have influenced the accuracy of the results. This study was retrospective, so the digital models which were used to determine molar relationship at all three time-points could have had inaccurate bite registrations. Furthermore, the available data that met the inclusion criteria led to an imbalance in sample size between patients treated with clear aligner therapy and fixed orthodontic appliances, decreasing the validity of any comparisons between these two groups. Additionally, this study evaluated dental and skeletal change strictly in the anteroposterior dimension, so any vertical or transverse influences on treatment effects of the appliance were not accounted for in the results. Finally, evaluation of patient compliance, which is a crucial component of successful treatment with the Carriere distalizer appliance, was only utilized to exclude subjects from the study, but was not incorporated to evaluate possible differences in effects achieved in subjects treated with the appliance.

H. Future Studies

Multiple components could be added or changed to augment the information yielded from this study. A study similar to the present study that incorporates information about the vertical facial morphologies of the subjects (e.g., dolichofacial, mesofacial, brachyfacial) may shed light on the vertical contributions, if any, to anteroposterior change in patients treated with the Carriere distalizer appliance. Similarly, a comparison between subjects treated with the Carriere distalizer, subjects treated with other maxillary molar distalization appliances, and a control group would provide more information about the effects of maxillary molar distalization during orthodontic treatment. As this study showed that anterior maxillary displacement is a challenge to Class II correction, a future study might use this methodology to compare to a group that is treated with the Carriere distalizer and with maxillary headgear in an attempt to mitigate the anterior maxillary displacement that was described in this study. Additionally, future studies might also compare the difference in treatment effects in patients treated with the Carriere distalizer appliance followed by clear aligner therapy and patients treated with the Carriere distalizer appliance followed by fixed orthodontic appliances; while the sample in this study attempted to make this comparison, the sample was insufficiently powered to generate clinically useful data. Furthermore, a comparison between the method of cephalometric analysis in the current study and those used in other studies evaluating the effects of distalization appliances may indicate whether or not any differences in findings between this study and previously reported literature are due to different methods of analyzing skeletal and dental changes during orthodontic treatment.

V. Conclusions

The maxillary molar distalization achieved from T0-T1 was completely (100%) lost during the remaining orthodontic treatment (T1-T2) for mild Class II relationships (2.0-3.0 mm), while only 63% of the maxillary molar distalization achieved in moderate-severe Class II relationships (3.1-7.0 mm) was lost at the end of treatment. Total (T0-T2) molar relationship correction was 1.8 mm for mild Class II relationships and 3.3 mm for moderate-severe Class II relationships. In mild class II individuals, 77% of the molar relationship correction occurred due to dental change, while in moderate-severe Class II individuals, 91% of the molar relationship correction was due to dental change. There were no statistically significant differences detected between gender or between groups by CVM at any of the three time intervals.

VI. Comprehensive Literature Review

One of the earliest studies measuring the effects of a maxillary molar distalization appliance was performed by Ghosh et al. in 1996.[1] This study aimed to determine the effects of the pendulum appliance introduced by Hilgers in 1992 for correction of Class II malocclusion in noncompliant patients.[27] Specifically, the objectives of the study were to measure maxillary molar movement in three dimensions, anteroposterior movement of anchor maxillary premolars and incisors, and effect of maxillary molar distalization on mandibular position in patients treated with the pendulum appliance. The sample consisted of 41 patients, 26 females (mean age 12 years 5 months ± 1 year 10 months) and 15 males (mean age 12 years 5 months ± 1 year 2 months). Patients included in the sample had Class II molar relationships of 2.12 ± 1.57 mm on the right and 2.17 ± 1.63 mm on the left and had the pendulum appliance as the first phase of nonextraction treatment. The appliance consisted of a palatal acrylic button with occlusal bonded rests on maxillary premolars and with 0.032-inch titanium molybdenum alloy (TMA) springs extending posteriorly with adjustment loops that were activated to engage in lingual sheaths on maxillary first molar bands. Activation of the springs by approximately 60° produced a disto-medial swinging arc of force of 230 grams per side. Lateral cephalograms and dental casts were obtained from before delivery (T1) and after removal (T2) of the pendulum appliance, with a mean T1-T2 duration of 6.2 ± 1.4 months.

Cephalometric tracing involved constructing a centroid point for the crowns of maxillary posterior teeth at the midpoint between the mesial and distal heights of convexity of the crowns. Angular changes in position of maxillary molars, maxillary first premolars, and central incisors were evaluated relative to the sella-nasion (SN) plane. While not stated explicitly by the authors, angular measurements were apparently made by estimating the long axis of a tooth passing through its apex and its constructed centroid or traced incisor tip. Anteroposterior positions of maxillary first molar, maxillary first premolar, and mandibular first molar were compared by superimposing on the constructed pterygoid vertical (PTV) plane. As explained by Enlow et al., the PTV plane extends downward from the intersection of the greater wings of the sphenoid bone and the floor of the anterior cranial fossa, also called the sphenoethmoidal suture or SE point, to the most inferior point of the pterygomaxillary fissure.[28] Anteroposterior position of the mandible was also compared by superimposing on the PTV plane and measuring the distance from B point to the PTV plane.

The maxillary first molar tipped distally by 8.36° ± 8.37° ($p < 0.001$) relative to SN plane. The maxillary first molar centroid moved distally by 3.37 ± 2.10 mm ($p < 0.001$) relative to the PTV plane. There was a modest statistically significant correlation between linear distal movement and angular distal tipping of the maxillary first molar ($r = 0.488$). The maxillary first premolar moved mesially by 2.55 ± 1.90 mm ($p < 0.001$) relative to the PTV plane. The authors explained that for every 1 mm of distal molar movement, approximately 0.75 mm of mesial premolar movement was observed. No significant change was detected in anteroposterior position of the mandible as measured by comparing distance from B point to PTV plane. This indicated that the correction of a Class II molar relationship with the pendulum appliance occurred via dental rather than skeletal anteroposterior changes.

The authors concluded that the pendulum appliance was effective for distalizing maxillary molars with moderate anchorage loss, meaning mesial movement of maxillary teeth anterior to the first molars occurred. One limitation of this study was that it did not consider the effects of gender or skeletal maturation stage on maxillary molar distalization. Furthermore, this study only measured the effects of the pendulum appliance immediately after appliance removal, but not at the end of orthodontic treatment or years after the retention period, so stability of changes in maxillary molar position could not be evaluated.

A study from 2013 by Caprioglio et al. aimed to describe molar movements and skeletal changes associated with pendulum and fixed appliance treatment over a long-term period.[15] The sample consisted of 76 patients, 41 females and 35 males with a mean age of 12 years 11 months ± 1 year 5 months, all at pubertal growth spurt (CVM stage CS3-4). Patients included in the sample had bilateral Class II molar relationships of 3.1 ± 1.01 mm on average and were treated with the pendulum appliance. Following removal of the pendulum appliance, a Nance button was placed to stabilize molar position for 4-5 months prior to placement of fixed appliances, and the retention protocol after fixed appliance treatment included a maxillary Hawley retainer and a mandibular fixed lingual retainer from canine to canine. Serial lateral cephalograms were available from four time-points: pre-treatment (T1), immediately after pendulum appliance removal (T2), immediately after fixed appliance removal (T3), and in the post-retention period (T4) an average of 7 years 2 months ± 6 months after fixed appliance removal. The mean distalization time (T1-T2) was 8 months ± 2 months, and the mean total treatment time (T1-T3) 2 years 4 months ± 3 months.

Cephalometric analysis involved 27 landmarks, six angular measurements, seven linear measurements, and four fiducial markers in the maxilla and mandible for superimpositions. Anteroposterior skeletal changes were measured as change in the angle made by SN plane and the line between Nasion and A point (SNA) and change in the angle made by SN plane and the line between Nasion and Pogonion (SN-Pg). Anteroposterior dental movement and crown tipping of maxillary first molar and maxillary first premolar were measured by superimposing on maxillary fiducial markers. The authors focused on results related to stability of Class I molar relationship and changes in anteroposterior maxillary first molar position.

On average, the maxillary first molar centroid moved distally by 5.1 ± 0.9 mm perpendicular to a line drawn through fiducial markers after distalization (T1-T2), but relapsed with 2.0 ± 0.8 mm mesial movement by the end of treatment (T2-T3) and 0.2 ± 0.5 mm mesial movement seven years after treatment (T3-T4). The authors noted that this suggests that 91% of the molar position relapse occurs during fixed appliance treatment. Furthermore, the total amount of molar relapse following distalization (T2-T4) was 2.2 ± 0.7 mm ($p < 0.01$), indicating that 57% of the distalizing effect was maintained post-retention. The maxillary first molar tipped distally 9.9° ± 1.5° relative to Frankfurt horizontal (FH) plane after distalization (T1-T2), and relapsed by tipping mesially 4.5° ± 1.3° ($p < 0.05$) by the post-retention period (T2-T4). Dental changes in molar and premolar position and angulation from the end of fixed appliance treatment to the post-retention time-point seven years later (T3-T4) were not statistically significant.

Changes in anteroposterior position of the maxilla and mandible were measured by SNA, the angle from A point (the most concave point on the anterior surface of the maxilla) to SN plane, and by SN-Pg, the angle from Pogonion (Pg, the most anterior point on the mandibular symphysis) to SN plane. The authors found no significant difference in skeletal position from T1-T2 but reported statistically significant change of maxillary and mandibular position from T2-T4. Both the SNA and SN-Pg angles increased from T2-T4 in patients treated with the pendulum appliance, with SNA increasing by 0.7 ± 0.8 and SN-Pg increasing by 2.4 ± 1.1. While statistically significant, these changes in anteroposterior skeletal position may be of limited clinical significance as they can be expected in the normal pattern of maxillary and mandibular growth from adolescence to adulthood. Furthermore, though these skeletal changes represent changes more toward a Class I molar relationship, they occurred during the post-retention period, hence demonstrating that molar relationship correction with the pendulum appliance occurred more through dental rather than skeletal effects.

Similar to previous studies, the authors concluded that the pendulum appliance used in combination with fixed appliances can effectively correct Class II malocclusions by distalizing maxillary molars into a Class I relationship. Furthermore, the results of this study offer longitudinal data indicating that the molar movement achieved with the pendulum appliance partially relapsed by the end of fixed appliance treatment, and the authors noted that this finding agreed with that of similar studies. The relapse of molar movement occurred primarily during fixed appliance therapy rather than during retention, and molar position as well as corrected molar relationship were maintained seven years after the end of treatment. The authors suggested that the Class I molar relationship obtained during treatment was maintained through dental compensation during maxillary and mandibular growth. This concept can be examined with a cephalometric analysis that separates dental and skeletal components of anteroposterior change during orthodontic treatment.

In 1996 Johnston described a cephalometric analysis designed to separately measure the skeletal and dental effects of growth and orthodontic treatment that combine to produce occlusal changes in molar and incisor relationships.[9] The analysis is limited to the anteroposterior dimension, allowing for simplified measurements of the physical displacements that lead to orthodontic correction of molar relationship and overjet. The four anteroposterior components are displacement of the maxilla relative to cranial base, displacement of maxillary teeth relative to maxilla, displacement of mandible relative to cranial base, and displacement of mandibular teeth relative to mandible. The method of measuring these components with cephalometric tracing and analysis is described in the protocol above. The sum of maxillary and mandibular translatory movement relative to the cranial base is termed ‘apical base change’ (ABCH), and often represents the amount that the mandible has outgrown the maxilla. ABCH can be added to total maxillary and mandibular molar or incisor movement relative to basal bone, equaling the changes in molar relationship (6/6) and overjet (1/1), respectively. These components can be visualized in the ‘pitch-fork’ diagram (Figure 3).

The pitch-fork analysis proposed by Johnston allows for simplified measurement of dental and skeletal components of anteroposterior change in molar relationship and overjet correction. Importantly, previous studies relating to maxillary molar distalization appliances have used heterogeneous methods with varying cephalometric analyses to measure the skeletal and dental effects.[1,7,8,10-15] This makes comparison of results between studies difficult to interpret, and indicates the need for a cephalometric analysis that focuses on anteroposterior change and molar relationship and overjet correction when evaluating the dental and skeletal effects of any maxillary molar distalization appliance.

The effects of various maxillary molar distalization appliances as measured by cephalometric analysis have been reported in the literature. Most studies reported the effects of the pendulum and distal jet appliances. While both maxillary appliances have palatal acrylic buttons and premolar attachments, the pendulum appliance has large springs that are activated to engage in lingual sheaths of molar bands, producing a disto-medial swinging arc of force, while the distal jet produces a produces a primarily distal force with compressed open-coil springs (Figure 3). Studies on the pendulum and distal jet appliances found that they distalized maxillary molars to achieve a Class I relationship compared to the pre-treatment Class II molar relationship, and that the change in molar relationship is primarily a result of dental rather than skeletal effects.[1,12-14]

One study compared dental and skeletal effects in two groups of 32 adolescents (19 female and 13 male), one treated with the pendulum appliance (mean age 12 years 6 months) and the other with the distal jet (mean age 12 years 3 months).[14] Both groups began with at least an end-to-end Class II molar relationship, and the appliances were activated until the achievement of Class I molar relationship signified the end of distalization. Comparing cephalometric images from pre-treatment (T1) and post-distalization (T2) time-points showed that the pendulum group had significantly more molar relationship correction (6.4 mm) and horizontal distal molar movement (6.1 mm) than the distal jet group (3.8 mm and 2.8 mm, respectively) immediately at the end of distalization. At the end of fixed appliance treatment (T3), maxillary first molars in the pendulum group were 0.6 mm distal to their pre-treatment position, while molars in the distal jet group were 0.5 mm mesial to their pre-treatment position. Though more absolute molar distalization occurred with the pendulum appliance, there was also more relapse, i.e. mesial movement of maxillary molars, in the pendulum group from T2-T3. Despite the discrepancy in molar movement between appliances, both groups had molar relationship corrections of 3.0 mm at the end of orthodontic treatment and the appliances were found to be equally effective at achievement of Class I molar relationship. However, the cephalometric analysis used in this study did not measure the separate skeletal and dental anteroposterior changes that contributed to the 3.0 mm molar correction. Furthermore, this study did not examine the stability of the achieved Class I molar relationship, which would require longitudinal data following the retention period.

One such long-term evaluation was performed on 76 subjects treated with the pendulum appliance (41 female and 35 male) with a mean age of 12 years 11 months all during pubertal growth spurt.[15] Lateral cephalograms were exposed at four time-points and compared to determine changes due to growth and treatment effects: pre-treatment (T1), immediately post-distalization (T2), at the end of orthodontic treatment (T3), and an average of 7 years 2 months into the post-retention period (T4). Subjects began with at least an end-to-end Class II molar relationship, with a bilateral average 3.1 mm class II molar relationship (i.e., the maxillary first molar mesiobuccal cusp tip was 3.1 mm mesial to the mandibular first molar buccal groove), and the pendulum appliances were activated until the achievement of Super Class I molar relationship (i.e., the maxillary first molar mesiobuccal cusp tip occluded slightly distal to the mandibular first molar buccal groove) signified the end of distalization. Following removal of the pendulum appliance, full fixed appliances were used to complete orthodontic treatment, and retention involved a maxillary Hawley retainer and a mandibular fixed lingual retainer from canine to canine. Comparison of cephalograms from T1-T2 showed that the pendulum appliance achieved 4.8 mm of molar relationship correction and 5.1 mm of absolute horizontal distal maxillary molar movement parallel to a line passing through maxillary fiducial markers. Comparison of changes from T2-T3 and T3-T4 showed that 2.2 mm of horizontal mesial maxillary molar movement occurred following the distalization period, and that 91% of that relapse occurred during fixed appliance treatment (T2-T3) rather than during the post-treatment period (T3-T4). The study also found that over half of the amount of maxillary molar distalization achieved with the pendulum appliance remained at the end of treatment and remained stable seven years after treatment. The authors noted that once a Class I molar relationship was achieved, it was maintained by dentoalveolar compensation during maxillary and mandibular growth, indicating that achievement of class I molar relationship occurs primarily due to dental rather than skeletal effects.

While dental and skeletal effects of distalization with the pendulum and distal jet appliances have been investigated, most of the literature describing treatment effects of the Carriere distalizer appliance is comprised of clinical case reports.[2-5] However, one study evaluated treatment effectiveness of the Carriere distalizer appliance using pre-treatment and post-treatment cephalometric analysis and digital study models.[8] Three groups of 18 adolescents aged 10-14 with within-group gender balance and pre-treatment Class II molar relationships at least end-to-end were treated with the Carriere distalizer appliance, intermaxillary Class II elastics, and the Forsus appliance. Absolute molar distalization with the Carriere distalizer appliance was not measured, but the pre-treatment to post-treatment molar relationship correction was found to be 3.5 mm with the Carriere distalizer appliance and intermaxillary elastics, and 4.5 mm with the Forsus appliance. The authors noted that these findings may not be clinically significant because evaluation of post-treatment molar relationship on digital study models showed that for most cases, there was a nonzero horizontal distance from the maxillary mesiobuccal cusp tip to the mandibular buccal groove (i.e., not a perfect Class I molar relationship). Furthermore, the study found more skeletal change measured by ANB angle and Wits appraisal with the Forsus appliance than with the Carriere distalizer appliance and intermaxillary elastics, suggesting that the molar relationship correction with the Carriere distalizer appliance is a result of dental change rather than skeletal change when compared to the correction achieved with the Forsus appliance. However, a cephalometric analysis that separates skeletal and dental components of molar relationship change would be necessary to determine to what extent skeletal and dental changes contribute to molar relationship correction.

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VIII. Appendix A

Subject	Group	Gender	Tx Phase	Start Phase Molar Avg	Δ Max	Δ Mand	ABCH	Δ MX6	Δ MD6	ABCH + MX6 + L6	End Phase Molar Avg	# days in Tx Phase	Start Phase CVM
1	A	F	T0-T1	-2.7	-1.0	0.0	-1.0	1.5	1.0	1.5	1.2	146	CS4
2	A	M	T0-T1	-5.4	0.0	3.0	3.0	1.0	2.5	6.5	1.3	167	CS3
3	A	F	T0-T1	-2.1	0.0	0.5	0.5	0.0	2.0	2.5	0.9	105	CS5
4	A	F	T0-T1	-3.5	-0.5	2.0	1.5	1.0	2.0	4.5	1.8	140	CS4
5	A	M	T0-T1	-4.0	0.0	1.0	1.0	1.5	1.0	3.5	0.5	190	CS2
6	A	M	T0-T1	-2.7	0.0	1.5	1.5	1.5	2.0	5.0	3.5	175	CS4
7	A	F	T0-T1	-3.8	-0.5	2.0	1.5	3.0	0.0	4.5	0.2	179	CS3
8	A	M	T0-T1	-2.7	0.0	0.0	0.0	2.0	2.0	4.0	2.3	132	CS3
9	A	F	T0-T1	-4.3	0.0	0.0	0.0	0.0	3.5	3.5	0.0	209	CS4
10	A	M	T0-T1	-2.0	0.0	0.0	0.0	0.5	2.0	2.5	0.0	146	CS4
11	A	F	T0-T1	-3.2	0.0	0.5	0.5	1.5	1.5	3.5	1.6	120	CS4
12	A	F	T0-T1	-2.5	-1.5	0.0	-1.5	1.5	1.5	1.5	1.0	145	CS3
13	A	F	T0-T1	-2.5	-1.5	1.0	-0.5	2.0	2.5	4.0	1.7	111	CS4
14	A	M	T0-T1	-3.5	-2.0	0.0	-2.0	3.5	2.0	3.5	1.6	358	CS3
15	A	F	T0-T1	-4.5	0.0	0.5	0.5	2.5	2.0	5.0	1.0	159	CS4
16	A	F	T0-T1	-3.2	-1.0	1.5	0.5	2.0	1.0	3.5	2.2	159	CS4
17	A	M	T0-T1	-4.0	-0.5	1.0	0.5	3.0	1.5	5.0	1.6	147	CS3
18	A	M	T0-T1	-4.8	-1.0	0.5	-0.5	2.5	1.0	3.0	0.6	169	CS4
19	A	M	T0-T1	-6.3	-0.5	2.0	1.5	2.0	2.0	5.5	0.3	153	CS1
20	A	M	T0-T1	-4.2	0.0	0.5	0.5	4.0	0.5	5.0	0.9	167	CS2
21	A	F	T0-T1	-2.7	-1.0	-2.0	-3.0	3.5	1.5	2.0	0.5	119	CS3
22	A	M	T0-T1	-2.7	-1.0	4.0	3.0	-1.0	1.0	3.0	1.8	138	CS2
23	A	F	T0-T1	-2.1	-1.0	-1.0	-2.0	2.0	2.0	2.0	0.5	123	CS4
24	A	F	T0-T1	-3.0	0.0	3.0	3.0	0.0	1.5	4.5	0.7	230	CS1
25	A	F	T0-T1	-2.2	0.0	0.0	0.0	1.0	1.5	2.5	1.8	124	CS3
26	A	M	T0-T1	-2.8	0.0	0.5	0.5	2.0	0.0	2.5	1.3	138	CS1
27	A	M	T0-T1	-3.9	0.0	0.0	0.0	4.5	1.0	5.5	1.4	160	CS2
28	B	M	T0-T1	-2.5	-1.5	1.5	0.0	0.5	0.5	1.0	0.0	173	CS4
29	B	F	T0-T1	-3.9	-1.0	-0.5	-1.5	1.0	4.0	3.5	0.5	153	CS4
30	B	F	T0-T1	-2.2	0.0	1.5	1.5	0.5	0.0	2.0	0.9	168	CS3
31	B	F	T0-T1	-2.7	0.0	1.5	1.5	2.0	1.0	4.5	0.4	196	CS2
32	B	M	T0-T1	-4.0	0.0	0.5	0.5	2.0	2.0	4.5	1.5	121	CS1
33	B	F	T0-T1	-3.9	0.0	-2.0	-2.0	2.5	3.5	4.0	0.2	56	CS2

Appendix A1. Raw data (measurements in mm) from T0-T1 grouped by appliance type (clear aligner therapy in Group A, fixed orthodontic appliances in Group B) for all 33 cases.

Subject	Group	Gender	Tx Phase	Start Phase Molar Avg	Δ Max	Δ Mand	ABCH	Δ MX6	Δ MD6	ABCH + MX6 + L6	End Phase Molar Avg	# days in Tx Phase	Start Phase CVM
1	A	F	T1-T2	1.2	-1.0	1.0	0.0	-2.5	1.0	-1.5	0.1	644	CS4
2	A	M	T1-T2	1.3	-1.5	1.0	-0.5	1.0	0.0	0.5	1.0	483	CS3
3	A	F	T1-T2	0.9	0.0	0.0	0.0	0.0	-1.0	-1.0	0.0	252	CS5
4	A	F	T1-T2	1.8	0.0	0.0	0.0	-2.0	1.0	-1.0	0.2	539	CS4
5	A	M	T1-T2	0.5	-1.5	1.5	0.0	-1.5	0.0	-1.5	-1.1	552	CS3
6	A	M	T1-T2	3.5	-0.5	1.0	0.5	-1.5	0.5	-0.5	0.8	786	CS4
7	A	F	T1-T2	0.2	0.0	-1.0	-1.0	-1.0	1.0	-1.0	-1.9	385	CS4
8	A	M	T1-T2	2.3	0.0	1.0	1.0	-3.5	1.0	-1.5	0.1	615	CS3
9	A	F	T1-T2	0.0	0.0	0.0	0.0	2.0	-2.5	-0.5	-1.0	932	CS4
10	A	M	T1-T2	0.0	0.0	0.0	0.0	-1.0	-1.0	-2.0	-1.5	370	CS4
11	A	F	T1-T2	1.6	-0.5	1.0	0.5	-2.0	0.5	-1.0	0.3	385	CS4
12	A	F	T1-T2	1.0	0.0	1.0	1.0	-1.5	0.0	-0.5	0.0	416	CS3
13	A	F	T1-T2	1.7	0.0	1.5	1.5	-2.0	-1.5	-2.0	-0.2	337	CS4
14	A	M	T1-T2	1.6	0.0	2.0	2.0	-0.5	-2.0	-0.5	0.4	635	CS4
15	A	F	T1-T2	1.0	-1.0	1.0	0.0	-2.0	1.5	-0.5	0.8	451	CS4
16	A	F	T1-T2	2.2	0.0	2.0	2.0	-2.0	-0.5	-0.5	1.1	415	CS4
17	A	M	T1-T2	1.6	-2.0	2.5	0.5	-1.0	-2.0	-2.5	0.0	275	CS4
18	A	M	T1-T2	0.6	-1.5	2.0	0.5	-2.0	1.5	0.0	0.0	747	CS4
19	A	M	T1-T2	0.3	-1.0	1.0	0.0	-2.0	1.0	-1.0	-0.1	433	CS2
20	A	M	T1-T2	0.9	0.0	0.5	0.5	-4.0	3.0	-0.5	1.4	540	CS2
21	A	F	T1-T2	0.5	-1.5	2.5	1.0	-1.5	-1.0	-1.5	-1.0	502	CS3
22	A	M	T1-T2	1.8	-2.0	0.5	-1.5	-2.0	2.0	-1.5	0.8	699	CS2
23	A	F	T1-T2	0.5	-0.5	0.0	-0.5	-0.5	1.0	0.0	0.3	406	CS4
24	A	F	T1-T2	0.7	0.0	0.0	0.0	0.0	-1.5	-1.5	0.0	118	CS2
25	A	F	T1-T2	1.8	0.0	1.0	1.0	-1.5	0.0	-0.5	0.2	405	CS4
26	A	M	T1-T2	1.3	-1.5	1.5	0.0	-1.5	0.5	-1.0	0.7	618	CS1
27	A	M	T1-T2	1.4	0.0	2.5	2.5	-5.5	2.0	-1.0	0.1	426	CS2
28	B	M	T1-T2	0.0	-1.0	-0.5	-1.5	-0.5	2.0	0.0	0.0	229	CS4
29	B	F	T1-T2	0.5	-2.0	-2.5	-4.5	2.0	-1.5	-4.0	-0.5	684	CS4
30	B	F	T1-T2	0.9	-1.0	-1.5	-2.5	-1.0	2.5	-1.0	1.1	544	CS4
31	B	F	T1-T2	0.4	0.0	3.0	3.0	-5.5	1.5	-1.0	0.0	618	CS2
32	B	M	T1-T2	1.5	-2.5	1.0	-1.5	1.0	-1.0	-1.5	0.5	1356	CS2
33	A	F	T1-T2	0.8	-1.1	0.8	-0.3	-1.7	0.7	-1.3	0.4	576	CS4

Appendix A2. Raw data (measurements in mm) from T1-T2 grouped by appliance type (clear aligner therapy in Group A, fixed orthodontic appliances in Group B) for all 33 cases.

Subject	Group	Gender	Tx Phase	Start Phase Molar Avg	Δ Max	Δ Mand	ABCH	Δ MX6	Δ MD6	ABCH + MX6 + L6	End Phase Molar Avg	# days in Tx Phase	Start Phase CVM
1	A	F	T0-T2	-2.7	-2.0	1.0	-1.0	-1.0	2.0	0.0	0.1	790	CS4
2	A	M	T0-T2	-5.4	-1.5	4.0	2.5	2.0	2.5	7.0	1.0	650	CS3
3	A	F	T0-T2	-2.1	0.0	0.5	0.5	0.0	1.0	1.5	0.0	357	CS4
4	A	F	T0-T2	-3.5	-0.5	2.0	1.5	-1.0	3.0	3.5	0.2	679	CS4
5	A	M	T0-T2	-4.0	-1.5	2.5	1.0	0.0	1.0	2.0	-1.1	742	CS2
6	A	M	T0-T2	-2.7	-0.5	2.5	2.0	0.0	2.5	4.5	0.8	961	CS4
7	A	F	T0-T2	-3.8	-0.5	1.0	0.5	2.0	1.0	3.5	-1.9	564	CS3
8	A	M	T0-T2	-2.7	0.0	1.0	1.0	-1.5	3.0	2.5	0.1	747	CS3
9	A	F	T0-T2	-4.3	0.0	0.0	0.0	2.0	1.0	3.0	-1.0	1141	CS4
10	A	M	T0-T2	-2.0	0.0	0.0	0.0	-0.5	1.0	0.5	-1.5	516	CS4
11	A	F	T0-T2	-3.2	-0.5	1.5	1.0	-0.5	2.0	2.5	0.3	505	CS4
12	A	F	T0-T2	-2.5	-1.5	1.0	-0.5	0.0	1.5	1.0	0.0	561	CS3
13	A	F	T0-T2	-2.5	-1.5	2.5	1.0	0.0	1.0	2.0	-0.2	448	CS4
14	A	M	T0-T2	-3.5	-2.0	2.0	0.0	3.0	0.0	3.0	0.4	993	CS3
15	A	F	T0-T2	-4.5	-1.0	1.5	0.5	0.5	3.5	4.5	0.8	610	CS4
16	A	F	T0-T2	-3.2	-1.0	3.5	2.5	0.0	0.5	3.0	1.1	574	CS4
17	A	M	T0-T2	-4.0	-2.5	3.5	1.0	2.0	-0.5	2.5	0.0	422	CS3
18	A	M	T0-T2	-4.8	-2.5	2.5	0.0	0.5	2.5	3.0	0.0	916	CS4
19	A	M	T0-T2	-6.3	-1.5	3.0	1.5	0.0	3.0	4.5	-0.1	586	CS1
20	A	M	T0-T2	-4.2	0.0	1.0	1.0	0.0	3.5	4.5	1.4	707	CS2
21	A	F	T0-T2	-2.7	-2.5	0.5	-2.0	2.0	0.5	0.5	-1.0	621	CS3
22	A	M	T0-T2	-2.7	-3.0	4.5	1.5	-3.0	3.0	1.5	0.8	837	CS2
23	A	F	T0-T2	-2.1	-1.5	-1.0	-2.5	1.5	3.0	2.0	0.3	529	CS4
24	A	F	T0-T2	-3.0	0.0	3.0	3.0	0.0	0.0	3.0	0.0	348	CS1
25	A	F	T0-T2	-2.2	0.0	1.0	1.0	-0.5	1.5	2.0	0.2	529	CS3
26	A	M	T0-T2	-2.8	-1.5	2.0	0.5	0.5	0.5	1.5	0.7	756	CS1
27	A	M	T0-T2	-3.9	0.0	2.5	2.5	-1.0	3.0	4.5	0.1	586	CS2
28	B	M	T0-T2	-2.5	-2.5	1.0	-1.5	0.0	2.5	1.0	0.0	402	CS4
29	B	F	T0-T2	-3.9	-3.0	-3.0	-6.0	3.0	2.5	-0.5	-0.5	837	CS3
30	B	F	T0-T2	-2.2	-1.0	0.0	-1.0	-0.5	2.5	1.0	1.1	712	CS3
31	B	F	T0-T2	-2.7	0.0	4.5	4.5	-3.5	2.5	3.5	0.0	814	CS3
32	B	M	T0-T2	-4.0	-2.5	1.5	-1.0	3.0	1.0	3.0	0.5	1477	CS1
33	B	F	T0-T2	-3.9	-1.5	-2.5	-4.0	-1.5	5.5	2.0	-1.6	747	CS2

Appendix A3. Raw data (measurements in mm) from T0-T2 grouped by appliance type (clear aligner therapy in Group A, fixed orthodontic appliances in Group B) for all 33 cases.

IX. Appendix B

Means, standard deviations, P values, partial eta-squared values, and observed power for all dependent variables. Tables 3-11 show differences in groups by T0 bilateral average Class II molar relationship (Group A = 2.0-3.0 mm, Group B = 3.1-7.0 mm). Tables 12-20 show differences in groups by appliance type: clear aligner therapy (CAT) or fixed orthodontic appliances (FOA). Significance was set at P≤0.05, and sufficient power was obtained at a value of 0.80. Values seen in bold represent statistically significant differences between groups.

Δ Phase	A (2.0-3.0 mm) Mean ± SD	B (3.1-7.0 mm) Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	-0.5 ± 0.64	-0.4 ± 0.57	0.327	0.038	0.161
T1-T2	-0.6 ± 0.68	-0.9 ± 0.88	0.045	0.151	0.526
T0-T2	-1.1 ± 1.05	-1.3 ± 0.97	0.370	0.032	0.142

Table 4. A (2.0-3.0 mm) vs. B (3.1-7.0 mm) Group Differences in ΔMX measured in mm.

Δ Phase	A (2.0-3.0 mm) Mean ± SD	B (3.1-7.0 mm) Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	0.8 ± 1.45	0.7 ± 1.16	0.208	0.063	0.237
T1-T2	0.8 ± 1.11	0.8 ± 1.32	0.883	0.001	0.052
T0-T2	1.5 ± 1.56	1.56 ± 1.92	0.201	0.065	0.244

Table 5. A (2.0-3.0 mm) vs. B (3.1-7.0 mm) Group Differences in ΔMN measured in mm.

Δ Phase	A (2.0-3.0 mm) Mean ± SD	B (3.1-7.0 mm) Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	0.2 ± 1.65	0.3 ± 1.30	0.463	0.022	0.111
T1-T2	0.2 ± 1.32	-0.1 ± 1.64	0.201	0.065	0.244
T0-T2	0.4 ± 1.85	0.3 ± 2.23	0.083	0.116	0.413

Table 6. A (2.0-3.0 mm) vs. B (3.1-7.0 mm) Group Differences in ABCH measured in mm.

Δ Phase	A (2.0-3.0 mm) Mean ± SD	B (3.1-7.0 mm) Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	1.2 ± 1.10	2.2 ± 1.17	0.086	0.113	0.404
T1-T2	-1.6 ± 1.37	-1.4± 2.07	0.281	0.046	0.185
T0-T2	-0.4 ± 1.39	0.8 ± 1.51	0.008	0.246	0.785

Table 7. A (2.0-3.0 mm) vs. B (3.1-7.0 mm) Group Differences in ΔMX6 measured in mm.

Δ Phase	A (2.0-3.0 mm) Mean ± SD	B (3.1-7.0 mm) Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	1.4 ± 0.74	1.8 ± 1.09	0.004	0.290	0.867
T1-T2	0.4 ± 1.30	0.2 ± 1.61	0.124	0.092	0.333
T0-T2	1.8 ± 1.00	2.1 ± 1.52	0.869	0.001	0.053

Table 8. A (2.0-3.0 mm) vs. B (3.1-7.0 mm) Group Differences in ΔMN6 measured in mm.

Δ Phase	A (2.0-3.0 mm) Mean ± SD	B (3.1-7.0 mm) Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	2.8 ± 1.22	4.4 ± 0.96	0.003	0.304	0.888
T1-T2	-1.1 ± 0.63	-1.1 ± 1.03	0.059	0.135	0.477
T0-T2	1.8 ± 1.18	3.3 ± 1.56	0.109	0.100	0.360

Table 9. A (2.0-3.0 mm) vs. B (3.1-7.0 mm) Group Differences in ABCH + ΔMX6 + ΔMN6 measured in mm.

Δ Phase	A (2.0-3.0 mm) Mean ± SD	B (3.1-7.0 mm) Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	1.2 ± 0.91	1.0 ± 0.67	0.711	0.006	0.065
T1-T2	0.1 ± 0.65	-0.0 ± 0.94	0.496	0.019	0.102
T0-T2	0.1 ± 0.65	-0.0 ± 0.94	0.496	0.019	0.102

Table 10. A (2.0-3.0 mm) vs. B (3.1-7.0 mm) Group Differences in End Phase Molar Average measured in mm.

Δ Phase	A (2.0-3.0 mm) Mean ± SD	B (3.1-7.0 mm) Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	148.1 ± 33.18	165.1 ± 59.79	0.488	0.019	0.104
T1-T2	472.4 ± 186.59	584.1 ± 256.37	0.496	0.019	0.102
T0-T2	620.5 ± 186.93	749.2 ± 262.10	0.001	0.338	0.930

Table 11. A (2.0-3.0 mm) vs. B (3.1-7.0 mm) Group Differences in Treatment Duration in Days.

Δ Phase	A (2.0-3.0 mm) Mean ± SD	B (3.1-7.0 mm) Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	4.9 ± 1.1	5.4 ± 2.0	0.488	0.019	0.104
T1-T2	15.5 ± 6.1	19.2 ± 8.4	0.496	0.019	0.102
T0-T2	20.4 ± 6.1	24.6 ± 8.6	0.001	0.338	0.930

Table 12. A (2.0-3.0 mm) vs. B (3.1-7.0 mm) Group Differences in Treatment Duration in Months.

Δ Phase	CAT Mean ± SD	FOA Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	-0.5 ± 0.60	-0.4 ± 0.66	0.848	0.002	0.054
T1-T2	-0.6 ± 0.72	-1.3 ± 0.88	0.016	0.211	0.699
T0-T2	-1.1 ± 0.95	-1.8 ± 1.13	0.056	0.138	0.486

Table 13. CAT vs. FOA Group Differences in ΔMX measured in mm.

Δ Phase	CAT Mean ± SD	FOA Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	0.8 ± 1.27	0.4 ± 1.43	0.610	0.011	0.079
T1-T2	1.0 ± 0.90	-0.2 ± 1.94	0.056	0.139	0.488
T0-T2	1.8 ± 1.32	0.3 ± 2.77	0.049	0.146	0.510

Table 14. CAT vs. FOA Group Differences in ΔMN measured in mm.

Δ Phase	CAT Mean ± SD	FOA Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	0.3 ± 1.47	0.0 ± 1.5	0.585	0.012	0.083
T1-T2	0.4 ± 0.90	-1.5 ± 2.5	0.004	0.289	0.865
T0-T2	0.7 ± 1.29	-1.5 ± 3.5	0.004	0.292	0.870

Table 15. CAT vs. FOA Group Differences in ABCH measured in mm.

Δ Phase	CAT Mean ± SD	FOA Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	1.8 ± 1.3	1.4 ± 0.86	0.549	0.015	0.090
T1-T2	-1.5 ± 1.5	-1.3 ± 2.89	0.478	0.020	0.107
T0-T2	0.3 ± 1.3	0.1 ± 2.56	0.690	0.006	0.067

Table 16. CAT vs. FOA Group Differences in ΔMX6 measured in mm.

Δ Phase	CAT Mean ± SD	FOA Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	1.6 ± 0.76	1.8 ± 1.63	0.711	0.006	0.065
T1-T2	0.2 ± 1.38	0.9 ± 1.72	0.387	0.030	0.135
T0-T2	1.7 ± 1.19	2.8 ± 1.48	0.222	0.059	0.226

Table 17. CAT vs. FOA Group Differences in ΔMN6 measured in mm.

Δ Phase	CAT Mean ± SD	FOA Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	3.7 ± 1.32	3.3 ± 1.44	0.289	0.045	0.181
T1-T2	-1.0 ± 0.68	-1.6 ± 1.36	0.259	0.051	0.199
T0-T2	2.7 ± 1.55	1.7 ± 1.47	0.136	0.087	0.317

Table 18. CAT vs. FOA Group Differences in ABCH + ΔMX6 + ΔMN6 measured in mm.

Δ Phase	CAT Mean ± SD	FOA Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	1.2 ± 0.79	0.6 ± 0.54	0.099	0.105	0.378
T1-T2	0.1 ± 0.79	-0.1 ± 0.92	0.882	0.001	0.052
T0-T2	0.1 ± 0.79	-0.1 ± 0.92	0.882	0.001	0.052

Table 19. CAT vs. FOA Group Differences in End Phase Molar Average measured in mm.

Δ Phase	CAT Mean ± SD	FOA Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	159 ± 49	144 ± 49	0.561	0.014	0.088
T1-T2	495 ± 176	687 ± 369	0.012	0.226	0.738
T0-T2	654 ± 194	831 ± 352	0.030	0.174	0.598

Table 20. CAT vs. FOA Group Differences in Treatment Duration in Days

Δ Phase	CAT Mean ± SD	FOA Mean ± SD	P Value	Partial Eta Squared	Observed Power
T0-T1	5 ± 1	4 ± 1	0.561	0.014	0.088
T1-T2	16 ± 5	22 ± 12	0.012	0.226	0.738
T0-T2	21 ± 6	27 ± 11	0.030	0.174	0.598

Table 21. CAT vs. FOA Group Differences in Treatment Duration in Months