Occlusal contacts before and after treatment in adolescents treated with fixed orthodontic appliances versus clear aligners

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Occlusal contacts before and after treatment in adolescents treated with fixed orthodontic appliances versus clear aligners

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Abstract

Objectives:

To compare occlusal contact numbers (OC#) in adolescents before (T_0) and after (T_1) treatment with fixed orthodontic appliances (FOA) versus clear aligner therapy (CAT).

Materials & Methods:

FOA and CAT groups had 31 subjects each. Objective Grading System (OGS) scores at T_0 were used to match groups. Anterior and posterior OC#, 0.0-<0.2 mm (definitive) and 0.0-<0.4 mm (near), were measured on T_0 and T_1 models via software (OrthoCAD). Upper and lower incisor angles (U1-SN, IMPA) were measured from lateral cephalograms. T-tests compared between groups at each time and within groups between times ($\alpha=0.5$).

Results:

OGS scores were not significantly different between groups at T_0. CAT versus FOA groups had significantly fewer definitive ($p = .01$) and near ($p = .03$) posterior OC# at T_1. From T_0 to T_1, posterior definitive and near OC# in the CAT group decreased significantly ($p < .001$ and $p = .003$), U1-SN and IMPA significantly increased in the FOA group (7.7 and 6.8°, $p <.001$ and $p =.001$, respectively) but changed minimally (0.1 and 0.6°, respectively) in the CAT group.

Conclusions:

Adolescent subjects treated with CAT versus FOA showed significantly fewer posterior OC# and less incisor angulation changes.

CHAPTER 1: INTRODUCTION

Clear aligners have evolved from their original application as positioner appliances used in detailing and finishing orthodontic treatment, to clear occlusal retainers post-treatment, to their current use as a removable appliance in treating comprehensive orthodontic malocclusions.[1] Align Technology introduced a clear aligner product called "Invisalign" to the orthodontic market in 1999, and since then clear aligner therapy (CAT) has gained increasing popularity.[1,2] With newer generations of aligners and competing products in the market, CAT is considered by many to be an esthetic treatment alternative to conventional fixed orthodontic appliance therapy (FOA), both in adult and adolescent populations.[1]

While clear aligner therapy is appealing to many orthodontic patients and providers due to its esthetic translucent appearance, potential for improved oral hygiene, and digital fabrication, like any appliance there are inherent limitations that are important to understand.[1,3-6] For instance, CAT requires significant patient compliance, there are high laboratory fees associated with the commercial production and customer distribution, risks of allergies to the polyurethane materials, only 36-55% of predicted tooth movements have been shown to occur (in studies of second generation aligners), and there are some reports in the literature of posterior open bites (no occlusal contacts, or surfaces that touch opposing teeth when biting, between posterior teeth) developing during treatment.[1,4,5,7-10]

It has been shown that orthodontic treatment with both FOA and CAT can decrease the number of occlusal contacts when compared with untreated controls.[11,12] Nevertheless, although the development of posterior open bites are reported as a side effect to CAT[4,10], few well controlled studies have directly evaluated the incidence of reduced occlusal contacts that result from CAT compared to FOA, and considered why such changes occur. Some authors report intrusion of posterior dentition results from the thickness of the clear aligner material and occlusal bite forces,[4,5,13] and difficulty in obtaining proper angulation of incisors with CAT has been reported, leading to interferences that prevent posterior occlusal contacts from occurring.[14] However none of these rationales are supported empirically.

In attempts to evaluate objectively the outcomes of CAT cases compared with FOA cases, several studies have utilized the American Board of Orthodontics (ABO) Objective Model Grading System (OGS), which includes scoring of posterior occlusal contacts where higher point scores indicate less number of contacts. Djeu et al. (2005) found that finished cases treated by CAT had statistically significantly higher final points scored for occlusal contacts compared with FOA (10.46 ± 7.06 and 5.65 ± 4.66, respectively), which indicated more deviation from what is considered ideal.[15] Additionally, Li et al. (2015) reported a significantly higher improvement in OGS occlusal contact scores pre- to post-treatment in FOA when compared with CAT (-1.88 for CAT cases and -3.90 for FOA).[16] These samples were adult subjects only, however, and the clinicians reported that they had minimal experience with CAT compared to FOA prior to the studies.[16]An additional limitation is while the study by Li et al. (2015) reports a seemingly independent sample and data, much of the text and some of the reported data are directly duplicated from the Djeu et al. (2005) study.

In contrast, Kuncio et al. (2017) found no significant difference between post-treatment OGS occlusal contact scores in an adult population (9.72 ± 5.02 in FOA compared to 8.27 ± 4.24 in CAT group), with higher mean scores in the FOA group.[17] In an adolescent sample treated by a clinician with over 10 years of experience with both FOA and CAT, Borda (2017) found no significant difference in CAT and FOA OGS post-treatment scores (7.65 ± 5.28 and 6.27 ± 3.84, respectively), with higher mean scores in the CAT group.[18] This study did not evaluate pre-treatment occlusal contacts, though.[18] To our knowledge, no study has evaluated pre- and post-treatment occlusal contact changes in adolescents treated by FOA compared to CAT.

The purpose of this study was to evaluate treatment outcomes by comparing the number of posterior and anterior occlusal contacts before treatment and at the end of treatment in adolescents treated with CAT compared with FOA. Another aim was to determine if posterior open bite is affected by vertical facial type, incisor angulation, tooth size discrepancies, and initial dental crowding. A third goal was to establish a novel method of virtually measuring occlusal contact areas. These aims were accomplished by testing the following null hypotheses: (1) there were no differences in numbers of occlusal contacts among orthodontic cases treated using clear aligner therapy or fixed orthodontic appliances in adolescents before and after treatment. (2) There were no differences in numbers of occlusal contacts between cases with hyperdivergent, hypodivergent, and mesodivergent facial types at the start of treatment.

CHAPTER II: MATERIALS AND METHODS

Sample

The sample was derived retrospectively from a single orthodontist in Portland, Oregon, with over a decade of experience in CAT and FOA. The clinician was certified by the American Board of Orthodontics and considered a “Diamond Invisalign Provider

(Greater than 150 cases of treated per year using CAT, second highest tier level of experience rated by Align Technology)".[19] This study was approved by the Institutional Review Board of Oregon Health & Science University (Appendix I).

The sample included consecutively treated adolescent patients younger than 18 years of age in CAT or FOA from 2015-2019. Inclusion criteria included cases that were started and finished by the clinician, received full orthodontic treatment involving a full complement of teeth (except third molars), and that had pre-treatment (T_0) and post-treatment (T_1) digital models, panoramic radiographs, and cephalograms available. The exclusion criteria entailed cases that had previous orthodontic treatment (including Phase I or early interceptive treatment by the clinician); limited or single arch treatment; had treatment involving tooth extractions, missing teeth, surgery or impacted teeth; had stopped treatment early due to poor compliance or hygiene; had dental caries during treatment; had significant medical history (bone pathology, Temporomandibular Joint Disorder symptoms, syndromes); were from patients greater than 18 years of age at the start of treatment;[18] or with poor records or other anomalies (i.e. inaccurate bite registration or cephalograms not made in centric occlusion). A list of potential subjects was generated by the practitioner's practice management software (Dolphin Management, version 11.9, Dolphin Imaging Systems, Chatsworth, Calif). The records and diagnostic criteria were evaluated by one researcher. Total treatment time (months) was assessed for each case by summing the number of days between T_0 and T_1 and dividing this number by 30.

OGS Scores

The OGS scores were calculated for each qualified case to match CAT and FOA groups by difficulty at the start of treatment. Digital models were analyzed using commercially available software (OrthoCad version 3.2.8.7, Cadent, San Jose, Calif) to evaluate subjects at each time-point (T_0 and T_1) according to ABO OGS standards.[20] Initial sagittal, vertical, and tooth size measurements were analyzed by the diagnostics tool in the software to the nearest tenth of a millimeter. Second molars were not included in the analyses as they were not erupted or fully erupted at the start of treatment in all subjects, and not all scans captured adequate second molar anatomy.

Occlusal Contact Number

A posterior occlusal contact was defined as an area in which one tooth cusp of a premolar or molar contacted an area on the opposing tooth. An anterior occlusal contact was defined as an area in which an incisal edge or cusp tip of a canine or incisor contacted an area on the opposing tooth. The occlusogram view (axial plane occlusal projections of each dental arch with markings where occlusal contacts are located) in the software (OrthoCad version 3.2.8.7, Cadent, San Jose, Calif) was utilized to determine the total number of anterior and posterior occlusal contacts. Contacts were categorized by the distance between the contacting maxillary and mandibular teeth as: "Definitive," 0.0 to <0.2 mm, which was the smallest distance between opposing teeth detectable by the software and shown in red; "Close," 0.2 to <0.4 mm, which was likely to contribute to functional occlusion during mastication[21] and shown in orange (Figure 7). Both groups were combined to establish clinically significant contacts and called "Near" contacts, where opposing teeth were separated by 0.0mm to <0.4mm and identified by red and orange in the occlusogram. Any contacts from one single cusp were counted only once, so that multiple separate contact points from one cusp were not considered separate occlusal contacts. The total number of occlusal contacts (OC#) in terms of definitive and near, anterior and posterior in an individual at each time-point were summed by one researcher.

Facial Types

Vertical facial types were evaluated on cephalograms (see below) by measuring the mandibular plane angle, defined as the angle between the sella to nasion plane (SN) and the gonion to menton plane (GoMe) and values that were empirically derived. Hypodivergent (Hypo) was defined SN-GoMe < 27°. Hyperdivergent (Hyper) was defined as SN-GoMe > 37°, and all remaining cases were categorized as Mesodivergent (Meso).[22,23]

Additional Variables

Cephalograms at T_0 and T_1 were traced using commercially available software (Dolphin Imaging, version 11.9, Dolphin Imaging Systems, Chatsworth, Calif) by one researcher to determine four angular measurements (Figure 1): the angle from A point to nasion point to B point representing position of maxilla and mandible in relation to cranial base (ANB, °); the mandibular plane angle, represented by the mandibular plane as defined from gonion to menton and the cranial base represented by sella to nasion plane (SN-GoMe, °); the angle of the upper incisor long axis in relation to SN plane (U1-SN, °); and the angle of the lower incisor long axis in relation to the mandibular plane

(IMPA, °). To account for growth changes, the final U1-SN values were calculated by superimposing the T_0 cephalograms over the cranial base of post-treatment T_1 cephalogram, and using the T_0 SN plane for calculations, according to ABO standards (Figure 2).[24] Similarly, final IMPA values were calculated by superimposing the T_0 cephalograms over the mandible on T_1 cephalograms, according to ABO standards (Figure 3).[24]

Digital dental models in maximum intercuspation relations and software (OrthoCad version 3.2.8.7, Cadent, San Jose, Calif) were used to determine Angle Classification of canine relations (I, II, III) on both right (R3) and left (L3) by measuring the distance, parallel to the plane of occlusion and to the facial axis points of the posterior dentition, of the maxillary canine cusp tip anterior to (II), posterior to (III), or coincident with (I) the embrasure between the opposing mandibular canine and first premolar (Figure 4A-C). Similar measurements were conducted to determine Angle classification of first molar relations on right (R6) and left (L6) by measuring the distance from the mesiobuccal cusp tip of maxillary first molars anterior to (II), posterior to (III), or coincident with (I) the buccal grove of mandibular first molars (parallel to the plane of occlusion and to the facial axis points of the posterior dentition). The overbite (OB) was measured by determining the distance of maximum vertical overlap between the mandibular and maxillary incisal edges (Figure 5). Anterior Bolton tooth size discrepancy (Bolton 3-3) analysis[25] was calculated at T_1 by measuring mesio-distal widths of anterior teeth (canine to canine) and dividing the summed widths of the mandibular anterior teeth by the summed width of the maxillary anterior teeth to obtain a ratio (Figure 6). This ratio was compared to the ideal ratio of .77 and the dental arch with relative excess of mesio-distal tooth widths was identified, where positive values represented mandibular tooth size excess and negative values represented maxillary tooth size excess, and the difference from ideal was calculated to the nearest tenth of a millimeter. Overall Bolton tooth size discrepancy (Bolton 6-6) was calculated similarly, measuring the widths of all anterior and posterior teeth up to and including first molars. Crowding was measured by calculating the amount of arch space available and subtracting the sum of individual tooth widths in the arch.

Data and Statistical Analyses

The cases were selected starting with most recently finished cases, inclusion and exclusion criteria applied, and qualified cases were divided into the CAT and FOA groups. The cases were then subdivided within each treatment group depending on category of facial type (Hypo, Hyper, Meso) for a total of 6 subgroups.

A power analysis was conducted to predict adequate sample size. Borda (2017) found that at the end of treatment, 26 teenage cases treated with CAT scored on average 7.65 ± 5.28 points for occlusal contacts in OGS scoring, whereas 26 matched (by malocclusion complexity) cases treated with FOA scored 6.27 ± 3.84 on average.[18] Using these data, a sample size of 80 cases in each group (CAT and FOA) was initially predicted for this study using a power of 80% and .05 level of significance, in order to determine a difference in OC# between groups before and after treatment.[18]

A t-test with unequal variance was used to evaluate overall differences in ABO OGS scores between the CAT and FOA cases to evaluate how well the groups matched with significance defined by $p \leq .05$. Similarly, t-tests were used to compare the number of occlusal contacts of each type (near and definitive, anterior and posterior) and the OGS occlusal contact scores within each treatment group pre- and post-treatment, and between the treatment groups at each time-point. Total treatment time was compared between the two groups also using a t-test. ANOVA was conducted to compare all dependent variables: treatment time, T_1 Bolton 3-3, T_1 Bolton 6-6, T_0 OB, T_0 ANB, T_0 crowding; plus: IMPA, U1-SN, canine and molar relationship, anterior near/definitive OC#, posterior near/definitive OC# at both time-points; between vertical facial type subgroups in males and females in each treatment group. Where significant differences ($p \leq .05$) were found, a Bonferroni post-hoc analysis was applied to determine if significant differences existed between individual categories of treatment outcome.

Five cases in each treatment group were randomly selected to be re-measured greater than 2 weeks apart from the initial measurement for intra-rater reliability tests and were compared to the same five cases measured by another researcher for inter-rater reliability tests.[15] Intra-rater reliability and inter-rater reliability were tested using the intra-class correlation coefficient (ICC), with the following parameters: High ≥ .85, .85 > Medium ≥ .6, Low < .6.

CHAPTER III: RESULTS

Sample

A total of 62 subjects (39 females, 23 males) met inclusion/exclusion criteria, with 31 subjects (18 females, 13 males) in the CAT group and 31 subjects (21 females, 10 males) in the FOA group (Table 1). Within each treatment group, there were nine hyperdivergent subjects (CAT: 5 females, 4 males; FOA: 8 females, 1 male), nine hypodivergent subjects (CAT: 4 females, 5 males; FOA 5 females, 4 males), and 13 mesodivergent subjects (CAT: 8 females, 5 males; FOA 8 females, 5 males) (Table 2).

Measurement Reliability Tests

Intra-rater reliability scores (Table 3, Table 4) were considered high at ICC ≥ 0.85 for T_0 molar classifications (right side = 0.997, left side = 0.998) and T_1 right side molar classifications (0.987), T_0 canine classifications (right side = 0.989, left side = 0.987) and T_0 right side canine classifications (0.917), U1-SN measurements (T_0 = 0.919, T_1 = 0.957), T_0 IMPA (0.954), MPA (0.985), Overbite (0.995), Final Bolton 3-3 (0.914), and crowding (0.973). The intra-rater reliability tests scored medium at 0.6 ≤ ICC < 0.85 for T_1 IMPA (0.845), T_1 left side molar classification (0.837), T_0 OGS (0.627), and T_0 anterior definitive OC# (0.836). The T_0 anterior near OC# (0.314) and T_1 left canine classification scored low (0.560) for intra-rater reliability.

ICC inter-rater reliability scores (Table 5) were medium at 0.6 ≤ ICC < 0.85 for T_0 posterior near OC# (0.720), and high at ICC ≥ 0.85 for all other occlusal contact scores (T_0 anterior near OC# = 1.000, T_0 anterior definitive OC# = 1.000, T_0 posterior definitive OC# = 1.000, T_1 anterior near OC# = 1.000, T_1 anterior definitive OC# = 0.923, T_1 posterior near OC# = 0.950, and T_1 posterior definitive OC# = 0.943).

OGS and OC#

Mean OGS scores ± standard deviation (SD) for FOA and CAT cases (Figure 8) were 62.9 ± 7.4 and 60.7 ± 7.5, respectively and not significantly different at T_0. Scores at T_1 versus T_0 showed significant decreases (improvements) for both groups where, on average, the OGS for the FOA decreased by 24.4 and for the CAT by 25.4 points (Figure 8, both $p < .001$). However, at T_1 mean OGS score ± SD for CAT cases was 35.3 ± 4.7

and was significantly lower, compared with that for FOA cases which was 38.5 ± 6.5 (Figure 8; $p = .02$). Similarly, when extrapolating just the occlusal contact portion of the OGS score at T_0, the mean (± SD) of the CAT group was 7.6 (± 3.9), which was not significantly different from the 9.6 (± 4.6) of the FOA group (Figure 9). The mean occlusal contact OGS score at T_1 for CAT was significantly higher ($p = .002$) at 12.3 (± 2.5), compared with the 9.8 (± 3.0) found in the FOA group (Figure 9). The values at T_0 and T_1 were significantly different within the CAT group ($p < .001$), but not within the FOA group (Figure 9).

There were no significant differences in average anterior occlusal contacts at either T_0 or T_1 between groups or time-points (Figures 10-11). Significantly fewer definitive and near posterior occlusal contacts were found in the CAT versus FOA groups at T_1 (Figure 10 and Figure 11, $p = .01$ and $p = .03$, respectively). There was a significant decrease of 2.9 and 2.4 in posterior definitive and near OC#, respectively in CAT from T_0 to T_1 on average (Figure 10 and Figure 11, $p < .001$ and $p = .003$, respectively). There was a non-significant decrease of 0.8 in posterior definitive OC# (Figure 10), and no change in posterior near OC# (Figure 11), in FOA on average from T_0 to T_1.

Secondary findings

The U1-SN values at T_0 were similar in FOA and CAT, at 100.6 ± 8.2° and 100.1 ± 8.2°, respectively (Figure 12). The FOA group had a significant increase of 7.7° in U1-SN ($p < .001$) from T_0 to T_1, whereas the CAT group had a minimal increase of 0.1° on average (Figure 12). When comparing the change in U1-SN values from T_0 to T_1 in FOA and CAT, the effect size (η^2) and Power (β) were 0.33 and 0.74 in the hypodivergent subgroup, 0.38 and 0.96 in the mesodivergent subgroup, and 0.28 and 0.65 in the hyperdivergent subgroup, respectively.

The IMPA values at T_0 were similar in FOA and CAT, at 90.1 ± 8.1° and 89.9 ± 6.9°, respectively (Figure 12). The FOA group had an increase of 6.8° in IMPA ($p = .001$), whereas the CAT group had a non-significant increase of 0.6° on average from T_0 to T_1 (Figure 12). When comparing the change in IMPA values from T_0 to T_1 in FOA and CAT, the η^2 and Power β were 0.27 and 0.63 in the hypodivergent subgroup, 0.17 and 0.56 in the mesodivergent subgroup, and 0.34 and 0.77 in the hyperdivergent subgroup.

Six subjects in the CAT group (19.4%) had a T_1 OGS score that was ≤ 30 (potentially passing ABO Phase III Exam, Table 8).[20] Five subjects (16.1%) in the FOA group in this study had a T_1 score that was ≤ 30 (Table 7).

Mean (± SD) total treatment time was 19.0 (± 7.1) months and significantly lower for CAT compared with 24.0 (± 6.9) months for FOA (Table 6). When comparing the mean total treatment time in FOA and CAT, the η^2 and β were 0.00 and 0.06 ($p = 0.83$) in the hypodivergent group, 0.37 and 0.95 ($p = 0.001$) in the mesodivergent group, and 0.19 and 0.44 in the hyperdivergent group ($p = 0.07$). In female CAT subjects, the mean (± SD) total treatment time was 28.1 (± 11.1) months in the hypodivergent subgroup and significantly higher ($p = .02$) than the 15.0 (± 4.6) months in the mesodivergent subgroup, with a η^2 of 0.41 and a β of 0.75 (Table 8). The mean (± SD) T_1 right maxillary molar classification was -1.28 (± 0.71) mm for the female CAT hyperdivergent subgroup and significantly lower (more class III, $p = .02$) compared with the -0.23 (±0.48) mm in the female CAT mesodivergent subgroup, with a η^2 of 0.41 and a β of 0.75 (Table 8). The mean (± SD) T_1 right canine classification was 0.88 (± 0.61) mm for the female CAT hyperdivergent subgroup and significantly lower (less class II, $p = .01$) compared with the 2.11 (±0.61) mm in the female CAT mesodivergent subgroup, with a η^2 of 0.43 and a β of 0.78 (Table 8). The mean (± SD) crowding at T_0 was -5.20 (±1.10) mm in the female CAT hyperdivergent subgroup and significantly higher (more negative, $p = .04$) than the 0.75 (±3.86) mm in the female CAT hypodivergent subgroup, with a η^2 of 0.36 and a β of 0.65 (Table 8). There were no significant differences in number of occlusal contacts or incisor angulations between subgroups in this category (Table 8).

In male CAT subjects, the mean (± SD) change in U1-SN from T_0 to T_1 in the hyperdivergent subgroup was -4.53° (± 3.39°) and significantly lower ($p = .03$) than the 4.80° (± 4.87°) in the hypodivergent subgroup, with a η^2 of 0.50 and a β of 0.68 (Table 9). In addition, the mean (± SD) T_1 Bolton 6-6 mandibular tooth size excess in the male CAT hypodivergent subgroup was -0.48 (±0.72) mm and significantly lower (the tooth size excess was in the maxillary teeth in this subgroup, $p =.02$ and $p = .01$, respectively) than the 1.60 (± 1.08) mm in the male CAT mesodivergent subgroup and the 2.13 (± 0.94) mm in the male CAT hyperdivergent subgroup, with a η^2 of 0.68 and a β of 0.95 (Table 9). There were no significant differences in any OC# measurements between subgroups in this category (Table 9).

In female FOA subjects, the mean (± SD) right side canine classification at T_0 in the hypodivergent subgroup was 4.32 (± 1.87) mm and significantly higher (more class II, $p = .03$) when compared with the 1.36 (± 1.70) mm in the mesodivergent subgroup, with a η^2 of 0.31 and a β of 0.65 (Table 10). The mean (± SD) change in right side canine classification in the female FOA hypodivergent subgroup from T_0 to T_1 was 2.70 (± 1.79) mm and significantly greater ($p = .04$ and $p = .03$) when compared with the 0.41 (± 1.51) mm and 0.33 (± 1.09) mm of the female FOA hyperdivergent and mesodivergent subgroups, respectively (Table 10). The η^2 of the right side canine classification in female FOA subjects between facial type subgroups was 0.36 and the β was 0.75. The mean (± SD) change in U1-SN values from T_0 to T_1 in the female FOA hypodivergent subgroup was 18.7° (± 9.45°) and significantly greater (p= .03) when compared with the 4.39° (± 9.14°) of female FOA hyperdivergent subgroup, with a η^2 of 0.34 and a β of 0.70 (Table 10). No significant differences between the subgroups were found for any OC# measurements (Table 10).

No comparison between subgroups was conducted in male FOA subjects because there was only 1 male hyperdivergent subject in this category.

CHAPTER IV: DISCUSSION

The OGS scores in the FOA and CAT groups were not significantly different at T_0, indicating that they were well matched pre-treatment. In the current study, OGS scores measured at T_0 allowed similar pre- and post-treatment comparisons within each treatment group. At T_1 the OGS scores were significantly lower within each group compared with T_0, and significantly lower for the CAT group (35.3 ± 4.7) compared with the FOA group (38.5 ± 6.5). The 19.4% of CAT subjects with a potentially passing OGS score at T_1 was similar to the 20.8% of CAT cases reported by Djeu et al. (2005) ,[15] and lower than the 66.7%, and 46.0% reported by Li et al. (2015) and Borda (2017), respectively.[15,16,18] The 16.1% of subjects in the FOA group in this study that had a potentially passing OGS score for the ABO Phase III Exam was lower than the 47.9%, 75.0%, and 23.0% of FOA cases reported by Djeu et al. (2015), Li et al. (2015), and

Borda (2017), respectively.[15,16,18] The lower percentage of potentially passing cases in this study could have been due to initial case complexity being potentially higher in the present study making it more difficult to achieve lower final scores, differences in practitioner's definition of when treatment is complete (and thus treatment time variation), differences in examiners grading the cases, or differences in hand grading models (Djeu et al. (2005) and Li et al. (2015)) versus digital grading models (Borda (2017) and the present study).[15,16,18] Though the cases in the aforementioned study involved closing premolar extraction cases and thus could require longer treatment time, the clinicians could have spent longer time attempting to achieve more ideal results when compared with the other studies mentioned.[15,16,18] In addition, OGS scores involve an accumulation of points where deviations from ideal occur at each tooth, and in cases in which four premolars are extracted, there are four fewer teeth to accumulate points. Thus, cases involving extraction are likely to have lower scores, all other parameters being equal.

Borda (2017) reported a final CAT OGS score of 30.08 ± 8.30, compared with 36.96 ± 9.34 in the FOA group in an adolescent population, despite a shorter mean treatment time of 16.9 (± 5.7) months in CAT compared with the 23.4 (±4.4) months in the FOA group.[18] The treatment times were similar to the present study, in which the mean treatment time of 18.8 (±7.0) months in the CAT group was shorter than the 23.7 (±6.8) months in the FOA group.[18] While the OGS scores reported by Borda (2017) were also significantly lower in the CAT group compared with the FOA group, the average initial Discrepancy Index (DI) score in the subjects of both groups included indicated a mild complexity of malocclusion according to ABO ranges.[18,23] The initial case complexity could have been higher on average in the present study (moderate to severe), which could explain the higher OGS scores overall in both groups at T_1 due to more difficulty achieving ideal occlusion given the treatment time. On the other hand, Djeu et al. (2005) reported a significantly higher final OGS score in the CAT group (45.35 ± 15.56) compared with the FOA group (32.21 ± 11.73).[15] However, in the aforementioned study the clinician was relatively inexperienced with CAT treatment, which may have negatively affected treatment results in the CAT compared to FOA groups; and the mean treatment time in the CAT group of 16.8 months was shorter compared to the 20.4 months of the FOA group.[15] Kuncio et al. (2007) reported no significant differences in OGS scores between FOA (40.18 ± 10.32) and CAT (39.45 ±10.26) subjects at the end of treatment time-point in an adult population.[17] Whereas, Li et al. (2015) reported a larger but non-significant improvement in OGS score for the FOA group (-38.57 ± 8.87) compared with CAT group (-30.48 ± 9.23) from pre- to post-treatment time-points whereas, in this study the CAT had significantly longer mean treatment time of 31.5 months than the 22 months of the FOA group.[16] However, the average DI scores reported in this study were greater than 25, which the authors considered severe complexity of malocclusion.[16,23] No analysis was made to compare initial OGS scores, so it is difficult to determine if the cases were well matched at initial time-points. In addition, these subjects were adult patients and treated with extractions,[16] which cannot be directly compared to the current study, where cases were of moderate complexity with non-extraction treatment.

Kassas et al. (2013) evaluated 31 adult subjects treated with clear aligner therapy, and similarly found a significant improvement in OGS scores from pre-treatment (45.03

± 7.47) to post-treatment time-points (35.87 ± 9.36).[12] The initial OGS score for CAT reported by Kassas et al. was lower than that reported in this study (60.7 ± 7.5), indicating that the initial complexity of malocclusion was perhaps higher in the current study.[12] The authors reported that the target range of malocclusion was mild to moderate, determined by a Discrepancy Index (DI) range of 10-20, however this is a wide range and can be influenced largely by cephalometric measurements.[12,26]

In the current study, no significant differences were found in anterior OC# between the two treatment groups at each time-point and within the groups from T_0 to T_1. Sullivan et al. (1991) found a significant decrease in anterior OC# when examining just FOA subjects using intraoral polyvinylsiloxane bite registrations from pre-treatment (2.87) to one month during treatment (0.71), which was sustained at 12-months during treatment (0.79).[11] However, no standard deviations were reported, and no post-treatment measurements were reported, so it is difficult to draw comparisons to the present study. In the current study, there were fewer total OC# recorded in the anterior region on average when compared with number of posterior contacts recorded (Figures 10-11). Perhaps with fewer possible contact areas in the anterior region (6) when compared with posterior region (14), there was less variability in numbers between the groups in this sample. This could have contributed to why no significant differences in OC# were seen between the groups or between time-points in the anterior region. This study presents a novel method of measuring occlusal contacts, and no other studies to date have reported differences in anterior contacts between FOA subjects and CAT subjects.

In the current study, the posterior occlusal contacts decreased in both FOA and CAT groups from T_0 to T_1, which is consistent with reports in the literature.[12,27] Subjects in the CAT group had significantly fewer posterior occlusal contacts. Previous studies have similarly reported higher OGS occlusal contact scores (signifying fewer number of posterior occlusal contacts compared with ideal) in CAT groups versus FOA groups.[15,16,18] However, Kuncio (2007) reported a non-significant larger OGS occlusal contact score for FOA (9.72 ± 5.02) compared with CAT (8.27 ± 4.24) subjects in an adult population.[17] These values were lower than the 9.81 (± 2.99) for FOA and 12.32 (± 2.52) for CAT at T_1 found in the present study.

Upper and lower incisor angulations increased significantly from T_0 to T_1 in FOA, but there were no significant changes in the CAT group (Figure 12). This could indicate that overall, FOA had more torque expression and third order changes than the CAT group in this study. In contrast to the present study, Hennessey et al. (2016) reported that the change of IMPA values from T_0 to T_1 in the FOA group of 5.3 ± 4.3° was not significantly higher than the 3.4 ± 3.2° in the CAT group.[28] Those findings indicate that an increase in mandibular incisor angulation in CAT is achievable, though perhaps to a lesser degree than in FOA subjects.[28] Insufficient anterior torque has been reported to be a potential reason for posterior open bites in CAT cases due to anterior interferences.[1,7,14,16,29] Moshiri recommends overcorrection of anterior torque prescription and moving lower incisors lingual in the virtual treatment planning for clear aligners to prevent such interferences.[29] However, the data in this current study do not indicate treatment goals for each subject, which could have influenced the practitioner's aim for post-treatment upper and lower incisor angulation.

In the vertical facial subgroupings, the only incisor angulation category which achieved significant power ($\beta > 0.8$) when comparing FOA and CAT was change in U1-SN from T_0 to T_1, obtained in the mesodivergent subgroup ($\beta = 0.96$). Similarly, the mesodivergent subgroup had a β of 0.95 in the overall treatment time category. This indicates that the mesodivergent had an adequate sample size, while other subgroups likely would require larger n values in order to achieve higher power.

When interpreting the subgroup data (Table 8), the longer treatment time in female hypodivergent subjects compared with other subgroups could have been because the total number of subjects in this subgroup was lower (4) compared with hyperdivergent and mesodivergent subjects (5 and 9, respectively). The differences in overall treatment time could have been due to outliers in this small group. For instance, one of the female hypodivergent CAT subjects was in treatment for 43.8 months. The OGS scores within this grouping were not significantly different at T_0, indicating that differences in complexity did not contribute to this finding. Another possibility is that the subjects in this subgroup were less compliant, necessitating a longer overall treatment time.

The right side canine and molar classifications at T_1 were shown to be more class III in the hyperdivergent females in the CAT group compared with other vertical facial types in this group (Table 8). The canine and molar classifications at T_0 were also less class II on average compared with the other vertical types, and there was significantly higher crowding at T_0, which could explain more of a class III tendency after treatment after the crowding was unraveled. There were no significant differences between Bolton discrepancies within this subgroup (Table 8).

The U1-SN values for hyperdivergent males in the CAT group decreased from T_0 to T_1, which was significantly different than in the hypodivergent subgroup, where the values increased after treatment (Table 9). There could have been more upper incisor interproximal reduction or more expansion in the hyperdivergent male CAT subgroup that could have led to more upright maxillary incisors when compared with the hypodivergent subgroup, but these variables were not evaluated in this study.

In the FOA female subgroup, the T_0 canine classifications were significantly larger on the right side for the hypodivergent group compared with the mesodivergent group (Table 10). This explains the larger change in right side canine classification from T_0 to T_1, because this subgroup had further distance required for the canine to move to obtain an ideal class I relationship. Additionally, the FOA female hypodivergent group had a significantly larger change in U1-SN from T_0 to T_1 compared with the FOA female hyperdivergent group (Table 10). This could be attributed to treatment goals, as conventionally hypodivergent individuals can tolerate more proclination esthetically when compared with hyperdivergent individuals.[30]

Except for the T_1 Bolton 6-6 mandibular tooth size excess in the male CAT hypodivergent subgroup ($\beta = 0.95$), the power did not reach 0.8 in these gender subgroupings, indicating that higher sample sizes in each gender subgrouping could have been necessary to achieve more convincing results between gender types.

This study has several limitations. Second molars were excluded from measurement of occlusal contacts and OGS scoring due to not all second molars included in all models at the initial time-point. The DI was not used in this study, as ranges reported in previous studies might not actually reflect severity of malocclusion or treatment need in subjects, and there is a reported overestimation of case complexity with digital measurement of models.[26,31] Several subjects in each FOA and CAT groups were treated using the Carriere motion appliance for sagittal correction of occlusion in addition to either FOA or CAT. This could have been part of the exclusion criteria but would have significantly lowered the sample sizes. Occlusal contact areas in this study were measured quantitatively in maximum intercuspation, whereas no qualitative assessment (i.e. pinpoint contacts versus larger contact areas) was conducted. The model analyses were dependent on the accuracy of the bite registration, which is a limitation in a retrospective study in which the individual taking the occlusal records were not calibrated to specific standards for duplicating occlusion accurately. Qualitative assessment could provide more information as to whether or not anterior interferences were present that prevented more posterior contacts. The results of this study were limited to adolescents only, and thus the findings of this study do not necessarily apply to a non-growing adult population. Studies in rates of tooth movement indicate up to 1.5:1 difference in tooth movement velocities for equivalent stress in growing children.[32] The subjects treated in this study were treated by one orthodontist, so the results cannot necessarily be applied to other practitioners who might have different techniques, experience levels, and treatment philosophies. In particular, total treatment times could be variable depending on when the practitioner determines treatment to be completed. The number of male and female subjects within each group and subgroup were unequal, so one should exercise caution when drawing assertions from the gender and facial type comparisons in this study.

All occlusal contact measurements were conducted on digital models made from commercially available scanner hardware (iTero Element®, Align Technology, San Jose, Calif) in the same private practice of one orthodontist. One report indicated that there are limitations to dimensional accuracy of occlusal contact measurements using digital models to mount cases for prosthodontic work, however this utilized different intraoral scanner technology than in the current study.[33] On the other hand, another report using a different scanner indicated digital scans are precise in determining size and location of contacts compared with bite registrations.[34]

The results of the intra-rater reliability tests indicate that one should exercise caution when interpreting the results of IMPA values at T_1, left molar and canine classifications at T_1, T_0 anterior near and definitive contacts, and T_1 OGS scores, as these did not score in the high category for reliability. In addition, the inter-rater reliability tests indicate that one should exercise caution when interpreting the T_0 near posterior occlusal contacts, as this score fell in the medium category.

Future directions to this research include increasing the male and female subjects in the subgroups, particularly male subjects in the FOA hyperdivergent subgroup, to allow adequate subgroup comparison and increase the power. In addition, a more sophisticated ANOVA analysis can be conducted to compare OC# in each treatment group with other categorical variables (i.e. Bolton, crowding, Δ3, Δ6, gender). Other directions include examining subjects at long term post treatment follow up to determine if OC# changes occur over time, a comparison of occlusal contacts in adolescent subjects with adult subjects treated with both treatment modalities, a multisite comparison involving different providers, qualitative measurements of total surface area of each contact, and analysis of number of appointments during treatment in subjects treated with FOA compared with CAT.

CHAPTER V: CONCLUSIONS

Null hypothesis (1) was rejected, as both FOA and CAT groups showed decreased numbers of occlusal contacts after treatment. Clear aligner therapy showed significantly decreased number of posterior occlusal contacts when compared with pre-treatment values. The number of posterior occlusal contacts was significantly lower post-treatment in the CAT group when compared with the FOA group. Null hypothesis (2) was sustained: there were no significant differences in occlusal contacts between cases in hypodivergent, mesodivergent, and hyperdivergent subgroups at the pre-treatment time-point.

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Table 1: Gender distribution amongst cases treated with fixed orthodontic appliances (FOA) and clear aligner therapy (CAT)

Subjects	FOA (n)	CAT (n)
Males	10	13
Females	21	18
Total	31	31

Table 2: Subgroup distribution (n = subject number)

Subject Groups	FOA (n)	CAT (n)
Hypodivergent	**9**	**9**
Mesodivergent	**13**	**13**
Hyperdivergent	**9**	**9**
Total	**31**	**31**

Table 3: Intra-rater reliability tests of dependent variables

Variable	ICC	$1-\eta^2$
R6: T_0	0.997	0.106
L6: T_0	0.998	0.002
R6: T_1	0.986	0.009
L6: T_1	0.837	0.099
R3: T_0	0.989	0.007
L3: T_0	0.987	0.008
R3: T_1	0.917	0.051
L3: T_1	0.560	0.253
U1-SN: T_0	0.919	0.050
U1-SN: T_1	0.957	0.027
IMPA: T_0	0.954	0.029
IMPA: T_1	0.845	0.095
MPA: T_0	0.985	0.010
ANB: T_0	0.708	0.176
OB: T_0	0.995	0.003
Bolton 3-3: T_1	0.914	0.053
Bolton 6-6: T_1	0.842	0.097
Crowding: T_0	0.973	0.017
OGS: T_0	0.875	0.077
OGS: T_1	0.627	0.223

Legend: ICC = intra-class correlation coefficient, $1-\eta^2$ = error, T_0 = initial, T_1 = final, R(n) = right molar/canine classification , L(n) = Left molar/canine classification, 3 = canine, 6 = molar, U1-SN = upper incisor angulation, IMPA = lower incisor angulation, MPA = mandibular plane angle, ANB = A point to nasion to B point, OB = Overbite, Bolton = tooth size discrepancy, 3-3 = anterior, 6-6 = overall, OGS = Objective grading system

Table 4: Intra-rater reliability tests for occlusal contact numbers

Contact numbers	ICC	$1-\eta^2$
T_0: Anterior Near	0.314	0.395
T_0: Anterior Definitive	0.836	0.097
T_0: Posterior Near	0.973	0.078
T_0: Posterior Definitive	0.968	0.020
T_1: Anterior Near	0.975	0.015
T_1: Anterior Definitive	1.000	0.000
T_1: Posterior Near	0.948	0.033
T_1: Posterior Definitive	0.923	0.048

Legend: ICC = intra-class correlation coefficient, $1-\eta^2$ = error, T_0 = initial, T_1 = final

Table 5: Inter-rater reliability tests for occlusal contact numbers (OC#)

Contacts	ICC	$1-\eta^2$
T_0: Anterior Near	1.000	0.00
T_0: Anterior Definitive	1.000	0.000
T_0: Posterior Near	0.720	0.169
T_0: Posterior Definitive	1.000	0.000
T_1: Anterior Near	1.000	0.000
T_1: Anterior Definitive	0.923	0.048
T_1: Posterior Near	0.950	0.031
T_1: Posterior Definitive	0.943	0.036

Legend: ICC = intra-class correlation coefficient, $1-\eta^2$ = error, T_0 = initial, T_1 = final, Definitive = 0.0 - < 0.2 (mm), Near = 0.0 - < 0.4 (mm)

Table 6: Treatment times (months)

	FOA	CAT
Mean	**23.7**	**18.8**
Standard Deviation	**6.8**	**7.0**

Legend: FOA = fixed orthodontic appliance, CAT = clear aligner therapy

Table 7: Initial American Board of Orthodontics Objective Grading System (OGS) Phase III results

Phase III Result	FOA: n (%)	CAT: n (%)
Pass (OGS ≤ 30)	5 (16.1%)	6 (19.4%)
Fail (OGS > 30)	26 (83.9%)	25 (80.6%)
Total	31	31

Legend: n = subject number, % = percent of subjects within treatment group

Table 8: Dental and cephalometric results (means ± SD) for clear aligner therapy in hypodivergent, hyperdivergent, and mesodivergent females.

Dependent Variable	Hypodivergent	Hyperdivergent	Mesodivergent
Treatment Time(months)	**28.1 (±11.1)^{A}**	13.4 (±6.4)	15.0 (±4.6)^{B}
R6: T_0 (mm)	1.02 (±0.67)	0.14 (±3.13)	1.12 (±1.12)
L6: T_0 (mm)	0.40 (±0.68)	0.62 (±2.18)	1.00 (±1.25)
R6: T_1 (mm)	-0.55 (±0.64)	**-1.28 (±0.71)^{A}**	-0.233 (±0.48)^{B}
Δ R6 (mm)	1.58 (±0.61)	1.42 (±2.73)	1.36 (±0.99)
L6: T_1 (mm)	-0.20 (±1.16)	-0.66 (±0.98)	-0.33 (±0.73)
Δ L6 (mm)	0.60 (±1.79)	1.28 (±1.62)	1.33 (±1.32)
R3: T_0 (mm)	4.55 (±0.69)	3.08 (±2.79)	3.77 (±1.51)
L3: T_0 (mm)	2.93 (±1.76)	2.96 (±2.51)	3.76 (1.40)
R3: T_1 (mm)	1.68 (±0.81)	**0.88 (±0.61)^{A}**	2.11 (±0.61)^{B}
ΔR3 (mm)	2.88 (±0.70)	2.11 (±0.61)	1.66 (±1.50)
L3: T_1 (mm)	1.20 (±0.91)	1.76 (±0.95)	1.97 (±0.47)
ΔL3 (mm)	1.73 (±0.93)	1.20 (±2.11)	1.79 (±1.54)
U1-SN: T_0 (◦)	104.08 (±7.93)	103.20 (±6.51)	99.11 (±10.76)
U1-SN: T_1 (◦)	100.53 (±6.22)	102.12 (±6.64)	99.76 (±5.39)
ΔU1-SN (◦)	-3.55 (±3.87)	-1.08 (±1.95)	0.64 (±8.39)
IMPA: T_0 (◦)	90.48 (±4.82)	84.20 (±6.39)	92.53 (±5.94)
IMPA: T_1 (◦)	88.75 (±7.20)	88.88 (±5.04)	95.03 (±5.08)
ΔIMPA (◦)	-1.73 (±7.96)	4.68 (±4.99)	2.50 (±4.67)
ANB: T_0 (◦)	1.75 (±0.90)	2.20 (±2.01)	2.90 (±1.62)
ANB: T_1 (◦)	1.18 (±0.76)	1.92 (±2.14)	2.42 (±1.97)
OB: T_0 (mm)	4.05 (±1.30)	3.66 (±1.02)	4.37 (±1.25)
Bolton 3-3: T_1 (mm)	-0.13 (±0.39)	0.84 (±1.41)	0.84 (±1.03)
Bolton 6-6: T_1 (mm)	0.05 (±1.05)	0.76 (±1.80)	0.76 (±1.76)
crowding: T_0 (mm)	0.75 (±3.86)^{B}	**-5.20 (±1.10)^{A}**	-1.56 (±3.50)
OGS: T_0	56.25 (±4.72)	63.40 (±11.13)	57.78 (±6.42)
OGS: T_1	36.25 (±3.50)	35.80 (±4.09)	34.89 (±6.13)
ΔOGS	20.00 (±4.24)	27.60 (±10.62)	22.89 (±6.83)
T_0: A OC# Near	3.75 (±2.22)	4.00 (±2.45)	3.56 (±1.88)
T_1: A OC# Near	2.75 (±1.50)	4.00 (±2.00)	3.56 (±1.81)
T_0: A OC# Definitive	1.50 (±1.73)	2.20 (±2.49)	1.22 (±1.64)
T_1: A OC# Definitive	1.25 (±0.96)	3.20 (±1.64)	2.11 (±1.62)
T_0: P OC# Near	8.00 (±2.58)	9.00 (±3.67)	8.22 (±2.17)
T_1: P OC# Near	7.50 (±2.89)	5.80 (±2.49)	7.56 (±2.24)
T_0: P OC# Definitive	5.25 (±3.30)	6.20 (±4.09)	5.56 (±3.25)
T_1: P OC# Definitive	1.00 (±1.41)	2.00 (±1.58)	2.89 (±2.09)

(Bonferroni post-hoc correction**, $p < 0.05$**)

Legend: T_0 = Pre-treatment, T_1 = Post-treatment, R(n) = right molar/canine classification , L(n) = Left molar/canine classification, 3 = canine, 6 = molar, U1-SN = upper incisor angulation, IMPA = lower incisor angulation, MPA = mandibular plane angle, ANB = A point to nasion to B point, OB = Overbite, Bolton = tooth size discrepancy, 3-3 = anterior, 6-6 = overall, OGS = Objective grading system, Δ = Change from T_0 to T_1, OB = Overbite, A = Anterior, P = Posterior, OC# = Occlusal Contact Number, Definitive = 0.0 - < 0.2 (mm), Near = 0.0 - < 0.4 (mm)

Table 9: Dental and cephalometric results (means ± SD) for clear aligner therapy in hypodivergent, hyperdivergent, and mesodivergent males.

Dependent Variable	Hypodivergent	Hyperdivergent	Mesodivergent
Treatment Time(months)	22.57 (±4.30)	18.87(±5.53)	18.17 (±4.03)
R6: T_0 (mm)	1.28 (±2.09)	-0.10 (±0.58)	1.15 (±2.35)
L6: T_0 (mm)	1.10 (±2.14)	0.33 (±1.01)	0.93 (±1.72)
R6: T_1 (mm)	-0.52 (±0.58)	-0.75 (±0.51)	-0.13 (±0.91)
Δ R6 (mm)	1.80 (±2.22)	0.65 (±0.70)	1.28 (±2.18)
L6: T_1 (mm)	-0.26 (±1.03)	-0.90 (±1.06)	-0.35 (±0.41)
Δ L6 (mm)	1.36 (±1.93)	1.23 (±1.33)	1.28 (±1.91)
R3: T_0 (mm)	3.74 (±2.38)	2.78 (±0.49)	3.43 (±2.44)
L3: T_0 (mm)	3.40 (±1.36)	2.70 (±1.73)	3.75 (1.59)
R3: T_1 (mm)	1.32 (±0.62)	0.75 (±0.54)	1.50 (±1.09)
ΔR3 (mm)	2.42 (±1.78)	2.03 (±0.71)	1.93 (±2.00)
L3: T_1 (mm)	1.74 (±0.50)	1.58 (±0.48)	1.65 (±0.17)
ΔL3 (mm)	1.66 (±1.36)	1.13 (±1.56)	2.10 (±1.72)
U1-SN: T_0 (◦)	98.4 (±8.38)	99.00 (±8.59)	97.78 (±4.18)
U1-SN: T_1 (◦)	103.16 (±5.13)	94.48 (±5.77)	100.35 (±7.05)
ΔU1-SN (◦)	4.80 (±4.87)^{A}	**-4.53 (±3.39)^{B}**	2.58 (±4.91)
IMPA: T_0 (◦)	90.02 (±10.59)	91.38 (±5.71)	89.03 (±6.22)
IMPA: T_1 (◦)	89.24 (±9.33)	89.03 (±5.11)	87.35 (±5.54)
ΔIMPA (◦)	-0.78 (±5.45)	-2.35 (±1.91)	-1.68 (±2.42)
ANB: T_0 (◦)	1.04 (±2.33)	3.43 (±1.73)	2.68 (±2.24)
ANB: T_1 (◦)	0.04 (±2.93)	3.53 (±1.31)	2.20 (±1.53)
OB: T_0 (mm)	6.14 (±1.68)	3.98 (±1.21)	4.73 (±0.35)
Bolton 3-3: T_1 (mm)	-0.36 (±1.28)	0.93 (±1.07)	1.35 (±0.68)
Bolton 6-6: T_1 (mm)	**-0.48 (±0.72)^{A}**	1.60 (±1.08)^{B}	2.13 (±0.94)^{B}
crowding: T_0 (mm)	-1.80 (±5.40)	-3.25 (±1.89)	1.50 (±6.14)
OGS: T_0	59.80 (±10.11)	64.50 (±2.08)	58.00(±6.06)
OGS: T_1	32.60 (±4.67)	36.75 (±2.22)	36.50 (±5.69)
ΔOGS	27.20 (±11.95)	27.75 (±3.95)	21.50 (±3.42)
T_0: A OC# Near	2.40 (±1.95)	3.00 (±1.41)	5.25 (±0.96)
T_1: A OC# Near	3.60 (±1.14)	2.50 (±2.52)	2.75 (±0.96)
T_0: A OC# Definitive	0.80 (±1.79)	1.50 (±1.29)	3.50 (±1.00)
T_1: A OC# Definitive	1.80 (±0.84)	1.25 (±1.89)	1.25 (±1.50)
T_0: P OC# Near	8.40 (±3.36)	10.00 (±1.41)	11.00 (±1.41)
T_1: P OC# Near	7.80 (±4.03)	4.25 (±3.78)	4.75 (±2.63)
T_0: P OC# Definitive	5.00 (±4.36)	3.75 (±0.50)	6.50 (±4.44)
T_1: P OC# Definitive	2.80 (±1.92)	2.25 (±2.63)	3.25 (±1.50)

(Bonferroni post-hoc correction**, P< 0.05**)

Legend: T_0 = Pre-treatment, T_1 = Post-treatment, R(n) = right molar/canine classification , L(n) = Left molar/canine classification, 3 = canine, 6 = molar, U1-SN = upper incisor angulation, IMPA = lower incisor angulation, MPA = mandibular plane angle, ANB = A point to nasion to B point, OB = Overbite, Bolton = tooth size discrepancy, 3-3 = anterior, 6-6 = overall, OGS = Objective grading system, Δ = Change from T_0 to T_1, OB = Overbite, A = Anterior, P = Posterior, OC# = Occlusal Contact Number, Definitive = 0.0 - < 0.2 (mm), Near = 0.0 - < 0.4 (mm)

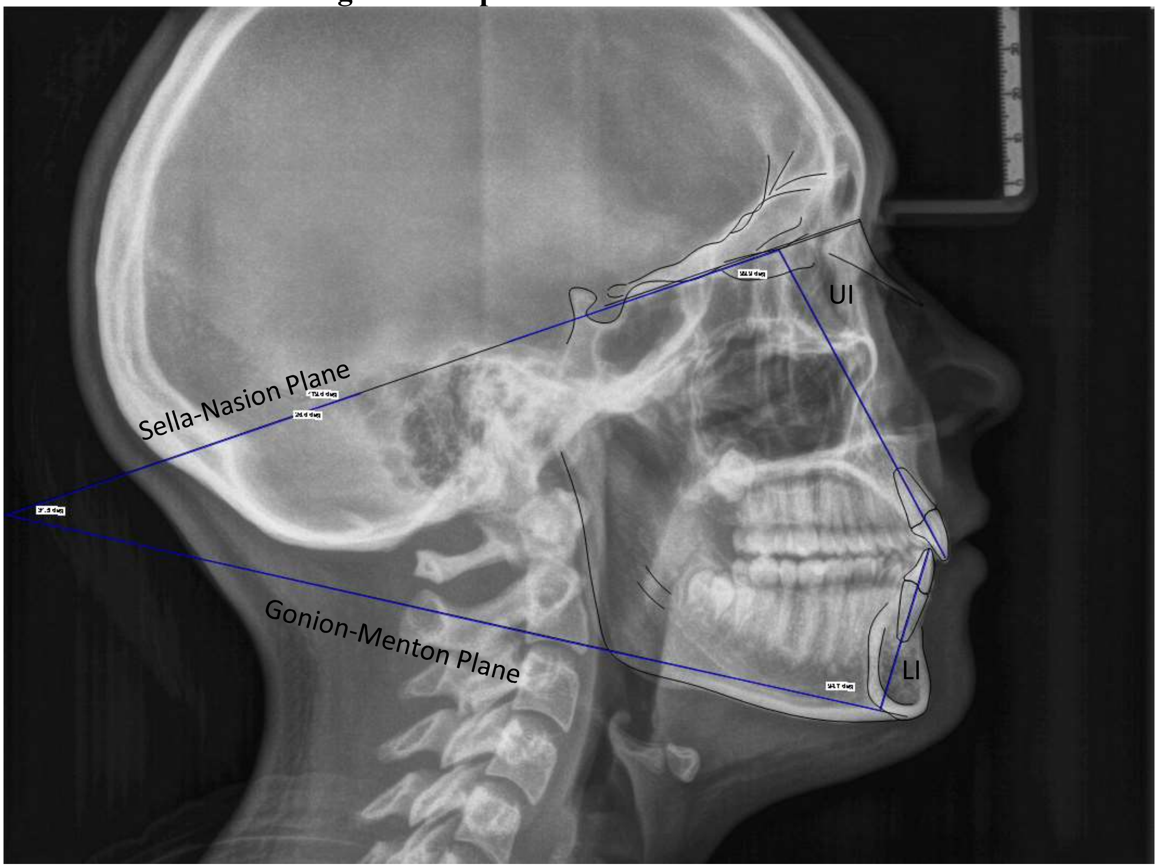
Table 10: Dental and cephalometric results (means ± SD) for fixed orthodontic appliances in hypodivergent, hypodivergent, and mesodivergent females.

Dependent Variable	Hypodivergent	Hyperdivergent	Mesodivergent
Treatment Time(months)	25.47 (±3.10)	22.57(±6.53)	23.00 (±6.47)
R6: T_0 (mm)	2.28 (±1.30)	0.95 (±1.90)	0.29 (±1.26)
L6: T_0 (mm)	1.18 (±0.84)	0.61 (±1.84)	0.51 (±1.67)
R6: T_1 (mm)	-0.16 (±0.80)	-0.01 (±0.67)	-0.56 (±0.61)
Δ R6 (mm)	2.44 (±1.27)	0.96 (±1.59)	0.85 (±1.06)
L6: T_1 (mm)	-0.02 (±1.18)	-0.46 (±1.04)	-0.46 (±0.61)
Δ L6 (mm)	1.20 (±1.52)	1.08 (±1.48)	0.98 (±1.38)
R3: T_0 (mm)	**4.32 (±1.87)^{A}**	2.23 (±1.91)	1.36 (±1.70)^{B}
L3: T_0 (mm)	3.66 (±0.46)	1.83 (±2.94)	2.53 (±1.58)
R3: T_1 (mm)	1.62 (±0.89)	1.81 (±0.83)	1.04 (±0.96)
ΔR3 (mm)	**2.70 (±1.79)^{A}**	0.41 (±1.51)^{B}	0.33 (±1.09)^{B}
L3: T_1 (mm)	1.82 (±1.07)	1.86 (±0.85)	1.75 (±0.95)
ΔL3 (mm)	1.84 (±1.00)	-0.04 (±2.49)	0.78 (±1.89)
U1-SN: T_0 (◦)	94.74 (±7.42)	100.01 (±8.42)	99.51 (±9.22)
U1-SN: T_1 (◦)	113.44 (±11.54)	104.40 (±5.77)	107.39 (±4.77)
ΔU1-SN (◦)	**18.7 (±9.45)^{A}**	4.39 (±9.14)^{B}	7.88 (±7.04)
IMPA: T_0 (◦)	92.04 (±13.74)	84.86 (±5.93)	88.70 (±4.84)
IMPA: T_1 (◦)	102.16 (±6.59)	93.84 (±6.60)	94.39 (±7.40)
ΔIMPA (◦)	10.12 (±7.54)	8.98 (±6.53)	5.69 (±5.47)
ANB: T_0 (◦)	2.60 (±2.88)	2.29 (±2.35)	3.05 (±2.09)
ANB: T_1 (◦)	1.68 (±2.52)	2.59 (±1.83)	2.58 (±1.69)
OB: T_0 (mm)	5.32 (±0.96)	3.50 (±1.47)	4.15 (±1.08)
Bolton 3-3: T_1 (mm)	0.82 (±1.79)	1.16 (±0.81)	-0.08 (±1.25)
Bolton 6-6: T_1 (mm)	1.18 (±1.63)	1.74 (±2.21)	1.01 (±1.36)
crowding: T_0 (mm)	-1.40 (±2.70)	-1.50 (±2.00)	-0.88 (±4.49)
OGS: T_0	64.20 (±11.21)	62.50 (±7.62)	61.00 (±8.11)
OGS: T_1	37.80 (±2.95)	38.38 (±5.01)	35.50 (±7.75)
ΔOGS	26.40 (±10.04)	24.13 (±6.94)	25.50 (±10.49)
T_0: A OC# Near	4.40 (±1.14)	3.13 (±1.89)	4.00 (±1.77)
T_1: A OC# Near	3.20 (±2.39)	2.25 (±1.28)	3.75 (±1.17)
T_0: A OC# Definitive	2.20 (±1.79)	1.00 (±1.07)	2.50 (±2.00)
T_1: A OC# Definitive	1.80 (±1.48)	1.50 (±1.20)	2.50 (±1.41)
T_0: P OC# Near	7.20 (±2.39)	7.75 (±2.87)	9.00 (±2.93)
T_1: P OC# Near	7.20 (±2.05)	7.63 (±2.77)	8.88 (±2.59)
T_0: P OC# Definitive	4.60 (±3.05)	4.75 (±2.12)	4.25 (±3.50)
T_1: P OC# Definitive	3.40 (±2.88)	3.75 (±3.66)	4.88 (±2.17)

(Bonferroni post-hoc correction, **$P < 0.05$**)

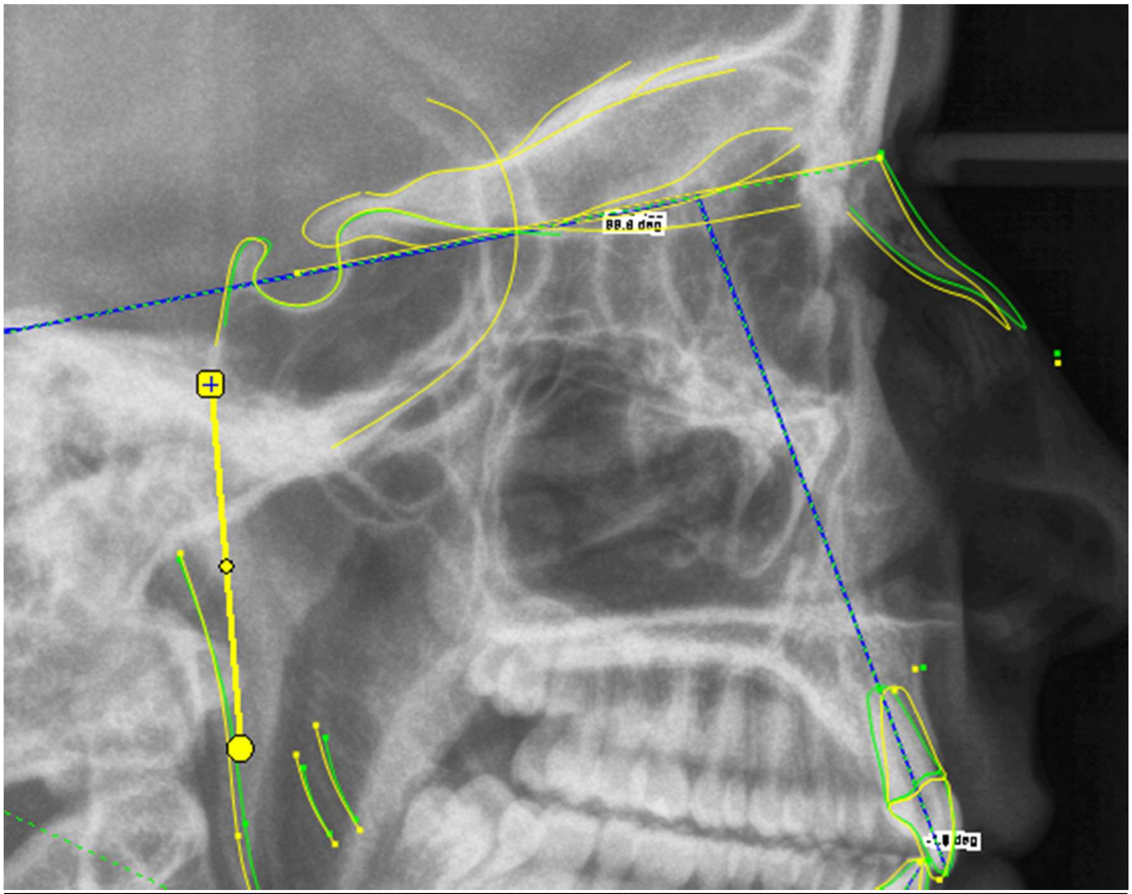
Legend: T_0 = Pre-treatment, T_1 = Post-treatment, R(n) = right molar/canine classification , L(n) = Left molar/canine classification, 3 = canine, 6 = molar, U1-SN = upper incisor angulation, IMPA = lower incisor angulation, MPA = mandibular plane angle, ANB = A point to nasion to B point, OB = Overbite, Bolton = tooth size discrepancy, 3-3 = anterior, 6-6 = overall, OGS = Objective grading system, Δ = Change from T_0 to T_1, OB = Overbite, A = Anterior, P = Posterior, OC# = Occlusal Contact Number, Definitive = 0.0 - < 0.2 (mm), Near = 0.0 - < 0.4 (mm)

Figure 1: Cephalometric measurements



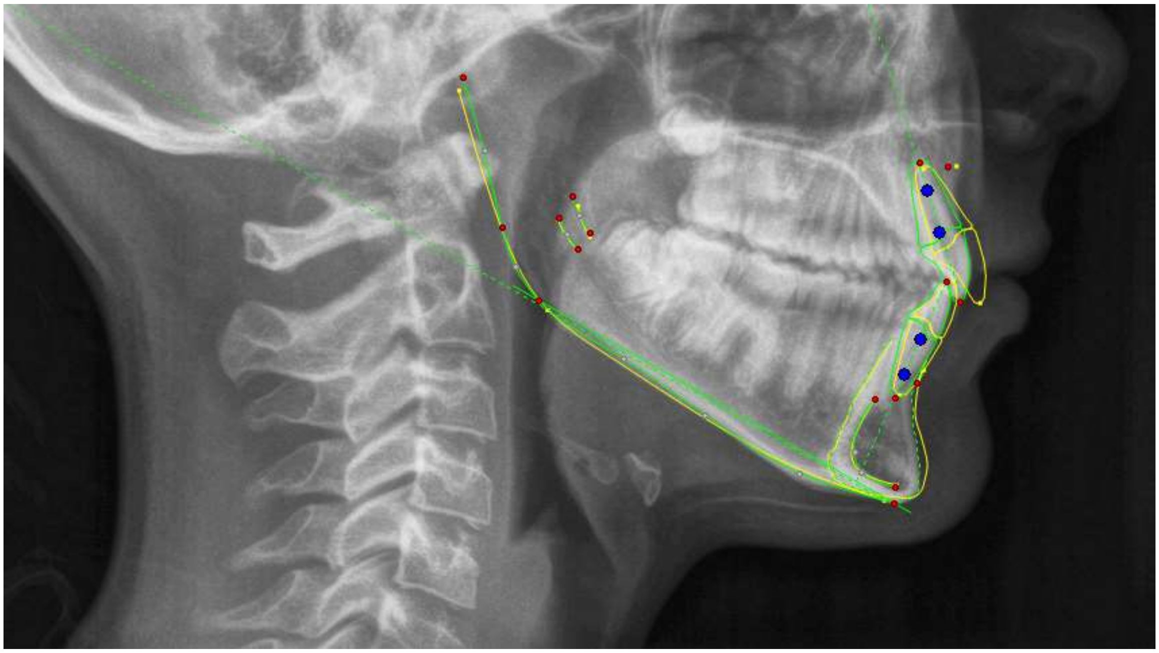
Legend: This figure shows an example of cephalometric tracing of Mandibular Plane Angle (The angle between Sella-Nasion plane and Gonion-Menton plane), U1-SN (Upper incisor long axis to sella-nasion plane), and IMPA (Lower incisor to Mandibular Plane Angle)

Figure 2: Superimposition of T_0 cranial base on T_1 cephalogram



Legend: This figure shows an example of cephalometric superimposition in which structures on the traced on the T_0 (initial time-point) cephalogram, shown in yellow, were superimposed over the cranial base structures of the T_1 (final time-point) cephalogram, shown in green, using the American Board of Orthodontics recommended anatomical landmarks for superimposition[24]

Figure 3: Superimposition of T_0 mandibular tracing on T_1 cephalogram



Legend: This figure shows an example of cephalometric superimposition in which structures on the traced on the T_0 (initial time-point) cephalogram, shown in yellow, were superimposed over the mandibular structures of the T_1 (final time-point) cephalogram, shown in green, using the American Board of Orthodontics recommended anatomical landmarks for superimposition[24]

Figure 4A-C Buccal view canine relationships showing A. Class I, B. Class II, C. Class III on digital dental models

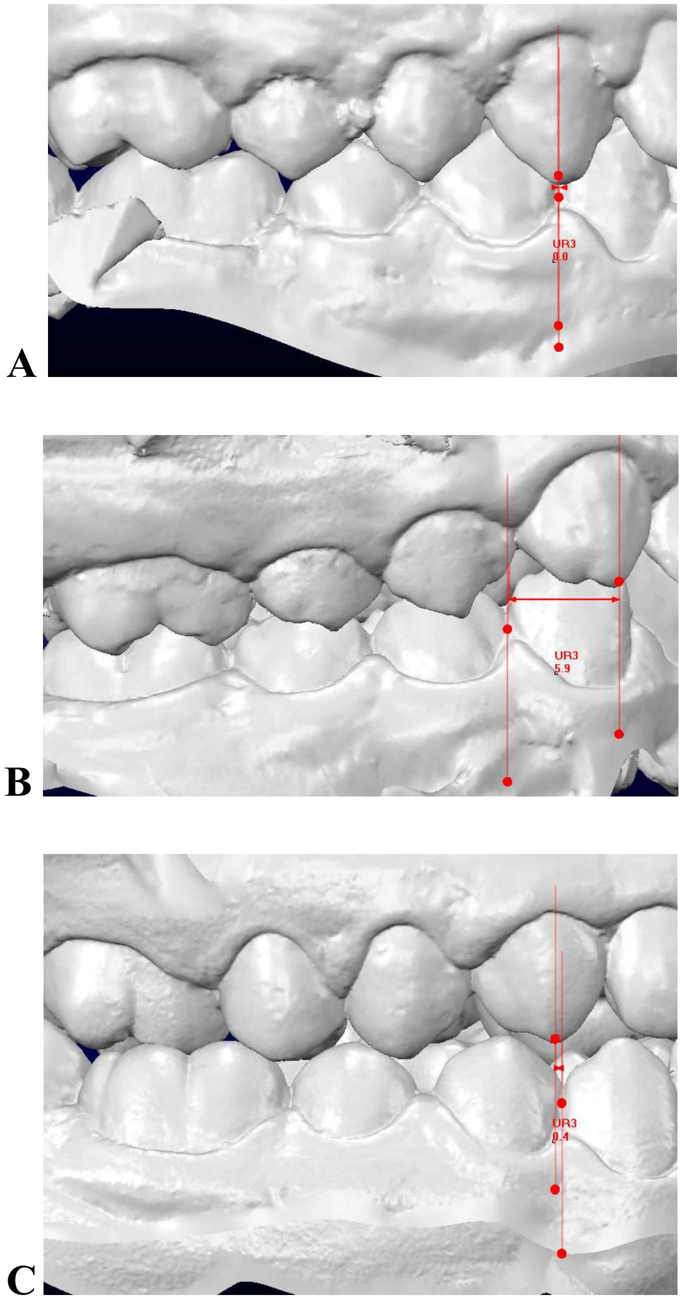
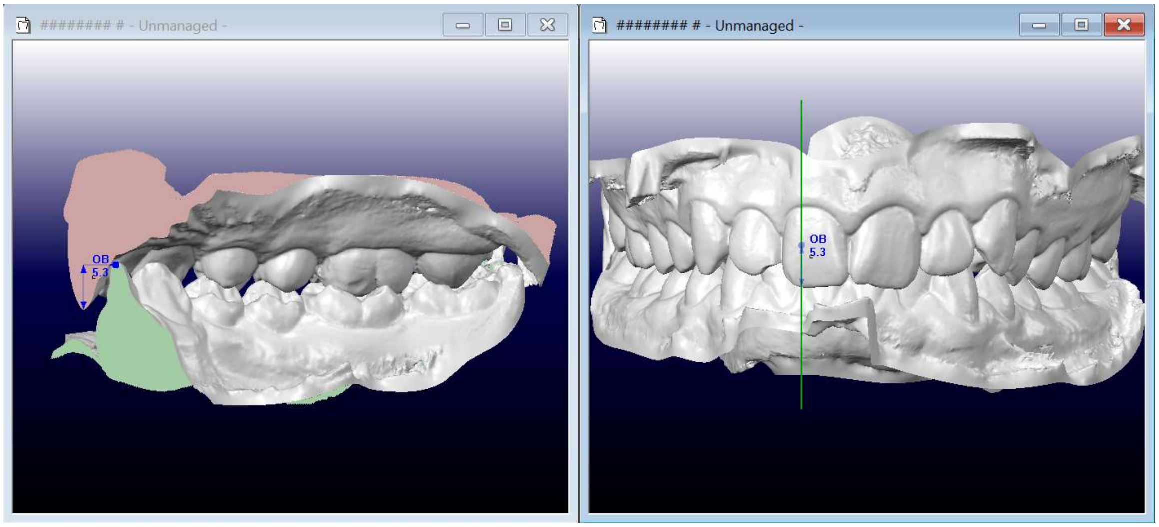
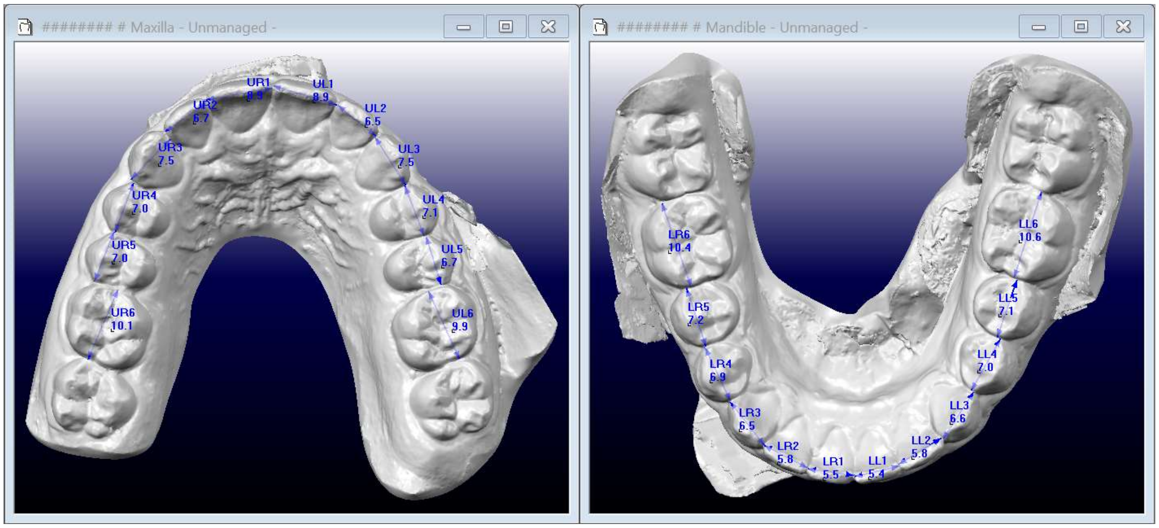


Figure 5: Overbite measurement



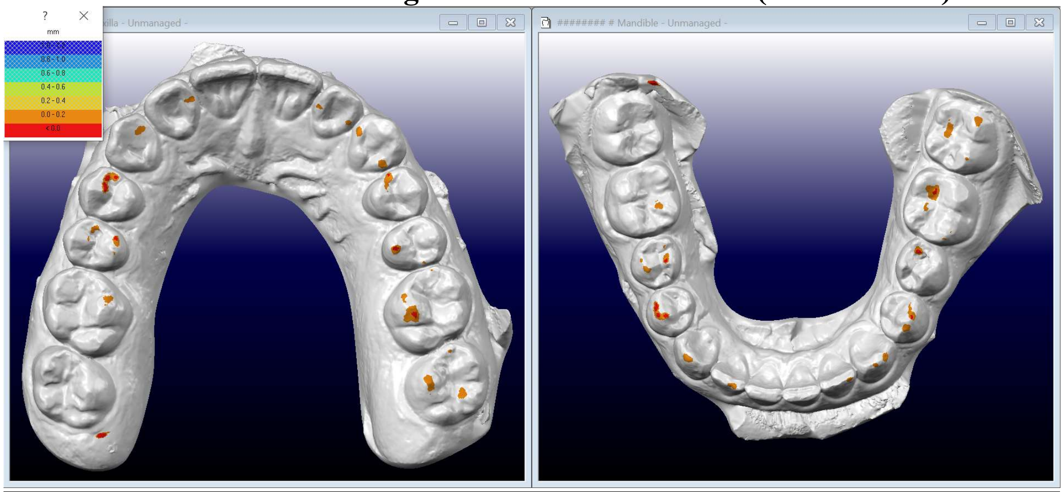
Legend: This figure shows the measurement of maximum overbite, or vertical overlap of the incisor teeth by scrolling through sagittal (left) and facial (right) views of the digital dental models and marking the incisal edges of upper and lower incisors (left) where the overbite is largest

Figure 6: Bolton tooth size discrepancy measurements



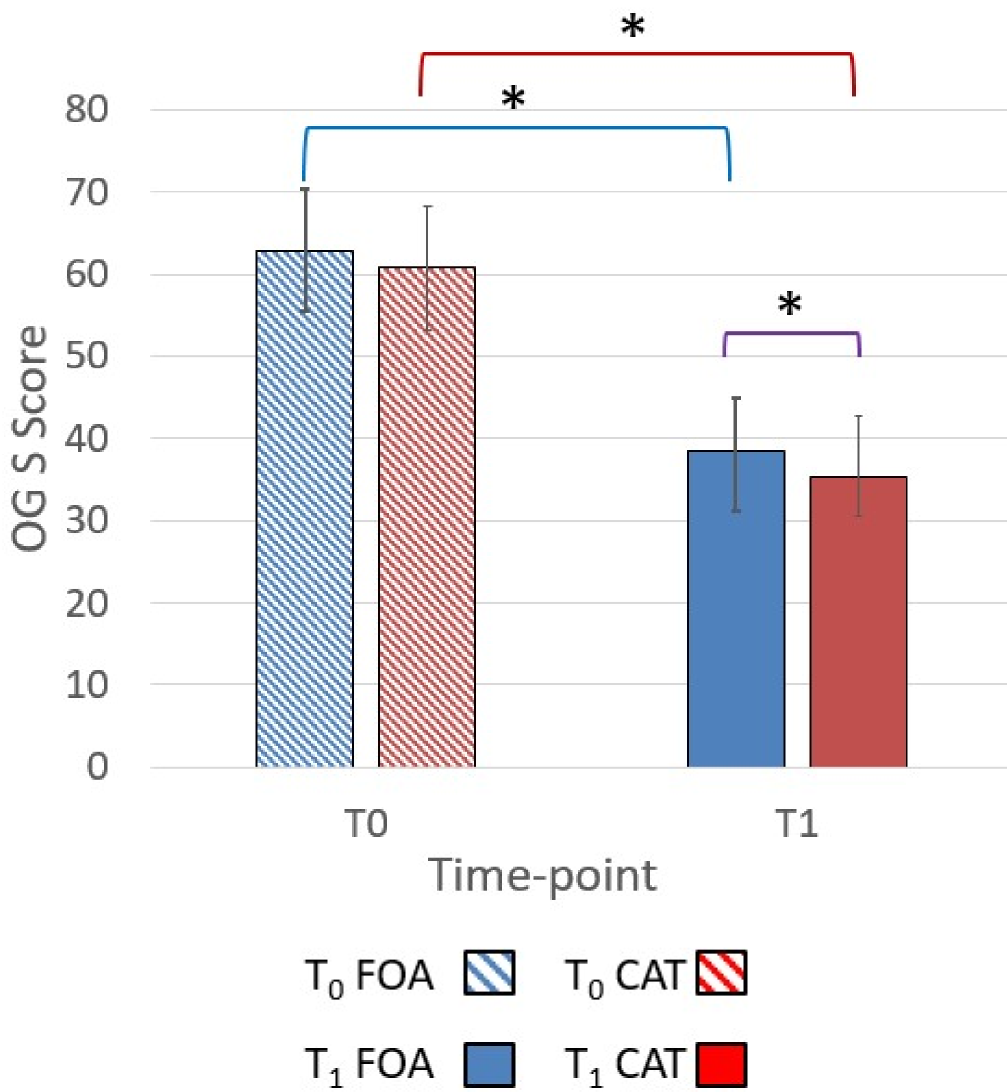
Legend: This figure shows the measurement of mesial-distal widths of upper and lower teeth from first molar on the right side through first molar on the left side, used for calculation of Bolton tooth size discrepancy (both anterior from canine through canine and overall from first molar through first molar in both arches)

Figure 7: Occlusogram views of maxillary (left) and mandibular (right) digital dental models showing Near Occlusal Contacts (0.0 < 0.4 mm)



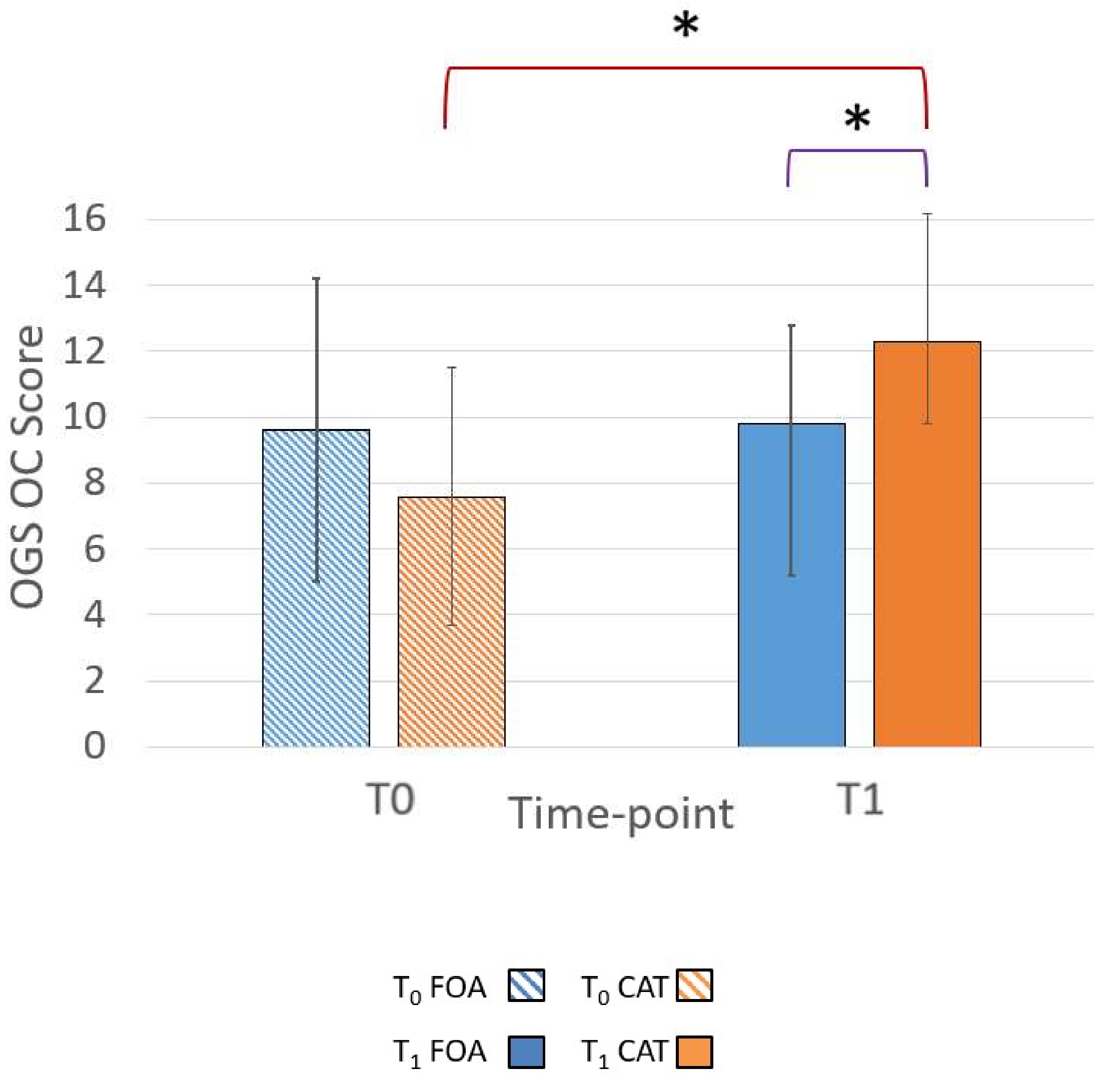
Legend: Anterior Near occlusal contact numbers are calculated by adding total number of incisal edge contact areas, including close (orange) and definitive (red) occlusogram markings on canines or incisors in one arch. Posterior near occlusal contact numbers are calculated by adding total number of cusp contact areas, including close (orange) and definitive (red) occlusogram markings on first molars and premolars

Figure 8 Mean OGS scores versus time-points for two treatment groups



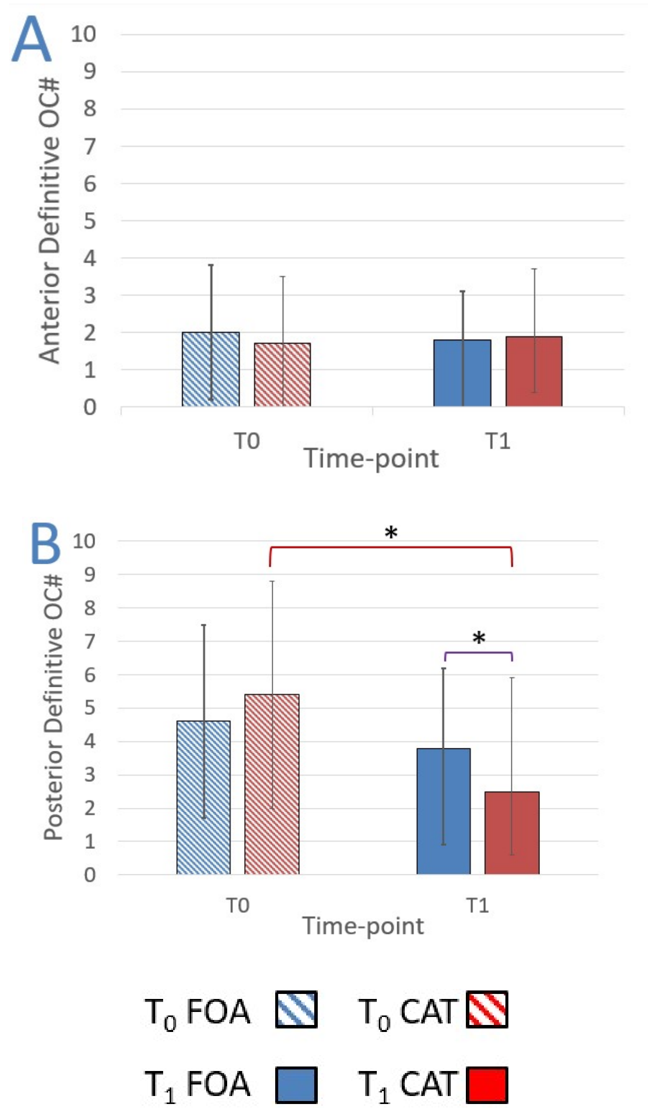
Legend: T_0 = initial, T_1 = final, OGS = Objective Grading System, FOA = fixed orthodontic appliance, CAT = clear aligner therapy, † Vertical bars indicate standard deviations about means and * indicate significant differences

Figure 9 Mean Objective Grading System (OGS) Occlusal Contact (OC) score versus time-point for two treatment groups



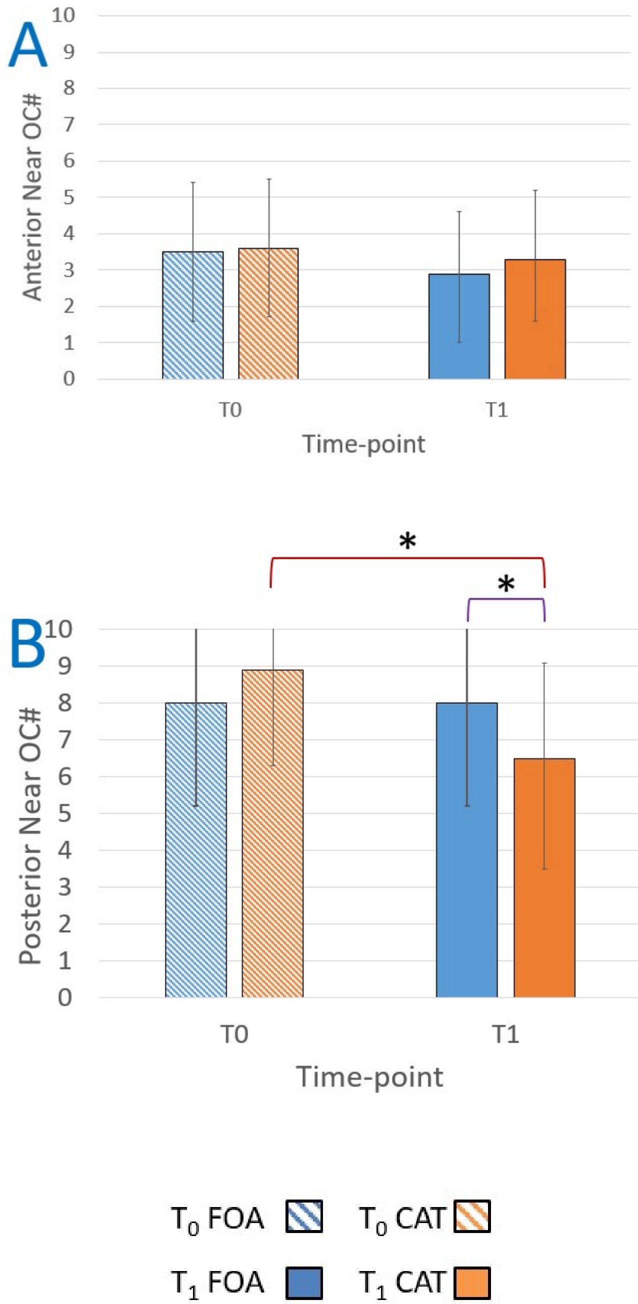
Legend: T_0 = initial, T_1 = final, FOA = fixed orthodontic appliance, CAT = clear aligner therapy, † Vertical bars indicate standard deviations about means and * indicate significant differences

Figure 10 Mean Definitive Occlusal Contact Number (OC#) A. Anterior and B. Posterior versus time-points for two treatment groups.



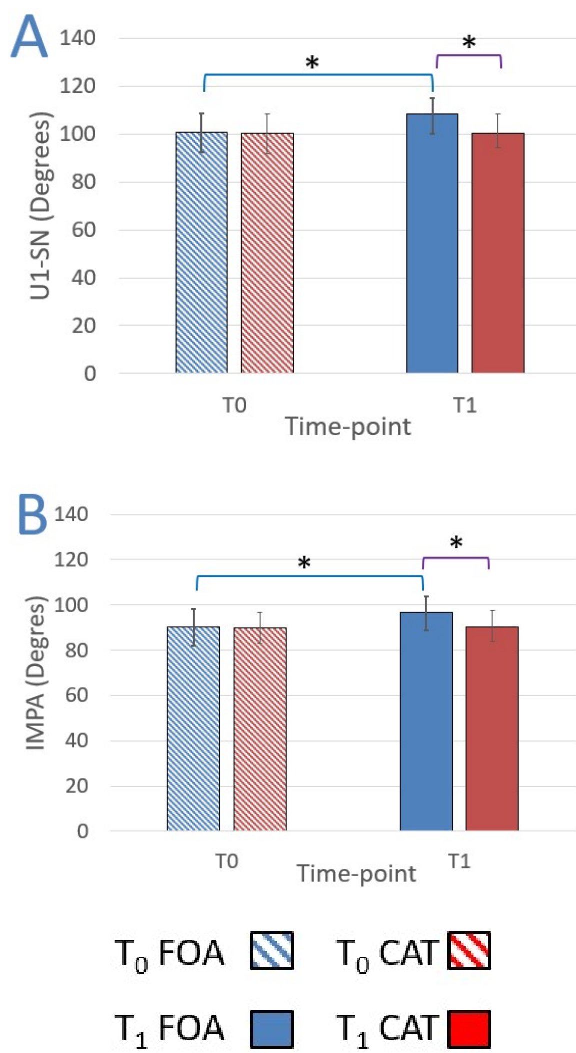
Legend: T_0 = initial, T_1 = final, FOA = fixed orthodontic appliance, CAT = clear aligner therapy, definitive = (0.0-0.2mm), † Vertical bars indicate standard deviations about means and * indicate significant differences

Figure 11 Mean Near Occlusal Contact Number (OC#) A. Anterior and B. Posterior versus time-points for two treatment groups.



Legend: T_0 = initial, T_1 = final, FOA = fixed orthodontic appliance, CAT = clear aligner therapy, near = (0.0-0.4mm), † Vertical bars indicate standard deviations about means and * indicate significant differences

Figure 12 Mean incisor angulations A. U1-SN and B. IMPA versus time-points for two treatment groups.†



Legend: T_0 = initial, T_1 = final, U1-SN = upper incisor angulation, IMPA = lower incisor angulation, OGS = objective grading system, FOA = fixed orthodontic appliance, CAT = clear aligner therapy, † Vertical bars indicate standard deviations about means and * indicate significant differences

Literature Review

Clear Aligner History and Limitations

Align Technology (Santa Clara, Calif.) introduced a new product in 1999 to the orthodontic market, which was a series of clear custom trays known as "aligners" with the product name "Invisalign" [1]. This product was marketed as an esthetic alternative to conventional fixed orthodontic appliances (FOA) [1]. Specifically, this appliance is composed of a series of thin semi-elastic polyurethane (plastic) clear aligners [5]. The orthodontist dictates treatment by specifying individual tooth movements through a computer-aided modeling technique [1,35]. Next, three-dimensional (3D) models of each sequence of tooth movements are printed, and the aligners are digitally fabricated to custom fit over the vestibular (cheek, lip side), lingual (tongue side), and occlusal (biting) surfaces of the dentition [35]. The aligners are worn for a recommended twenty two hours per day and sequentially changed every one to two weeks [5,35]. Incremental tooth movements, generally between .25mm and .30mm, are made with each aligner by pushing the teeth into alignment as programed by the clinician [5]. Over the past two decades, improvements have been applied to such clear aligner therapy (CAT) and its popularity continues to increase [1] (Align Technology 2017*). When given the choice, some patients prefer clear aligners due to the esthetic appearance of the translucent materials, relative to conventional orthodontic appliances [5,6]. As with any tool or appliance, the benefits to its use also come with limitations. Navigating these limitations provides important information to clinicians, particularly when deciding which treatment options are most favorable for the individual case being treated. One issue with CAT reported among practitioners is that patients sometimes end up with lack of posterior occlusal contacts (areas in which opposing teeth touch each other when biting down), known as a posterior open bite [4,5,36]. However, few studies have compared occlusal contacts in subjects with CAT compared to FOA therapy.

Occlusal Contacts in Clear Aligner Therapy v Fixed Orthodontic Appliances

Li, Wang, and Zhang (2015) conducted a multicenter Randomized Control Trial (RCT) comparing treatment outcomes in adult subjects with four premolar extractions treated either with CAT or FOA. The participants were randomized to a treatment group, in total 72 subjects received CAT and 72 subjects received FOA therapy [16]. While there were no control groups, the initial and final occlusal results in each group were assessed objectively using indices of the American Board of Orthodontics (ABO). The subjects were matched using the ABO Discrepancy Index (DI) scores, which evaluate diagnostic models and radiographs to score malocclusions by severity, with higher scores indicating more case complexity and expected difficulty treating. The DI scores were 18.67 for the CAT cases and 19.85 in FOA therapy cases and were not statistically significantly different from each other. The pre- and end of treatment diagnostic models and panoramic radiographs were scored via ABO Objective Grading System (OGS) criteria, which evaluates 8 occlusal features, and scores them with higher scores indicating greater deviation from ideal occlusion. Pre- and end of treatment differences in OGS scores were compared, where negative scores (-) indicated improvement. Differences in total OGS scores were -30.48 for CAT cases and -38.57 for FOA therapy cases and not significantly different ($p=0.25$). However, differences in occlusal contact scores at the end of treatment compared to pretreatment were -1.88 for CAT cases and -3.90 for FOA therapy cases and statistically significantly different ($p = 0.000$). That is, FOA therapy cases had significant improvement in scores for occlusal contacts. The authors attributed this to difficulty in completing extrusive tooth movements (moving teeth in an eruptive or upward fashion away from the gingiva) with CAT, and to the thickness of the aligners inhibiting occlusal "settling" (vertical eruption of teeth until they are in contact with opposing teeth). Interestingly, these CAT cases took 31.5 months to complete treatment on average, whereas FOA therapy cases required 22 months of treatment on average. However, it was reported that the 4 providers in this study had no prior experience with CAT, whereas they had "decades" of experience with conventional fixed appliances. In addition, only adult subjects were recruited, so these data cannot necessarily be applied to a teenage, growing population. Also, the authors did not report on compliance in the CAT group, which could affect the outcomes (if subjects did not wear aligners as prescribed). While there was no significant difference between the initial DI scores, this does not necessarily indicate the difficulty of treatment, (i.e. some cases could score higher in certain categories such as skeletal discrepancies, which could lead to similar overall scores but create more challenges in treatment to ideal).

Borda (2017) conducted a retrospective analysis on CAT (mean age 13.67 ± 1.41) and FOA therapy (mean age 12.97 ±1.34) in teenaged subjects (under age 18 years) treated by an orthodontist experienced with both modalities. Each group had 26 cases, with comparable initial DI scores (CAT: 11.85 ± 5.33, FOA therapy: 11.58 ± 4.74). Final models and panoramic radiographs were scored using ABO OGS, and the mean occlusal contacts score was 7.65 ± 5.28 for CAT cases and 6.27 ± 3.84 for FOA cases. While more points were scored on average for occlusal contact deviation from ideal in CAT cases, the difference was not statistically significant. It can also be noted that there were high standard deviations, particularly in the CAT cases. A larger sample size could have helped elucidate a relationship between treatment modality and occlusal contacts.

Djeu et al. (2005) conducted a retrospective analysis of CAT and FOA treatment in adult subjects over 18 (Average age in CAT group: 33.6 ± 11.8, in FOA group: 23.7 ± 11.0) [15]. Each group had 48 cases with comparable initial DI scores (CAT: 18.67 ± 8.42, FOA: 19.85 ±10.87). Final models and panoramic radiographs were scored using ABO OGS, and the mean points scored for occlusal contacts were 10.46 ± 7.06 for CAT cases and 5.65 ± 4.66 for FOA cases. This was a statistically significant difference (p=0.0004) indicating that CAT cases had more deviations from ideal occlusal contacts. However, the 48 CAT cases were the first subjects this orthodontist treated. Another limitation is that the study sample included adults only, and most orthodontic treatment involves treatment of teenaged individuals. As biological responses to orthodontic treatment can be different in a growing compared to a mature adult populations, these data cannot be generalized to a teenaged population.

Kuncio et al. (2007) studied adult CAT and FOA subjects (11 subjects in each group; mean age 33.97 ± 8.98 CAT group, 26.79 ± 12.12) immediately after appliance removal (T1) and at 3 years posttreatment (T2) [17]. OGS scores were compared. Higher occlusal contact scores were seen in FOA subjects (9.72 ± 5.02 compared to 8.27 ± 4.24 in CAT group), but there was no statistically significant difference. The OGS occlusal contact scores decreased over time after treatment (meaning more occlusal contacts were generated over time posttreatment), and a larger decrease was seen in FOA subjects (1.91 ± 3.36) compared to CAT subjects (0.36 ± 4.63), though this was also not statistically significant. Interestingly, the final occlusal contact scores were 7.9 ± 5.11 and 7.82 ± 3.57

for CAT and FOA groups respectively. The scores between the groups became closer over time, indicating that regardless of finish and type of appliance, settling occurred and increased the number of occlusal contacts as time after active orthodontic treatment went on.

Kassas et al. (2013) evaluated 425 adult CAT cases (mean age 35.2 ± 13.2) treated by one orthodontist in Buffalo, New York to further examine clinical effectiveness of CAT. The cases included were considered mild to moderate severity of malocclusion, deemed by an initial DI score of 10-20. The pre-treatment and post-treatment records were scored using the OGS and the scores were compared. It was found that while the overall OGS scores significantly improved after treatment (-9.16, $p < .001$), the occlusal contact scores increased from 5.48 ± 3.79 to 6.71 ± 3.67 (+1.23). While this was not a statistically significant difference ($p = 0.125$), it agrees with the previous literature in a trend of decreasing number of occlusal contacts after orthodontic treatment.

To date, no study has evaluated the occlusal contacts in teenagers before and after treatment with CAT compared to FOA therapy by an orthodontist with experience in both modalities.

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Appendix

I. IRB Approval Letter (pp.69-70)

OREGON HEALTH & SCIENCE UNIVERSITY OHSU

IRB MEMO

Research Integrity Office
3181 SW Sam Jackson Park Road - L106RI
Portland, OR 97239-3098
(503)494-7887 irb@ohsu.edu

APPROVAL OF SUBMISSION

January 17, 2019

Dear Investigator:

On January 17, 2019, the IRB reviewed the following submission:

IRB ID:	STUDY00019430
Type of Review:	Initial Study
Title of Study:	A retrospective comparison of dental occlusal contacts before and after treatment in teenage orthodontic patients treated with fixed appliances versus clear aligners
Principal Investigator:	Laura Iwasaki
Funding:	None
IND, IDE, or HDE:	None
Documents Reviewed:	• Protocol • PPQ • HIPAA Waiver

The IRB granted final approval on 1/17/2019. The study is approved until 1/16/2020.

Review Category: Expedited Category # 5

Copies of all approved documents are available in the study's **Final** Documents (far right column under the documents tab) list in the eIRB. Any additional documents that require an IRB signature (e.g. IIAs and IAAs) will be posted when signed. If this applies to your study, you will receive a notification when these additional signed documents are available.

Ongoing IRB submission requirements:

- Six to ten weeks before the expiration date, you are to submit a continuing review to request continuing approval.
- Any changes to the project must be submitted for IRB approval prior to implementation.
- Reportable New Information must be submitted per OHSU policy.
- You must submit a continuing review to close the study when your research is completed.

Guidelines for Study Conduct

In conducting this study, you are required to follow the guidelines in the document entitled, "Roles and Responsibilities in the Conduct of Research and Administration of Sponsored Projects," as well as all other applicable OHSU IRB Policies and Procedures.

Requirements under HIPAA

If your study involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the HIPAA and Research website and the Information Privacy and Security website for more information.

IRB Compliance

The OHSU IRB (FWA00000161; IRB00000471) complies with 45 CFR Part 46, 21 CFR Parts 50 and 56, and other federal and Oregon laws and regulations, as applicable, as well as ICH-GCP codes 3.1-3.4, which outline Responsibilities, Composition, Functions, and Operations, Procedures, and Records of the IRB.

Sincerely,

The OHSU IRB Office