

**A Retrospective Comparison of Mandibular Incisor Inclination Changes Produced by  
Class II Elastics in Adolescent Orthodontic Patients Treated with Clear Aligners versus  
Fixed Appliances**

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**ABSTRACT**

**Objective:** to compare mandibular incisor inclination change and treatment duration in adolescents using Class II elastics and clear aligners (CAT) or fixed appliances (FAT).

**Materials and Methods:** Records of patients previously treated by one orthodontist were collected. Eligibility criteria were adolescents with cervical vertebral maturation stage  $\geq 4$ , Little's Irregularity Index  $< 4$ , use of CAT or FAT and bilateral Class II elastics, and  $\geq 1$  mm decrease in molar Class II relationship. Irregularity Index and molar relationship were measured via digital model software. Pre- and post-treatment lateral cephalograms were used to trace and measure mandibular central incisor long axis-to-mandibular plane angle (IMPA,  $^{\circ}$ ). Data were analyzed using t-tests where  $P < .05$  defined significance.

**Results:** Thirty-two CAT and 34 FAT cases fit criteria and had similar baseline characteristics: mean ages  $15.1 \pm 1.6$  and  $15.1 \pm 1.6$  years, respectively; Irregularity Index  $2.0 \pm 1.3$  and  $1.9 \pm 1.3$  mm, respectively; pre-treatment Class II molar relationships  $2.6 \pm 1.0$  and  $2.7 \pm 1.0$  mm, respectively; mean pre-treatment IMPA  $97.0 \pm 6.1$  and  $94.4 \pm 7.1^{\circ}$ , respectively. CAT uprighted mandibular incisors by  $-0.1 \pm 5.1$ , whereas FAT proclined mandibular incisors by  $5.3 \pm 5.7^{\circ}$  and these IMPA changes were significantly different ( $P = .00$ ). Treatment duration was significantly shorter for CAT at  $20.4 \pm 6.9$  months compared to FAT at  $24.3 \pm 5.7$  months ( $P = .02$ ).

**Conclusions:** FAT showed significantly greater mandibular incisor proclination and treatment duration than CAT in Class II malocclusion adolescent cases with mild crowding treated using Class II elastics.

## **A. Introduction:**

Class II malocclusion is a common chief complaint of orthodontic patients, affecting nearly 15% of 12- to 15-year-olds in the United States.<sup>1</sup> Dentally, a Class II malocclusion is defined by the mesiobuccal cusp tip of the upper first molar lying anterior to the buccal groove of the mandibular first molar (Fig 1). One of the most widely used treatment protocols for correction of Class II malocclusion is Class II intermaxillary elastics (Fig 2).<sup>2</sup> Some authors have reported side effects of Class II elastics, such as extrusion of maxillary incisors and mandibular molars, and proclination of mandibular incisors.<sup>3</sup> These dental effects occur due to the forces of the stretched elastic pulling maxillary anterior teeth towards the mandibular molars posteriorly and inferiorly, and mandibular molars towards the maxillary anterior teeth anteriorly and superiorly. As the mandibular molars move anteriorly, lower incisors procline due to lack of resisting forces. Although each intermaxillary elastic is meant to apply force vectors mainly in anteroposterior directions, vertical force vector components are present due to the vertical distance between maxillary and mandibular teeth, especially during jaw opening. The result is extrusion of maxillary incisors and mandibular molars as they are pulled towards each other. It is important for a clinician to prepare for these side effects in order to achieve predictably the best possible facial esthetics, functional efficiency, health of teeth and surrounding tissues, and long-term stability.<sup>4</sup>

The degree of proclination of mandibular incisors is a factor that affects periodontal health (such as gingival recession), stability of the treatment result, anterior tooth guidance, and facial esthetics.<sup>4,5</sup> It has been reported that more prominently positioned teeth in an arch have less keratinized gingiva than adjacent lingually positioned teeth.<sup>6</sup> Less keratinized gingiva is more susceptible to recession upon labial proclination of the tooth, especially in the lower incisor

area, and particularly if it is less than 0.5 mm in thickness or less than 2 mm in height. Animal studies have shown that moving mandibular incisors anteriorly can resorb vestibular alveolar bone and produce bone dehiscences.<sup>7</sup> Excessive proclination of the mandibular incisors can also be linked to unstable orthodontic results. Pushing teeth past their anterior limit impinges on the normal muscular balance and risks relapse as the lingually directed forces of the lower lip try to achieve equilibrium with the new position of the mandibular incisors.<sup>4,8</sup> Furthermore, keeping mandibular incisors upright over basal bone allows maxillary incisors to be moved distally and superiorly. These incisor movements allow counterclockwise rotation of the occlusal plane and mandible, decreasing facial convexity and improving jaw relationships in patients with Class II malocclusions.<sup>4</sup> As a suggested guideline for ideal lower face-to-tooth relationships, the ratio between prominence of the mandibular incisal edge and the anteroposterior width of the bony chin relative to a line between Nasion (N) and Supramentale (B) points should be 1:1 (Fig 3).<sup>9,10</sup> Facial esthetics (in the measures of perceived attractiveness and desire for surgery) is also significantly influenced by lower lip prominence.<sup>10</sup> Upper and lower lips are supported by the labial surface of maxillary incisors, which are directly related to the position of the mandibular incisors.<sup>4</sup> Therefore, proclination of mandibular incisors not only influences lip protrusion, but also contact of maxillary and mandibular anterior teeth during protrusive and excursive movements of the mandible to avoid occlusal interferences.<sup>5</sup>

Mandibular incisor proclination can be measured by relating the long axis of the incisor (Li) to the Occlusal Plane (OP), A Point-Pogonion Line (APg), Nasion-B Point Line (NB), Frankfort Horizontal (FH), and Mandibular Plane (MP) (Fig 4). Each of these paints a picture of how the tooth position relates to different components of facial harmony. However, occlusal plane and mandibular plane can rotate clockwise with use of Class II elastics, affecting Li-OP

and Li-APg measurements. Furthermore, forward pull of the mandible with class II elastics often causes patients to develop a habit of posturing their jaw forward. B Point measurement on a lateral cephalogram made with a patient in this postured position would be unreliable and obscure the true contribution of lower incisor proclination to changes in Li-NB. While mandibular incisor proclination can be assessed by evaluating its relationship to FH (FMIA) and mandibular plane (IMPA), the points necessary to calculate FMIA, (i.e. Porion and Orbitale) are more difficult to identify consistently and reliably on a lateral cephalogram than those necessary to calculate IMPA (i.e. Gonion and Menton). IMPA is a good guide to use in positioning mandibular incisor teeth in their underlying basal bone.<sup>4</sup> Bone remodeling at Gonion and Menton during facial growth can alter the shape of the inferior border of the mandible. This may cause changes in the steepness of the mandibular plane, in turn influencing the value of IMPA even though mandibular incisor angulation may have remained unchanged. However, these changes would be minimal in patients who are past their peak growth spurt. Therefore, our study was limited to such patients in Cervical Vertebral Maturation Stage (CVMS) 4 or 5.<sup>11</sup>

IMPA and FMIA, together with Frankfort-Mandibular Plane Angle (FMA), make up the diagnostic facial triangle (Fig 5).<sup>8</sup> In patients with FMA of  $22^{\circ}$  to  $26^{\circ}$ , the standard for IMPA is  $90^{\circ}$  ( $SD \pm 5^{\circ}$ ), indicating upright mandibular incisor position.<sup>8</sup> In patients with steeper FMA, incisors should be made more upright to prevent excessive lip protrusion and have the best facial balance.<sup>4</sup> A numerical value to define incisor proclination as “excessive” is not agreed upon in the orthodontic community. More important factors to consider are initial thickness of bone and attached gingiva supporting mandibular incisors and the amount of change in mandibular incisor proclination achieved during orthodontic treatment. Patients with thinner alveolar housing are more likely to develop gingival recession during active treatment, and the amount is further



associated with the vestibulolingual thickness of the alveolar process.<sup>7</sup> In cases with a minimal vestibulolingual thickness of keratinized tissue initially, even a small amount of labial movement of the incisors is likely to decrease the thickness of this tissue.<sup>6</sup> Greater than 10° changes in incisor proclination has been shown to cause significantly more gingival recession than changes of less than 2°, especially if the alveolar housing is thin.<sup>7</sup> Nevertheless, individual variation exists; some patients have shown no increase in clinical crown height despite 17° of change in proclination.<sup>7</sup> Based on this, some may argue that proclination of 10° is not considered “excessive”. However, if the center of rotation is at the apex of the root, 10° of proclination represents 4 mm anterior movement of the incisal edge.<sup>7</sup>

Proclination of mandibular incisors is often the solution chosen by orthodontists to treat mild to moderate mandibular crowding. Subjective assessment of dental crowding and Class II correction is only moderately consistent between individuals.<sup>12</sup> Alternatively, Little’s Irregularity Index (IR) provides a simple and reliable way to quantify mandibular incisor crowding directly from the mandibular cast.<sup>12</sup> It is calculated by measuring the linear displacement (in millimeters) of the anatomic interproximal contact points on each mandibular incisor (Fig 6).<sup>12</sup> These five measurements are summed to represent the magnitude of anterior irregularity. An IR score of <4 mm represents mild crowding, while  $\geq 4$  mm to <7 mm represents moderate crowding.<sup>12</sup>

While the literature does not provide good evidence to dictate specifics surrounding the effective use of Class II elastics (i.e. force and hours of use needed), it is generally accepted that they can be successful in correcting end-to-end or “half-cusp” Class II malocclusions.<sup>3</sup> Based on empirical clinical evidence, a half-cusp Class II molar relationship relates to ~3 mm discrepancy with the mesiobuccal cusp of the maxillary first molar mesial to the buccal groove of the

mandibular first molar. Similarly, a full-cusp Class II molar relationship relates to ~6 mm of such a discrepancy.

Clear aligner therapy (CAT) offers esthetic benefits of being less noticeable than metal, clear, or tooth-colored brackets and wires used in fixed appliance therapy (FAT).<sup>13</sup> FAT (“braces”) utilizes wires to change the position of the teeth, specifically, rectangular wires to control the vestibulolingual angulation of the teeth. CAT utilizes plastic trays that cover the teeth and use squeezing pressures to change the positions of the teeth. Since most movements achieved by CAT are through crown tipping, CAT was expected to procline mandibular incisors more than FAT in similarly crowded cases.<sup>14</sup> However, in 2016, Hennessy et al. found no statistically or clinically significant differences in mandibular incisor proclination with CAT or FAT in mildly crowded cases.<sup>14</sup> This can be explained by evaluating the position at which the force is applied in each appliance. Fixed appliances can place a force coronal and labial to the center of resistance of an incisor tooth, resulting in tipping and proclination. While forces applied by clear aligners are less well-studied, some claim that clear aligners place a force along the complete length of the crown, creating forces closer to the center of resistance of the tooth and minimizing the amount of proclination that occurs.<sup>14</sup> Another explanation is that clear aligners can be engineered to move individual teeth, minimizing incisor proclination. Because Hennessy et al. did not employ elastics in their study, it is still unknown whether the increased tendency for mandibular incisor proclination resulting from use of Class II elastics would overpower the factors minimizing incisor proclination in CAT.

No known study has evaluated the change in mandibular incisor inclination and treatment time duration resulting from Class II elastics with FAT compared to CAT. Hence, this retrospective pilot study addressed the null hypothesis that Class II orthodontic treatment using

Class II elastics in adolescents was no different between FAT and CAT in terms of change in lower incisor inclination and treatment duration.

## **B. Materials and Methods:**

### **i. Sample material**

A retrospective sample of adolescent cases that were consecutively treated by an orthodontist (JSG) with certification by the American Board of Orthodontists (ABO) and over ten years of experience treating patients with fixed appliances and clear aligners in a private practice in Portland, Oregon, was employed for this pilot project. Cases were treated with either a fixed system with labial 0.022- x 0.028-inch orthodontic brackets (Damon, Ormco, Orange, Calif) and engagement of sequential archwires or a commercially available CAT system (Invisalign, Align Technology, San Jose, Calif). Written consent was obtained from all individuals to allow use of their records for this study. Approval of the study protocol was obtained on May 14<sup>th</sup>, 2019 (IRB # STUDY00019944) from the Institutional Review Board of the Oregon Health & Science University, Portland, Oregon (Appendix I).

Digital patient records from the previous seven years were reviewed at the private orthodontic office. All cases had similar digital pre- and post-treatment records available: lateral cephalogram, panoramic radiograph, and intraoral scans of maxillary and mandibular arches with an occlusal registration record. The type of treatment appliance (FAT vs. CAT) to be used was determined by each patient without preference from the orthodontist. Regardless of the treatment appliance chosen, in cases with pre-treatment Class II relationships greater than end-to-end on at least one side, a fixed Class II-correction appliance (Carriere® Motion 3D™ appliance, Henry Schein Orthodontics, Carlsbad, Calif) was used first in conjunction with a mandibular clear

thermoplastic retainer or aligner. In these cases, the clinical protocol for Class II elastics involved full time wear until super Class I molar relationship was achieved, then switching to night time wear to stabilize until the next set of aligners were delivered or full fixed appliances were bonded. Furthermore, Bolton's discrepancy was calculated for each case and then, initial alignment completed via proclination of teeth using CAT or FAT. In cases with mandibular anterior excess Bolton's discrepancy, interproximal reduction (IPR) was completed by hand with abrasive strips on contact surfaces of all teeth from mesial of mandibular right to mesial of mandibular left canines after teeth were aligned. In all cases, regardless of treatment modality, elastic protocol involved use of 3/16" diameter 6 oz elastics, with change to 8 oz elastics as clinically determined by the orthodontist.

Clinical protocols in cases treated with CAT involved a set of aligners for sequential tooth movements with instructions to wear each aligner full time (at least 20 hours/day) for a week then change to the next aligner in sequence, and scheduled visits on a 7-weekly basis. If tooth movement progress was judged to be slow, instructions were amended to wear each aligner for two weeks before changing to the next aligner. Refinements in the planned tooth movements were achieved based on updated records submitted to the aligner manufacturer and a subsequent set of serial aligners was used. Clinical protocols in cases treated with fixed labial appliances involved a standard archwire sequence with cross-section dimensions and material as follows: 0.014-inch diameter round nickel-titanium alloy, 0.018-inch diameter round nickel-titanium alloy, 0.020- x 0.020-inch nickel-titanium alloy; 0.019 x 0.025-inch copper nickel-titanium alloy, and 0.019- x 0.025-inch titanium molybdenum alloy (TMA). At six to nine months into

treatment, a panoramic radiograph was made and brackets repositioned as indicated. When indicated, finishing bends were placed in the 0.019- x 0.025-inch TMA wire.

## **ii. Inclusion and Exclusion Criteria**

Case records from patients with the following criteria at the start of orthodontic treatment were considered for the study: age range 11 to 18 years old, CVMS of 4 or 5, permanent dentition, Angle Class II molar relationship of  $\geq 1$  mm bilaterally, and Little's Irregularity Index (IR)  $< 4$  mm.<sup>12</sup> Of these, case records from patients who used Class II elastics bilaterally during orthodontic treatment, and showed changes in Class II molar relationships bilaterally of 1 mm to 6 mm at the end of treatment, were included in the study. Cases where treatment ended prematurely before treatment goals were achieved were included in the study as long as change in class II molar relationship of at least 1 mm was observed. Exclusion criteria were cases with craniofacial deformities, congenitally missing or supernumerary teeth, periodontal disease, or dental extractions as part of the orthodontic treatment.

## **iii. Data Collection**

Cases with digital records for the study were selected based on if inclusion criteria were met, if exclusion criteria were not met and type of orthodontic treatment. Qualified cases were assigned to either CAT or FAT group and one of four sub-groups according to degree of post-treatment changes in Class II molar relations and pre-treatment irregularity indices (Table 1). Class II correction was separated into categories of 1 mm to 3 mm and  $>3$  mm to 6 mm to reflect half-cusp and full-cusp changes, respectively. These sub-groups were compared to evaluate if degree of Class II correction was related to amount of change in mandibular incisor proclination. In order to rule out effects of severe crowding on proclination of mandibular incisors and evaluate proclination as a true result of the use of Class II elastics, only cases with Little's

Irregularity Index of  $<4$  mm were included to represent minimal crowding. Thus, CAT sub-groups were A and B which had post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $\leq 2$  mm and  $>2$  to  $<4$  mm, respectively, and E and F which had post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $\leq 2$  mm and  $>2$  to  $<4$  mm, respectively (Table 1). Similarly, FAT sub-groups were C and D which had post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $\leq 2$  mm and  $>2$  to  $<4$  mm, respectively, and G and H which had post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $\leq 2$  mm and  $>2$  to  $<4$  mm, respectively.

Cases were selected sequentially from a consecutively treated population starting with most recently treated and dating back seven years for a target convenience sample of 10 cases for each sub-group, matched by age and sex. Case drop-outs were not a factor since all cases were previously treated.

All records were de-identified and assigned a random case number for record keeping purposes in a database. Digitized, de-identified copies of the records that met the inclusion criteria and did not meet the exclusion criteria were transported and stored via the secure cloud storage system, OHSU BOX, for analysis in the OHSU Orthodontics Department.

#### **iv. Measurements**

Data from each qualified case included at pre-treatment (T1): age of patient (years), molar relationship measurements on right and left (mm), and IR score; at post-treatment (T2): change in molar relationships (mm), change in mandibular incisor inclination ( $\Delta\text{IMPA}_{T2-T1}$ ,  $^{\circ}$ ), total treatment time (months), duration of elastic use (months), and elastic compliance score (good, fair, poor). Elastic compliance score was determined based on the patient's self-report of elastic wear from clinical notes. A good score meant elastics were worn more than 85% of the

time, fair meant between 70% to 85% of the time, and poor meant less than 70% of the time. For cases with different Class II molar relationships on right and left, the side that had the higher measurement at the start of treatment was used for data analysis.

Molar relationships at T1 and T2 and IR scores for mandibular anterior teeth at T1 were evaluated using digital dental models and available commercial software (OrthoCad, Align Technology, San Jose, Calif). To measure the molar relationship, models were oriented in the default “buccal” view in the software and linear distance measured between the mesiobuccal cusp of the maxillary first molar to the buccal groove of the mandibular first molar using the “ABO Analysis: Occlusal Relationships” function (Fig 7). All measurements were rounded to the nearest 1/10<sup>th</sup> of a mm. IR scores were measured by orienting the mandibular model in the default “occlusal” view. The “Diagnostics: Teeth Width” feature was used to calculate the distance between discrepant interproximal contact points on each mandibular incisor tooth (Fig 6). All individual measurements were rounded to the nearest 1/10<sup>th</sup> of a mm and added together to determine the final IR score.

Digital lateral cephalograms, all made using the same equipment, settings and protocols, were uploaded from the secure storage system into and analyzed using commercial software (Dolphin Imaging & Management Solutions Chatsworth, California) to determine the IMPA (°) at T1, T2, and overall change in IMPA between these time points ( $\Delta\text{IMPA}_{\text{T2-T1}}$ , °) all to the nearest 1/10<sup>th</sup> degree. Cephalometric measurements were made using the Downs analysis.<sup>14</sup> The most prominent mandibular incisor was traced and the angle between its long axis and the mandibular plane (Gonion – Menton) measured as the IMPA (Fig 8). Projections of bilateral structures were bisected to locate landmarks. To minimize effects of head position on perception of true Gonion and Menton, concrete definitions for these landmarks were used. Gonion was

defined as the intersection of the posterior curvature of the ramus and inferior border of the mandible. Menton was defined as the most inferior point under the mandibular symphysis. In order to further test the accuracy and consistency in measurements, two examiners, PKP and SMK, repeated IMPA measurements on all cases independently using the same definitions for the above landmarks. Any cases in which the two examiners'  $\Delta$ IMPA measurements varied by more than  $1.5^\circ$  were discussed and re-assessed by both examiners.

Elastic wear duration (months) was noted as the total time a patient was prescribed to wear Class II elastics (unilaterally and/or bilaterally). Though all included patients wore bilateral Class II elastics at some point in treatment, only the total duration was collected because even unilateral Class II elastic use provides an anteroposterior force component that can influence mandibular incisor inclination. Details of recommended hours per day of wear and strength/size of elastic were not collected due to high variability in recommendations for each individual. General clinical protocol involved use of 3/16" 6oz elastics with increase to 8 oz if necessary.

#### **v. Statistical Analyses**

Statistical analysis software (SPSS version 25; IBM, Armonk, NY) was used. Descriptive statistics including mean  $\pm$  standard deviation (SD) were computed by CAT and FAT group for independent variables of T1 age, T1 Class II molar relationship (mm), change in molar relationships (mm), T1 IR (mm), T1 IMPA ( $^\circ$ ), T2 IMPA ( $^\circ$ ), and compliance (good, fair, poor); and for dependent variables of  $\Delta$ IMPA<sub>T2-T1</sub>, total treatment time, and elastic wear duration (Table 2). Dependent variables between groups and sub-groups were compared using t-tests. Elastic wear compliance (good, fair, poor) between groups and sub-groups was compared using a Likelihood Ratio test. Statistical significance was defined by  $P < .05$ .



Intra-rater reliability was evaluated using intraclass correlation coefficient (ICC) calculations based on repeating the severity of Class II malocclusion and IMPA measurements on one set of digital records ten times, each five days apart and five days after the original measurements. Inter-rater reliability was evaluated using intraclass correlation coefficient calculations from  $\Delta\text{IMPA}_{T2-T1}$  measurements. Values between 0.40 and 0.59 indicate fair reliability, between 0.60 and 0.74 indicate good reliability, and between 0.75 and 1.00 indicate excellent reliability.

## C. Results

### i. Overall Sample

A total of 66 cases were included in this study (32 CAT, 34 FAT) with 10 in sub-groups A and C, nine in sub-groups B, D, and G, seven in sub-group E, and six in sub-groups F and H (Table 1). All of the comparable sub-groups in CAT vs. FAT groups had identical sample sizes except sub-groups F and G, which differed only by two. The sample showed an overall mean age of  $14.5 \pm 1.5$  years old and average treatment duration of  $22.4 \pm 6.5$  months. The sex distribution of cases in each group was CAT: 15 males (M) and 17 females (F), FAT: 13 M and 21 F; and sub-groups was A: 5 M and 5 F, B: 3 M and 6 F, C: 0 M and 10 F, D: 5 M and 4 F, E: 4 M and 3 F, F: 3 M and 3 F, G: 3 M and 6 F, H: 5 M and 1 F (Table 1).

### ii. Comparison of Groups

For the CAT and FAT groups, the mean ages at T1 were  $15.1 \pm 1.6$  years and  $14.0 \pm 1.1$  years, respectively and significantly different ( $P < .01$ , Table 3). Average T1 Class II molar relationships in the CAT and FAT groups were  $2.6 \pm 1.0$  mm and  $2.7 \pm 1.0$  mm, respectively, and were not statistically different ( $P = .72$ , Table 3). Similarly, average changes in Class II molar

relationships in the CAT and FAT groups were  $2.7 \pm 1.0$  mm and  $2.5 \pm 0.9$  mm, respectively, and not significantly different ( $P=.32$ , Table 3). For CAT and FAT groups, the mean IR was  $2.0 \pm 1.2$  mm and  $1.9 \pm 1.3$  mm, respectively, and also not significantly different ( $P=.85$ , Table 3). Furthermore, both groups began with similar average IMPA at T1 (CAT:  $97.0 \pm 6.1^\circ$ , FAT:  $94.4 \pm 7.1^\circ$ ), which were not significantly different ( $P=.12$ , Table 3).

Average  $\Delta\text{IMPA}_{\text{T2-T1}}$  in the CAT group was  $-0.1 \pm 5.1^\circ$  and in the FAT group was  $5.3 \pm 5.7^\circ$ , and significantly different ( $P<.001$ , Fig 9). For both groups, mean treatment duration was  $20.4 \pm 6.9$  months and  $24.3 \pm 5.7$  months, respectively and significantly different ( $P=.02$ , Fig 10). Similarly, average prescribed duration of Class II elastic wear for CAT was  $11.8 \pm 6.9$  months, and for FAT was  $17.5 \pm 6.2$  months, and significantly different ( $P<.001$ , Fig 10). Elastic compliance was noted categorically and was significantly better in the CAT group (81.3% good, 12.5% fair, 6.3% poor) than the FAT group (52.9% good, 32.4% fair, 14.7% poor) with  $P=.05$  (Fig 11).

### iii. Comparison of Sub-Groups

The sub-groups of similar type were paired in the following manner to compare effects of CAT versus FAT for each treatment modality (Table 4): A versus C, B versus D, E versus G, and F versus H. Results for each sub-group are noted in Tables 5 and 6.

For sub-groups A and C, the mean ages at T1 were  $15.4 \pm 1.0$  years and  $14.2 \pm 1.0$  years, respectively, and significantly different ( $P=.02$ , Table 4). Average T1 Class II molar relationships in sub-groups A and C were  $2.3 \pm 0.9$  mm and  $2.3 \pm 0.7$  mm, respectively and not significantly different ( $P=.94$ , Table 4). Similarly, in sub-groups A and C changes in Class II molar relationships were  $1.9 \pm 0.6$  mm and  $2.0 \pm 0.4$  mm, respectively, and not significantly different ( $P=.80$ , Table 4); mean IR were  $1.0 \pm 0.5$  mm and  $1.0 \pm 0.3$  mm, respectively, and also

not significantly different ( $P=.73$ , Table 4). Furthermore, both groups began with similar average IMPA at T1 (A:  $97.9 \pm 7.3^\circ$ , C:  $93.5 \pm 6.6^\circ$ ), which were not significantly different ( $P=.19$ , Table 5). Average  $\Delta\text{IMPA}_{T2-T1}$  in sub-group A was  $-0.9 \pm 3.2^\circ$  and in sub-group C was  $6.2 \pm 7.1^\circ$ , which was significantly different ( $P=.01$ , Fig 12). For A and C sub-groups, mean treatment durations were  $16.7 \pm 6.6$  months and  $22.7 \pm 5.4$  months, respectively and significantly different ( $P=.04$ , Table 4). Similarly, average prescribed duration of Class II elastic wear for sub-group A was  $9.4 \pm 4.9$  months, and for sub-group C was  $16.2 \pm 6.6$  months, and also significantly different ( $P=.02$ , Table 4). Elastic compliance for sub-group A was 88.9% good and 11.1% fair. Elastic compliance for sub-group C was 80.0% good, 10.0% fair and 10.0% poor (Fig 13).

For sub-groups B and D, the mean ages at T1 were  $15.4 \pm 2.5$  years and  $14.0 \pm 1.2$  years, respectively and not significantly different ( $P=.14$ , Table 4). Average T1 Class II molar relationships in sub-groups B and D were  $2.0 \pm 0.8$  mm and  $2.3 \pm 1.0$  mm, respectively and not significantly different ( $P=.56$ , Table 4). Similarly, change in Class II molar relationship was  $2.3 \pm 1.0$  mm and  $1.6 \pm 0.6$  mm, respectively, and not significantly different ( $P=.09$ , Table 4). For each group, the mean IR was  $2.9 \pm 1.7$  mm and  $3.1 \pm 0.8$  mm, respectively, and also not significantly different ( $P=.69$ , Table 4). Furthermore, both groups began with similar average IMPA at T1 (B:  $96.5 \pm 5.8^\circ$ , D:  $91.9 \pm 7.8^\circ$ ), which were not significantly different ( $P=.20$ , Table 4). Average  $\Delta\text{IMPA}_{T2-T1}$  in sub-group B was  $2.0 \pm 7.0^\circ$  and in sub-group D was  $7.8 \pm 4.9^\circ$ , and almost, but not significantly different ( $P=.06$ , Fig 12). For sub-groups B and D, mean treatment durations were  $21.8 \pm 7.3$  months and  $24.2 \pm 6.7$  months, respectively and not significantly different ( $P=.49$ , Table 4). Similarly, average prescribed duration of Class II elastic wear for sub-group B was  $12.9 \pm 5.3$  months, and for sub-group D was  $16.8 \pm 7.2$  months, and also not significantly different ( $P=.21$ , Table 4). Elastic compliance for sub-group B was 66.7% good,

22.2% fair and 11.1% poor. Elastic compliance for sub-group D was 22.2% good, 44.4% fair and 33.4% poor (Fig 13).

For sub-groups E and G, the mean ages at T1 were  $14.4 \pm 0.5$  years and  $13.4 \pm 0.9$  years, respectively and significantly different ( $P=.01$ , Table 4). Average T1 Class II molar relationships in sub-groups E and G were  $3.4 \pm 0.9$  mm and  $3.2 \pm 0.6$  mm, respectively and not significantly different ( $P=.57$ , Table 4). Similarly, change in Class II molar relationships in sub-groups E and G were  $3.6 \pm 0.6$  mm and  $3.4 \pm 0.5$  mm, respectively, and not significantly different ( $P=.41$ , Table 4). For sub-groups E and G, the mean IR were  $1.0 \pm 0.6$  mm and  $0.7 \pm 0.2$  mm, respectively, and also not significantly different ( $P=.12$ , Table 4). Furthermore, both groups began with similar average IMPA at T1 (E:  $96.7 \pm 6.6^\circ$ , G:  $95.9 \pm 5.6^\circ$ ), which were not significantly different ( $P=.83$ , Table 4). Average  $\Delta\text{IMPA}_{T2-T1}$  in sub-group E was  $-1.2 \pm 5.7^\circ$  and in sub-group G was  $1.3 \pm 4.0^\circ$ , and not significantly different ( $P=.32$ , Fig 12). For sub-groups E and G, mean treatment durations were  $25.4 \pm 5.2$  months and  $26.8 \pm 6.5$  months, respectively and not significantly different ( $P=.64$ , Table 4). Similarly, average prescribed duration of Class II elastic wear for sub-group E was  $14.5 \pm 10.8$  months, and for sub-group G was  $18.3 \pm 5.2$  months, also not significantly different ( $P=.36$ , Table 4). Elastic compliance for sub-group E was 100% good. Elastic compliance for sub-group C was 55.6% good, 33.3% fair and 11.1% poor (Fig 13).

For sub-groups F and H, the mean ages at T1 were  $15.0 \pm 1.8$  years and  $14.7 \pm 1.2$  years, respectively and not significantly different ( $P=.74$ , Table 4). Average T1 Class II molar relationships in sub-groups F and H were  $3.2 \pm 1.2$  mm and  $3.4 \pm 1.3$  mm, respectively and not significantly different ( $P=.73$ , Table 4). Similarly, change in Class II molar relationships for sub-groups F and H were  $3.7 \pm 0.6$  mm and  $3.3 \pm 0.2$  mm, respectively, and not significantly

different ( $P=.15$ , Table 4). For sub-groups F and H, the mean IR were  $3.1 \pm 0.7$  mm and  $3.4 \pm 0.7$  mm, respectively, also not significantly different ( $P=.48$ , Table 4). Furthermore, both groups began with similar average IMPA at T1 (F:  $96.5 \pm 2.9^\circ$ , H:  $97.3 \pm 7.2^\circ$ ), which were not significantly different ( $P=.83$ , Table 4). Average  $\Delta\text{IMPA}_{\text{T2-T1}}$  in sub-group F was  $-0.4 \pm 4.2^\circ$  and in sub-group H was  $6.1 \pm 4.5^\circ$ , and significantly different ( $P=.03$ , Fig 12). For sub-groups F and H, mean treatment durations were  $18.8 \pm 5.1$  months and  $23.3 \pm 2.5$  months, respectively, and not significantly different ( $P=.08$ , Table 4). Similarly, average prescribed duration of Class II elastic wear for sub-group F was  $11.2 \pm 6.6$  months, and for sub-group H was  $19.2 \pm 6.1$  months, and also not significantly different ( $P=.76$ , Table 4). Elastic compliance for sub-group F was 66.7% good, 16.7% fair and 16.6% poor. Elastic compliance for sub-group H was 50.0% good and 50.0% fair (Fig 13).

#### iv. Intra-rater and Inter-rater Comparisons

The Cronbach's alpha and ICC were  $\geq 0.74$  for all measurements (Table 7). Reliability calculations showed reliability within 0.1 mm for measurements of severity of Class II relationship and  $0.9-1.0^\circ$  for T1 and T2 IMPA measurements.

#### D. Discussion

The aim of this study was to compare change in lower incisor inclination and duration of treatment with use of Class II elastics in adolescent patients with mild mandibular crowding treated with fixed appliances versus clear aligners. CAT group showed a mean change in incisor proclination of  $-0.1 \pm 5.1^\circ$  while FAT group showed  $5.3 \pm 5.7^\circ$  of proclination. CAT group also showed a shorter treatment duration ( $20.4 \pm 6.9$  months) compared to FAT group ( $24.3 \pm 5.7$  months). Treatment duration is influenced by Class II elastic wear duration, which is dependent

not only upon the orthodontist's goals for correction of a Class II malocclusion, but also on patient compliance with elastic wear. Therefore, it is difficult to classify elastic wear duration and treatment duration as independent or dependent variables. In this study, both of these variables were considered as dependent variables and elastic compliance an independent variable.

In 2016, Hennessy et al. conducted a randomized prospective study on 44 adults (mean age of  $26.4 \pm 7.7$  years) with skeletal Class I bases and minimal mandibular incisor crowding ( $< 4$  mm using the Nance brass-wire technique) treated without extractions to compare change in lower incisor inclination with self-ligating fixed appliances (Forestadent, Pforzheim, Germany) versus clear aligners (Invisalign). Without use of Class II elastics, Hennessy et al. found that IMPA changes for CAT versus FAT were  $3.4 \pm 3.2^\circ$  and  $5.3 \pm 4.3^\circ$ , respectively, and not significantly different, and treatment durations were also not significantly different, at 10.2 months for CAT and 11.3 months for FAT.<sup>14</sup> The current study found similar changes in lower incisor inclination in the FAT group at  $5.3 \pm 5.7^\circ$ , but a significantly different change in the CAT group, at  $-0.1 \pm 5.1^\circ$ . Mean treatment duration also differed significantly between both studies, being twice as long or longer in this study (20.4 months for CAT group and 24.3 months for FAT group). Therefore, differences between the two studies in  $\Delta\text{IMPA}_{T2-T1}$  may be due to longer treatment duration, use of class II elastics, differing quality of case finishes, differing amounts of interproximal reduction completed, different target population (i.e. adults versus adolescents), and/or potential differences in goal tooth positions for CAT cases and FAT cases. Due to lack of other studies evaluating mandibular incisor inclination changes with CAT, it is difficult to determine the cause of lower incisor uprighting seen with CAT in this study.

In this study, locating the root apex of lower incisors on lateral cephalograms proved

challenging in some of the cases due to superimposition of adjacent teeth. To minimize operator error, image clarity was enhanced by adjusting contrast. In addition, pre-treatment and post-treatment intraoral scans were referenced to gain a general idea of whether lower incisors proclined or uprighted at the end of treatment. These methods, as well as the use of specific definitions for Go and Me landmarks to identify mandibular plane in each case, were successful, as the intra-rater and inter-rater reliability calculations for measuring IMPA were within the “excellent” range.

Attempt was made to obtain 10 cases for each subgroup, matched by sex and age. However, there were insufficient cases which met the inclusion criteria to achieve the desired sample size. As a result, 66 cases were included with all comparable sub-groups in CAT versus FAT having identical sample sizes except sub-groups F and G, which differed only by two (Table 1). Sex distribution in each sub-group varied significantly, with sub-group C only consisting of females (Table 1). Furthermore, average age was significantly greater in the CAT group by approximately one year. This was due to mean age being significantly higher in CAT sub-groups A and E versus FAT sub-groups C and G, respectively. This may be explained by older patients choosing CAT due to expected increased compliance of aligner wear and/or increased focus on esthetics with increased age and maturity. Therefore, groups and sub-groups could not be matched by sex and age. However, use of CVMS as another measure of skeletal maturity helped to mitigate the effects of this variation in age on the study’s results. Meaning, although pre-treatment chronological age did vary in some sub-groups, all patients began at CVMS 4 or 5, indicating similar skeletal and dental maturity in all cases.

Independent variables (age, T1 severity of Class II molar relationship, change in Class II molar relationship, IR, T1 IMPA, and elastic compliance) were intended to show minimal

variability among groups and sub-groups (Table 2) to assess true effects of treatment modality on the dependent variables ( $\Delta\text{IMPA}_{T2-T1}$ , treatment duration, and elastic wear duration) and rule out effects of confounding variables within the samples. Other than differences in age discussed above, none of the aforementioned independent variables showed significant differences between groups or sub-groups. The CAT group showed more change in molar relationship ( $2.7 \pm 1.1$  mm) than initial severity of the Class II relationship ( $2.6 \pm 1.0$  mm), indicating that some cases were overcorrected to a Class III molar relationship. This may suggest that the mandibular incisors needed to remain upright in order to preserve ideal overjet. However, the orthodontist did not prescribe lingual crown torque for mandibular incisors specifically in the CAT group to facilitate this. Therefore, the overcorrected molar relationship was likely a result of excellent elastic wear compliance in the CAT group.

Despite beginning with similar amount of crowding (IR) and pre-treatment mandibular incisor inclination (T1 IMPA), CAT and FAT groups showed a significant difference in change in mandibular incisor proclination with treatment. CAT group showed slight uprighting ( $-0.1 \pm 5.1^\circ$ ) while FAT group showed  $5.3 \pm 5.7^\circ$  of proclination. This may be a result of FAT applying force coronal and labial to the center of resistance of an incisor tooth, allowing more labial tipping of the crown.<sup>14</sup> This may also indicate influence of other factors on change in mandibular incisor proclination, such as duration of Class II elastic wear or difference in prescribed torque for lower incisor in each appliance. However, the latter factor does not play a considerable role because final torque is a result of treatment goals, which were similar regardless of appliance type: 1-2mm overjet and overbite and Class I canines.

Overall, treatment duration and prescribed elastic wear duration were significantly longer in the FAT group by approximately four months and six months, respectively. Significantly



poorer elastic wear compliance among FAT patients (52.9% good, 32.4% fair, 14.7% poor) compared to CAT patients (81.3% good, 12.5% fair, 6.3% poor) in this study can in part explain the longer duration of treatment and prescribed Class II elastic use in the FAT group. Assuming that younger patients were less compliant with wearing elastics, it would make sense that patients in the FAT group had longer average prescribed Class II elastic wear duration since the average age of these patients was approximately one year younger than those in the CAT group. Patient burnout may be an additional factor. Elastic wear in CAT groups was prescribed at initial delivery of aligners, when patients would be most motivated and compliant. Elastic wear in FAT groups was not usually prescribed until archwire progression to rectangular cross-section nickel-titanium wires, which occurred a few months into treatment, when patients may have become less motivated. However, how much of the difference in treatment duration is due to treatment modality versus due to poorer compliance with elastics remains unknown because elastic compliance was self-reported by patients and may not be fully reliable. Furthermore, the number of appliance breakages and variability in compliance with aligner wear were not noted during data collection, but may have also contributed to longer treatment duration in the FAT group.

Not all CAT versus FAT sub-group comparisons showed significant differences in  $\Delta\text{IMPA}_{T2-T1}$ . Sub-groups A versus C showed a significant difference in all dependent variables. As seen above, the FAT sub-group C in this comparison showed significantly greater mandibular incisor proclination by  $7.1 \pm 3.9^\circ$  likely due to significantly longer treatment and elastic wear duration, both longer by approximately six months compared to the CAT sub-group A. Unlike in CAT versus FAT groups, this significant difference cannot be explained by a difference in elastic wear compliance between the sub-groups, as most cases in each of these sub-groups reported >85% (i.e. good) compliance. Instead, it can be explained by inclusion in sub-group A of a case

which was only treated for five months. In this case, the patient complied well with elastics, was satisfied with the results at the end of the first set of aligners, and requested to complete treatment early. If this case were to be excluded, the average treatment duration in sub-group A would be  $18.0 \pm 5.1$  months, which would not be significantly different ( $P=.08$ ) from the average treatment duration of sub-group C of  $22.7 \pm 5.4$  months, nevertheless shorter on average by approximately 5 months.

Sub-groups B versus D came close to a significant difference in  $\Delta\text{IMPA}_{T2-T1}$  ( $P=.06$ ) even though duration of treatment and prescribed Class II elastic wear were not significantly different. Both sub-groups varied almost significantly in change in Class II molar relationship ( $P=.09$ ), which would indicate that perhaps the sub-group with the greater change experienced greater incisor proclination. However, this was not the case. FAT sub-group (D) showed greater mandibular incisor proclination while CAT sub-group (B) showed the greater change in Class II molar relationship. Therefore, the almost significantly greater incisor proclination seen in the FAT sub-group can be explained primarily by the difference in treatment modalities used in each sub-group and not by pre-treatment factors or patient compliance. A larger sample size may be needed to more clearly highlight the underlying difference.

Sub-groups E versus G did not show a significant difference in  $\Delta\text{IMPA}_{T2-T1}$ , treatment duration or prescribed elastic wear duration. This may indicate low power and need for a larger sample size in order to detect differences, especially since there is a mismatch in the number of cases included in sub-group E (seven cases) versus G (nine cases).

Sub-groups F and H did not show significant differences in any independent variables, but differed significantly in  $\Delta\text{IMPA}_{T2-T1}$  with the FAT sub-group (H) showing approximately  $6^\circ$  more mandibular incisor proclination than the CAT sub-group (F). Poorer compliance with

elastic wear in sub-group H (50% good, 50% poor) than in sub-group F (67% good, 17% fair, 16% poor), requiring longer treatment and prescribed elastic wear durations may help to explain this difference. Although duration of treatment and prescribed elastic wear were not significantly different between sub-groups F and H, they approached significance at  $P=.08$  and  $P=.05$ , respectively.

Since the samples consisted of adolescents, growth was taken into account as a factor for changes seen in mandibular incisor proclination. The inferior border of the ramus is resorptive, with posterior and superior drift of Gonion during growth.<sup>15</sup> This, in addition to the slight deposition of bone that occurs inferior to the mandibular symphysis, may steepen the mandibular plane, thus decreasing IMPA. This would mean that younger patients (who are closer to or just past their peak growth spurt) would display less mandibular incisor proclination. In this study, the FAT group consisted of younger patients but showed more mandibular incisor proclination. Additionally, cases in both groups began as CVMS 4 or 5, suggesting that these patients were past their peak growth spurt. Therefore, it is unlikely that growth played a role in the significant difference in  $\Delta\text{IMPA}_{T2-T1}$  seen between CAT and FAT groups, and more likely that this difference is due to treatment modality, duration of Class II elastic wear, and/or duration of treatment. Furthermore, potential differences in the orthodontist's and/or patient's criteria used to define a case as "finished" influence treatment duration and may also contribute to the differences in outcomes between the groups. However, this factor also contributes minimally to the results found in this study. A retrospective study in 2017 compared CAT and FAT treatment of mild malocclusions in adolescents who were treated by the same orthodontist who treated all cases included in this study. Final records were evaluated using the American Board of Orthodontics Cast-Radiograph Evaluation (CRE) and showed equivalent effectiveness of both

therapies.<sup>16</sup> Therefore, quality of finished cases with both therapies were similar and do not undermine the significant differences in outcome measures found in this study.

In summary, although lack of differences in most independent variables between CAT and FAT groups underscores the significantly different  $\Delta\text{IMPA}_{\text{T2-T1}}$  found with each treatment modality, a future prospective, randomized study with larger samples matched by age and sex and an objective method to record Class II elastic wear compliance and determine when the case was “finished” with active treatment may provide stronger results. That is, it would also be beneficial to assess case completion with objective measures (e.g. 1-2 mm overjet, Class I canines, maintained inter-canine width, quantified amount of IPR) to determine how much contribution to  $\Delta\text{IMPA}$  is from treatment modality versus from patient compliance.

#### **E. Limitations and Future Research**

There are four main limitations in this study. Firstly, because groups and sub-groups were not matched by age and sex, the effect of these variables on treatment time and elastic wear compliance could not be studied.

Secondly, elastic compliance scores were self-reported by the patient and therefore, lack reliability. Since elastic wear compliance directly affects treatment duration, the significant difference found in treatment duration between CAT and FAT groups in this study cannot be fully attributed to treatment modality used.

Thirdly, initial Bolton’s discrepancy and amount of IPR performed in each case were not noted. The orthodontist reported only completing sufficient IPR to relieve Bolton’s discrepancy in each case and no cases were completed with anterior spacing. Therefore, proclination due to a

residual Bolton discrepancy does not contribute to our findings or undermine our results.

However, since post-treatment canine relationships were not recorded, an argument can still be made that greater IPR was completed in CAT cases, resulting in more upright mandibular incisor position than is seen with FAT.

Lastly, objective criteria were not applied to assess treatment completion for each included case. Cases were classified by amount of change in Class II molar relationship and pre-treatment IR without regard for post-treatment canine relationship and anterior overjet. This means that cases finishing faster due to remaining Class II canine relationship or excess anterior overjet may have been compared with cases that were being treated to a more ideal finish, and therefore, had longer treatment duration. This prevents differentiation of the effect of treatment modality versus quality on treatment duration and changes in mandibular incisor proclination.

Another objective measurement of importance is inter-canine width. Although not specifically prescribed in the orthodontist's clinical preferences to the aligner manufacturer, cases treated with CAT may have ended with inter-canine width expansion, another reason for CAT resulting in lesser mandibular incisor proclination than FAT. Future studies would need to evaluate initial Bolton's discrepancy, amount of IPR performed, post-treatment canine relationship, anterior overjet, and change in inter-canine width in order to determine true effects of treatment modalities on changes in mandibular incisor proclination and treatment duration.

## **F. Conclusions**

In this study, comparison of CAT versus FAT showed statistically significant differences in  $\Delta\text{IMPA}_{T2-T1}$  and treatment duration with use of Class II elastics in adolescent patients with similar pre-treatment Class II dental malocclusions and similar amounts of Class II correction.

That is, cases treated with FAT showed significantly greater mandibular incisor proclination by an average of  $5.4 \pm 0.6^\circ$ , significantly longer treatment duration by an average of  $3.9 \pm 1.2$  months, and also significantly longer elastic wear duration by an average of  $5.7 \pm 0.7$  months than cases treated with CAT. Therefore, the null hypothesis that Class II orthodontic treatment using Class II elastics in adolescents was no different between FAT and CAT in terms of change in lower incisor inclination and treatment duration was rejected.

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## H. Figures

**Figure 1. Class I (left) and Class II (right) malocclusions are portrayed.**



**Class I**

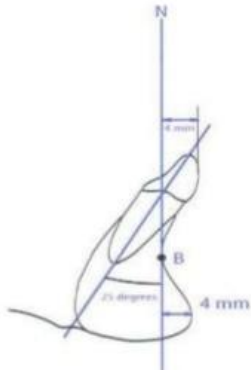
**Class II**

**Figure 2. Class II elastic pattern is displayed.** (source: <https://www.ortho-specialists.com/elastics>)

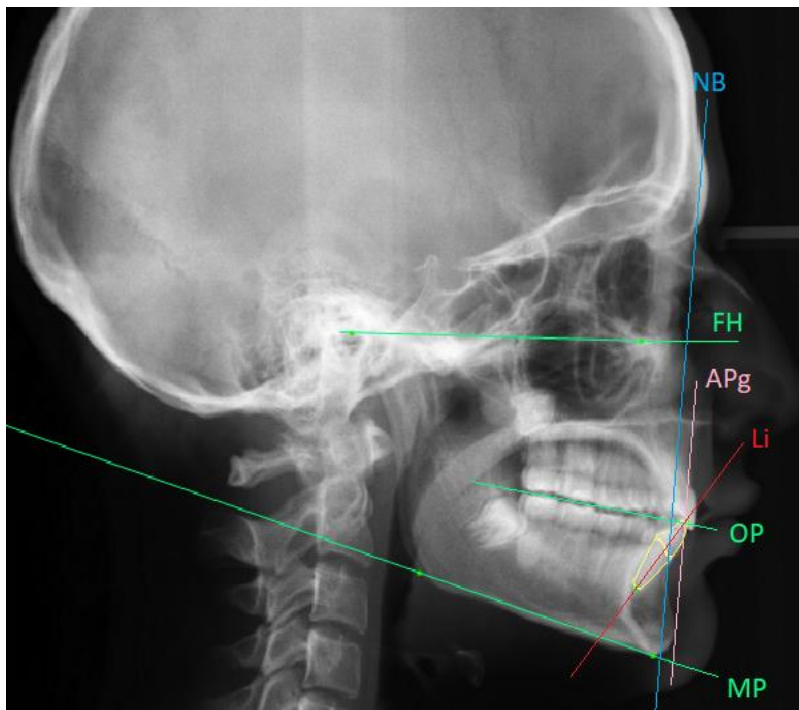


**Figure 3.** Holdaway Ratio: the linear distance of the labial surface of the mandibular incisor to the NB line is in 1:1 ratio with the linear distance of the chin point to the same line. (source:

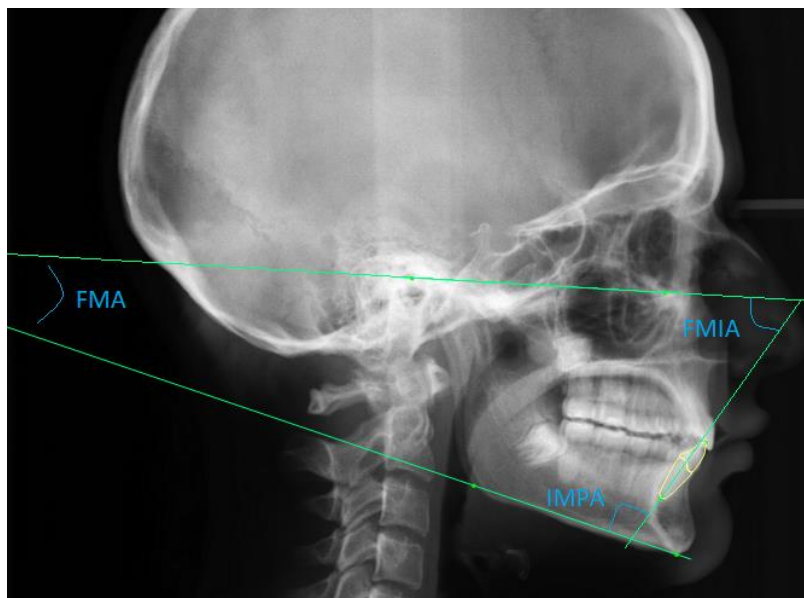
<https://www.slideshare.net/drabbasnaseem/cephalometric-analysis-28754015>)



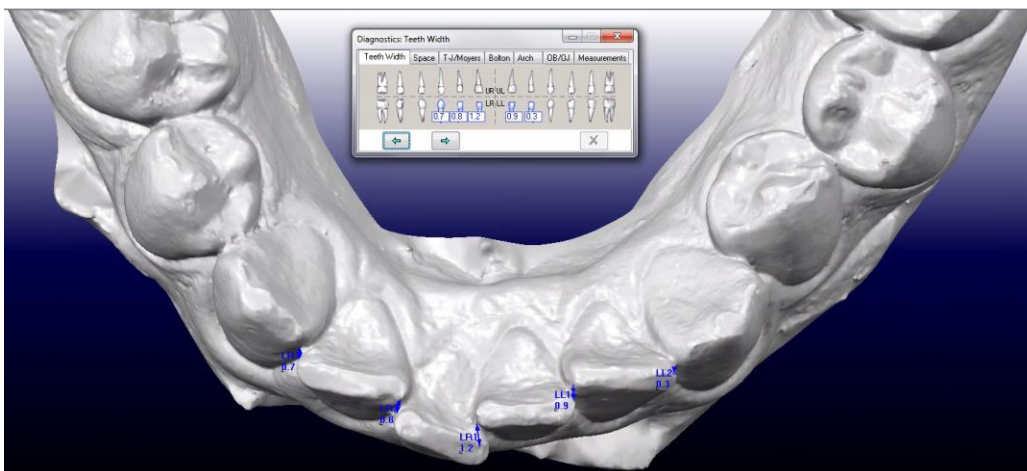
**Figure 4.** Reference planes to evaluate mandibular incisor proclination, including: long axis of the incisor (Li), Occlusal Plane (OP), A Point-Pogonion Line (APg), Nasion-B Point line (NB), Frankfort Horizontal (FH), and Mandibular Plane (MP).



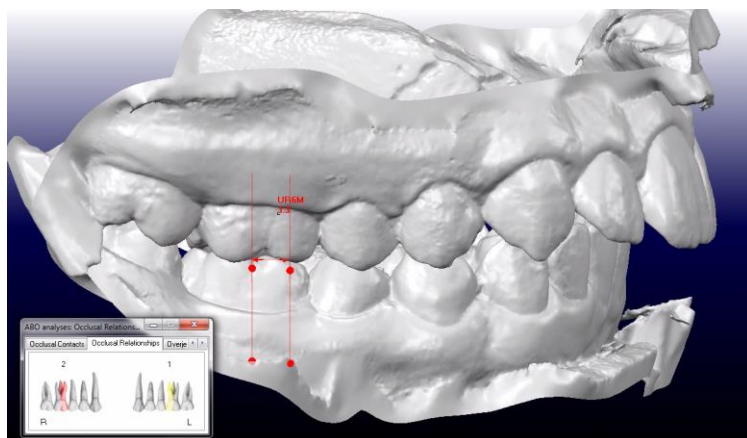
**Figure 5.** Diagnostic Facial Triangle showing the relationship of the long axis of mandibular incisor to Frankfort Horizontal (FMIA) and to Mandibular Plane (IMPA), and relationship of the mandibular plane to Frankfort Horizontal (FMA).



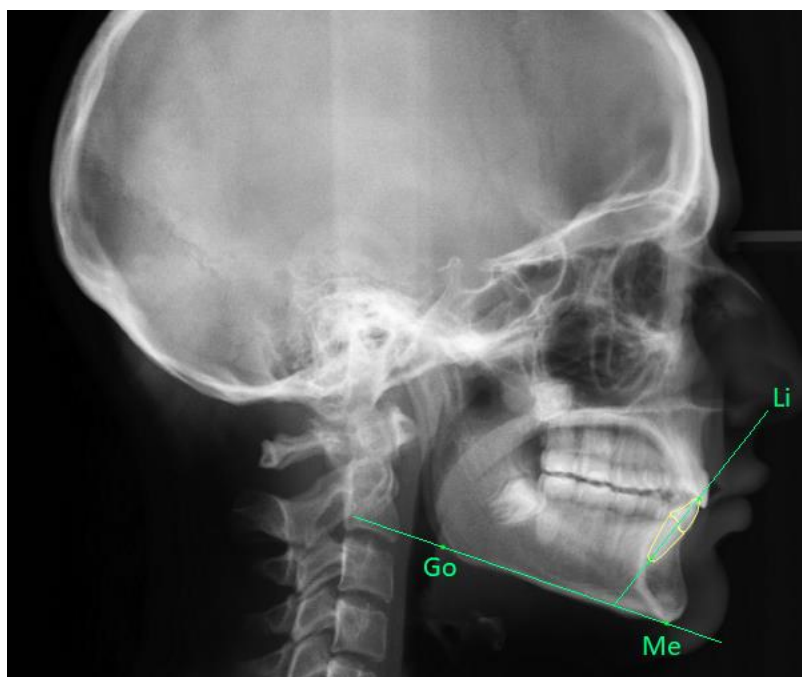
**Figure 6.** Little's Irregularity Index calculated by adding the labiolingual distances between adjacent interproximal contacts of the lower anterior teeth.



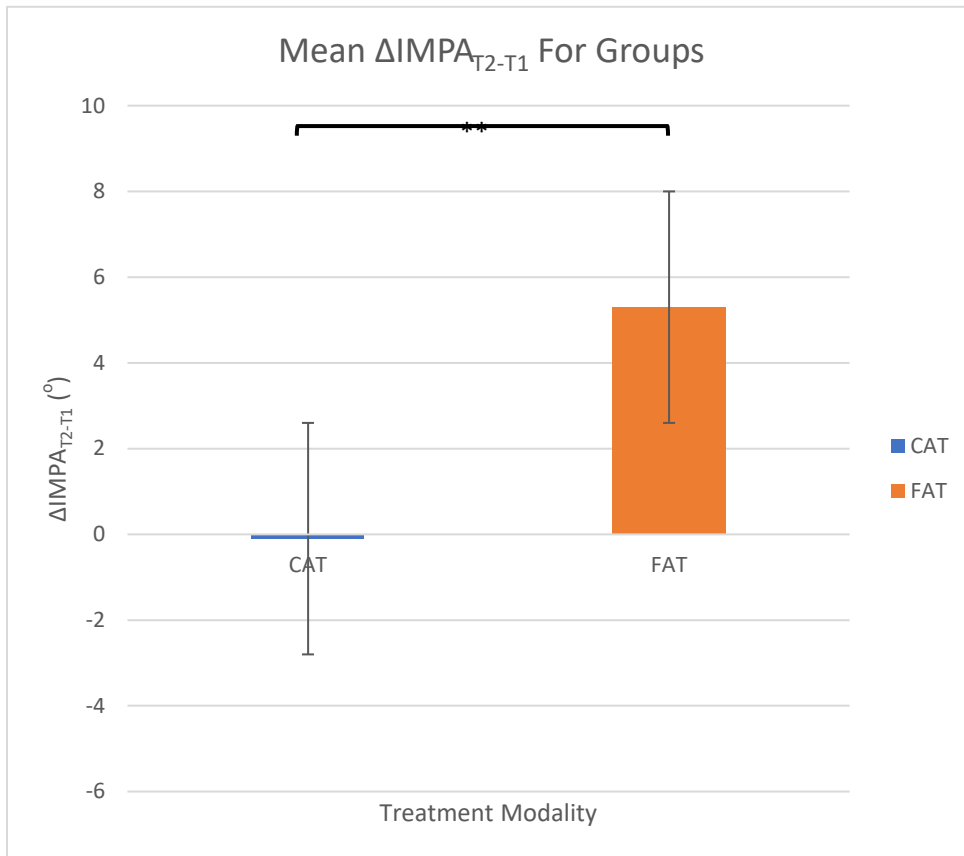
**Figure 7.** Class II relationship quantified using “ABO analysis: Occlusal Relationship” tool in software (OrthoCAD) with model oriented in buccal occlusion position for each side.



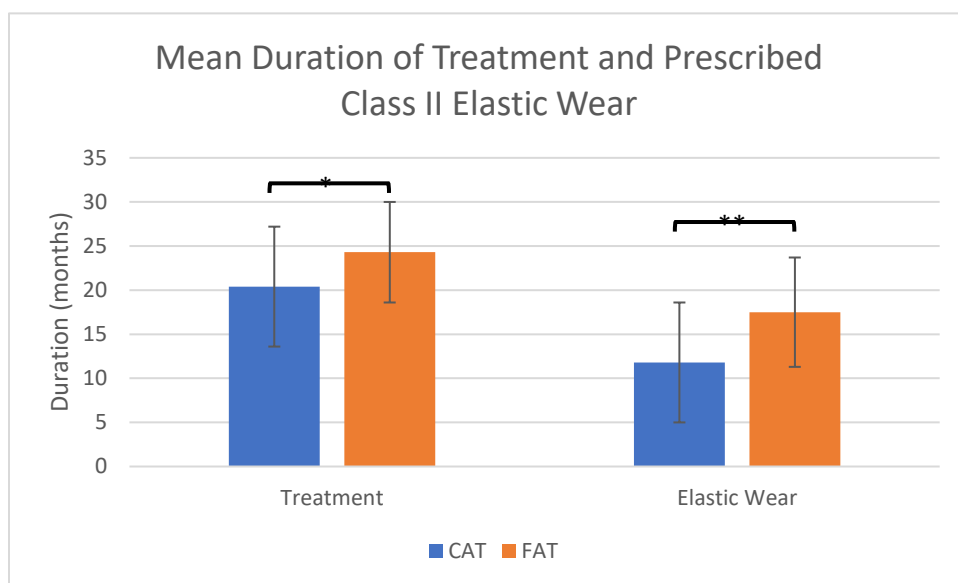
**Figure 8.** Down’s method of measuring mandibular incisor (Li) inclination uses Gonion (Go) and Menton (Me) as the reference points for Mandibular Plane.



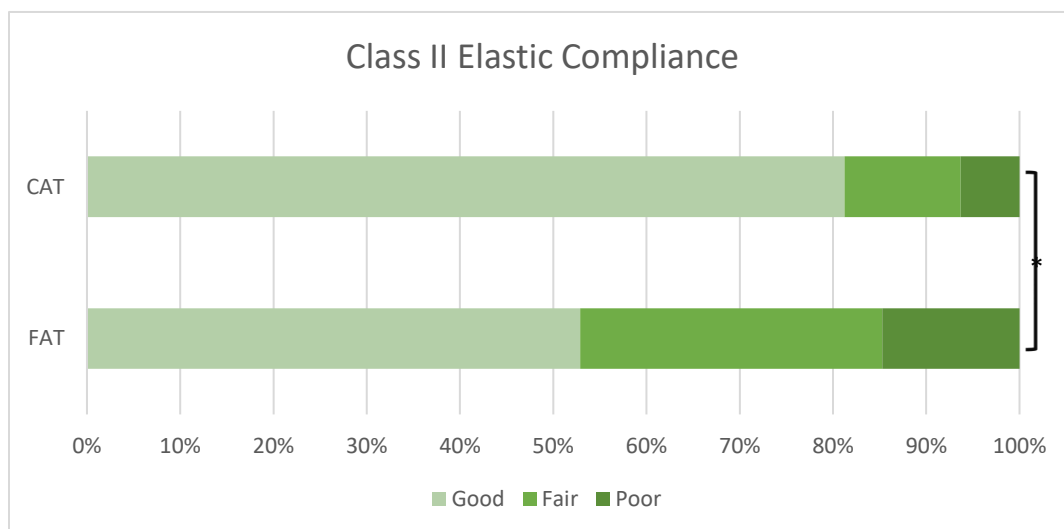
**Figure 9.** Mean change in mandibular incisor inclination relative to mandibular plane ( $\Delta\text{IMPA}_{T2-T1}$ ) for each group, Clear Aligner Therapy (CAT) and Fixed Appliance Therapy (FAT), where vertical bars indicate standard deviations and \*\* indicates significant difference ( $P < .001$ ).



**Figure 10.** Mean treatment duration and prescribed elastic wear duration for each group, Clear Aligner Therapy (CAT) and Fixed Appliance Therapy (FAT), where vertical bars indicate standard deviations, \* indicates significant difference ( $P < .05$ ) and \*\* indicates significant difference ( $P < .001$ ).

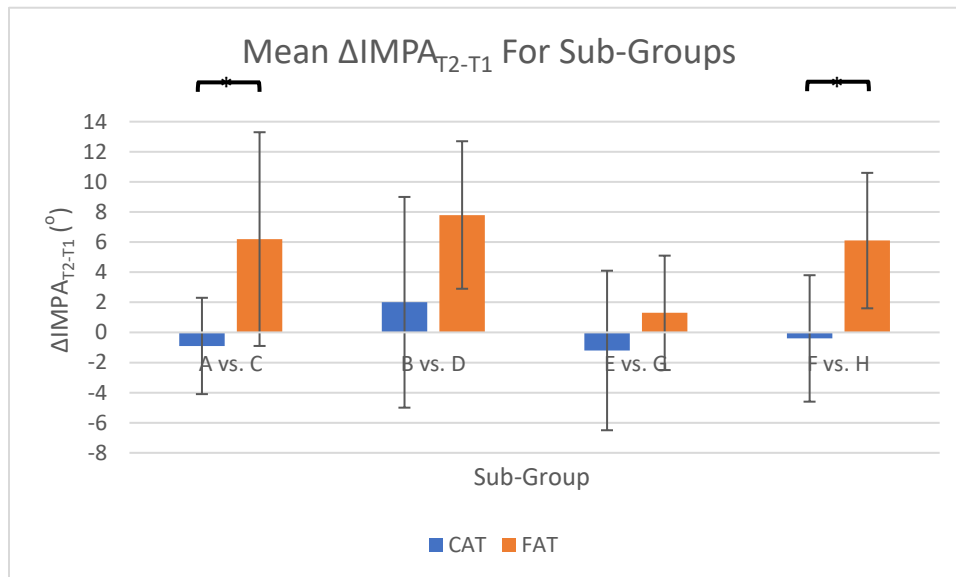


**Figure 11.** Class II elastic compliance by group, where CAT = Clear Aligner Therapy, FAT = Fixed Appliance Therapy, Good = elastics were worn >85% of the time, Fair = between 70% – 85% of the time, Poor = <70% of the time, and \* indicates significant difference ( $P < .05$ )

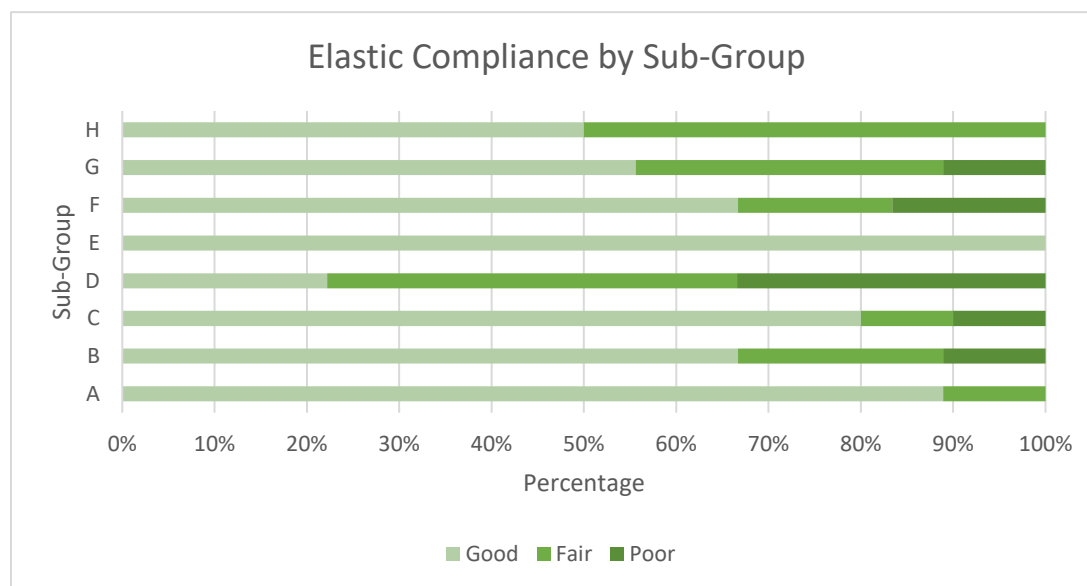


**Figure 12.** Mean change in mandibular incisor inclination relative to mandibular plane

( $\Delta\text{IMPA}_{T2-T1}$ ) for each sub-group in Clear Aligner Therapy (CAT) and Fixed Appliance Therapy (FAT). Vertical bars indicate standard deviations, \* indicates significant difference ( $P < .05$ ). A = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $\leq 2$  mm, B = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $>2$  to  $<4$  mm, E = post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $\leq 2$  mm, and F = post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $>2$  to  $<4$  mm. Sub-groups for Fixed Appliance Therapy (FAT) are as follows: C = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $\leq 2$  mm, D = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $>2$  to  $<4$  mm, G = post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $\leq 2$  mm, and H = post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $>2$  to  $<4$  mm.



**Figure 13.** Class II elastic compliance by sub-group, where A = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $\leq 2$  mm, B = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $>2$  to  $<4$  mm, E = post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $\leq 2$  mm, and F = post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $>2$  to  $<4$  mm. Sub-groups for Fixed Appliance Therapy (FAT) are as follows: C = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $\leq 2$  mm, D = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $>2$  to  $<4$  mm, G = post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $\leq 2$  mm, and H = post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $>2$  to  $<4$  mm. Good = elastics were worn  $>85\%$  of the time, Fair = between  $70\%$  –  $85\%$  of the time, and Poor =  $<70\%$  of the time.





## I. Tables

**Table 1.** Study groups based on type of therapy and sub-groups based on post-treatment changes in Class II molar relationships and pre-treatment mandibular anterior irregularity indices.

Number of cases and sex distribution in each sub-group.

	Clear Aligner Therapy				Fixed Appliance Therapy			
	A	B	E	F	C	D	G	H
<b>Post-Treatment Changes in Class II Molar Relations</b>	1 mm – 3 mm		>3 mm – 6 mm		1 mm – 3 mm		>3 mm – 6 mm	
<b>Pre-Treatment Irregularity Index</b>	≤2 mm	>2 mm to <4 mm	≤2 mm	>2 mm to <4 mm	≤2 mm	>2 mm to <4 mm	≤2 mm	>2 mm to <4 mm
<b>Sample Size</b>	10	9	7	6	10	9	9	6
<b>Number of Males, Females</b>	5, 5	3, 6	4, 3	3, 3	0, 10	5, 4	3, 6	5, 1

**Table 2.** Independent and dependent variables in this study, where T1 = pre-treatment and T2 = post-treatment.

Independent Variables	Dependent Variables
T1 age	T2-T1 Incisor Mandibular Plane Angle
T1 severity of Class II molar relationship	Treatment duration
T2-T1 Class II molar relationship	Elastic wear duration
T1 Little's Irregularity Index	
T1 Lower Incisor-Mandibular Plane Angle	
Elastic wear compliance	

**Table 3.** Comparison of independent variables and dependent variables between treatment modalities using t-test, where CAT = Clear Aligner Therapy, FAT = Fixed Appliance Therapy, T1 = pre-treatment, T2 = post-treatment, and IMPA = Lower Incisor to Mandibular Plane Angle.

	CAT	FAT	P value
Age (years)	15.1 ± 1.6	14.0 ± 1.1	0.00*
T1 Class II molar relationship (mm)	2.6 ± 1.0	2.7 ± 1.2	0.72
T1-T1 Class II molar relationship (mm)	2.7 ± 1.1	2.5 ± 0.9	0.32
Little's Irregularity Index (mm)	2.0 ± 1.3	1.9 ± 1.3	0.85
T1 IMPA (°)	97.0 ± 6.1	94.4 ± 7.1	0.12
T2 IMPA (°)	96.9 ± 6.0	99.7 ± 7.0	0.09
T2-T1 IMPA (°)	-0.1 ± 5.1	5.3 ± 5.7	0.00*
Treatment Duration (months)	20.4 ± 6.9	24.3 ± 5.7	0.02*
Elastic Wear Duration (months)	11.8 ± 6.9	17.5 ± 6.2	0.00*

\* Indicates significant differences between therapy groups ( $P < .05$ ).

**Table 4.** P-values resulting from comparison of independent and dependent variables between sub-groups using t-test, where T1 = pre-treatment, T2 = post-treatment, and IMPA = Lower Incisor to Mandibular Plane Angle. Sub-groups for Clear Aligner Therapy (CAT) are as follows: A = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $\leq 2$  mm, B = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $>2$  to  $<4$  mm, E = post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $\leq 2$  mm, and F = post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $>2$  to  $<4$  mm. Sub-groups for Fixed Appliance Therapy (FAT) are as follows: C = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $\leq 2$  mm, D = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment

IR of >2 to <4 mm, G = post-treatment changes in Class II molar relations of >3 – 6 mm and pre-treatment IR of  $\leq$ 2 mm, and H = post-treatment changes in Class II molar relations of >3 – 6 mm and pre-treatment IR of >2 to <4 mm.

CAT versus FAT Sub-group Comparisons	Age (years)	T1 Class II (mm)	T2-T1 Class II (mm)	Little's Irregularity Index (mm)	T1 IMPA (°)	T2-T1 IMPA (°)	Treatment Duration (months)	Elastic Wear Duration (months)
A – C	0.02*	0.94	0.80	0.73	0.19	0.01*	0.04*	0.02*
B – D	0.14	0.56	0.10	0.69	0.20	0.06	0.49	0.21
E – G	0.01*	0.57	0.41	0.12	0.83	0.32	0.64	0.36
F – H	0.74	0.73	0.15	0.48	0.83	0.03*	0.08	0.05

\* Indicates statistical significance ( $P < .05$ ).

**Table 5.** Results for each sub-group in Clear Aligner Therapy (CAT) group, where T1 = pre-treatment, T2 = post-treatment, IR = Little's Irregularity Index, IMPA = Lower Incisor to Mandibular Plane Angle, and Tx = Treatment. Sub-groups are as follows: A = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $\leq$ 2 mm, B = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of >2 to <4 mm, E = post-treatment changes in Class II molar relations of >3 – 6 mm and pre-treatment IR of  $\leq$ 2 mm, and F = post-treatment changes in Class II molar relations of >3 – 6 mm and pre-treatment IR of >2 to <4 mm.

	Sub-group	Age (years)	T1 Class II (mm)	T2-T1 Class II (mm)	IR (mm)	T1 IMPA (°)	T2-T1 IMPA (°)	Tx Duration (months)	Elastic Duration (months)
CAT	A	15.4 $\pm$ 1.0	2.3 $\pm$ 0.9	1.9 $\pm$ 0.6	1.0 $\pm$ 0.5	97.9 $\pm$ 7.3	-0.9 $\pm$ 3.2	16.7 $\pm$ 6.6	9.4 $\pm$ 4.9
	B	15.4 $\pm$ 2.5	2.0 $\pm$ 0.8	2.3 $\pm$ 1.0	2.9 $\pm$ 1.7	96.5 $\pm$ 5.8	2.0 $\pm$ 7.0	21.8 $\pm$ 7.3	12.9 $\pm$ 5.3
	E	14.5 $\pm$ 0.5	3.4 $\pm$ 0.9	3.6 $\pm$ 0.6	1.0 $\pm$ 0.6	96.7 $\pm$ 6.6	-1.2 $\pm$ 5.3	25.4 $\pm$ 5.2	14.5 $\pm$ 10.8
	F	15.0 $\pm$ 1.8	3.2 $\pm$ 1.2	3.7 $\pm$ 0.6	3.1 $\pm$ 0.7	96.5 $\pm$ 2.9	-0.4 $\pm$ 4.2	18.8 $\pm$ 5.1	11.3 $\pm$ 6.6

**Table 6.** Results for each sub-group in Fixed Appliance Therapy (FAT) group, where T1 = pre-treatment, T2 = post-treatment, IR = Little's Irregularity Index, IMPA = Lower Incisor to Mandibular Plane Angle, and Tx = Treatment. Sub-groups are as follows: C = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $\leq 2$  mm, D = post-treatment changes in Class II molar relations of 1 – 3 mm and pre-treatment IR of  $>2$  to  $<4$  mm, G = post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $\leq 2$  mm, and H = post-treatment changes in Class II molar relations of  $>3$  – 6 mm and pre-treatment IR of  $>2$  to  $<4$  mm.

	Sub-group	Age (years)	T1 Class II (mm)	T2-T1 Class II (mm)	IR (mm)	T1 IMPA ( $^{\circ}$ )	T2-T1 IMPA ( $^{\circ}$ )	Tx Duration (months)	Elastic Duration (months)
FAT	C	14.2 $\pm$ 1.0	2.3 $\pm$ 0.7	2.0 $\pm$ 0.4	1.0 $\pm$ 0.3	93.5 $\pm$ 6.6	6.2 $\pm$ 7.1	22.7 $\pm$ 5.4	16.3 $\pm$ 6.6
	D	14.0 $\pm$ 1.2	2.3 $\pm$ 1.0	1.6 $\pm$ 0.6	3.1 $\pm$ 0.8	91.9 $\pm$ 7.8	7.8 $\pm$ 4.9	24.2 $\pm$ 6.7	16.8 $\pm$ 7.2
	G	13.4 $\pm$ 0.9	3.2 $\pm$ 0.6	3.4 $\pm$ 0.5	0.7 $\pm$ 0.2	95.9 $\pm$ 5.6	1.3 $\pm$ 3.8	26.8 $\pm$ 6.5	18.3 $\pm$ 5.2
	H	14.7 $\pm$ 1.2	3.4 $\pm$ 1.3	3.3 $\pm$ 0.2	3.4 $\pm$ 0.7	97.3 $\pm$ 7.2	6.1 $\pm$ 4.5	23.3 $\pm$ 2.5	19.3 $\pm$ 6.1

**Table 7.** Intraclass Correlation Coefficient measured using Cronbach's Alpha for intra-rater and inter-rater reliability, where T1 = pre-treatment, T2 = post-treatment, IMPA = Lower Incisor to Mandibular Plane Angle. Cronbach's Alpha values between 0.60 and 0.74 indicate good reliability and greater than 0.74 suggest excellent reliability. Standard deviations indicate the range within which the measurements are reliable.

Measurements	Intra-Rater		Inter-Rater
	T1 IMPA, T2 IMPA ( $^{\circ}$ )	T1 Class II molar relationship (mm)	T1 IMPA, T2 IMPA ( $^{\circ}$ )
Cronbach's Alpha	0.75	0.74	0.76
Standard Deviation	1.0, 0.9	0.1	Not applicable

## **J. Comprehensive Literature Review**

### **i. Clear Aligner Therapy versus Fixed Appliances**

Fixed braces have been the conventional orthodontic appliance and the gold standard for over a hundred years.<sup>14</sup> However, clear aligners have gained popularity especially amongst adult patients due to being more esthetic. Align Technology, Inc. released Invisalign® in 1998.

Although initial cases were minor crowding or spacing, improvements in material and computer design have expanded the indications of clear aligners so much so that many clinicians utilize them to treat almost everything from mild to severe malocclusions.<sup>17,18</sup>

In recent years, increasing numbers of patients demanding more esthetic and comfortable orthodontic treatment has fueled more research comparing fixed appliance therapy (FAT) to clear aligner therapy (CAT). Multiple systematic reviews have concluded that clear aligners have an advantage in shortening treatment duration and chair time in mild-to-moderate cases.<sup>19,20</sup> However, the performance of clear aligners in creating occlusal changes remains controversial. Zheng et al. concluded that clear aligners show no difference in stability and occlusal characteristics after treatment when compared to FAT.<sup>19</sup> A more recent retrospective study conducted in 2017 by Borda et al. found equivalent effectiveness of CAT and FAT in treatment of mild malocclusions in adolescents.<sup>16</sup> On the other hand, Ke et al. found that though both treatment modalities were effective in treating malocclusion, clear aligners were not as effective as braces in producing adequate occlusal contacts, controlling teeth torque, and retention.<sup>20</sup> Despite its popularity, CAT is not effective in anterior extrusion, anterior and root torque control, and controlling rotation of rounded teeth.<sup>5,14,21</sup> Due to these limitations, many clear aligner treatments are completed without extractions. Clinicians then rely on other techniques to relieve crowding, such as proclination of the mandibular labial segment or interproximal reduction

(IPR).<sup>14</sup>

In the past, it was postulated that clear aligners would result in greater lower incisor proclination to relieve crowding in non-extraction cases by creating moments of force away from the centers of resistance of the incisors.<sup>14</sup> Krieger et al reported that 58% of their patients had some increase in mandibular arch length post-CAT treatment, indicating labial segment protrusion.<sup>22</sup> Nonetheless, Hennessy found no statistically significant difference in the amount of lower incisor proclination achieved with labial FAT ( $5.3 \pm 4.3^\circ$ ) vs. CAT ( $3.4 \pm 3.2^\circ$ ) in adult patients with mild mandibular incisor crowding (<4 mm) and Class I skeletal bases (ANB 1-4°).<sup>14</sup> This can be explained by evaluating the position of the applied force in each appliance. Fixed appliances place a force coronal and buccal to the center of resistance of a tooth, resulting in tipping and proclination. Clear aligners place a force along the complete length of the crown, presumably creating forces closer to the center of resistance of the tooth and minimizing the amount of proclination that occurs.<sup>14</sup> Another explanation may be that improvements in the design of aligners include accurately placed composite attachments and indentations in the polyurethane to allow root torque and increased control of tooth movement.<sup>14</sup>

Other non-tangible benefits of CAT attract patients to choose this treatment modality over FAT. Miller et al. found that adults treated with Invisalign aligners experienced less pain and fewer negative impacts on their quality of life (functional and psychosocial) during the first week of orthodontic treatment than did those treated with fixed appliances.<sup>23</sup> In addition to being less painful, it has also been reported that clear aligners cause less root resorption and allow for improved oral hygiene compared to fixed appliances.<sup>23,14</sup>

## ii. Self-Ligating vs. Conventional Appliances

Majority of clinicians utilize conventional labial brackets. The differences in effects of conventional vs. self-ligating brackets on angular changes of the mandibular incisors must be considered in order to apply the findings of this study to patients treated with conventional labial braces. Although self-ligating appliances have been shown to produce slightly more expansion in the molar region, bracket type has shown to have little effect on incisor inclination and intercanine width.<sup>24,25</sup> These results suggest that correction of mandibular crowding is achieved through similar mechanisms (i.e. proclination and expansion) with conventional and self-ligating brackets.<sup>25</sup>

Pandis et al. found  $2.4 \pm 2.7^\circ$  more proclination with conventional braces in patients with mandibular irregularity index greater than 2 mm treated with non-extraction in both arches.<sup>25</sup> Scott et al. found  $0.61 \pm 0.34^\circ$  more proclination with conventional braces in patients treated with four first premolar extractions.<sup>26</sup> These differences may be simply because torque on the mandibular incisor brackets was  $-1^\circ$  for the conventional and  $-6^\circ$  for the Damon group. Even so, both studies found that the differences were not statistically significant ( $P < .05$ ). Therefore, the results of our study can be extended to apply to cases treated with self-ligating brackets as well as conventional brackets.

## iii. Class II Elastics

Class II malocclusion affects one third of patients seeking orthodontic treatment.<sup>1</sup> Among orthodontic treatment modalities for class II malocclusion are Class II elastics. One main concern regarding use of Class II elastics is the resulting side effects, such as proclination of mandibular incisors, extrusion of maxillary incisors and mandibular molars, and clockwise rotation of the

occlusal plane and the mandible.<sup>3,27</sup> Class II elastics have also shown to restrain forward maxillary growth, allow forward mandibular growth, decrease overbite and overjet, and move mandibular molars forward to correct the molar relationship.<sup>3</sup> Despite having some influence over skeletal growth, the effects of Class II elastics are primarily dentoalveolar.<sup>3</sup>

The long-term effects of Class II elastics are similar to those produced by other appliances used for Class II malocclusion treatment: headgear, Frankel, and Forsus.<sup>3,28</sup> The belief that functional appliances have mainly skeletal effects is not based on strong scientific evidence. The orthopedic effects produced by functional appliances do not last over the years. Thus, in the long term, there are no significant differences between treatment effects produced by functional appliances and Class II elastics.<sup>29</sup> The Herbst appliance has shown greater skeletal changes than Class II elastics in the short term.<sup>29</sup> This difference is most likely due to the fixed nature of the Herbst appliance, allowing it to act continuously, whereas Class II elastics are a compliance-driven appliance and only act once placed in position.<sup>3,29</sup>

There are no significant data available to determine the most efficient protocols to correct Class II malocclusion with Class II elastics due to most studies omitting sample description such as age, severity of initial Class II malocclusion, and details of the use of Class II elastics (i.e. duration, size, pattern of wear, etc.).<sup>3</sup> Current literature suggests using light forces (mean 2.6 oz) obtained with a 3/16-in diameter elastic and a 0.016 x 0.022-in rectangular SS archwire.<sup>3</sup> Full time usage is recommended due to the appliance being compliance-driven, and correction of end-to-end Class II malocclusion takes an average period of 8.5 months.<sup>3</sup> Soft-tissue changes resulting from use of Class II elastics have not been well-studied.<sup>3</sup> What is well-established is that Class II elastics are effective in treating Class II malocclusions and their effects are predominantly dentoalveolar.<sup>3</sup>



#### **iv. Mandibular Incisor Proclination and Its Consequences**

Fifty percent of people 18 to 64 years of age and 88% of people 65 years of age and older have one or more sites with gingival recession.<sup>30</sup> The presence and extent of gingival recession also increase with age. Periodontal disease and mechanical trauma are believed to be the primary etiologic factors in the development of gingival recession.<sup>30</sup> Orthodontic therapy may also contribute to gingival recession, though this hypothesis has been disputed.<sup>31</sup>

Analysis of 12 studies included in a systematic review suggested that orthodontic treatment results in small detrimental effects to the periodontium, specifically 0.03 millimeters of gingival recession (95% confidence interval [CI], 0.01-0.04) and 0.13 mm of alveolar bone loss (95% CI, 0.07-0.20) when compared to no treatment.<sup>31</sup> More recently, Morris et al found no relationship between mandibular incisor proclination in adolescent orthodontic patients and post-treatment gingival recession.<sup>32</sup> However, almost 60% of the sample in this study was treated with premolar extractions. Mandibular incisors in orthodontic cases treated with extraction of premolars have been associated with increased width of keratinized gingiva post-treatment due to retraction and more lingual positioning of the lower incisors.<sup>6</sup> Nonetheless, reliable studies with adequate comparison groups, follow-up times, focus on adult populations or specific current orthodontic expansion techniques are lacking.<sup>31</sup>

Clinical observation shows that the more prominently a tooth is positioned in an arch, the less keratinized gingiva it will have relative to an adjacent lingually placed tooth.<sup>6</sup> This principle is reinforced by the high frequency of gingival recession observed on the labial aspect of prominent teeth in adults who have not previously received orthodontic treatment.<sup>7</sup> Multiple studies speculate that alveolar bone thinning due to orthodontic intervention may make gingival tissues more susceptible to long-term recession. A significant inverse relationship between width

of the mandibular symphysis and increase in clinical crown height in patients with excessive incisor proclination (more than  $10^\circ$ ) has been found.<sup>7</sup> Furthermore, significantly more number of teeth with recession have been identified in adult patients with excessive proclination of mandibular incisors during orthodontic appliance therapy and at 3 years post-treatment.<sup>7</sup>

Clinical problems associated with gingival recession include cemental sensitivity, loss of periodontal support, increased susceptibility to caries, difficult maintenance of oral hygiene, and unacceptable esthetics.<sup>6</sup> Physical attractiveness is related to favorable self-image, and therefore, social and psychological development.<sup>9</sup> It can be considerably influenced by orthodontic treatment results. According to Holdaway, the ideal position of the lower lip is 0 to 0.5 mm anterior to the H line (harmony line tangent to the soft tissue pogonion and upper lip).<sup>9</sup> According to Steiner, the lower lip should be  $0 \pm 2$  mm from the S line (drawn from the midpoint between subnasale and pronasale to soft tissue pogonion)<sup>33</sup> Regardless of which measure we accept as ideal, lip prominence can be affected by incisor position and has significant effect on perceived attractiveness and desire for surgery.<sup>10</sup> Lower lip prominence also influences perception of chin prominence. In facially convex patients with a retrusive chin, laypeople and orthodontists have ranked an ideal lower lip position as being more attractive than retrusive or protrusive lips.<sup>10</sup> Lip support is determined by the facial surfaces of maxillary incisors, whose position is in turn determined by mandibular incisor position.<sup>4</sup> Excessive proclination of mandibular incisors and resulting recession may not only cause unattractive black triangles, but also lip protrusion and/or an acute mentolabial groove.

Moreover, excessive proclination may predispose to relapse.<sup>25</sup> Mandibular anterior teeth pushed their anterior limit experience lingual pressure from the lower lip as muscular and dental harmony is re-established.<sup>4,8</sup> However, multiple studies also suggest that increase in incisor

irregularity with age is not related to changes in incisor inclination during appliance therapy, but rather, to normal physiologic changes that occur throughout life.<sup>34,35</sup> These include decrease in arch perimeter and mandibular inter-canine width with age. Furthermore, high pre-treatment incisor irregularity has also been implicated as a significant predictor of post-treatment relapse.<sup>35</sup> The amount of influence changes in incisor inclination during treatment have on occurrence of post-treatment incisor irregularity remains undetermined. However, it is generally accepted that a normal relationship of the mandibular incisors to their basal bone (meaning IMPA of 90° and FMIA of 68° when FMA is 22° to 28°) and maintenance of inter-canine width are the most reliable guides to achieving stability of post-orthodontic tooth position.<sup>4,8,35</sup>

## K. Appendix I - IRB Approval and Modification



# IRB MEMO

Research Integrity Office

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### APPROVAL OF SUBMISSION

May 14, 2019

Dear Investigator:

On May 14, 2019, the IRB reviewed the following submission:

IRB ID:	STUDY00019944
Type of Review:	Initial Study
Title of Study:	A retrospective comparison of mandibular incisor inclination changes produced by Class II elastics in adult orthodontic patients treated with fixed appliances versus clear aligners.
Principal Investigator:	Sohyon Kim
Funding:	Name: American Association of Orthodontists Foundation, PPQ #: 1015274
IND, IDE, or HDE:	None
Documents Reviewed:	<ul style="list-style-type: none"> <li>• Kim OFDFA Letter</li> <li>• HIPAA-Waiver-or-Alteration-of-Authorization</li> <li>• Protocol- MK 051019 2</li> </ul>

The IRB granted final approval on 5/14/2019. The study requires you to submit a check-in before 5/12/2022.



# IRB MEMO

Research Integrity Office

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## APPROVAL OF SUBMISSION

April 27, 2020

Dear Investigator:

On April 27, 2020, the IRB reviewed the following submission:

IRB ID:	STUDY00019944	MOD ID:	MOD00026817
Type of Review:	Modification		
Title of Study:	A retrospective comparison of mandibular incisor inclination changes produced by Class II elastics in adult orthodontic patients treated with fixed appliances versus clear aligners.		
Title of modification	A retrospective comparison of mandibular incisor inclination changes produced by Class II elastics in orthodontic patients treated with fixed appliances versus clear aligners.		
Principal Investigator:	Sohyon Kim		
Funding:	Name: American Association of Orthodontists Foundation, PPQ #: 1015274		
IND, IDE, or HDE:	None		
Documents Reviewed:	• Protocol- MK 041420		

The IRB granted final approval on 4/27/2020. The study requires you to submit a check-in before 5/12/2022.

L. Appendix II - Research Data Sheet Tx = treatment, T1 = pre-treatment, T2 = post-treatment, IMPA = incisor to mandibular plane angle.

Sub ject ID	Sub- Grp up	Sex	Start Age (year)	Tx Dureti mn	Tx Type	IR	T1 Class II II (mm)	T2 Class II (mm)	T2-T1 Class II (mm)	Elastic Compliance (Good >45%, (mmar)	Elastic Duratims (mmar)	T1 IMPA (°)	T2 IMPA (°)	T2-T1 IMPA (°)
2	A	M	16.1	18.5	CAT	1.5	2.1	1.1	1.0	good	6.0	84.2	81.3	-2.9
3	A	F	15.3	15.0	CAT	0.9	1.9	0.2	1.7	good	4.0	97.1	92.9	-4.2
4	A	F	13.2	15.5	CAT	2.0	2.3	0.2	2.1	good	12.5	95.5	97.2	1.7
5	A	M	15.7	14.5	CAT	0.4	4.4	3.0	1.3	fair	14.5	109.7	106.0	-3.7
6	A	F	14.4	25.0	CAT	0.8	2.6	0.0	2.6	good	14.5	104.2	103.3	-0.9
7	A	F	16.0	12.0	CAT	1.3	2.5	0.0	2.5	good	4.5	103.4	104.3	0.9
8	A	F	15.5	19.5	CAT	1.0	2.7	0.2	2.5	good	10.5	102.4	96.0	-6.4
9	A	M	15.3	5.0	CAT	1.5	1.0	0.0	1.0	good	1.5	88.5	91.9	3.4
10	A	M	15.7	28.5	CAT	0.4	2.5	0.2	2.3	good	12.5	94.1	96.0	1.9
11	A	M	16.7	13.5	CAT	0.5	1.4	-0.8	2.2	good	13.0	99.8	100.8	1.0
12	B	F	12.9	24.5	CAT	2.1	2.9	0.0	2.9	good	20.5	86.2	97.3	11.1
13	B	M	20.2	9.0	CAT	2.2	1.3	-1.1	2.4	good	9.0	96.8	104.3	7.5
14	B	F	16.1	26.0	CAT	1.3	3.3	-0.7	4.0	good	12.5	94.4	97.2	2.8
15	B	F	12.3	27.0	CAT	3.9	2.7	0.0	2.7	good	19.0	94.5	100.0	5.5
16	B	F	14.7	27.0	CAT	1.4	2.1	-0.6	2.7	good	17.5	95.3	88.1	-7.2
17	B	F	15.3	24.5	CAT	3.9	1.7	-0.6	2.3	good	5.5	96.7	96.2	-0.5
18	B	M	16.1	9.0	CAT	3.9	1.5	0.4	1.1	fair	8.5	110.1	100.2	-9.9
19	B	F	17.4	25.0	CAT	3.9	1.3	0.0	1.3	poor	9.0	97.0	98.1	1.1
20	B	M	13.3	24.5	CAT	3.9	1.4	0.4	1.0	fair	15.0	97.9	105.2	7.3
21	C	F	13.7	24.5	FAT	1.1	2.6	0.0	2.6	good	10.5	97.1	109.8	12.7
22	C	F	14.7	27.0	FAT	1.2	2.0	0.0	2.0	good	12.0	88.4	104.4	16.0
23	C	F	15.7	14.0	FAT	0.5	3.1	1.4	1.7	poor	10.0	88.4	81.5	-6.9
24	C	F	12.2	24.5	FAT	0.8	3.0	0.5	2.5	good	24.5	105.1	104.0	-1.1
25	C	F	13.3	27.0	FAT	0.7	2.4	0.0	2.4	fair	23.5	85.4	94.7	9.3
26	C	F	13.7	14.5	FAT	0.8	1.8	0.0	1.8	good	5.5	84.4	96.2	11.8
27	C	F	15.2	25.0	FAT	1.6	3.1	1.2	1.9	good	22.0	96.9	97.0	0.1
28	C	F	14.6	29.5	FAT	0.7	1.4	-0.4	1.8	good	19.5	95.9	102.5	6.6
29	C	F	15.1	17.5	FAT	1.3	2.5	0.6	1.9	good	14.0	91.1	99.7	8.6
30	C	F	14.0	23.5	FAT	0.9	1.2	0.0	1.2	good	21.0	101.8	106.9	5.1
31	D	F	14.3	17.5	FAT	3.9	2.7	0.0	2.7	good	13.0	89.7	106.5	16.8
32	D	M	12.3	34.5	FAT	3.9	2.0	0.0	2.0	poor	29.0	83.2	87.7	4.5
33	D	F	16.1	22.0	FAT	3.2	4.0	3.0	1.0	fair	19.5	106.6	112.6	6.0
34	D	F	14.2	22.5	FAT	3.8	1.8	0.7	1.1	poor	18.0	88.7	101.5	12.8
35	D	M	13.0	27.0	FAT	2.2	2.9	0.8	2.1	fair	19.0	82.7	89.5	6.8
36	D	M	13.2	26.0	FAT	3.9	1.5	0.0	1.5	poor	9.0	97.1	100.6	3.5
37	D	F	14.2	24.0	FAT	2.1	1.2	0.0	1.2	good	10.0	85.7	95.0	9.3
38	D	M	15.0	12.5	FAT	2.7	3.1	1.6	1.5	fair	9.0	101.1	102.1	1.0
39	D	M	13.3	31.5	FAT	2.5	1.2	0.0	1.2	fair	25.0	92.5	101.9	9.4
40	E	M	14.0	31.5	CAT	0.5	3.4	0.0	3.4	good	13.0	94.6	93.1	-1.5
41	E	F	15.4	22.5	CAT	0.5	3.2	0.0	3.2	good	4.5	83.0	86.1	3.1
42	E	M	14.2	23.0	CAT	0.5	3.6	0.5	3.1	good	5.0	102.2	95.0	-7.2
43	E	M	14.4	18.0	CAT	1.7	4.8	0.4	4.4	good	17.5	96.4	102.2	5.8
44	E	F	15.0	23.0	CAT	0.9	2.0	-1.3	3.3	good	4.5	105.3	95.2	-10.1
45	E	M	14.0	27.5	CAT	1.2	2.9	-0.5	3.4	good	26.0	95.6	94.8	-0.8
46	E	F	14.2	32.0	CAT	1.8	3.9	-0.5	4.4	good	31.0	99.7	102.0	2.3
47	F	F	13.0	22.5	CAT	3.1	3.1	0.0	3.1	good	21.0	100.0	102.1	2.1
48	F	F	15.1	10.0	CAT	2.2	3.6	-0.5	4.1	good	5.5	99.9	104.4	4.5
49	F	M	14.5	18.5	CAT	3.9	1.2	-2.0	3.2	poor	17.5	94.0	90.7	-3.3
50	F	M	17.7	22.5	CAT	2.9	4.8	0.4	4.4	good	10.0	92.3	85.1	-7.2
51	F	F	16.5	16.0	CAT	3.9	3.1	0.0	3.1	good	5.0	95.2	95.9	0.7
52	F	M	13.4	23.0	CAT	2.5	3.2	-1.0	4.2	fair	8.5	97.7	98.4	0.7
53	G	M	14.4	24.0	FAT	0.8	3.2	0.0	3.2	fair	15.0	97.7	97.1	-0.6
54	G	F	13.2	23.5	FAT	0.5	2.6	-0.7	3.3	good	10.0	100.2	97.5	-2.7
55	G	M	14.6	30.0	FAT	0.6	4.0	0.5	3.5	poor	13.5	92.7	94.0	1.3
56	G	F	12.2	24.5	FAT	0.4	2.9	-1.2	4.1	fair	19.5	95.7	93.2	-2.5
57	G	F	13.1	28.0	FAT	0.7	3.1	0.0	3.1	good	26.0	89.4	95.8	6.4
58	G	F	12.8	22.5	FAT	0.6	3.2	0.0	3.2	good	20.0	103.5	104.3	0.8
59	G	F	12.4	21.0	FAT	0.7	2.4	-0.3	2.7	good	16.5	98.0	96.6	-1.4
60	G	M	14.2	25.0	FAT	1.1	4.2	0.0	4.2	good	25.0	85.1	94.1	9.0
61	G	F	13.3	42.5	FAT	0.7	3.1	0.0	3.1	fair	19.5	101.2	102.6	1.4
62	H	M	14.6	23.0	FAT	2.2	3.3	0.0	3.3	fair	9.5	89.1	92.0	2.9
63	H	M	16.8	22.5	FAT	2.8	1.0	-2.1	3.1	good	20.0	108.0	114.3	6.3
64	H	M	13.6	19.0	FAT	3.9	3.9	0.6	3.3	fair	15.5	95.7	98.5	2.8
65	H	F	13.6	24.5	FAT	3.6	4.7	1.6	3.1	good	24.5	104.7	106.4	1.7
66	H	M	14.7	25.0	FAT	3.9	3.7	0.0	3.7	fair	20.0	89.0	100.8	11.8
67	H	M	15.1	26.0	FAT	3.9	3.9	0.8	3.1	good	26.0	97.1	108.4	11.3