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Original Article

Assessment of dental, skeletal, and soft tissue changes following mandibular advancement with Invisalign in skeletal Class II

Hassan Al Subaie, Ghassan Alturki, Fahad Alsulaimani, Salma Ghoneim, Hosam Baeshen *

Orthodontic Department, Faculty of Dentistry, King Abdulaziz University, Jeddah, Makkah Region 21589, Saudi Arabia

A R T I C L E I N F O

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A B S T R A C T

Objective: This study evaluated the dentoskeletal and soft tissue changes for Class II malocclusion patients treated with Invisalign clear aligners with mandibular wings (IAMW).

Methods: This retrospective study included 50 skeletal Class II patients treated with Invisalign clear aligner with mandibular wings. Records of 20 subjects were collected from the AAOF Legacy Collection (The Case Western Bolton Brush Growth Study) and were used as a control. The dental, skeletal, and facial soft tissue changes were assessed by digitizing and analyzing lateral cephalograms using Dolphin Imaging software (version 11.95 Premium; Dolphin Imaging & Management Solutions, Chatsworth, Calif). Paired t-tests and independent t-tests were used to assess the changes before and after and to compare between the IAMW and control groups.

Results: The different measurements of the maxilla have shown that IAMW effect on the maxilla included minimal, non-significant retraction compared to the control group. The SNB and mandibular base position increased by 1.17° (±2.63) and 3.79 (±8.13), respectively. The mandible advanced significantly in the treatment group compared to the control group. Dentally, the lower incisors tipped slightly buccally, but the change was not significant ($p > 0.05$). The facial convexity angle decreased by 1.16° (±4.36).

Conclusion: Invisalign clear aligner with mandibular advancer wings was able to correct the Class II malocclusion. This correction was mainly skeletal with some dental changes. This device can be used to address the growth modification problem in Class II malocclusion at the same time as addressing the other occlusal problems.

1. Introduction

1.1. Prevalence of Class II malocclusion

Class II malocclusion is a dentofacial anomaly commonly encountered in the clinic. A systematic review search about the global disruption of malocclusion among different populations found that Class II malocclusion accounts for almost 20%, ranging from 1.6% to 63% among different populations (Alhammadi et al., 2018). In a recent systematic review, Class II malocclusion counted for 5% during the primary dentition stage and increased to 18% during the permanent dentition of the total Saudi population (Almotairy and Almutairi 2022).

1.2. Timing of Class II growth modification correction

Starting treatment early in the prepubertal period is necessary in case of severe skeletal Class II disharmony to prevent trauma to the teeth. Also, it can provide better skeletal and soft tissue morphological growth. On the other hand, commencing treatment during pubertal growth spurt has the advantage of reducing the retention in which fixed orthodontic treatment phase to finalize the treatment and provide stable occlusion can be started directly after the first phase and maximize the benefits of the increased growth of the condyle at this stage (Pancherz and Hagg 1985). According to Pancherz, the stability of treatment outcomes largely depends on the age at the time commencing the treatment, which would be more stable when started at pubertal spurt (Pancherz 1997).

1.3. How functional appliances affect growth

Controversies still exist on whether functional appliances can produce actual growth of the mandible or change the position of the mandible and TMJ components, allowing the surrounding structures to

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* Corresponding author at: Orthodontic department, King Abdulaziz University, Jeddah, Makkah Region 21589, Saudi Arabia.
E-mail addresses: has.1992@hotmail.com (H. Al Subaie), galturki@kau.edu.sa (G. Alturki), falsulaimani@kau.edu.sa (F. Alsulaimani), shghoneim@kau.edu.sa (S. Ghoneim), habaeshen@kau.edu.sa (H. Baeshen).

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accommodate this new position. Varying degree of increase in mandibular length and skeletal changes was reported by many researchers after the use of functional appliances in comparison to a control group (McNamara et al., 1985, McNamara et al., 1990, O'Brien et al., 2003, Ishaq et al., 2016, Zymperdikas et al., 2016).

Recently, Align Technology (Align Technology, San Jose, California, United States) has introduced a clear aligner device with wings (inclined planes in the upper and lower trays) to advance the mandible.

To the best of our knowledge, thus far, no research has studied the effect of this treatment modality on the skeletal, dental, and facial soft tissues compared to a non-treated control group. This study aims to evaluate the dental, skeletal, and soft tissue effect of the Invisalign aligner device with mandibular wings (IAMW) using lateral cephalograms.

2. Materials and methods

The study was conducted at the Faculty of Dentistry, King Abdulaziz University. Ethical approval was obtained from the Research Ethics Committee (No. 337–11-21).

Sample size calculation was done using G-power software, version 3.1. From a similar previous study with a similar effect of the device being tested, a sample size of 18 was found adequate to obtain a Type-I error rate of 0.05 and a power of 95% (based on a 3.5 mm detectable difference and 2.8 mm standard deviation) (O'Brien et al., 2003).

Retrospective records for 50 patients who underwent Invisalign clear aligners with mandibular advancer wings (IAMW) treatment were collected from the Invisalign gallery and private practices. Records of 20 untreated subjects with skeletal Class II malocclusion were collected from the AAOF Legacy Collection (The Case Western Bolton Brush Growth Study) and were used as controls. The IAMW are removable aligners with precision wings incorporated into aligners designed to force the patient's mandible forward (Fig. 1).

The records included in the treatment and the control groups were for patients still in their growth spurt, with skeletal and dental Class II malocclusion, no previous orthodontic treatment, no dentofacial anomalies, and should have complete records before and after the treatment. Records with any artifact that might affect the analyses, incomplete data, or cases that ended with extraction were excluded. The control group was matched for age and duration of the second cephalograms.

Fig. 1. Invisalign clear aligners with mandibular wings.

Lateral cephalograms were used to evaluate the effect of the IAMW, with radiographs taken before starting the treatment and after obtaining Class I occlusion and normal overjet.

The dental, skeletal, and facial soft tissue changes were assessed by digitizing and analyzing the lateral cephalograms using the Dolphin Imaging software (version 11.95 Premium; Dolphin Imaging & Management Solutions, Chatsworth, Calif). Linear and angular measurements for the mandibular and maxillary position in relation to the cranial base, length of maxilla and mandible, and incisors in relation to the related jaw were analyzed (Table 1). The linear and angular measurements for the dental and skeletal changes were included from multiple analyses (Downs 1948, Steiner 1953, Ricketts et al., 1976, McNamara 1981, McNamara 1984, Pancherz 1984) (Fig. 2). Legan-burstone (Legan and Burstone 1980) and Holdaway (Holdaway 1983) analyses were used for the facial soft tissue changes.

Descriptive statistics included means and standard deviations for the continuous variables and frequencies for categorical variables. Bivariate analysis included paired t-tests to assess the changes in the values before and after treatment and independent sample t-tests to compare the means of the study and control group. Data will be analyzed using IBM SPSS statistical software (IBM Corp. released 2011. IBM SPSS statistics for Macintosh, version 20.0 Armonk, NY: IBM Corp.). The significance

Table 1
The skeletal, dental, and soft tissue cephalometric variables.

Skeletal	
SNA°	The sagittal relation of the maxilla to the anterior cranial base
SNB°	The sagittal relation of the mandible to the anterior cranial base
ANB°	The relationship between maxilla and mandible in relation to the anterior cranial base
Wits (mm)	The projection of point A and B on the functional occlusal plane
Maxillary base position (mm)	Horizontal distance from a line through Sella and perpendicular to FH to the ANS
Mandibular base position (mm)	Horizontal distance from a line through Sella and perpendicular to FH to pogonion
A point N perpendicular to FH (mm)	Indicates the position of the maxilla in relation N-perpendicular line.
Pg point N perpendicular to FH (mm)	Indicates the position of the mandible in relation N-perpendicular line.
Condylion to point A (mm)	Midface length
Condylion to Gnathion (mm)	Length of the mandible
Go-Gn (mm)	Length of the body of the mandible
Co-Go (mm)	Length of the ramus of the mandible
Mandibular plane angle°	in relation to the cranial base
Palatal plane°	Palatal angle in relation to the mandibular plane
Dental	
Overjet (mm)	
Overbite (mm)	
Upper incisor to palatal plane (U1-PP) °	Inclination of the upper incisors in relation to the palatal plane.
Maxillary incisors position (H) (mm)	Horizontal distance from a line through Sella and perpendicular to FH to the tip of upper incisor.
Maxillary molar position (H) (mm)	Horizontal distance from a line through Sella and perpendicular to FH to the mesial surface of the upper first molar.
Mandibular incisor position (H) (mm)	Horizontal distance from a line through Sella and perpendicular to FH to the tip of lower incisor.
Mandibular molar position (mm)	Horizontal distance from a line through Sella and perpendicular to FH to the mesial surface of the lower first molar.
IMPA°	Lower incisors inclination in relation to the mandibular plane
Soft tissue	
G-Sn-Pog' 1	Facial convexity angle
Sn-Gn'/c-Gn' 1	Lower vertical height–depth ratio (%)
Cm-Sn-Ls 1	Nasolabial angle
Ls to E-plane-Pog' 1	Upper lip protrusion (mm)
Li to E-plane-Pog'1	Lower lip protrusion (mm)
Si to Li-Pog' 1	Mentolabial sulcus depth

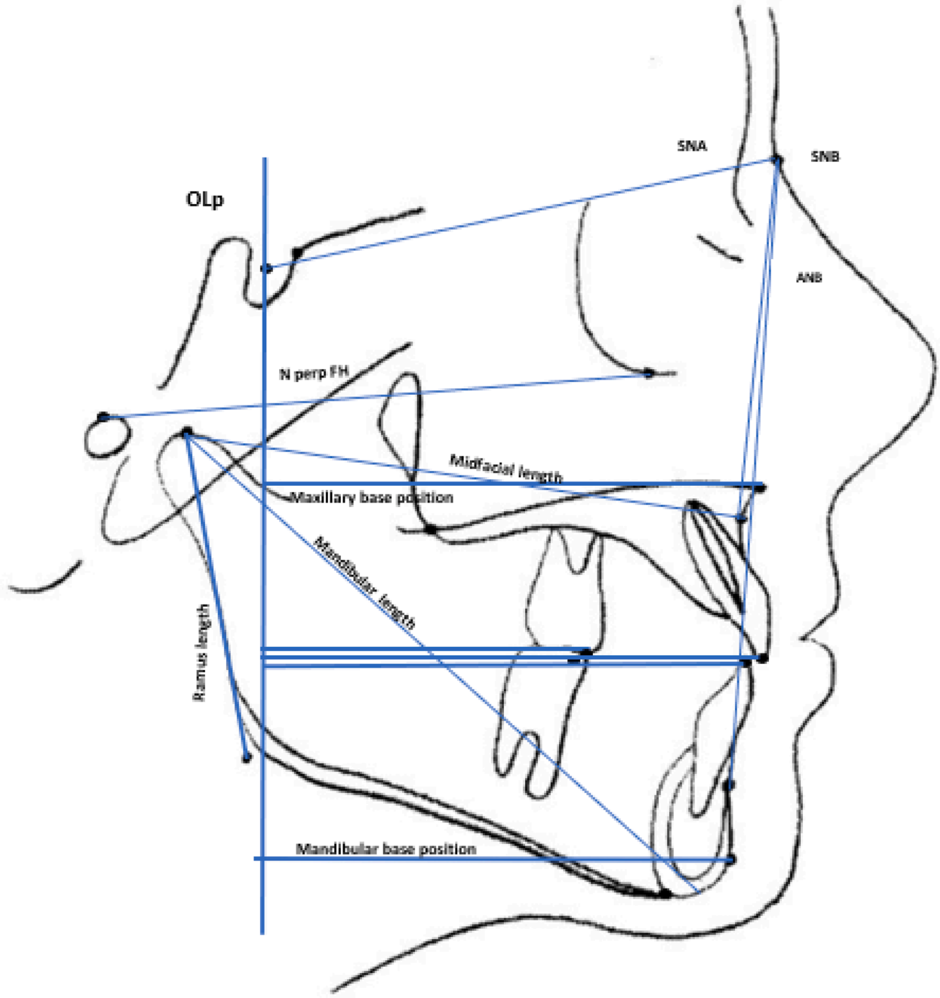

Fig. 2. Linear and angular measurments to assess the changes.

level was set at α = 0.05. To evaluate intra-examiner repeatability, 18 random cephalograms were analysed one month after the first analysis, and readings were compared using the Intraclass Correlation Coefficient test.

3. Results

The total subjects that were enrolled in the analysis were 70 patients. Thirty-four were females (48.6%), and 36 were males (51.4%). The mean age of the treatment group was 11.98 (±2.18), while for the control group, it was 11.75 (±1.59), and we found that 62.9 % of the patients were younger than 12 years of age. The mean treatment duration was 18.38 months (±5.05), while for the control group, the mean follow-up time between the radiographs was 19.2 (±9.85) (Table 2).

The means and standard deviation of skeletal, dental, and soft tissue changes for the IAMW and control groups are shown in Table 3. The position of the maxilla did not change significantly between the IAMW and control group.

The mandibular measurements showed significant improvement occurred when compared to the control group. The SNB and mandibular base position increased significantly, 1.17° (±2.63), P = 0.01, and 3.79 mm (±8.13), P = 0.003, respectively. Also, when the mandible was measured from Pogonion to N perpendicular to FH, a mean difference of 1.98 mm more in the treatment group than the control, and this difference was statistically significant (P = 0.02). The mandibular length (Condylion to Gnathion) increased by 5.75 mm (±15.23) in the IAMW group, while for the control group increased by 2.73 (±4.73); however, the difference was not significant (P = 0.21).

Table 2
Descriptive statistics for the participants' age and gender.

	Gender		Age category		Age/gender distribution			
	Males	Females	≤ 12 years	> 12 years	Males ≤ 12 years	Males > 12 years	Females ≤ 12 years	Females > 12 years
IAMW	23	27	33	17	14	9	19	8
	46.0%	54.0%	66.0%	34.0%	28.0%	18.0%	38.0%	16.0%
Control	13	7	11	9	8	5	3	4
	65.0%	35.0%	55.0%	45.0%	40.0%	25.0%	15.0%	20.0%
Total	36	34	44	26	22	14	22	12
	51.4%	48.6%	62.9%	37.1%	31.4%	20.0%	31.4%	17.1%
Chi-Square	0.15		0.39		0.32			

Table 3
Means (±Standard Deviation) of the IAMW and control groups and the difference between the two groups.

	Mean (±SD)		Difference	P-value
	IAMW	Control		
Age	11.98 ± 2.18	11.75 ± 1.59	0.23	0.63
Duration	18.38 ± 5.06	19.2 ± 9.85	0.82	0.73
SNA°	−0.48 ± 2.44	−0.57 ± 1.55	−0.09	0.87
SNB°	1.17 ± 2.63	−0.04 ± 1.22	1.21	0.01
ANB°	−1.66 ± 1.45	−0.51 ± 0.86	2.18	0.001
Wits mm	−3.44 ± 2.71	0.29 ± 0.99	3.73	0.001
Maxillary base position mm	1.24 ± 6.49	0.04 ± 2.69	1.20	0.28
Mandibular base position mm	3.79 ± 8.13	−0.44 ± 3.49	4.23	0.003
A point N perpendicular to FH mm	−0.64 ± 1.74	−0.81 ± 2.12	1.45	0.77
Pg point N perpendicular to FH mm	1.28 ± 3.56	−0.7 ± 3.01	1.98	0.02
Condylion to point A mm	1.10 ± 7.87	0.83 ± 3.52	0.27	0.84
Condylion to Gnathion mm	5.74 ± 15.23	2.73 ± 4.73	3.01	0.21
Go-Gn mm	2.99 ± 7.28	1.76 ± 4.54	1.23	0.4
Co-Go mm	2.41 ± 6.51	2.04 ± 4.57	0.37	0.78
Overjet mm	−3.03 ± 2.54	−0.08 ± 1.18	2.95	<0.001
Overbite	−1.13 ± 2.87	−0.46 ± 1.3	0.67	0.184
Upper incisor to palatal plane°	−0.37 ± 12.58	0.63 ± 3.27	1.00	0.606
Maxillary incisors position (H)	0.78 ± 7.08	0.19 ± 2.93	0.59	0.624
Maxillary molar position (H)	2.03 ± 5.59	1.34 ± 2.79	0.69	0.491
Mandibular incisor position (H)	4.04 ± 7.35	0.31 ± 2.6	3.71	0.003
Mandibular molar position	3.87 ± 6.42	0.94 ± 2.54	2.93	0.008
IMPA°	1.53 ± 7.14	0.11 ± 3.66	1.42	0.278
MPA°	−0.41 ± 2.91	−0.09 ± 1.96	0.5	0.597
Palatal plane°	−0.76 ± 1.89	−0.41 ± 2.20	0.35	0.533
Facial convexity angle°	−1.16 ± 4.36	−0.17 ± 3.45	1.33	0.320
Lower vertical height–depth ratio	−0.26 ± 4.58	0.03 ± 0.76	0.29	0.663
Nasolabial angle°	20.37 ± 12.52	−0.76 ± 11.13	21.00	0.233
Upper lip protrusion	−1.91 ± 1.67	−0.45 ± 2.12	2.36	0.010
Lower lip protrusion	−0.94 ± 1.99	0.03 ± 1.66	0.97	0.045
Mentolabial sulcus depth	−2.82 ± 14.89	0.54 ± 2.71	3.36	0.131

Dentally, the position of the upper incisors did not change significantly between both groups. As for the lower incisors, they tipped buccally in both groups, but again, the change was not significant. Overjet decreased significantly in the treatment group with a mean of 3.03 (SD = 2.54), while in the control group, it decreased only by 0.08 (SD = 1.18). The mean difference between the two groups is 2.95, which was statistically significant (P = 0.001).

Soft tissue changes have shown some improvement. The facial convexity angle decreased by 1.16 (±4.36), and the nasolabial angle increased, but these changes were not significant ($p > 0.05$). However, the upper lip retruded significantly (Table 3).

Fig. 3. shows the tracing superimposition with changes in the treatment and control group over the follow-up period.

4. Discussion

This study is the first to report the dentoskeletal and soft tissue effects of using IAMW in Class II malocclusion patients compared to a no-treatment control group by analyzing lateral cephalograms before and after. The functional appliances generally act by posturing the mandible in a more forward position and stimulating the growth of the condyles, along with the changes on the teeth to bring the occlusion to normal (Baccetti et al., 2000, Antonarakis and Kiliaridis 2007). Twin block, for instance, acts by positioning the mandible in a favorable anterior direction, stimulating the growth and correcting the Class II malocclusion (Mills and McCulloch 1998). This study reported many significant skeletal, dental, and soft tissue findings. A decrease in the overjet, minimal flaring of the lower incisors, correction of the molar relationship, and an improvement in the position and growth of the mandible were reported in this study. Both dental and skeletal correction aided in the treatment results.

The IAMW demonstrated a minimal, non-significant effect on the maxilla. Variables from different analyses measured changes in the maxilla. Those variables showed no significant difference between the two groups. This finding was observed similarly in other studies used other functional appliances for Class II correction in which the position of the maxilla did not add to the correction of skeletal Class II malocclusion (Tulloch et al., 1998, Toth and McNamara 1999, Baccetti et al., 2000, O'Brien et al., 2003). One possible explanation for this minimal change in the maxilla could be due to the dentoalveolar changes that might obstruct the maxillary restriction effect(Antonarakis and Kiliaridis 2007). Another probable reason is that the retruclination of the upper incisors produced by the clear aligner might affect the A point, which might affect the other cephalometric measurements of the maxilla.

Different measurements from different analyses also evaluated the mandibular skeletal effect reported in this study. Compared to the control group, we found significant skeletal improvement in the mandibular dimensions and anteroposterior position over the treatment duration. Both SNB and mandibular base position improved significantly. The length of the mandible, ramus, and body of the mandible all showed a significant increase. Mills et al. 1998, reported an increase of 6.5 mm in the mandibular length (condylion to gnathion) after using a twin block in comparison to only a 2.3 increase in the control group; those findings are similar to our results (Mills and McCulloch 1998). Many researchers have reported that most of the skeletal effect in correcting Class II malocclusion treated with twin block was almost confined to the lower jaw (Lund and Sandler 1998, Baccetti et al., 2000, Mills and McCulloch 2000). The skeletal mandibular effect is brought about by the condylar growth and the translation of the temporal fossa in response which was reported after using different functional appliances (Baume and Derichsweiler 1961, Charlier et al., 1969, McNamara and Carlson 1979, Williams and Melsen 1982, Woodside et al., 1983, Rabie et al., 2003, Voudouris et al., 2003).

On the other hand, some have reported that overjet reduction is achieved mainly because of dentoalveolar changes(Lund and Sandler 1998). However, we should note the large deviation, meaning that not all patients responded well to the treatment, which might be because of the soft tissue response of each individual. Those findings come in agreement with the results of other studies that used different functional appliances (Falck and Frankel 1989, Livieratos and Johnston 1995, Toth and McNamara 1999, Baccetti et al., 2000, O'Brien et al., 2003, Antonarakis and Kiliaridis 2007).

The overjet reduction in our study was statistically significant. The reduction demonstrates that IAMW can reduce the amount of overjet to

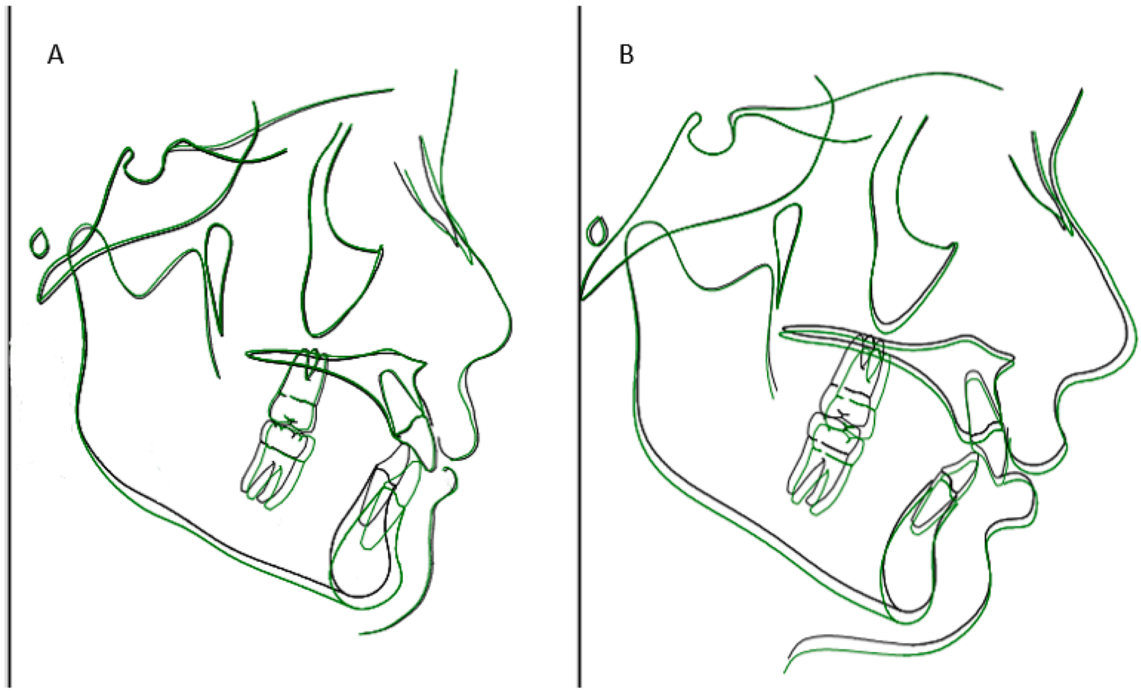

Fig. 3. Tracing superimposition showing the changes over the treatment period. (A, treatment group treatment changes and B, control group growth changes).

a clinically significant level. In conjunction with the skeletal effect, the overjet dentoalveolar correction was achieved by a combination of palatal tipping of the upper incisors and labial tipping of the lower incisors.

The soft tissue changes demonstrated in our study involved a decrease in the soft tissue convexity, an increase in the nasolabial angle, and an improvement in the lip position. The nasolabial angle measured from the tip of the nose, subnasale, to the upper lip, increased. Our study's findings agree with the results of Morris et al. (Morris et al., 1998), and Varlik et al. (Varlik et al., 2008) who used other functional appliances.

An important factor that might affect the treatment results is the patient's compliance and the amount of wear time of functional appliances. This could be why many orthodontists move to fixed functional appliances. With IAMW, the patients are assumed to wear the aligner tray for at least 20 h a day, and this might be the reason for the main skeletal effect of treating Class II malocclusion. The well-known aesthetic advantage of Invisalign clear aligners might aid in patient acceptance and wear time of the aligners.

This study had a limitation of selection bias in which the records of the participants with the previously mentioned inclusion criteria were conveniently collected from different clinics. Thus, other confounders might affect the inference of this study. Also, the records of the control group collected from the AAOF Legacy Collection differ from those in the treatment group. Recruiting participants with similar backgrounds and characteristics for both groups would add more value to the conclusion.

5. Conclusions

The findings of this study can be summarized in the following points:

- Growing patients with skeletal class II malocclusion showed significant correction using the mandibular advancement feature with Invisalign clear aligners.
- This correction was achieved mainly by skeletal forward projection in the mandible.
- The overjet was reduced significantly by the skeletal change and the dentoalveolar tipping of the upper incisors and labial tipping of the lower incisors.
- Soft tissue facial convexity, nasolabial angle, and upper and lower lip position were significantly improved.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.sdentj.2023.09.005.

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