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### Cephalometric evaluation of the short-term skeletal, dental and soft tissue changes in growing subjects with class II division 1 malocclusion treated with Invisalign® mandibular advancement

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**Aim:** The aim of this study was to evaluate the short term skeletal, dental and soft tissue changes in growing subjects with Class II division 1 malocclusion treated with Invisalign mandibular advancement.

**Materials and methods:** This was a retrospective study conducted on 15 growing subjects with Class II Division 1 malocclusion treated with Invisalign® Aligners with Mandibular Advancement Feature. Pre-treatment and post-treatment lateral cephalograms were collected from the Online Align Global Gallery and were traced using Dolphin Imaging Software. Paired Sample t-test was used to compare the measurements before and after treatment.

**Results:** The average number of aligners used was 63.8 maxillary aligners and 61.47 mandibular aligners within a mean duration of 17.73 months treatment time. Statistically significant differences were observed in the ANB angle, facial convexity, and SNB angle in direction of Class II correction. Statistically significant changes were also seen in the interincisal and nasolabial angle. Counterclockwise rotation of the mandible was evident with decrease of mandibular plane to SN angle (mean difference -1.11 degrees; CI, -2.18 – -0.04 degrees). The upper incisors were retroclined (mean difference -7.03 degrees; CI, -10.94 – -3.11) while the lower incisors showed no significant changes after treatment.

**Conclusions:** Invisalign® mandibular advancement was effective in treating mandibular retrusion with improvement in the anteroposterior jaw relationship, with good control of the vertical component and lower incisors inclination, and improvement of facial convexity and upper lip protrusion.

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## Introduction

Class II malocclusion is a commonly encountered malocclusion with prevalence of 26% in the Caucasian population, caused by retrusion of the mandible in about 80% of the cases, rather than maxillary protrusion.<sup>1</sup> During the active growth stage (pubertal growth spurt), myofunctional appliances could be used to improve the skeletal relationship.<sup>2</sup> Myofunctional appliances primarily affects the growing individual's jaw relation by causing changes in condylar and sutural areas, and by correcting the underlying muscular imbalance, altering soft tissue tone and oronasopharyngeal complex function.<sup>3</sup>

Many functional appliances have been used over the past years. These can be fixed functional appliances such as the Herbst, or removable functional appliances such as Andersen's activator and the Twin Block appliances.<sup>3</sup> Skeletal treatment outcome of functional appliances is manifested by enhancement of total mandibular length and moving point B more anteriorly.<sup>4</sup> While the main dentoalveolar effect of functional appliances is teeth tipping which results in 70% reduction of the overjet.<sup>5</sup> Additionally, clockwise rotation of the occlusal plane is enhanced through inhibiting the eruption of the maxillary posterior teeth while allowing the mandibular posterior teeth to erupt occlusally and forwards, contributing to the improvement of the Class II relation.<sup>6</sup> The efficacy of the long term effects of early treatment of Class II malocclusion is controversial. According to a study performed by Keski-Nisula et al. (2003) these long-term effects seem to be unmaintained.<sup>7</sup>

Since 1997, Invisalign clear aligners have become widely used in the orthodontic practice. Recently, advancement of the mandible was added as a feature in Invisalign® Aligners for the correction of skeletal Class II in growing patients. Similar to the Twin Block appliance, mandibular advancement is achieved by lateral inclined planes that are positioned posteriorly in the aligners.<sup>8</sup> These are called precision wings and result in an advanced position of the mandible upon closure of the mouth. This reduces both, the use of interarch elastics, and the treatment time by the correction of the jaw relation along with alignment of the teeth rather than the conventional approach of first treating the Class II relationship followed by dental alignment in a later stage.<sup>9</sup>

Blackham in 2020 performed a retrospective study to measure the effects of using Invisalign® mandibular advancement for subjects with Class II malocclusion.<sup>10</sup> They reported that the ANB Angle and overjet were significantly decreased following treatment, together with improvement of the skeletal and profile convexity by an effect on both the skeletal and dental components of the malocclusion. These findings are consistent with those of a study later conducted by Caruso et al. (2021)<sup>11</sup> and a study conducted by Ravera et al. (2021)<sup>12</sup>, both of which reported that Invisalign® mandibular advancement improved facial convexity and the Wits appraisal. Therefore, treatment of the Class II malocclusion with Invisalign® mandibular advancement, like with all other functional appliances, appears to be achieved through both skeletal and dental changes.

Wu et al. (2023) concluded that Invisalign® Mandibular Advancement helps to establish a proper occlusion together with alignment and leveling of the teeth with advanced positioning of the mandible and distalization of the maxillary molars, which may shorten total treatment time for treatment of Class II malocclusion, without significant proclination of the lower incisors.<sup>13</sup> Standard treatment with Invisalign® Aligners with Mandibular Advancement Feature consisted of multiple mandibular posturing of approximately 2 mm for each jump, with about 8 aligners for each incremental posturing in a forward position, depending on the severity and complexity of the case. Incremental and gradual advancement of the mandible can be more comfortable to the patient than a single advancement to an edge-to-edge incisor relation from the beginning of treatment.

There is still controversy regarding the treatment outcome following the use of Invisalign® mandibular advancement; some studies reported the appliance can help in the treatment of Class II malocclusion with retrusion of the mandible.<sup>3,8</sup> The correction of the malocclusion, like with all functional appliances, is caused by an effect on the bone as well as the teeth. Other studies didn't report significant skeletal and dental results.<sup>9</sup> Accordingly, we conducted the current study with the aim to evaluate the skeletal, dental and soft tissue effects in growing subjects with Class II division 1 malocclusion treated with Invisalign® (Align Technology, San Jose, CA, USA) with the mandibular advancement feature.

## Materials and methods

In this retrospective study, all 67 cases included in the Online Align Global Gallery (Align Technology™, San José, CA, USA) treated with mandibular advancement were screened for inclusion in the study. Cases were selected based on the following inclusion criteria: Skeletal Class II malocclusion characterized by retrusion of the mandible ( $SNB < 78^\circ$ ,  $ANB > 4^\circ$ ), Class II / Division I malocclusion, mild crowding in the upper and lower arches ( $< 4\text{mm}$ ), growing patients based on the Cervical Vertebrae Maturation Index: CVM 2, CVM3 and CVM4, and patients should be treated based on non-Extraction treatment modality. Subjects were excluded if the records were of poor quality, or if they show signs of severe bone loss, severe dental or skeletal vertical and transverse anomalies as well as subjects with craniofacial anomalies or syndromes. The final sample consisted of 15 subjects (10 females and 5 males) with mean age of 11.5 years (SD 2.35).

Sample size calculation was based on the study by Caruso et al. (2021) which reported that the mean difference in the response of matched pairs for measurement of ANB angle is equal to 3.4 degrees with a standard deviation 1.9 degrees. (11) G\*power software (Universitat Dusseldorf, Dusseldorf, Germany) was used for sample size calculation. Sample size of at least 5 pairs of subjects would be required to have a study power of 80% power and a significance level (alpha) of 0.05.

## Mandibular Advancement Invisalign® Protocol

All subjects received the Invisalign® Aligners with Mandibular Advancement for the treatment of mandibular retrognathia. The

mean number of aligners used was 63.8 maxillary aligners and 61.47 mandibular aligners within a mean duration of 17.73 months treatment time (Table 1).

Table 1. Sample Demographic Characteristics describing mean chronological age, pre-treatment readings, treatment time and number of treatment aligners.

Sample Demographic characteristics	Mean	SD
Age	11.6	2.35
Pre-treatment SNA (°)	81.80	4.69
Pre-treatment SNB (°)	76.89	4.01
Pre-treatment ANB (°)	4.92	2.01
Total treatment time (Month)	17.73	4.2
No. of Maxillary aligners	63.8	11.63
No. of Mandibular aligners	61.47	12.88

Patients were treated with Invisalign® mandibular advancement feature until a Class I molar relationship was obtained. Three patients had a limited phase of treatment prior to undergoing the mandibular advancement. The three qualifying factors for a pre-advancement phase of treatment were (1) the presence of a deep overbite of 8mm or more where some leveling of the curve of Spee would be accomplished prior to the first advancement jump, (2) the requirement of upper arch expansion prior to the advancement if there was a posterior crossbite, and (3) if the upper molars were severely rotated, this would be corrected prior to the advancement phase.

During the advancement phase, precision wings were added into the aligners. These are designed to posture the mandible forward when the patient closes his mouth. This is similar to the principle employed in

other functional appliances. In addition, parallel to the incremental advancement, alignment of the upper and lower anterior teeth was performed. The curve of Spee was also leveled by intrusion of the lower anterior teeth. In the post advancement phase of treatment, any remaining Class II relationship would be corrected through upper molar sequential distalization or Class II elastics. Treatment was completed once the buccal relationship had been corrected to a Class I occlusion with the teeth well aligned and overbite and overjet within normal limits.

### Cephalometric Analysis

For all patients, lateral cephalograms were collected from the Online Align Global Gallery (Align Technology™, San José, CA, USA) taken at the pre-treatment and post-treatment stages of treatment. The digital radiographs were imported into Dolphin Imaging Software (Chatsworth, CA, USA). To account for magnification, the cephalometric radiographs were calibrated using the ruler to enable accurate measurements to be done. Tables 2 and 3 show the cephalometric landmarks and measurements used in the study (Figure 1).

In addition, superimposition of the lateral cephalograms were done (superimposing on SN, registered at Sella) to evaluate the overall treatment changes. Figure 2 shows the overall superimposition of one case that was treated by the Invisalign® Aligners with Mandibular Advancement Feature.

Table 2. Cephalometric landmarks definitions and abbreviations.

Landmark	Abbreviation	Definition
Porion	Po	Most superior point of the external auditory meatus.
Orbitale	Or	Lower most point in the lower margin of bony orbit that may be palpated under the skin.
Sella	S	Geometric center of the pituitary fossa of the sphenoid bone.
Nasion	Na	Intersection of the internasal suture with the nasofrontal suture in the midsagittal plane.
Basion	Ba	Lowest point on the anterior border of the foramen magnum.
Soft tissue Glabella	G'	Most anterior point of the soft tissue frontal bone profile. (Krogman & Sassouni, 1957).
Soft tissue Nasion	N'	Soft tissue profile's most concave point at the bridge of the nose.
Subnasale	Sn	Point at which the nasal septum merges, in the midsagittal planes, with the human's upper lip.
Soft tissue A-Point	A'	Most concave point between the subnasale and the anterior point of the upper lip.
Upper Lip	UL	Most anterior point on the curve of the upper lip.
Lower Lip	LL	Most anterior point on the curve of the lower lip.
Soft tissue B-Point	B'	Most concave point between the upper lip and the soft tissue chin.
Soft tissue Pogonion	Pog'	Point on the anterior curve of soft tissue chin.
Soft tissue Gnathion	Gn'	The midpoint between the most anterior and inferior points of the soft tissue chin in the midsagittal plane (Spiro J. Chacones, 1980).
Soft tissue Menton	Me'	The most inferior point in the soft tissue chin.
B-Point	B	Most posterior point in the concavity along the anterior border of the symphysis.
Pogonion	Pog	Most anterior point on the midsagittal symphysis.
Anatomical Gnathion	Gn	Midpoint between the most anterior and inferior point on the body of the symphysis, along the midsagittal plane (Brodie, 1941).
Menton	Me	Most inferior point of the chin along the body of the symphysis, along the midsagittal plane.
Gonion	Go	Point on the curvature of the mandibular angle located by bisecting the angle formed by lines tangent to the posterior ramus and inferior border of the mandible.
Articulare	Ar	Posterior border of the neck of the mandibular Condyle.
Condylion	Co	Most posterior superior point of the mandibular Condyle.
A-Point	A	Deepest point of the curve of the Maxilla, between anterior nasal spine (ANS) and the maxillary dental alveolus.
ANS	ANS	Most anterior midpoint of the nasal spine of the Maxilla.
PNS	PNS	Most posterior midpoint of the nasal spine of the Maxilla.
U1 Tip		Incisal tip of the upper central incisor.
U1 Root		Root apex of the upper central incisor.
L1 Tip		Incisal tip of the lower central incisor.
L1 Root		Root apex of the lower central incisor.
U6 Occlusal		Mesial buccal cusp tip of the maxillary molar.
L6 Occlusal		Mesial buccal cusp tip of the mandibular molar.

Table 3. Cephalometric measurements used in the study.

Variable	Definition
<b>Skeletal Sagittal Relationship</b>	
SNA (°)	The angle between the Sella-Nasion plane and the Nasion-Point A plane. This angle assesses the antero-posterior position of the Maxilla relative to the upper cranial structures.
SNB (°)	The angle between Sella-Nasion plane and the Nasion-Point B plane. This angle assesses the antero-posterior position of the Mandible relative to the upper cranial structures.
ANB (°)	The ANB angle highlights the relative antero-posterior position between the maxilla and the Mandible.
<b>Skeletal Vertical Relationship</b>	
Cranio-Mx Base/SN-Palatal Plane (°)	Angle between the cranial base SN and the plane passing through anterior and posterior nasal spines.
SN - GoGn (°)	Angle between the cranial base SN and the mandibular plane (Go-Gn).
Palatal-Mand Angle (PP-GoGn) (°)	Angle between mandibular plane (Go-Gn) and the plane passing through anterior and posterior nasal spines.
Y-Axis (SGn-SN) (°)	The angle between the cranial base SN and the line joining S-Gn, indicating the growth pattern of the individual.
<b>Dento-Basal and Dental Relationship</b>	
U1 - Palatal Plane/Mx Base (°)	Angle between the long axis of the upper central incisor and the plane passing through anterior and posterior nasal spines.
L1 - GoGn (°)	Angle between the long axis of the lower central incisor and the mandibular plane.
Overjet (mm)	Horizontal antero-posterior distance between the most prominent labial point of the incisal edge of the upper central incisor and the labial surface of the lower central incisor.
Overbite (mm)	The perpendicular labial overlap between the upper and lower central incisors.
U1 - L1 (°)	The angle between the long axis of the upper central incisor and the long axis of the lower central incisor.
<b>Soft Tissue Measurements</b>	
Nasolabial Angle (°)	The angle between the line tangent to the lower edge of the nose (the columella) and the line tangent to the edge of the upper lip.
Facial Convexity (G'-Sn-Pog') (°)	This angle measures the balance among the features of the facial complex (Forehead, Maxilla, mandible).
UFH to LFH (G'-Sn/G'-Me')(%)	The ratio that calculates the proportions between upper and lower facial heights.
UL Protrusion (UL-SnPog') (mm)	The perpendicular distance from the upper lip tip to the line from subnasale to soft tissue pogonion.
LL Protrusion (LL-SnPog') (mm)	The perpendicular distance from the lower lip tip to the line from subnasale to soft tissue pogonion.

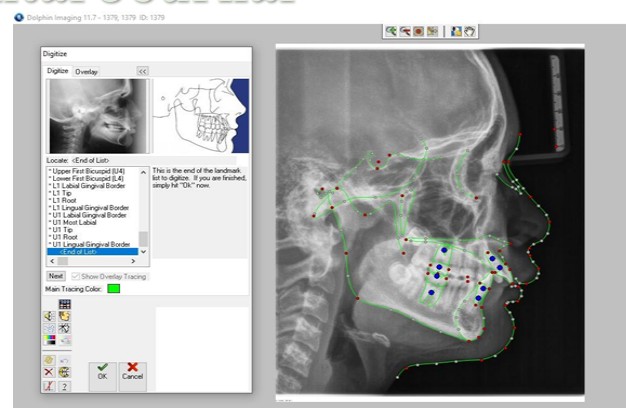


Figure 1. Pre-treatment cephalometric landmark identification and tracing using Dolphin Software.

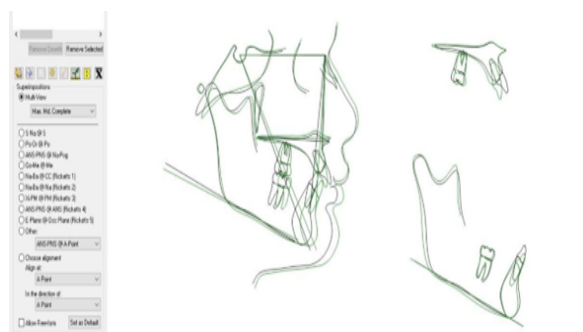


Figure 2. Cephalometric superimposition of pre-treatment and post-treatment lateral cephalometric radiographs.

All cephalometric measurements were performed by one trained orthodontist to reduce fluctuations in measurement accuracy. Measurements of 10 randomly selected subjects were repeated by the same observer after two weeks to assess the intra-observer error. Dahlberg's formula<sup>14</sup> and concordance correlation coefficient were used in order to quantify measurement error.

### Statistical analysis

SPSS software was used for the statistical analysis. Normality distribution of the data was evaluated with the Shapiro-Wilk test. Parametric tests were used as all variables were normally distributed. Paired Sample t-test was used to compare pre-treatment and post-treatment skeletal, dental and soft tissue effects (significant at  $P < 0.05$ ).

### Results

Table 4 shows the treatment changes after treatment. In our study, treatment with Invisalign® mandibular advancement resulted in a significant increase in SNB angle (mean difference 2.14; CI, 1.02 – 3.26), and significant decrease in ANB angle (mean difference -1.5; CI, -2.34 – -0.72).

Table 4. Skeletal, dental and soft tissue changes after treatment with Invisalign mandibular advancement feature.

Measurement		Mean (SD)	Mean Difference (SD)	95% Confidence Interval		P-value
				Lower	Upper	
SNA(°)	Before	81.80 (4.69)	0.59 (1.63)	-0.32	1.49	0.18529
	After	82.39 (4.27)				
SNB(°)	Before	76.89 (4.01)	2.14 (2.02)	1.02	3.26	0.00106 *
	After	79.03 (4.34)				
ANB(°)	Before	4.92 (2.01)	-1.53 (1.46)	-2.34	-0.72	0.00119 *
	After	3.39 (1.34)				
SN-Palatal Plane (°)	Before	7.19 (3.86)	-0.79 (1.61)	-1.68	0.10	0.07881
	After	6.41 (4.09)				
SN - GoGn (°)	Before	31.02 (5.99)	-1.11 (1.93)	-2.18	-0.04	0.04383 *
	After	29.91 (6.14)				
Palatal-Mand angle (°)	Before	23.85 (3.94)	-0.35 (1.33)	-1.09	0.38	0.32128
	After	23.50 (3.89)				
V-Axis (°)	Before	69.63 (4.49)	-1.46 (1.75)	-2.43	-0.49	0.00606 *
	After	68.17 (4.66)				
U1 - Palatal Plane (°)	Before	117.02 (5.19)	-7.03 (7.07)	-10.94	-3.11	0.00176 *
	After	109.99 (4.16)				
LI - GoGn (°)	Before	98.39 (8.08)	-0.59 (5.30)	-3.53	2.34	0.67092
	After	97.80 (5.46)				
Overjet (mm)	Before	7.14 (2.21)	-3.80 (2.24)	-5.04	-2.56	0.00001 *
	After	3.34 (0.76)				
Overbite (mm)	Before	1.89 (2.22)	0.07 (2.08)	-1.08	1.22	0.89309
	After	1.96 (0.89)				
U1 - LI (°)	Before	120.81 (6.25)	7.89 (8.75)	3.05	12.74	0.00357 *
	After	128.70 (5.98)				
Nasolabial Angle (°)	Before	107.18 (11.79)	2.19 (2.00)	-3.34	7.73	0.40976
	After	109.37 (9.87)				
Facial Convexity (°)	Before	13.95 (3.92)	-1.71 (2.18)	-2.92	-0.50	0.00882 *
	After	12.24 (3.55)				
UFH to LFH (%)	Before	52.84 (2.02)	-1.06 (1.94)	-2.14	0.02	0.05310
	After	51.78 (2.86)				
UL Protrusion (mm)	Before	6.10 (1.89)	-0.95 (1.66)	-1.87	-0.04	0.04272 *
	After	5.15 (2.07)				
LL Protrusion (mm)	Before	3.69 (2.32)	-0.13 (1.81)	-1.13	0.88	0.79086
	After	3.57 (2.04)				

No significant changes occurred for the SNA angle ( $p > 0.05$ ). A significant decrease in cranial base to mandibular plane angle (SN – GoGn) with a mean difference -1.11 degrees; CI, -2.18 – -0.04 degrees, as well as Y-Axis angle (SGn-SN) with a mean difference -1.46 degrees; CI, -2.43 – -0.49 degrees) were found. No significant changes occurred for the mandibular plane – palatal plane angle (PP-GoGn) or the cranial base – palatal plane angle (SN-Palatal Plane), ( $p > 0.05$ ).

Regarding the dental and soft tissue changes, a highly significant decrease in Upper Incisor – Palatal Plane angle with a mean difference -7.03 degrees; CI, -10.94 – -3.11 degrees, as well as the Overjet with a mean difference -3.80 mm; CI, -5.04 – -2.56 mm, and a highly significant increase in the Inter-incisal (U1 - L1) angle with a mean difference 7.89 degrees; CI, 3.05 – 12.74 degrees were found. Interestingly, no significant changes occurred for the Lower Incisor – Mandibular Plane (L1 - GoGn) angle or the Overbite ( $p > 0.05$ ). Soft Tissue Measurements revealed a highly significant decrease in both Facial convexity (mean difference -1.71 degrees; CI, -2.92 – -0.50 degrees) and Upper lip protrusion (mean difference -0.95 mm; CI, -1.87 – -0.04 mm).

## Discussion

The objective of this study was to evaluate the resultant changes in the skeletal, dental and soft tissues from the use of Invisalign® mandibular advancement. With this feature, precision wings on the aligners posture the mandible forward when the patient closes his mouth, similar to the mechanism of action of other functional

appliances. Posturing the mandible forward would stretch the muscles and soft tissues which then create a force that is transmitted to the teeth. In addition, the soft tissues would change and the facial profile would improve. Recently, Align Technology has further improved the design of precision wings, by making them more rigid and longer. This aims to minimize the chance of the patient chewing on the wings.

Regarding the Skeletal Sagittal Relations: there were no significant changes in the SNA angle ( $P > 0.05$ ); the position of point A remained unchanged (Table 4). The literature is controversial regarding this finding. O'Brien et al. (2003) reported that 13% of the skeletal effect resulted from a slight restraint of maxillary growth after the use of the Twin Block appliance.<sup>15</sup> Similarly, Illing et al. (1998) showed a small decrease in the SNA angle. (16) The restraint of maxillary growth could result from the stretching of the muscles and soft tissues as the mandible is advanced and result in a headgear-type effect. On the other hand, similar to our finding, other studies did not find a significant change in the maxillary position following functional appliance therapy. Caruso et al. (2021)<sup>11</sup> reported insignificant change in SNA angle ( $p > 0.05$ ) and Ravera et al. (2021)<sup>12</sup> further reported a minimal insignificant change of SNA angle from  $81.84 \pm 4.64$  to  $81.34 \pm 4.10$ .

On the other hand, there was a highly significant increase in SNB angle (mean difference 2.14; CI, 1.02 – 3.26,  $P < 0.01$ ) and decrease in ANB angle (mean difference -1.5; CI, -2.34 – -0.72,  $P < 0.01$ ); which confirmed the clinical efficacy of Invisalign® mandibular advancement in

correcting skeletal Class II malocclusion (Table 4). A similar finding was also reported by Caruso et al. (2021)<sup>11</sup> in their retrospective controlled study; SNB angle significantly increased from  $73.8 \pm 2.1$  to  $78.2 \pm 2.6$ ; and ANB angle was significantly reduced from  $5.7 \pm 1.9$  to  $2.3 \pm 0.8$ . This is further confirmed by Ravera et al. (2021) prospective controlled study with ANB reduction from  $5.12 \pm 2.36$  to  $4.28 \pm 2.17$ .<sup>12</sup>

In response to Invisalign® Aligners with Mandibular Advancement Feature, significant changes could also be found in the Skeletal Vertical Relationship. The maxillary plane to SN angle, and maxillary plane to mandibular plane angle, both showed insignificant change (mean difference -0.79 and -0.35 respectively,  $P > 0.05$ ). On the contrary, there was a significant reduction in the SN to mandibular plane angle with a mean difference -1.11 ( $P < 0.05$ ), and Y-Axis angle with a mean difference -1.46 ( $P < 0.01$ ), indicating counterclockwise rotation of the mandible. On the other hand, Caruso et al. (2021)<sup>11</sup> reported that Invisalign® aligners, with mandibular advancement feature produced no significant changes in the inclination of the palatal plane to the cranial base and the maxillo-mandibular plane angles. Blackham also found no significant changes in the mandibular plane angle to the cranial base and the ratio of posterior to anterior face height.<sup>10</sup> This finding is important, given the intimate relationship between the sagittal and vertical relationships of the jaws. In some cases, despite an obvious increase in mandibular length, facial profile is not significantly improved, and chin prominence is not affected. This can be sometimes attributed to vertical growth of the

maxilla and the clockwise rotation of the mandible. In our study, counterclockwise rotation of the mandible was evident, and this possibly would have a positive effect on the facial profile.

Regarding the Dento-Basal and Dental relations, our results revealed highly significant changes with a decrease in both the U1-palatal plane angle (mean difference -7.03,  $P < 0.01$ ), the Overjet (MD: -3.8,  $P < 0.001$ ), and increase in the interincisal angle (mean difference 7.89,  $P < 0.01$ ). Conversely, lower incisors to mandibular plane angle showed no significant change (mean difference -0.59,  $P > 0.05$ ). This is an important finding, given the often seen proclination of the lower incisors with the use of functional appliances. Clear aligners can thus offer the advantage of good control of tooth movement (according to the patient's need) while the mandible is postured forward to correct the Class II jaw relationship.

Overjet is decreased due to the combined effect of mandibular advancement and the retroclination of the upper incisors. In the Cochrane review, Thiruvengkatachari *et al.* reported an average of 4.62 mm reduction of the overjet following treatment with functional orthopedics.<sup>17</sup> In our current study as well as the study by Caruso et al.,<sup>11</sup> the mean decrease in overjet was around 3.8mm. By reducing the proclination of the upper incisors and overjet, children are less likely to experience incisor trauma and bullying,<sup>18</sup> protecting their ability to develop psychologically normally. When evaluating interceptive therapy during the pre-pubertal growth phase, these factors should be well considered.

Maxillary incisors retroclination and



mandibular incisors proclination is almost always seen following the use of functional orthopedics for treatment of Class II malocclusion.<sup>19,20</sup> In our present sample, the appliance showed a good control of the inclination of the lower incisors. This can be attributed to the coverage of the tooth surface. It can thus be assumed that the correction of the Class II jaw relationship could be achieved without excessive lower dentoalveolar compensation. Blackham's (2020) study with the Invisalign® Aligners with Mandibular Advancement Feature, showed less proclination of the lower incisors when compared to the Twin Block.<sup>10</sup> The good control over the inclination of the lower incisor was also found by Caruso et al. (mean increase 2.4 °) and Ravera et al. (mean decrease -1.68 °). This finding can have important clinical implications. As many of our Class II patients originally present with proclined lower incisors as a part of the dental compensation to the skeletal Class II jaw relationship. Further advancement of the lower incisors as a result of functional appliances treatment is often an undesirable side effect that we need to control. Harradine & Gale (2000) suggested that capping of the lower incisors with acrylic can help in minimizing unwanted lower incisor proclination.<sup>5</sup> However, Trenouth & Desmond (2012) reported that even with lower incisor capping,  $4.6 \pm 4^\circ$  increase in proclination of the lower incisors was achieved with treatment.<sup>6</sup> In our study, using Invisalign® Aligners with Mandibular Advancement Feature, excellent control of the lower incisors inclination was found.

Lastly, regarding the Soft Tissue Measurements, significant improvement in

the facial convexity (mean difference -1.71 degrees,  $P < 0.01$ ) was achieved with a significant reduction in upper lip protrusion (mean difference -0.95 mm,  $P < 0.05$ ). While the nasolabial angle showed non-significant increase (mean difference 2.19 degrees,  $P > 0.05$ ) and lower lip protrusion was unchanged (mean difference -0.13,  $P > 0.05$ ). Our findings agree with Caruso et al.<sup>11</sup> and Ravera et al.<sup>12</sup> who also reported that Invisalign® Aligners with Mandibular Advancement Feature resulted in improved profile convexity.

In summary, Invisalign® mandibular advancement was effective in the treatment of growing subjects with Class II malocclusion with retrusion of the mandible. This was achieved through an effect on both skeletal and dental tissues. In addition, it presented the advantage of enhancing counter-clockwise rotation of the mandible and producing no significant proclination of lower incisors.

#### **Limitations of the study**

There are few limitations for the current study. The absence of a comparison with an untreated control group did not allow treatment changes to be distinguished from normal growth changes. In addition, there is a need to evaluate the long-term effects of this treatment modality. Additionally, caution is needed when interpreting cephalometric studies due to the inherent limitations of a two-dimensional projection. Accordingly, changes in the transverse dimension were not evaluated. Further, the retrospective nature of the study with the selection of cases from Align Global Gallery must have introduced bias as only the

successful cases are included in this way. For this reason, further studies with a prospective randomized design with a control group are recommended, with analysis of results based on an intention-to-treat basis, including any possible dropouts or unsuccessful cases.

## Conclusions

Within the limitations of the current study, the following conclusions can be drawn:

1. Invisalign® Aligner with the Mandibular Advancement Feature was effective over the short term in treating skeletal Class II malocclusion with mandibular retrusion in growing subjects. The results showed an increase in the SNB angle and a decrease in the ANB angle, highlighting an improvement in the sagittal jaws relationship along with significant reduction of the overjet.
2. Vertically, Invisalign® Aligner with the Mandibular Advancement Feature enhanced counter-clockwise rotation of the mandible.
3. Invisalign® Aligner allowed a good control of the lower incisors inclination, while the mandibular advancement feature is moving the mandible forward.
4. Regarding the soft tissue parameters, results demonstrated highly significant improvement in facial convexity and reduction in upper lip protrusion.

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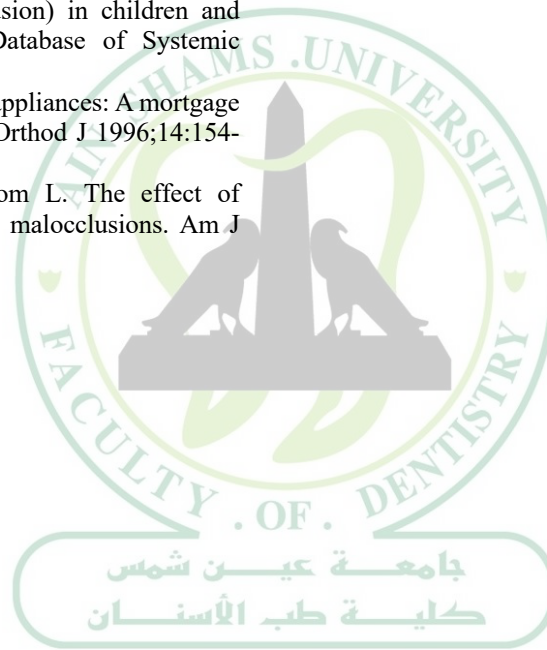
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