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RESEARCH ARTICLE

Effectiveness of the Invisalign Mandibular Advancement Appliance in Children with Class II Division 1 Malocclusion

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Background: This study aimed to determine the skeletal and dental effects in pediatric and adolescent Korean patients with Class II Division 1 malocclusion treated using the Invisalign Mandibular Advancement (MA®) appliance.
Methods: The study included patients aged 6 to 18 years who received orthodontic treatment with the MA® appliance for Class II Division 1 malocclusion at the Department of Pediatric Dentistry, Wonkwnag University Daejeon Dental Hospital, between July 1, 2018, and December 31, 2021. The treatment group consisted of 20 patients, 10 boys and 10 girls. The control participants were also 10 boys and 10 girls. Lateral cephalometric radiographs were taken before and after treatment, and 41 measurements of skeletal and dental changes were measured and analyzed using the V-Ceph™ 8.0 (Osstem Implant). All analyses were performed using SPSS software (IBM SPSS for Windows, ver 26.0; IBM Corp.), and statistical significance was tested using paired and independent samples t-tests for within-group and between-group comparisons, respectively.
Results: The patients in the treatment group showed significant decreases in ANB (A point, Nasion, B point), maxillary protrusion, maxillary anterior incisor labial inclination, and maxillary protrusion after treatment. However, when compared with the growth changes observed in the control group, only ANB and maxillary protrusion decreased, with no significant differences in SNA, SNB, and mandibular length.
Conclusion: Collectively, the results of this study confirm that the use of MA® appliance in pediatric and adolescent Korean patients with Class II Division 1 malocclusion results in a reduction of anteroposterior skeletal and dental disharmony.

Key Words: Class II malocclusion, Clear aligner, Invisalign, Mandibular advancement

Introduction

1. Background

What is a clear aligner? A clear aligner is an appliance that responds to the esthetic requirements of patients for orthodontic appliances, is removable, and is transparent when worn, in contrast to conventional metal or ceramic brackets. First conceptualized in 1945 with Kesling's elastic positioner[1)], clear aligners are effective only for mild to moderate crowding and spacing; however, their indications are gradually expanding. Compared with fixed appliances, they have the advantage of being more esthetically pleasing and easy to remove by patients; however, they obtain variable results depending on the appliance fit and the patient's cooperation in wearing them[2)]. Functional appliances have been used to correct skeletal Class II malocclusions for over 100 years since Robin and Andresen found them to be effective in promoting mandibular bone growth[3)]. Class II malocclusions are one of the most common orthodontic challenges, occurring in approximately one-third of the population[4)], and various methods have been used to treat this type of malocclusion, such as activators, twin

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blocks, Frankl, and Herbst. Recently, an invisible appliance called Invisalign Mandibular Advancement (MA®) (Align Technology, Santa Clara, CA, USA), which can align the teeth while repositioning the lower jaw forward through "precision wings," was developed by Align Technology and is gradually being used clinically (Fig. 1).

In 2017, Align Technology introduced the MA® appliance. This device replicates the action of functional appliances as it commonly features buccal "precision wings" between the first molar and premolars, which can only interlock when the patient pushes the mandible forward (a mechanism similar to Twin-Block) while simultaneously correcting malocclusion and crowding[5,6].

Compared with conventional appliances, the MA® appliance is more esthetically pleasing, comfortable, and accurate and can simultaneously complete both orthognathic and orthodontic treatments. MA® appears to be effective in the treatment of Class II malocclusion with mandibular retraction[7-9]. The American Academy of Pediatric Dentistry recommends screening children for malocclusion at an early age because many conditions are easier to treat in the early stages of a child's natural growth process. Early intervention can correct abnormal muscle morphology, eliminate abusive oral habits, improve facial esthetics and self-esteem to promote normal growth and development, and, most importantly, avoid or reduce the likelihood of needing aggressive fixed appliance treatment involving multiple

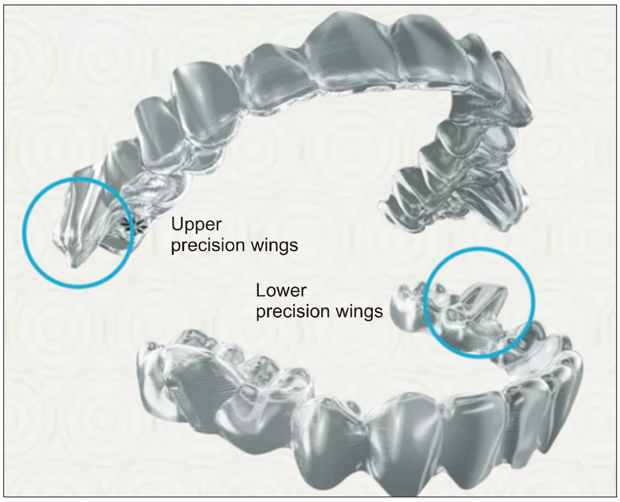

Fig. 1. Precision wings' components of Invisalign Mandibular Advancement (MA®) appliance.

extractions or later bimaxillary surgery[10].

As with functional appliances, correction of the occlusal relationship has combined skeletal and dental effects, and Sabouni et al. reported minimal associated skeletal changes[11].

2. Objectives

The effectiveness of functional appliances is ambiguous, and while some previous controlled trials have focused on traditional functional appliances in general, studies based on MA® are limited. Therefore, this study was conducted to determine the treatment effects on skeletal, dental in pediatric and adolescent Korean patients with Class II Division 1 malocclusion treated using MA® appliances.

Materials and Methods

1. Ethics statement

This study was conducted in compliance with the guidelines of the Institutional Review Board (IRB) of the Wonkwang University Daejeon Dental Hospital (IRB No. WKIRB-202009-BM-062) after passing the IRB review process.

Table 1. Distribution of Treatment Group (n=20)

Sex	Pre-treatment age (y)	Post-treatment age (y)	Treatment period (mo)
Male	11.0	11.1	9.0
	10.1	11.1	11.0
	10.3	11.4	13.0
	10.4	11.4	11.0
	8.1	10.0	12.0
	10.1	11.7	7.0
	9.5	10.5	11.0
	10.1	10.8	7.0
	8.0	8.9	7.0
	9.6	10.4	8.0
Female	11.6	12.4	10.0
	11.4	11.1	6.0
	10.3	11.2	11.0
	10.1	10.1	10.0
	8.2	10.0	9.0
	12.6	13.7	13.0
	9.8	10.3	6.0
	9.9	10.1	14.0
	8.1	9.6	6.0
	8.2	9.1	10.0
Mean	9.8	10.7	9.5

2. Study design

Forty patients with Class II malocclusion who underwent treatment at Wonkwnag University Daejeon Dental Hospital from July 1, 2018, to December 31, 2021 were selected. The patients were aged from 6 to 18 years and were divided into two groups, each comprising 10 girls and 10 boys having Class II malocclusion; one group was treated using the mandibular advancement appliance and the other was not treated (Table 1 and 2).

In Table 1, the patient's age before treatment is based on the temporal cephalometric radiograph obtained at the start of device treatment, and the age after treatment is based on the temporal cephalometric radiograph obtained at the end of treatment. The pre- and post-observation ages of the control group in Table 2 were taken from patients who did not undergo any orthodontic treatment and whose growth was monitored by periodic temporal cephalometric radiographs, whose temporal cephalometric radiographs were taken at an age similar to that of the treatment group.

Table 2. Distribution of Control Group (n=20)

Sex	Pre-treatment age (y)	Post-treatment age (y)	Treatment period (mo)
Male	11.1	12.1	11.0
	9.8	10.1	14.0
	10.0	11.0	12.0
	10.0	10.7	7.0
	10.1	11.9	11.0
	10.1	11.2	12.0
	10.6	11.0	6.0
	11.4	11.1	7.0
	7.6	8.2	8.0
	11.7	12.1	6.0
Female	7.0	7.1	10.0
	8.4	10.1	20.0
	9.1	11.1	15.0
	8.9	10.2	16.0
	6.1	8.9	22.0
	8.0	9.0	12.0
	9.5	10.1	8.0
	8.3	9.0	8.0
	9.6	10.4	10.0
	9.2	10.3	12.0
Mean	9.3	10.2	11.3

Retrospective lateral superimposition cephalometric analyses were recorded. The principal investigator conducted the tracing to execute the cephalometric analysis using Steiner, Down, McNamara, and Ricketts analyses. Cephalometric landmarks and planes are illustrated in Fig. 2. This numerical assessment can provide detailed information on the relationship of skeletal, dental and soft tissue elements within the craniofacial region. The following is a summary of commonly used cephalometric points and horizontal reference planes (Table 3).

All patients were instructed to use the appliance for at least 12 hours during the day and during sleep every night. The study hypothesis was that after wearing the MA® appliance, significant changes would occur, including the reduction of the posterior enlargement of the ramus, with an increase in SNB (SN to point B), decrease in ANB (A point, Nasion, B point), reduction in the overjet, and better teeth alignment, compared with the non- treatment group.

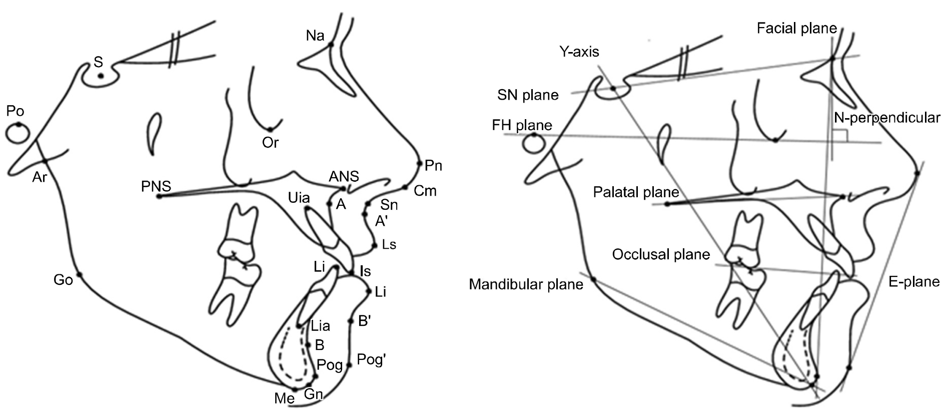

Fig. 2. Cephalometric landmarks and planes.

Table 3. Definition of Cephalometric Analysis Measurements

	Measurement	Definition
Commonly used cephalometric points	Sella (S)	The midpoint of the sella turcica (pituitary fossa)
	Nasion (N)	The most anterior point on the frontonasal suture in the midline
	Porion (Po)	The upper- and outer-mostpoint on the external auditory meatus
	Orbitale (Or)	The most inferior and anterior point on the orbital margin
	Condylion (Cd)	The most posterior and superior point on the mandibular condyle
	Articulare (Ar)	The point of intersection of the posterior margin of the ascending mandibular ramus and the outer margin of the posterior cranial base
	Gnathion (Gn)	The most anterior and inferior point on the bony chin
	Menton (Me)	The most inferior point of the mandibular symphysis in the midline
	Pogonion (Pog)	The most anterior point on the bony chin
	Gonion (Go)	The most posterior and inferior point on the angle of the mandible
	Point A	The deepest point on the curved profile of the maxilla between the anterior nasal spine and alveolar crest
	Point B	The deepest point on the curved profile of the mandible between the chin and alveolar crest.
Skeletal	SNA (°)	Angle of S-Na and Na-A
	SNB (°)	Angle of S-Na and Na-B
	ANB difference (°)	Difference between measure SNA and SNB
	Facial convexity (°)	Angle of Na-A and A-Pog
	Facial angle (°)	Angle of facial plane and FH plane
	Pog to N-perp. (mm)	Distance from Pog to N-perpendicular
	Wits (mm)	Subtract distance of A from distance of B, parallel to occlusal plane
	Ramus height (mm)	Distance from Ar to Go
Dental	U1 to NA (mm)	Distance from Is to Na-A
	U1 to NA (°)	Angle of Uia-Is and Na-A
	U1 to SN (°)	Angle of Uia-Is and SN plane
	U1 to FH (°)	Angle of Uia-Is and FH plane
	L1 to NB (mm)	Distance from Ii to Na-B
	L1 to NB (°)	Angle of Lia-Ii and Na-B
	Interincisal angle (°)	Angle of Uia-Is and Lia-Ii
	Incisor overbite (mm)	Subtract distance of Ii from distance of Is, perpendicular to occlusal plane
	Incisor overjet (mm)	Subtract distance of Ii from distance of Is, parallel to occlusal plane
	Occ. plane to SN (°)	Angle of occlusal plane and SN plane
Horizontal reference planes	SN plane	This line, connecting the midpoint of sella turcica with nasion, is taken to represent the cranial base
	Frankfort plane	This is the line joining porion and orbitale. This plane is difficult to define accurately because of the problems inherent in determining orbitale and porion
	Mandibular plane	The line joining gonion and menton
	Occlusal plane	A line drawn between the cusp tips of the permanent molars and premolars (or deciduous molars in mixed dentition)

3. Experimental methods

1) Evaluation of skeletal measurement changes

To evaluate the change in the anteroposterior positional relationship between the maxilla and mandible, the following measurements were observed: SNA (SN to point A) (°), SNB (°), ANB difference (°), facial convexity (°), facial angle (°), Pog to N-perpendicular (mm), and Wits (mm). The Wits appraisal was created to relate patient's jaws anteroposteriorly to the cranial reference planes. To evaluate the change in the horizontal positional relationship and assess the vertical relationship between the maxilla and mandible, ramus height (mm) was measured.

2) Evaluation of dental measurement changes

To evaluate the change in position and angle of the maxillary central incisors, the following were measured: U1 to NA (mm), U1 to NA (°), U1 to SN (°), and U1 to FH (°). To evaluate the change in position and angle of the mandibular central incisors, the following were measured: L1 to NB (mm), and L1 to NB (°). To evaluate the change in the positional relationship between the upper and lower incisors, the interincisal angle (°), incisor overbite (mm), and incisor overjet (mm) were measured. To evaluate the change in the occlusal plane, the occlusal plane to SN (°) and cant of the occlusal plane (°) were measured.

4. Statistical analysis

All analyses were performed using SPSS software (IBM SPSS for Windows, ver 26.0; IBM Corp., Armonk, NY, USA), and statistical significance was tested using paired samples t-test for within-group comparisons and independent samples t-test for between-group comparisons.

Results

1. Evaluation of skeletal changes

There were some sex differences in the results of this study. For facial convexity, which commonly corresponds to skeletal changes, there was a statistically significant change in the female treatment group and none in the male treatment group. In the female treatment group, SNA (°) was 80.86 before treatment and 79.84 after treatment, while in the control group, to exclude the effect of growth, SNA values at the start and end of observation were 81.43 and 81.54, respectively. SNB (°) was 75.12 before treatment and 75.26 after treatment, while in the control group, excluding the effect of growth, SNB values at the start and end

Table 4. Intragroup Values for the Female Treatment and Control Groups: Skeletal and Dental Measurements of the Pre- and Post-Treatment Lateral Cephalograms

Measurement	Treatment group (n=10)					Control group (n=10)				
	Pre-treatment		Post-treatment		p-value	Pre-treatment		Post-treatment		p-value
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Facial angle	83.42	1.85	84.23	1.92	0.043	84.52	2.47	84.85	2.37	NS
Cant of occlusal plane	11.77	2.57	10.98	2.24	NS	11.79	2.87	10.12	2.58	0.006
Interincisal angle	123.19	10.10	125.84	11.13	NS	126.08	5.20	119.03	6.49	0.01
Upper incisor to A-Pog line	7.54	3.03	7.41	2.76	NS	7.72	1.33	8.88	1.48	0.003
Ramus height	38.36	1.88	40.33	2.21	NS	37.66	2.83	38.88	2.94	0.026
Facial convexity	12.06	4.61	9.77	4.58	0.044	12.93	5.03	12.73	5.06	NS
U1 to SN	102.30	6.94	102.45	6.74	NS	101.94	4.02	105.55	5.67	0.018
Pog to N-Perp (FH)	−11.39	4.05	−10.44	4.15	NS	−9.39	4.33	−9.10	4.39	NS
L1 to A-Pog (°)	23.31	4.27	21.77	6.57	NS	20.48	5.03	24.22	3.99	0.004
L1 to A-Pog (mm)	2.88	2.30	3.31	2.30	NS	2.65	1.53	3.65	1.54	0.021
SNA	80.86	1.79	79.84	1.64	NS	81.43	2.71	81.54	2.20	NS
SNB	75.12	2.22	75.26	2.79	NS	75.67	2.84	75.62	2.58	NS
ANB	5.75	1.62	4.57	1.65	0.028	5.76	1.88	5.91	1.68	NS
Occlusal plane to SN angle	19.81	3.53	19.80	4.23	NS	20.89	3.57	19.26	3.57	0.008
Wits appraisal	2.36	2.24	1.29	2.36	0.014	1.22	2.52	2.54	2.08	0.011
U1 to FH	110.35	6.96	111.26	5.82	NS	111.04	3.20	114.70	4.71	0.015
U1 to SN	102.30	6.94	102.45	6.74	NS	101.94	4.02	105.55	5.67	0.018
U1 to UOP	55.52	5.80	55.72	5.36	NS	55.13	2.58	52.73	3.73	0.037
U1 to NA (mm)	3.27	2.31	4.09	1.50	NS	3.13	1.64	4.18	1.54	0.039
U1 to NA (°)	21.44	7.03	22.62	6.29	NS	20.51	4.82	24.01	5.12	0.038
L1 to NB (mm)	6.30	2.70	6.11	2.68	NS	5.70	1.64	7.19	1.59	0.008
L1 to NB (°)	29.62	6.41	26.97	7.72	NS	27.65	4.69	31.04	5.16	0.023
Nasolabial angle	101.00	15.27	87.34	17.44	0.005	100.36	15.96	104.58	8.86	0.25

SD: standard deviation, NS: not significant.

of observation were 75.67 and 75.62, respectively. The ANB difference (°) was 5.75 before treatment and 4.57 after treatment, and increased slightly in the control group from 5.76 at the start of observation to 5.91, while it decreased significantly in the treatment group (Table 4).

In the male treatment group, SNA (°) was 81.62 before treatment and 83.09 after treatment, while in the control group, it was 80.75 at the beginning of observation and 81.02 at the end of observation, excluding effects due to growth. SNB (°) was 77.54 before treatment and 79.17 after treatment, while in the control group, it was 75.35 and 75.90 at the beginning and end of observation, respectively. In the treatment group, both SNA and SNB significantly increased, while the ANB difference (°) was 4.08 pre-treatment and 3.91 post-treatment, and in the control group, to rule out effects due to growth, there was a slight, but not statistically significant, decrease in both, from 5.41 at the beginning of observation to 5.12 at the end (Table 5, 6).

Similar to ANB, there were statistically significant changes in facial convexity (°), facial angle (°), and Wits (mm) in the female treatment group; however, similar changes in Wits were observed in the control group and were excluded as treatment effects. There were statistically significant changes in facial angle (°) and Pog to N-Perp (FH) in the male treatment group; however, similar changes were observed in the control group and were excluded from the treatment effect.

2. Evaluation of changes in dental measurements

The results of this study showed a highly significant difference by sex. Statistically significant changes were observed at all baseline points in the female treatment group, while no statistically significant changes were observed in the

Table 5. Intragroup Values for the Male Treatment and Control Groups: Skeletal and Dental Measurements of the Pre- and Post-Treatment Lateral Cephalograms

Measurement	Treatment group (n=10)					Control group (n=10)				
	Pre-treatment		Post-treatment		p-value	Pre-treatment		Post-treatment		p-value
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Facial angle	85.22	2.02	86.15	1.72	0.02	84.34	3.30	85.06	3.15	0.004
Cant of occlusal plane	11.58	2.80	10.80	3.98	NS	12.05	3.56	10.98	3.11	0.003
Interincisal angle	124.17	7.80	126.94	4.83	NS	124.05	4.73	123.98	5.60	NS
Upper incisor to A-Pog line	7.37	1.85	7.16	1.31	NS	8.03	1.03	8.26	1.16	NS
Ramus height	40.08	2.43	42.30	3.63	0.01	38.82	4.35	40.88	6.34	NS
Facial convexity	9.46	9.46	8.83	4.51	NS	11.08	6.05	10.31	6.69	NS
U1 to SN	105.91	5.89	105.98	4.23	NS	102.92	7.90	103.88	6.83	NS
Pog to N-Perp (FH)	−8.22	3.48	−6.80	2.95	0.03	−9.93	5.75	−8.72	5.79	0.006
L1 to A-Pog (°)	22.07	3.79	21.35	3.00	NS	22.11	3.25	22.84	4.06	NS
L1 to A-Pog (mm)	2.73	1.81	2.54	1.50	NS	2.83	1.19	3.20	1.21	NS
SNA	81.62	4.23	83.09	3.49	0.025	80.75	3.61	81.02	3.45	NS
SNB	77.54	3.37	79.17	2.73	0.003	75.35	4.15	75.90	3.94	NS
ANB	4.08	1.50	3.91	1.73	NS	5.41	2.68	5.12	2.95	NS
Occlusal plane to SN angle	19.11	2.91	17.79	3.25	NS	20.80	4.23	19.92	4.06	0.027
Wits appraisal	−0.05	1.53	−0.46	1.98	NS	1.14	2.48	1.10	2.68	NS
U1 to FH	113.66	6.48	112.97	4.63	NS	111.66	7.04	112.83	5.59	NS
U1 to SN	105.91	5.89	105.98	4.23	NS	102.92	7.90	103.88	6.83	NS
U1 to UOP	52.46	4.47	53.77	2.10	NS	53.82	3.64	53.69	2.84	NS
U1 to NA (mm)	4.36	2.15	3.90	2.07	NS	3.83	2.26	4.20	2.34	NS
U1 to NA (°)	24.29	8.33	22.89	5.26	NS	22.16	7.98	22.86	6.45	NS
L1 to NB (mm)	5.06	1.71	4.85	1.07	NS	6.15	1.90	6.57	2.45	NS
L1 to NB (°)	27.47	3.52	26.26	3.10	NS	27.78	5.67	28.04	7.31	NS
Nasolabial angle	87.30	11.08	88.71	14.63	NS	102.69	11.23	106.81	9.58	NS

SD: standard deviation, NS: not significant.

Table 6. Intergroup Values for Treatment and Control Group by Sex: Skeletal and Dental Measurements of the Pre- and Post-Treatment Lateral Cephalograms

Measurement	Boy					Girl				
	Treatment group (n=10)		Control group (n=10)		p-value	Treatment group (n=10)		Control group (n=10)		p-value
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Facial angle	0.93	1.04	0.82	0.69	NS	0.81	1.09	0.33	0.83	NS
Cant of occlusal plane	−0.78	1.74	−1.07	0.83	NS	−0.79	2.02	−1.67	1.46	NS
Interincisal angle	2.76	5.58	−0.67	4.50	NS	2.65	6.26	−7.04	4.08	<0.001
Upper incisor to A-Pog line	−0.21	1.11	0.23	0.68	NS	−0.13	1.10	1.16	0.90	0.01
Ramus height	2.22	2.14	2.07	3.47	NS	1.96	2.88	1.22	1.45	NS
Facial convexity	−0.64	2.50	−0.77	1.10	NS	−2.29	3.09	−0.20	2.32	NS
U1 to SN	0.07	4.33	0.97	2.56	NS	0.15	4.73	3.61	3.93	NS
Pog to N-Perp (FH)	1.42	1.74	1.22	1.07	NS	0.95	1.83	0.28	1.52	NS
L1 to A-Pog (°)	−0.73	3.78	0.74	2.99	NS	−1.53	5.55	3.75	3.08	0.02
L1 to A-Pog(mm)	−0.19	1.21	0.38	0.80	NS	0.43	0.69	1.00	1.14	NS
SNA	1.47	1.73	0.27	0.71	NS	−1.03	2.38	0.11	1.83	NS
SNB	1.63	1.28	0.56	0.88	0.04	0.15	1.71	−0.05	0.99	NS
ANB	−0.16	0.91	−0.29	0.59	NS	−1.18	1.43	0.16	1.07	0.03
Occlusal plane to SN angle	−1.32	2.18	−0.87	1.05	NS	−0.02	2.63	−1.62	1.50	NS
Wits appraisal	−0.41	1.49	−0.04	1.02	NS	−1.07	1.11	1.32	1.30	NS
U1 to FH	−0.69	4.25	1.17	2.65	NS	0.91	4.77	3.66	3.86	NS
U1 to SN	0.07	4.33	0.97	2.56	NS	0.15	4.73	3.61	3.93	NS
U1 to UOP	1.32	4.75	−0.14	1.93	NS	0.20	3.34	−2.40	3.11	NS
U1 to NA (mm)	−0.46	1.31	0.37	0.85	NS	0.82	1.32	1.06	1.38	NS
U1 to NA (°)	−1.40	5.48	0.70	2.45	NS	1.18	5.46	3.50	4.55	NS
L1 to NB (mm)	−0.22	1.46	0.41	1.23	NS	−0.19	1.18	1.49	1.38	0.01
L1 to NB (°)	−1.21	3.29	0.26	3.48	NS	−2.65	6.95	3.39	3.93	0.03
Nasolabial angle	1.41	13.47	4.12	11.43	NS	−13.66	11.89	4.23	10.75	<0.001

SD: standard deviation, NS: not significant.

male treatment group. In the female treatment group, U1 to FH increased from 110.35 before treatment to 111.26 after treatment, and in the control group, from 111.04 before observation to 114.70 after observation, showing a statistically significant change (Table 4, 6). U1 to SN was maintained from 102.30 before treatment to 102.45 after treatment and increased in the control group from 101.94 before observation to 105.55 after observation, showing a statistically significant change. U1 to UOP slightly increased from 55.52 before treatment to 55.72 after treatment and decreased in the control group from 55.13 before observation to 52.73 after observation, showing a statistically significant change. U1 to NA (mm) increased from 3.27 before treatment to 4.09 after treatment, and in the control group, it increased from 3.13 before observation to 4.18 after observation, a statistically significant change. U1 to NA (°) increased from 21.44 before treatment to 22.62 after treatment, and the control group showed a statistically significant change from 20.51 before observation to 24.01 after observation. L1 to NB (mm) decreased from 6.30 before treatment to 6.11 after treatment and increased in the control group from 5.70 before observation to 7.19 after observation, which was a statistically significant change. L1 to NB (°) decreased from 29.62 before treatment to 26.97 after treatment and increased from 27.65 before observation to 31.04 in the control group, which showed a statistically significant change (Table 4).

Among male patients, U1 to FH decreased from 113.66 before treatment to 112.97 after treatment and increased from 111.66 before observation to 112.83 in the control group, which was not statistically significant (Table 5, 6). U1 to SN remained at 105.98 post-treatment from 105.91 pre-treatment and increased from 102.92 pre-observation to 103.88 post-observation in the control group, but was not statistically significant. U1 to UOP increased from 52.46 pre-treatment to 53.77 post-treatment and slightly decreased from 53.82 pre-treatment to 53.69 post-treatment in the control group; however, this was not statistically significant. U1 to NA (mm) decreased from 4.36 pre-treatment to 3.90 post-treatment and increased from 3.83 pre-observation to 4.20 post-observation in the control group; U1 to NA (°) also decreased from 24.29 pre-treatment to 22.89 post-treatment and increased slightly from 22.16 pre-observation to 22.86 post-observation in the control group; however, this was not statistically significant. L1 to NB (mm) decreased from 5.06 pre-treatment to 4.85 post-treatment and slightly increased from 6.15 pre-treatment to 6.57 post-treatment in the control group; however, this was not statistically significant. L1 to NB (°) decreased from 27.47 pre-treatment to 26.26 post-treatment and increased from 27.78 pre-observation to 28.04 post-observation in the control group, which was not statistically significant (Table 5).

Discussion

1. Interpretation

As the MA® appliance has only been used clinically since 2017, the literature on its effectiveness is limited globally and mostly consists of case studies[7]. As the MA® appliance was only recently licensed by the Korean Ministry of Food and Drug Safety, this study is the first analysis of the MA® appliance's treatment effectiveness in Korean children and adolescents.

2. Key results and comparison

Previous studies investigating the effects of the MA® appliance on patients with Class II Division 1 malocclusion have reported skeletal and dental changes. For example, Blackham observed that the MA® appliance is effective in improving skeletal and soft tissue convexity, the Wits appraisal, and the ANB angle[5]. Caruso et al.[7] and by Ravera et al.[8] effectively improved face convexity and the Wits index. Blackham[5] found that the overjet was decreased through retraction of the upper incisors and protrusion of the lower incisors, and the overbite was also reduced. Ravera et al.[8] showed that if the patients were at cervical vertebrae maturation growth stage 2 (CVM2), the MA® appliance would produce more dentoalveolar effects; whereas if the patients were at CVM3, the skeletal component of the Class II correction was greater.

The most recent study by Wu et al.[12] compared four devices: the Vanbeek Activator (n=14); Herbst (n=11); Twin-Block (n=12); and MA (n=14) in patients with Cl II malocclusion with ANB 4 or higher and CVM stage 2. Growth stimulation of the mandible was observed in Twin-Block and MA (Co-Go and Co-Pog) and Herbst (Co-Pog), while maxillary inhibition was only observed in Vanbeek Activator. This result was consistent with previous studies that reported that headgear had some effects on maxillary restraint[13,14]. However, clinically significant restraint of maxillary growth was not clear in other functional appliances[15,16].

Compared with the results of previous studies, changes in dental and skeletal measurements were observed in the treatment group when compared with the control group in this study. In the male treatment group, the ramus height significantly increased, SNA and SNB increased, and ANB decreased, but not significantly. In the female treatment group, facial angle increased and ANB, facial convexity, and nasolabial angle significantly decreased, similar to the results of previous studies that showed improvement in facial convexity and ANB, and the improvement in Wits index seen in previous studies was not seen in the treatment group in this study.

In between-group comparisons, the female patients showed significant changes in several measures, but only the reduction in SNB was significant in the male patients; this difference is cautiously attributed to boys' treatment compliance, which is generally lower than girls', but further research is needed to clarify this.

3. Suggestion

From the results of this study, it can be concluded that treating patients with Class II Division 1 malocclusion in the growth phase using MA® appliance reduces antero-posterior discrepancies in the skeletal, dental, and soft tissue structures.

4. Limitations

The limitations of this study included a small sample size; non-randomized controlled trials design; large variations in treatment, observation periods, and patient ages; and the lack of long-term follow-up. Additionally, a long-term prospective study is needed comparing the effectiveness of functional appliances with other appliances reviewed in previous studies.

Notes

Conflict of interest

No potential conflict of interest relevant to this article was reported.

Ethical approval

This study was conducted in compliance with the guidelines of the Institutional Review Board (IRB) of the Wonkwang University Dental Hospital (IRB No. WKIRB-201905-BM-035) after passing the IRB review process.

Author contributions

Conceptualization: Youn-Soo Shim and So-Youn An. Formal analysis: Youn-Soo Shim and So-Youn An. Funding acquisition: So-Youn An. Investigation: Hyeon-Jin Kim, Ho-Uk Lee, Sang-Ho Bak, Hyo-Jin Kang, and So-Youn An. Methodology: Ho-Uk Lee and Sang-Ho Bak. Project administration: So-Youn An. Supervision: So-Youn An. Validation: So-Youn An. Visualization: Hyo-Jin Kang. Writing – original draft: Youn-Soo Shim. Writing – review & editing: Ho-Uk Lee, Sang-Ho Bak, and Hyo-Jin Kang.

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Data availability

The Invisalign Mandibular Advancement (MA®) data can be obtained https://www.invisalign.co.kr/.

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