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RESEARCH ARTICLE

Effects of a Prefabricated Functional Orthodontic Appliance on Children with Class II Division 1 Malocclusion

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Background: This study aimed to evaluate the effect of a prefabricated functional appliance (Myobrace®) on skeletal, dental, and soft tissue components in children with Class II, division 1 malocclusion.
Methods: Thirteen patients with Class II, division 1 malocclusion (9 girls and 4 boys; mean age, 8.2±0.9 years at the start and 9.3±1.0 years at the end of the treatment) were treated with Myobrace® for a mean period of 12.9±4.0 months. Patients were instructed to use the appliance daily for 1 hour and overnight while sleeping. A control group of 10 patients with untreated Class II, division 1 malocclusion (3 girls and 7 boys; mean age, 9.0±1.6 years at the start and 10.4±2.1 years at the end of the observation) was included to eliminate possible growth effects. The mean observation period for this group was 17.7±11.2 months. Lateral cephalograms were taken at the start and end of the treatment, and findings from 41 measurements were analyzed using the V-Ceph™ program. The mean and standard deviation of cephalometric measurements were analyzed using paired and independent sample t-tests.
Results: The treatment group showed significant changes in SNB, ANB, maxillary protrusion, ramus height, proclination of upper anterior teeth, interincisal angle, overjet, and upper lip protrusion compared with the control group. However, only decrease in ANB, maxillary protrusion, overjet, upper lip protrusion, and increase in interincisal angle were significantly higher in the treatment group than in the control group.
Conclusion: The prefabricated functional appliance induced skeletal, dentoalveolar, and soft tissue changes, resulting in a significant reduction in anteroposterior discrepancy.

Key Words: Angle Class II, Fuinctional orthodontic appliances, Malocclusion

Introduction

1. Background

Occlusion is affected by the muscles and teeth. The dentition receives external pressure from the orbicularis oris, buccinator, and superior pharyngeal constrictor muscles of the buccinator mechanism, and internal pressure from the lingual muscle. Its shape is maintained at the point where external and internal pressures are balanced, thereby forming an occluding junction. Stronger external pressure causes inward inclination of the teeth, resulting in crowded dentition, while stronger internal pressure causes protrusion of the anterolateral teeth. Therefore, in addition to being a dental problem, occlusion is a morphological and functional variation caused by the interaction of the skeletal and muscular systems[1)].

Angle's classification system, which categorizes malocclusion into Classes I, II, and III based on the anteroposterior relationship of the first molars, is the most widely used method for classifying malocclusion. However, it

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may not account for muscular or skeletal problems[2]. According to a study on malocclusion prevalence in the United States, Class II malocclusion, in which the mandible is positioned posterior to the maxilla, is one of the most common orthodontic problems, affecting one-third of the population[3]. Similarly, approximately one-third of orthodontic patients in South Korea receive treatment for Class II malocclusion[4]. McNamara, who studied the morphology of Class II malocclusion, reported that an estimated 80% of patients with Class II malocclusion had normally positioned maxillae, whereas approximately 70% had retrusive mandibles[5]. Therefore, Class II malocclusion treatment focuses on improving mandibular position using various devices[6,7]. These devices aim to eliminate abnormal muscle function, induce mandibular growth, and retract the anterior maxillary region. In particular, children with Class II Division 1 malocclusion, who have a large overjet and labially inclined maxillary incisors, frequently experience incisal trauma due to the protruding maxillary anterior region. Therefore, facial improvement is greatly desired, making early correction a high priority[8,9].

However, functional appliances such as activators, bionators, and FR (frankel)-II are complex and bulky. The Herbst and twin block appliances are less bulky, but come with the inconvenience of 24-h intraoral wear or adjustments. To overcome these drawbacks, prefabricated functional appliances such as the Myobrace® (Myofunctional Research Co., Helensvale, Queensland, Australia) have been developed. In South Korea, interest in the effects of muscles on malocclusion is growing; subsequently, demand for prefabricated functional appliances is increasing owing to their ease of use. Similar studies conducted in South Korea have reported positive results. For example, Kim et al.[10] reported a decrease in abnormal oral habits such as mouth breathing and tongue thrusting, as well as an improvement in deep bite, in 8～10-year-old children with Class II malocclusion treated with a prefabricated functional appliance for 6～8 months and An et al.[11] used a prefabricated functional appliance to treat 9-year-old children with Class II malocclusion and large overjet and overbite for 6～12 months, resulting in a decrease in the overjet, overbite, and difference between measured SNA and SNB. However, beyond these case reports, limited research has tested the effectiveness of prefabricated functional appliances.

2. Objectives

This study aimed to examine changes in skeletal, dental, and soft tissue structures of growing patients diagnosed with Class II Division 1 malocclusion, following a 1-year period of Myobrace® usage, by performing lateral cephalometric radiography, and comparing the measurements obtained from the treatment group with those obtained from the control group.

Materials and Methods

1. Study design

From March 1, 2015, to December 31, 2018, children aged 6～12 years who had received orthodontic treatment at the Wonkwang University Daejeon Dental Hospital were screened, and patients who were treated only with Myobrace® were selected (Fig. 1). Among them, 15 patients with Class II Division 1 malocclusion who had worn Myobrace® for at least 6 months were enrolled in the treatment group. Based on a study by Usumez[12], Class II Division 1 malocclusion was defined as malocclusion with the maxillary first molar positioned anterior to the mandibular first molar and an ANB of ＞4. Of the 15 patients, two were excluded for noncompliance (not wearing the device for 1 month or longer); hence, 13 patients were

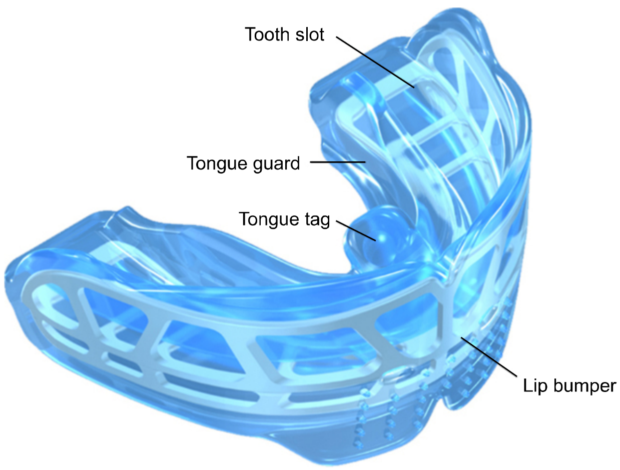

Fig. 1. Components of Myobrace® appliance.

retained for analysis as the final treatment group (Table 1). Girls outnumbered boys (nine to four). The overall mean age was 8.2±0.9 years (range: 6.9～10.5 years) at the start of treatment and 9.3±1.0 years (range: 7.9～12.0 years) at the end of treatment, with the mean treatment period ranging from 8～22 months (12.9±4.0 months).

To observe and compare the changing patterns with those of the treatment group, controls were age-matched with cases to control for the effects of growth and dental conditions (Class II Division 1 malocclusion). Patients who delayed or refused orthodontic treatment after it was explained to them were included in the control group. Lateral cephalometric radiographs were obtained at intervals of 6 months or more; finally, 10 patients were enrolled in the control group (Table 2). Boys outnumbered girls (seven to three). The overall mean age was 9.0±1.6 years (range: 6.3～11.3 years) at the start of observation and 10.4±2.1 years (range: 7.0～15.1 years) at the end of observation, with the mean observation period ranging from 6～46 months (17.7±11.2 months).

All patients were treated using a prefabricated functional appliance (Myobrace®). They were instructed to use the device for at least 1 hour during the day as well as overnight.

Table 1. Distribution of Treatment Group (N=13)

Sex	Pre-treatment age (y)	Post-treatment age (y)	Treatment period (mos)
Male	7.3	9.1	22
	7.8	9.3	19
	8.0	9.1	13
	9.1	10.0	11
Female	6.9	7.9	12
	7.4	8.3	11
	7.4	8.2	9
	8.0	8.7	8
	8.3	9.3	12
	8.5	9.5	12
	8.8	9.6	9
	9.2	10.2	12
	10.5	12.0	18
Mean±SD	8.2±0.9	9.3±1.0	12.9±4.0

Values are presented as number only, or mean±standard deviation.

2. Experimental Methods

1) Lateral cephalometric radiography and analysis

Lateral cephalograms were taken before and after treatment (for cases) or observation (for controls). Cranial measurements and analysis were conducted using the V-Ceph™ 8.0 (Osstem Implant, Seoul, Korea) program. To verify the reliability of measurements, five randomly selected patients underwent replicate measurements. This resulted in a high degree of agreement with a mean intraclass correlation coefficient (ICC) value of 0.999, establishing the reliability of measurement results[13]. To standardize measurements, several clinical analysis methods, such as Steiner, Down, McNamara, and Ricketts analyses, were consulted. A total of 41 measurements using 25 measurement points and eight reference planes were selected as the basis for comparison.

2) Evaluation of skeletal measurement changes

To evaluate the change in anteroposterior positional maxillomandibular relationship, the SNA (°), SNB (°), ANB difference (°), AB plane angle (°), AB to occlusal plane (°), facial convexity (°), facial angle (°), convexity of A point (mm), A to N-perpendicular (mm), Pog to N-perpendicular (mm), and Wits (mm) were measured. To evaluate the change in horizontal positional maxillomandibular relationship, the SN-GoGn (°), mandibular plane (°), Y-axis (°), ramus height (mm), and palatal plane angle (°) were measured. To evaluate the vertical maxi-

Table 2. Distribution of Control Group (N=10)

Sex	Pre-treatment age (y)	Post-treatment age (y)	Treatment period (mos)
Male	7.3	8.5	15
	8.5	11.3	33
	9.8	10.8	12
	10.2	11.4	15
	10.7	11.6	11
	10.8	11.2	6
	11.3	15.1	46
Female	6.3	7.0	8
	7.2	8.7	18
	7.7	8.8	13
Mean±SD	9.0±1.6	10.4±2.1	17.7±11.2

Values are presented as number only, or mean±standard deviation.

llomandibular relationship, SN-GoGn (°), mandibular plane (°), Y-axis (°), ramus height (mm), and palatal plane angle (°) were measured.

3) Evaluation of dental measurement changes

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

4) Evaluation of soft tissue changes

To evaluate changes in shape of the lateral facial soft tissue, the following measurements were recorded: upper lip to E-plane (mm), lower lip to E-plane (mm), nasolabial angle (°), upper nasolabial angle (°), lower nasolabial angle (°), upper lip to A'B' (mm), lower lip to A'B' (mm), and Pog' to A'B' (mm).

3. Statistical analysis

All analyses were performed using IBM SPSS statistics 25.0 (IBM Corp., Armonk, NY, USA). A paired-sample t-test was used to test the statistical significance of intra-group changes, and an independent-sample t-test was used to test statistical significance of intergroup differences.

Results

1. Evaluation of skeletal changes

In the treatment group, no changes were seen in the SNA (°) or A-to-N-perp. (mm), which indicate the position of point A relative to the reference planes for the skeleton, SN, and FH planes. However, facial convexity (°) and convexity of point A (mm), which indicate relative position of point A to Pog ($p < 0.01$). In the mandible, SNB (°) increased ($p < 0.1$), were significantly reduced. No significant changes were observed in facial angle (°) or Pog to N-perp. (mm), which indicate the position of Pog relative to the FH plane. ANB difference (°), AB plane angle (°), and Wits (mm), which indicate the anteroposterior maxillomandibular relationship, decreased ($p < 0.01$), whereas AB to Occ. Plane (°) increased ($p < 0.01$). Ramus height (mm) increased ($p < 0.05$), while Sn- GoGn (°), mandibular plane (°), Y-axis (°), and palatal plane angle (°), which indicate the angle between the mandibular and reference planes, showed no significant changes (Table 3). In the control group, there were no significant skeletal changes other than those in the ramus height ($p < 0.01$) (Table 4). On comparing the treatment and control groups, no intergroup differences were observed in SNB (°), AB plane angle (°), or ramus height (mm); however, significant intergroup differences were observed in ANB difference (°) ($p < 0.05$), AB to Occ. Plane (°) ($p < 0.05$), facial convexity (°) ($p < 0.01$), convexity of point A (mm) ($p < 0.01$), and Wits (mm) ($p < 0.05$) (Table 5).

2. Evaluation of changes in dental measurements

Evaluation of the treatment group revealed no changes in the position of maxillary incisors, indicated by U1 to NA (mm) and U1 to NA (°); however, upper occlusal plane to U1 (°) increased ($p < 0.05$), and U1 to A-Pog (mm), U1 to SN (°), and U1 to FH (°) decreased ($p < 0.05$), indicating significant changes in the maxillary incisor angle. Among the mandibular incisor-related parameters, only L1 to A-Pog (mm) increased ($p < 0.01$). In terms of the positional relationship in the anterior mandibular region, the interincisal angle (°) increased and the overjet (mm) decreased ($p < 0.01$); however, no changes in overbite (mm) or occlusal plane (Table 3) were observed. In the control group, U1 to NA (mm) ($p < 0.05$) and U1 to A-Pog (mm) increased ($p < 0.1$); however, no changes in maxillary incisor angle-related parameters were observed. However, partial changes were observed in mandibular incisor angle- and position-related parameters, with an increase in L1 to NB (mm) ($p < 0.05$), L1 to A-Pog (mm) ($p < 0.05$), and L1 to NB (°) ($p < 0.1$).

Table 3. Intragroup Values for the Treatment Group: Skeletal, Dental and Soft Tissue Measurements of the Pre- and Post-Treatment Lateral Cephalograms (N=13)

Measurement	Pre-treatment	Post-treatment	Difference	p-value
	Mean±SD	Mean±SD	Mean±SD	
SNA (°)	81.21±2.14	80.17±2.99	−1.04±2.76	NS
SNB (°)	74.33±3.1	75.51±2.81	1.18±1.88	0.051
ANB difference (°)	6.88±1.5	4.66±1.87	−2.22±1.81	0.001
AB plane angle (°)	−9.84±1.83	−6.48±2.57	3.35±2.88	0.002
AB to Occ. Plane (°)	88.57±3.81	92.65±3.64	4.08±3.09	0.001
Facial convexity (°)	15.31±4.29	10.95±4.61	−4.36±3.99	0.003
Facial angle (°)	82.86±2.91	83.86±2.6	1±2.2	NS
Convexity of A point (mm)	7.52±2.27	5.53±2.44	−1.99±2.13	0.007
A to N-perp. (mm)	−0.05±2.17	−1.14±1.76	−1.08±3.32	NS
Pog to N-perp. (mm)	−13.97±6.06	−12.29±5.32	1.68±4.5	NS
Wits (mm)	0.91±2.23	−1.8±2.45	−2.71±1.98	0.000
SN-GoGn (°)	39.51±4.72	38.15±5.29	−1.36±2.98	NS
Mandibular plane (°)	30.76±4.8	29.4±6.07	−1.36±3.18	NS
Y-axis (°)	65.23±3.18	64.53±2.88	−0.7±2.2	NS
Ramus height (mm)	41.57±3.65	45.35±3.74	3.78±5.03	0.023
Palatal plane angle (°)	−0.22±2.86	−1.12±2.21	−0.9±3.1	NS
U1 to NA (mm)	3.49±1.59	3.99±1.24	0.5±1.46	NS
U1 to A-Pog (mm)	9.27±2.1	8.13±1.66	−1.14±1.61	0.031
U1 to NA (°)	26.48±5.49	23.95±4.99	−2.53±5.99	NS
Upper Occ. Plane to U1 (°)	48.01±4.92	51.86±3.92	3.85±5.31	0.027
U1 to SN (°)	107.69±6.45	104.12±4.3	−3.58±5.75	0.052
U1 to FH (°)	116.44±5.98	112.87±4.36	−3.57±5.75	0.052
L1 to NB (mm)	7.61±2.44	7.27±2.48	−0.34±2.12	NS
L1 to A-Pog (mm)	3.3±1.81	4.4±1.74	1.1±1.13	0.006
L1 to NB (°)	31.24±5.47	29.83±5.26	−1.41±4.15	NS
L1 to Occ. Plane (°)	66.95±6.11	68.93±6.07	1.98±4.71	NS
L1 to Mn plane (°)	7.41±6.17	6.18±5.26	−1.23±3.41	NS
L1 to A-Pog (°)	22.82±3.83	23.55±3.66	0.73±4.21	NS
Interincisal angle (°)	115.39±8.67	121.55±5.35	6.16±5.5	0.002
Incisor overbite (mm)	0.87±2.19	1.12±1.71	0.25±1.52	NS
Incisor overjet (mm)	6.03±0.98	3.86±1.26	−2.17±1.16	0.000
Occ. Plane to SN (°)	23.86±3.87	23.26±4.26	−0.6±3.25	NS
Cant of Occ. Plane (°)	15.12±3.74	14.52±4.06	−0.6±3.36	NS
UL to E-plane (mm)	4.11±2.29	1.89±1.43	−2.21±2.17	0.005
LL to E-plane (mm)	3.52±2.1	2.4±1.99	−1.12±2.05	0.083
Nasolabial angle (°)	97.84±15.02	94.43±9.37	−3.41±13.46	NS
U-nasolabial angle (°)	25.79±10.93	20.91±8.87	−4.88±11.38	NS
L-nasolabial angle (°)	72.05±10.25	73.52±6.26	1.47±8.95	NS
UL to A'B' (mm)	7.03±1.89	5.16±1.55	−1.87±1.58	0.001
LL to A'B' (mm)	5.41±1.11	4.59±1.35	−0.82±1.53	0.087
Pog' to A'B' (mm)	−0.08±2.08	−0.35±2.53	−0.27±2.43	NS

Values are presented as number only, or mean±standard deviation.
Paired samples t-test.

Meanwhile, L1 to occlusal plane (°) decreased ($p<0.05$), indicating labially inclined mandibular incisors. No significant changes in the interincisal relationship were observed (Table 4).

Comparing the treatment and control groups, there were no significant intergroup differences in U1 to NA (mm), upper

Table 4. Intragroup Values for the Control Group: Skeletal, Dental and Soft Tissue Measurements of the Pre- and Post-Observation Lateral Cephalograms (N=10)

Measurement	Pre-observation	Post-Observation	Difference	p-value
	Mean±SD	Mean±SD	Mean±SD	
SNA (°)	82.54±2.84	82.44±2.85	−0.11±0.73	NS
SNB (°)	76.79±3.01	77.23±3.68	0.44±1.04	NS
ANB difference (°)	5.75±1	5.21±1.39	−0.55±0.73	NS
AB plane angle (°)	−8.52±1.73	−7.33±2.79	1.18±1.75	NS
AB to Occ. Plane (°)	90.96±4.65	90.87±4.95	−0.08±2.92	NS
Facial convexity (°)	12.37±2.32	11.69±2.72	−0.68±2.12	NS
Facial angle (°)	84.41±2.5	84.42±2.72	0.01±1.05	NS
Convexity of A point (mm)	6.04±1.41	5.96±1.54	−0.07±0.97	NS
A to N-perp. (mm)	0.25±2.33	−0.05±1.9	−0.3±1.11	NS
Pog to N-perp. (mm)	−10.74±4.67	−11.31±5.52	−0.57±2.13	NS
Wits (mm)	0.1±2.4	−0.29±3.81	−0.4±2.1	NS
SN-GoGn (°)	35.41±4.08	35.33±4.37	−0.08±2.48	NS
Mandibular plane (°)	27.83±3.41	27.87±3.89	0.04±2.54	NS
Y-axis (°)	62.99±2.79	63.69±2.66	0.7±1.17	NS
Ramus height (mm)	42.44±3.17	46.2±5.03	3.76±3.27	0.007
Palatal plane angle (°)	−0.07±3.03	−0.3±1.66	−0.23±3.39	NS
U1 to NA (mm)	4.65±1.65	5.4±1.18	0.75±0.84	0.025
U1 to A-Pog (mm)	9.28±1.27	9.82±1.51	0.54±0.67	0.037
U1 to NA (°)	27.57±6.58	26.99±4.33	−0.58±3.8	NS
Upper Occ. Plane to U1 (°)	47.24±4.48	49.33±2.29	2.09±4.19	NS
U1 to SN (°)	110.11±6.15	109.43±5.24	−0.69±3.56	NS
U1 to FH (°)	117.7±5.44	116.89±4.48	−0.81±3.22	NS
L1 to NB (mm)	7.55±1.12	8.18±1.19	0.63±0.87	0.059
L1 to A-Pog (mm)	3.64±1.43	4.66±1.3	1.02±0.81	0.004
L1 to NB (°)	28.65±2.71	30.53±3.28	1.88±2.27	0.035
L1 to Occ. Plane (°)	69.59±3.97	67±4.77	−2.59±3.46	0.051
L1 to Mn plane (°)	6.45±5.28	7.98±5.43	1.53±3.47	0.051
L1 to A-Pog (°)	22.04±2.85	24.05±3.52	2.02±2.95	0.071
Interincisal angle (°)	118.03±5.57	117.27±5.33	−0.76±4.87	NS
Incisor overbite (mm)	1.94±2.29	1.57±2.05	−0.37±1.97	NS
Incisor overjet (mm)	5.74±1.64	5.22±1.75	−0.52±1.2	NS
Occ. Plane to SN (°)	21.45±2.56	20.3±4.54	−1.15±2.59	NS
Cant of Occ. Plane (°)	13.87±2.73	12.84±3.67	−1.02±2.63	NS
UL to E-plane (mm)	4.27±1.84	3.97±2.35	−0.3±1.65	NS
LL to E-plane (mm)	4.4±1.86	4.5±2.23	0.1±1.61	NS
Nasolabial angle (°)	92.09±6.81	92.53±12.88	0.44±12.06	NS
U-nasolabial angle (°)	21.3±5.28	21.76±7.78	0.46±9.27	NS
L-nasolabial angle (°)	70.79±4.28	70.77±7.03	−0.03±5.69	NS
UL to A'B' (mm)	7.55±1.38	7.55±2.41	−0.01±1.45	NS
LL to A'B' (mm)	6.89±2.15	7.21±2.05	0.31±1.69	NS
Pog' to A'B' (mm)	0.79±3.04	0.62±3.04	−0.17±1.42	NS

Values are presented as number only, or mean±standard deviation.
Paired samples t-test.

occlusal plane to U1 (°), U1 to SN (°), U1 to FH (°), L1 to A-Pog (mm), and L1 to Mn. Plane (°), and L1 to A-Pog (°). In contrast, significant intergroup differences were found in U1 to A-Pog (mm) ($p < 0.01$), L1 to NB (°) ($p < 0.05$), L1 to occ. Plane (°) ($p < 0.05$), interincisal angle (°) ($p < 0.01$), and incisor overjet (mm) ($p < 0.01$) (Table 5).

Table 5. Intergroup Comparisons of Difference for Treatment (N=13) and Control Group (N=10)

Measurement	Treatment group	Control group	p-value
	Mean±SD	Mean±SD	
SNA (°)	−1.04±2.76	−0.11±0.73	NS
SNB (°)	1.18±1.88	0.44±1.04	NS
ANB difference (°)	−2.22±1.81	−0.55±0.73	0.015
AB plane angle (°)	3.35±2.88	1.18±1.75	NS
AB to Occ. Plane (°)	4.08±3.09	−0.08±2.92	0.005
Facial convexity (°)	−4.36±3.99	−0.68±2.12	0.02
Facial angle (°)	1±2.2	0.01±1.05	NS
Convexity of A point (mm)	−1.99±2.13	−0.07±0.97	0.019
A to N-perp. (mm)	−1.08±3.32	−0.3±1.11	NS
Pog to N-perp. (mm)	1.68±4.5	−0.57±2.13	NS
Wits (mm)	−2.71±1.98	−0.4±2.1	0.017
SN-GoGn (°)	−1.36±2.98	−0.08±2.48	NS
Mandibular plane (°)	−1.36±3.18	0.04±2.54	NS
Y-axis (°)	−0.7±2.2	0.7±1.17	NS
Ramus height (mm)	3.78±5.03	3.76±3.27	NS
Palatal plane angle (°)	−0.9±3.1	−0.23±3.39	NS
U1 to NA (mm)	0.5±1.46	0.75±0.84	NS
U1 to A-Pog (mm)	−1.14±1.61	0.54±0.67	0.007
U1 to NA (°)	−2.53±5.99	−0.58±3.8	NS
Upper Occ. Plane to U1 (°)	3.85±5.31	2.09±4.19	NS
U1 to SN (°)	−3.58±5.75	−0.69±3.56	NS
U1 to FH (°)	−3.57±5.75	−0.81±3.22	NS
L1 to NB (mm)	−0.34±2.12	0.63±0.87	NS
L1 to A-Pog (mm)	1.1±1.13	1.02±0.81	NS
L1 to NB (°)	−1.41±4.15	1.88±2.27	0.042
L1 to Occ. Plane (°)	1.98±4.71	−2.59±3.46	0.022
L1 to Mn plane (°)	−1.23±3.41	1.53±3.47	NS
L1 to A-Pog (°)	0.73±4.21	2.02±2.95	NS
Interincisal angle (°)	6.16±5.5	−0.76±4.87	0.007
Incisor overbite (mm)	0.25±1.52	−0.37±1.97	NS
Incisor overjet (mm)	−2.17±1.16	−0.52±1.2	0.004
Occ. Plane to SN (°)	−0.6±3.25	−1.15±2.59	NS
Cant of Occ. Plane (°)	−0.6±3.36	−1.02±2.63	NS
UL to E-plane (mm)	−2.21±2.17	−0.3±1.65	0.038
LL to E-plane (mm)	−1.12±2.05	0.1±1.61	NS
Nasolabial angle (°)	−3.41±13.46	0.44±12.06	NS
U-nasolabial angle (°)	−4.88±11.38	0.46±9.27	NS
L-nasolabial angle (°)	1.47±8.95	−0.03±5.69	NS
UL to A'B' (mm)	−1.87±1.58	−0.01±1.45	0.011
LL to A'B' (mm)	−0.82±1.53	0.31±1.69	NS
Pog' to A'B' (mm)	−0.27±2.43	−0.17±1.42	NS

Values are presented as number only, or mean±standard deviation.
Paired samples t-test.

3. Evaluation of changes in soft tissue measurements

In the treatment group, a decrease in UL to E-plane (mm) ($p<0.01$), LL to E-plane (mm) ($p<0.1$), and UL to A'B' (mm) ($p<0.01$) was observed (Table 3). In the control group, no significant changes in soft tissue measurements were observed (Table 4). However, an intergroup comparison revealed that UL to E-plane (mm)

($p < 0.05$) and UL to A'B' (mm) ($p < 0.01$) were significantly lower in the treatment group than in the control group, whereas LL to E-plane (mm) showed no significant intergroup difference (Table 5).

Discussion

1. Interpretation

Class II malocclusion tends to persist or worsen over time, declining from deciduous tooth eruption to mixed dentition eruption[14]. In addition, oral habits such as nonnutritive sucking or mouth breathing can create abnormal muscular pressure, leading to dental, dentoalveolar, and skeletal symptoms that may escalate to Class II malocclusion[15]. Therefore, in addition to improving dental arch and maxillomandibular relationship, patients undergoing treatment for Class II malocclusion should attempt to address functional issues, such as abnormal tongue position, dysfunctional labial and perioral soft tissue, and mouth breathing.

Orthopedic treatment refers to inducing changes in skeletal structure through growth in growth-phase patients. Patients with Class II malocclusion have traditionally undergone orthopedic treatment using functional appliances during the growth phase. Linder-Aronson et al.[16] found that a shift from oral to nasal breathing increased horizontal mandibular growth, normalizing incisal position.

Traditionally used functional appliances are bulky, complex, and must be custom-made for each patient. To overcome these drawbacks, prefabricated functional appliances have been developed. Myobrace®which was used in this study, was initially called Pre-orthodontic Trainer, Trainer for Kids™ (T4K®), and Trainer for Alignment™ (T4A™). Similarly shaped products include the education function line® (Orthoplus, Igny, France), Preortho (Biomaterials Korea Inc., Gyeong-gi, Korea) and LM-Activator™ (LM-dental, Pargas, Finland). Products such as Occlus-o-Guide® (Orthotain, IL, USA) are called eruption guidance appliances; however, their shape and function are similar enough to those of the aforementioned devices to be considered prefabricated functional appliances[17].

Prefabricated functional appliances can effectively alleviate Class II Division 1 malocclusion, especially in growing children[12,18,19]. Among them, Myobrace® is a functional appliance that improves malocclusion by repositioning the mandible and eliminating abnormal muscle function[20]. Its anterior part looks similar to that of an oral shield. However, unlike an oral shield, it has a tooth slot, tongue guard, and tongue tag to induce correct tooth alignment and tongue positioning. Similarly to the Fränkel[6] appliance, it has a buccal shield and a lip pad. The basic design principle of the oral shield and Fränkel[6] appliance is to relieve the pressure on the buccal and labial muscles by separating them from the teeth, inducing bone growth and removing abnormal perioral myofunctional habits.

In this study, skeletal, dental, and soft tissue changes occurring during treatment of Class II Division 1 malocclusion with a prefabricated functional appliance were evaluated using cephalometric radiographs. The results were compared with those of the control group, which did not use the appliance.

2. Comparison with previous studies

Previous studies investigating the effects of prefabricated functional appliances in patients with Class II Division 1 malocclusion have reported skeletal changes. For example, Usumez et al.[12] observed an increase in facial height; however, in the present study, no vertical skeletal changes were observed. Janson et al.[18] noted mandibular growth induction, mandibular incisor protrusion, and increase in mandibular anterior and total anterior facial heights; however, in this study, no skeletal changes were found in maxillomandibular position relative to the basal plane. Although SNB increased in the treatment group, no significant differences were found between the treatment and control groups. However, our measurements indicated that the anteroposterior positional maxillomandibular relationship (ANB, AB to occlusal plane) showed significant changes; this was consistent with previous studies, such as those conducted by Janson et al.[18] and Keski-Nisula et al.[19]. In addition, a significant decrease was observed in facial convexity, i.e., perpendicular distance from point A to the facial plane.

A significant dental change observed in previous studies was a decrease in overjet[12,18,20-23]. In this study, the treatment group had significantly reduced overjet compared to that in the control group. Although interincisal angle was increased due to reduced labial inclination of maxillary incisors, the difference in degree of inclination change was not statistically significant between groups. In addition, there were no changes in overbite or mandibular incisor angle. However, a statistically significant labial inclination of the mandibular incisors was observed in the control group, as compared with the inclination observed in the treatment group. Little research has been conducted to observe changes in soft tissue, except for the study by Čirgić et al.[22], which confirmed an improvement in lip seal. In the present study, a significant decrease in upper lip protrusion was observed.

In this study, the treatment group showed skeletal changes, including a decrease in maxillary protrusion and anteroposterior maxillomandibular discrepancy, compared with the same parameters as observed in the control group. However, no significant vertical skeletal changes were observed. In addition, an improvement in anteroposterior discrepancy in the maxillary and mandibular incisors was observed. This was due to an increase in interincisal angle and decrease in overjet, presumably because of reduced labial inclination of the maxillary incisors. Soft tissue analysis revealed a significant decrease in maxillary protrusion, indicating improved facial aesthetics. Thus, this study verified the effectiveness of the appliance in reducing anteroposterior discrepancies in skeletal, dental, and soft tissue structures.

In addition to affecting skeletal growth, muscles and soft tissues contribute to the stability of orthodontic treatment. Since dentition is the result of complex interactions between many factors affecting growth and development, it is likely to return to its previous state without changes in the muscles after treatment, even if the teeth are correctly aligned[24]. In this regard, functional appliances are useful post-treatment maintenance devices.

However, functional appliances may not be suitable for cases with high tooth mobility, such as orthodontic extraction. In the event of low patient compliance, appropriate cases should be selected for treatment with functional appliances.

3. Limitations

The limitations of this study included its small sample size, non-randomized clinical trial design, large variations in treatment, observation periods, and patient age, and lack of long-term follow-up. Additionally, it is necessary to conduct a long-term prospective study comparing the effectiveness of functional appliances with those of other appliances reviewed in previous studies.

4. Suggestions

The results of this study indicate that treating Class II Division 1 malocclusion patients in the growth phase with functional appliances reduces anteroposterior discrepancies in skeletal, dental, and soft tissue structures.

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: Eun-Hee 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: Eun-Hee Kim, Ho-Uk Lee, Sang-Ho Bak, and Hyo-Jin Kang.

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Data availability

The Myobrace® data can be obtained here (www.myobrace.com).

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