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Effects of the long-term use of maxillary protraction facemasks with skeletal anchorage on pharyngeal airway dimensions in growing patients with cleft lip and palate

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Objective: To investigate the effects of the long-term use of a maxillary protraction facemask with miniplate (FM-MP) on pharyngeal airway dimensions in growing patients with cleft lip and palate (CLP). **Methods:** The study included 24 boys with CLP (mean age, 12.2 years; mean duration of FM-MP therapy, 4.9 years), divided into two groups according to the amount of A point advancement to the vertical reference plane (VRP): Group 1, > 4 mm; Group 2, < 2 mm; n = 12/group. After evaluating the skeletodental and airway variables using lateral cephalograms acquired before and after FM-MP therapy, statistical analyses were performed. **Results:** Group 1 showed greater forward and downward displacements of the posterior maxilla (posterior nasal spine [PNS]-horizontal reference plane [HRP]; PNS-VRP), greater increase in ANB, more forward tongue position (tongue tip-Pt vertical line to Frankfort horizontal plane), and greater increase in the oropharynx (superior posterior airway space [SPAS]; middle airway space [MAS]) and upper nasopharynx (PNS-adenoid2) than did Group 2. While maxillary advancement (A-VRP and PNS-VRP) correlated with increases in SPAS, MAS, and PNS-adenoid2, downward displacement of the PNS (PNS-HRP) correlated with increases in SPAS, MAS, PNS-adenoid1, and PNS-adenoid2, and with a decrease in vertical airway length (VAL). Mandibular forward displacement and decrease in mandibular plane correlated with increases in MAS. **Conclusions:** FM-MP therapy had positive effects on the oropharyngeal and nasopharyngeal airway spaces without increases in VAL in Group 1 rather than in Group 2. However, further validation using an untreated control group is necessary.
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Key words: Growing patients with cleft lip and palate, Maxillary protraction, Facemask with miniplate, Pharyngeal airway dimension

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INTRODUCTION

Patients with cleft lip and palate (CLP) have been reported to present impaired craniofacial and upper airway development.[1,2] They have craniofacial deformities characterized by nasomaxillary deficiency mostly due to the inhibitory effects of scar tissues from primary surgeries.[3-5] The maxillomandibular skeletal discrepancies relative to the cranium influence the morphology and dimension of the upper airway, which encompasses the nasal cavity and pharyngeal airway spaces.[6,7] A previous study demonstrated that nasal airway patency was significantly lower on the cleft side than on the non-cleft side.[8] A recent cone-beam computed tomography study also revealed that oropharyngeal airway dimension and volume were significantly reduced in patients with CLP than in age-matched controls without CLP.[1] Accordingly, patients with CLP are liable to experience respiratory functional disorders like mouth breathing, snoring, and obstructive sleep apnea.[9,10]

As a treatment modality for skeletal modification in preadolescent or adolescent patients with CLP, the maxillary protraction facemask has been commonly supplemented with or without maxillary expansion. The main skeletal and dental effects of the protraction facemask include forward and downward displacements of the maxilla, counterclockwise rotation of the palatal plane, clockwise rotation of the mandible that increases lower facial height, proclination of the upper incisors, retroclination of the lower incisors, and decrease of overbite.[11,12] A few studies elucidated that short-term application of the facemask increased nasopharyngeal airway dimensions, including increasing airway length, without causing significant changes in oropharyngeal or hypopharyngeal airway spaces in children with Class III malocclusion.[13-15] However, only few studies have reported the effects of the facemask on skeletal and upper airway morphology in patients with CLP by comparing them to controls without CLP. Moreover, the scar tissues affect not only abnormal growth and development but also treatment response and stability, and the treatment effect of maxillary protraction in patients with CLP may differ from that of patients with Class III malocclusion without CLP.

Recently, the introduction of skeletal anchorage to maxillary protraction has increased the range of skeletal effects up to post-adolescent age groups with less dentoalveolar effects.[16] Baek et al.[17] suggested facemask with miniplate (FM-MP) therapy as an effective option for maxillary deficiency in patients with CLP. Based on the findings of previous studies reporting more favorable skeletodental effects of FM-MP therapy over those of conventional facemask therapy, representing greater maxillary advancement with lesser clockwise rotation of the mandible in adolescent patients with CLP,[18,19] we anticipated a different influence on the upper airway dimension and morphology. Accordingly, the aim of this retrospective study was to investigate the effects of the long-term use of the FM-MP on pharyngeal airway dimensions in growing patients with CLP who are liable to experience upper airway impairment.

MATERIALS AND METHODS

Patients

Seventy-five patients with CLP who underwent FM-MP therapy at the Department of Orthodontics, Seoul National University Dental Hospital, were initially recruited. The inclusion criteria were as follows: (1) patients diagnosed with non-syndromic unilateral or bilateral CLP (UCLP or BCLP, respectively); (2) patients treated using an identical surgical technique performed by a single surgeon (Millard rotation and advancement flap for cheiloplasty at 3 to 5 months after birth or Furlow double-opposing Z-plasty for one-stage palatorrhaphy at 12 to 18 months after birth); (3) patients whose miniplates were installed by a single surgeon and who underwent FM-MP therapy for at least or more than 2 years under a single orthodontist; (4) boys in the growth stage with a skeletal maturation index of less than 5 before the start of FM-MP therapy;[20] and (5) patients who had skeletal Class III relationship with maxillary hypoplasia (SNA < 78° and ANB < 0°). The exclusion criteria were as follows: (1) patients who had craniofacial anomalies; (2) patients who had a history of primary gingivoperiosteoplasty or velopharyngoplasty; (3) patients who were girls, in order to avoid the influence of sex; and (4) patients with A point advancement ranging between 2 mm and 4 mm. Patients who had more than 4 mm of A point advancement were included in the experimental group, because this amount of advancement shows a therapeutic effect of one cusp width correction. Since less than 2 mm of A point advancement might be comparable to natural growth changes in patients with CLP,[21] these patients were included in the positive control group.

The final study sample comprised 24 boys with CLP (13 with UCLP and 11 with BCLP; mean age, 12.2 ± 2.2 years; mean duration of FM-MP therapy, 4.9 ± 1.6 years). They were divided into two groups according to the amount of A point advancement to the vertical reference plane (VRP): Group 1 included 12 boys with advancement > 4 mm, mean age of 11.7 years, and mean duration of FM-MP therapy of 4.9 years; Group 2 included 12 boys with advancement < 2 mm, mean age of 12.1 years, and mean duration of FM-MP therapy of 4.8 years (Table 1). This study was reviewed and approved by the Institutional Review Board of Seoul National Uni-

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Table 1. Demographic data of patients

Variable	Group 1 (n = 12 boys with 6 UCLP and 6 BCLP)		Group 2 (n = 12 boys with 7 UCLP and 5 BCLP)		*p*-value
	Mean	SD	Mean	SD	
Age at the T0 stage (yr)	11.7	3.1	12.1	2.3	0.135
Mean duration of FM-MP (yr)	4.9	1.6	4.8	2.2	0.865

Independent *t*-test was performed.
Group 1, A point advancement > 4 mm; Group 2, A point advancement < 2 mm; UCLP, unilateral cleft lip and palate; BCLP, bilateral cleft lip and palate; SD, standard deviation; T0, before treatment; FM-MP, facemask with miniplate.

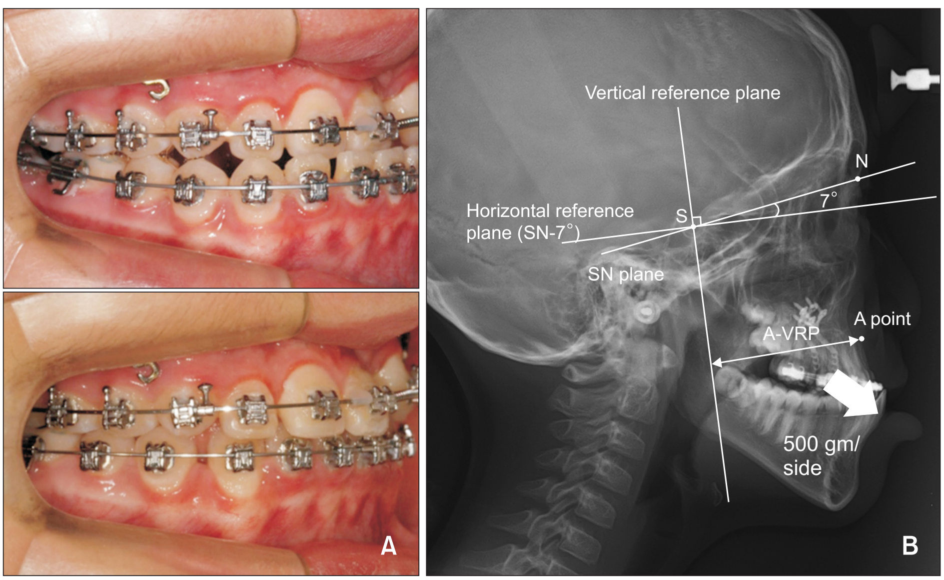

Figure 1. A, An example of facemask with miniplate (FM-MP) therapy. **B**, Reference lines. The horizontal reference plane (HRP) passes the Sella (S) at an angle of 7 degree clockwise to the Sella-Nasion (SN) plane. The vertical reference plane (VRP) is perpendicular to the HRP passing through the S. A-VRP is the horizontal distance from the VRP to A point.

versity School of Dentistry (ERI 18019).

Protocol of FM-MP therapy

The protocol of FM-MP therapy was as follows.[17,18] After placement of curvilinear surgical miniplates (KLS Martin, Tuttlingen, Germany) on the infrazygomatic crest area (1 per side), the ends of the miniplates were exposed through the attached gingiva between the maxillary canine and first premolar. At 8 weeks after the placement of the miniplates, a Petit-type facemask (Kwang Myung DAICOM, Seoul, Korea) was delivered. Patients were instructed to apply the elastics from the miniplates to the facemask hooks for at least 12 to 14 hours per day with 500 g of force on each side (Figure 1).

Cephalometric analysis

Lateral cephalograms were assessed before (T0) and at the time of completion of FM-MP therapy (T1). While acquiring the lateral cephalograms, the patients were asked to stand with a natural head position, to occlude slightly after a usual swallow, and to hold their breath after the end of expiration.[22] The reference planes, landmarks, and cephalometric variables used in this study are shown in Figures 1 and 2, and Table 2. Since the nasion area showed forward growth during FM-MP therapy, the actual sagittal and vertical changes of point A and the posterior nasal spine (PNS) had to be evaluated using the VRP and horizontal reference plane (HRP) passing the Sella point.[19]

A single investigator traced the lateral cephalograms and measured the cephalometric variables using the V-ceph software ver. 7.0 (Osstem Implant Co., Seoul, Korea). All variables from randomly selected patients were remeasured by the same operator after a 2-week interval. The intraoperator measurement error was assessed using the intraclass correlation coefficient. Since no significant differences were observed between the first and second measurements, the first set of measurements was used for analysis.

Statistical analysis

The power analysis was performed to determine the sample size with G*Power version 3.1.9.4 (Kiel University, Kiel, Germany; 0.05 two-sided significance level) using

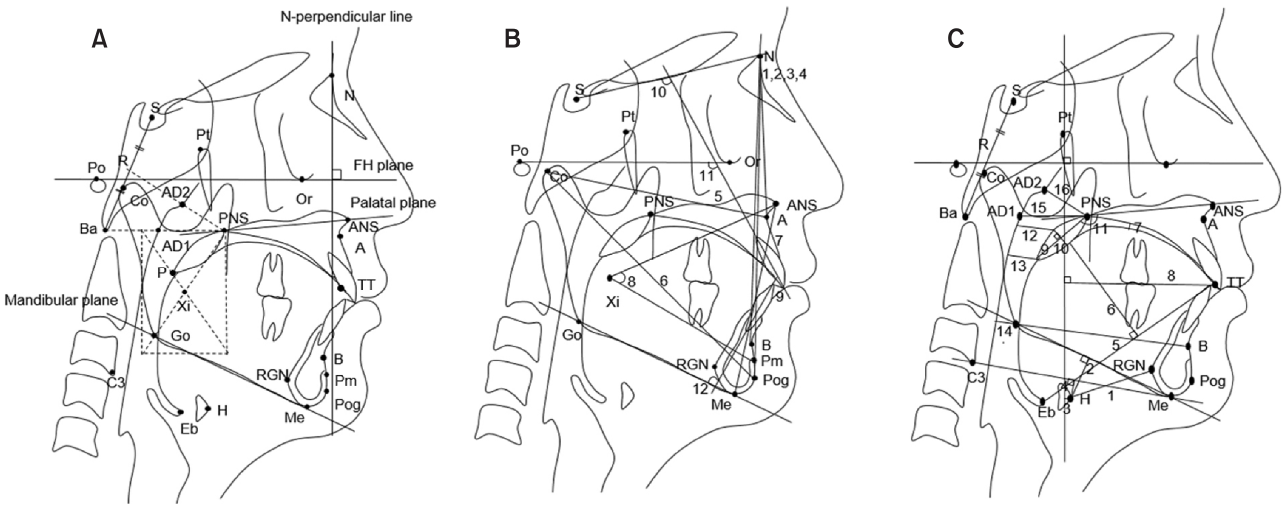

Figure 2. Cephalometric landmarks and measurements. **A**, Landmarks. S, Sella; N, nasion; Ba, basion; Or, orbitale; Po, porion; Pt, pterygoid point; R, midpoint between sella and basion; AD1, adenoid point 1 (adenoid tissue on the PNS-Ba line); AD2, adenoid point 2 (adenoid tissue on the R-PNS line); Co, condylion; Go, gonion; ANS, anterior nasal spine; PNS, posterior nasal spine; A, point A; B, point B; TT, tongue tip; Pog, pogonion; Me, menton; P, tip of the soft palate; Eb, base of the epiglottic fold; H, hyoidale (the most anterosuperior point on the body of the hyoid bone); RGN, retrognathion; Pm, protuberance menti; Xi, geometric center of the ramus; FH, Frankfort horizontal; C3, the third vertebrae. **B**, Skeletodental variables. 1, SNA; 2, SNB; 3, SN-Pog; 4, ANB; 5, effective maxillary length (EMxL); 6, effective mandibular length (EMnL); 7, ANS-Me; 8, lower facial height (ANS-Xi-Pm); 9, overjet; 10, U1-SN; 11, U1-FH; 12, L1-MP. **C**, Airway-related variables. hyoid bone 1, H-RGN; 2, MP-H; 3, H-PTV; 4, H-C3Me; tongue 5, TGL; 6, TGH; 7, Td-PP; 8, TT-PTV; soft palate 9, SPL; 10, SPT; 11, SPA; pharyngeal airway 12, SPAS; 13, MAS; 14, IAS; 15, PNS-AD1; 16, PNS-AD2.
See Table 2 for definitions of each landmark or measurement.

the mean and standard deviation values of SNA from a previous study.[18] Since the sample size required for 80% power for the significance levels of representative cephalometric parameters was more than 10 per group, we selected 12 patients per group to account for potential dropouts.

All data were analyzed using IBM SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, NY, USA). Following the Shapiro–Wilk test to assess the normality of data distribution, the paired *t*-test was performed to assess the treatment changes in each group, and the independent *t*-test was performed to compare the treatment changes in each cephalometric variable between the two groups. To identify correlation factors contributing to the treatment changes in pharyngeal airway dimensions, Pearson's correlation analysis was used. The level of significance was established as $p < 0.05$.

RESULTS

Comparison of the demographic data and cephalometric variables at T0

No significant differences were observed in age, mean duration of FM-MP therapy (Table 1), and skeletodental and airway space variables at T0 between groups 1 and 2 (all $p > 0.05$; Table 3).

Evaluation of the change in cephalometric variables during T0–T1 in each group (Table 4)

Group 1 showed advancement of A point (A-VRP, 6.1 mm, $p < 0.01$; SNA, 2.5° and A-N perp, 2.7 mm, all $p < 0.001$), downward and forward displacements of the PNS (PNS-HRP, 4.5 mm; PNS-VRP, 4.8 mm, all $p < 0.001$), increase in ANB (3.4°, $p < 0.01$), increase in effective maxillary and mandibular lengths (EMxL, 6.0 mm and EMnL, 8.8 mm, all $p < 0.001$), increase in overjet (4.3 mm, $p < 0.001$) and labioversion of the upper incisors (U1-FH, 7.4° and U1-SN, 7.5°, all $p < 0.05$), increase in tongue length and forward repositioning of the tongue tip (TGL, 12.8 mm, $p < 0.001$; TT-PTV, 5.8 mm, $p < 0.01$), decrease in soft palate angle (SPA, −3.8°, $p < 0.01$), and increase in the pharyngeal airway spaces (superior posterior airway space [SPAS], 4.9 mm, $p < 0.01$; middle airway space [MAS], 3.6 mm, $p < 0.001$; inferior airway space [IAS], 2.0 mm, $p < 0.05$; and nasopharyngeal airway space [PNS-ad1, 6.0 mm and PNS-ad2, 7.4 mm], all $p < 0.001$).

Group 2 showed advancement of A point (A-VRP, 1.3 mm, $p < 0.01$), downward displacement of the PNS (PNS-HRP, 2.9 mm, $p < 0.001$), increase in effective

Table 2. Definition of the cephalometric skeletodental and airway variables

Variable			Definition
Skeletodental		A-VRP (mm)	Distance between point A (A) and vertical reference plane (VRP)
		SNA (°)	The angle between Sella-Nasion (SN) plane and Nasion-A plane
		A-N perp (mm)	The shortest linear distance between A and N-perpendicular line
		PNS-HRP (mm)	Distance between posterior nasal spine (PNS) and horizontal reference plane (HRP)
		PNS-VRP (mm)	Distance between PNS and VRP
		SNB (°)	The angle between SN plane and Nasion-B plane
		B-N perp (mm)	The shortest linear distance between point B and N-perpendicular line
		SN-Pog (°)	The angle between SN plane and Nasion-Pogonion (Pog) plane
		Pog-N perp (mm)	The shortest linear distance between Pog and N-perpendicular line
		ANB (°)	The angle between Nasion-A plane and Nasion-B plane
		EMxL (mm)	Distance between condylion (Co) and A
		EMnL (mm)	Distance between Co and Pog
		PP-FH (°)	The angle between palatal plane and Frankfort horizontal (FH) plane
		MP-FH (°)	The angle between FH plane and mandibular plane (MP)
		LFH (°)	The angle between anterior nasal spine (ANS)-geometric center of the ramus (Xi) plane and Xi-protuberance menti (Pm) plane
		Overjet (mm)	Horizontal distance between incisal edges of maxillary and mandibular incisors
		U1-SN (°)	The angle between the SN plane and the axis of upper central incisor
		U1-FH (°)	The angle between the FH plane and the axis of upper central incisor
		L1-MP (°)	The angle between MP and the axis of lower central incisor
Airway space	Hyoid bone	H-RGN (mm)	Distance between hyoidale (H) and retrognathion (RGN)
		MP-H (mm)	Distance along perpendicular line from H to MP
		H-PTV (mm)	Distance along perpendicular line from H to pterygomandibular vertical plane (PTV) line
		H-C3Me (mm)	Distance along perpendicular line from H to the third vertebrae (C3)-Menton (Me) line
	Tongue	TGL (mm)	Tongue length (distance between base of the epiglottic fold [Eb] and tongue tip [TT])
		TGH (mm)	Tongue height (maximum height of line perpendicular to Eb-TT line at tongue dorsum)
		Td-PP (mm)	Distance along perpendicular line from tongue dorsum (Td) to palatal plane
		TT-PTV (mm)	Distance along perpendicular line from TT to PTV line
	Soft palate	SPL (mm)	Soft palate length (distance between PNS and tip of the soft palate [P])
		SPT (mm)	Soft palate thickness (maximum thickness of soft palate measured on line perpendicular to PNS-P)
		SPA (mm)	Soft palate angle (angle between P-PNS and palatal plane)
		P-PTV (mm)	Distance along perpendicular line from P to PTV line
	Pharyngeal airway	SPAS (mm)	Superior posterior airway space (width of airway behind soft palate along line parallel to gonion [Go]-B plane)
		MAS (mm)	Middle airway space (width of airway along line parallel to Go-B line through P)
		IAS (mm)	Inferior airway space (width of airway along Go-B line)
		VAL (mm)	Vertical airway length (distance between PNS and Eb)
		PNS-ad1 (mm)	The distance between PNS and Ad1 (the point where PNS-Basion [Ba] line intersects the posterior pharyngeal wall)
		PNS-ad2 (mm)	The distance between PNS and Ad2 (the point where a line perpendicular to Sella [S]-Ba plane passing through PNS intersects the posterior pharyngeal wall)

Table 3. Comparison of the cephalometric variables between groups 1 and 2 at T0

Variable			Group 1		Group 2		*p*-value
			Mean	SD	Mean	SD	
Skeletodental		A-VRP (mm)	56.61	3.51	60.00	5.47	0.123
		SNA (°)	74.18	2.79	73.53	3.46	0.618
		A-N perp (mm)	–3.62	3.11	–2.25	3.27	0.305
		SNB (°)	75.48	2.84	73.42	2.74	0.084
		B-N perp (mm)	–3.31	4.23	–4.03	2.78	0.629
		SN-Pog (°)	75.55	2.71	73.56	2.86	0.094
		Pog-N perp (mm)	–3.36	4.62	–3.56	3.18	0.903
		ANB (°)	–1.29	2.89	0.12	4.09	0.160
		EMxL (mm)	79.17	4.53	80.03	7.06	0.726
		EMnL (mm)	108.27	6.07	106.04	8.13	0.455
		PP-FH (°)	0.15	2.40	–0.95	1.45	0.188
		MP-FH (°)	28.09	4.52	27.67	4.71	0.823
		ANS-Me (mm)	69.72	5.90	72.79	6.42	0.235
		LFH (°)	49.72	4.34	52.70	4.71	0.121
		Overjet (mm)	–2.75	2.39	–2.90	3.04	0.893
		U1-SN (°)	97.63	6.32	93.74	9.19	0.240
		U1-FH (°)	112.04	8.07	107.06	8.40	0.152
		L1-MP (°)	87.02	4.51	92.04	8.61	0.087
Airway space	Hyoid bone	H-RGN (mm)	34.67	5.90	38.85	5.00	0.078
		MP-H (mm)	14.10	6.38	13.98	5.52	0.963
		H-PTV (mm)	0.21	5.78	–3.27	6.61	0.184
		H-C3Me (mm)	1.41	3.91	0.11	4.28	0.128
	Tongue	TGL (mm)	68.15	6.35	74.34	8.61	0.057
		TGH (mm)	31.72	4.32	31.72	4.11	0.887
		Td-PP (mm)	8.08	4.20	11.47	3.80	0.128
		TT-PTV (mm)	46.18	4.29	48.29	3.95	0.225
	Soft palate	SPL (mm)	32.61	3.50	36.40	5.78	0.065
		SPT (mm)	8.28	1.16	9.50	2.20	0.104
		SPA (°)	142.05	4.76	140.58	6.60	0.539
	Pharyngeal airway	SPAS (mm)	13.81	3.42	13.84	2.76	0.983
		MAS (mm)	13.11	2.77	11.89	3.40	0.551
		IAS (mm)	12.40	3.43	12.49	2.88	0.945
		VAL (mm)	63.73	4.90	67.71	8.16	0.219
		PNS-ad1 (mm)	22.73	3.81	23.26	4.91	0.770
		PNS-ad2 (mm)	17.99	2.61	19.10	2.81	0.330

Independent *t*-test was performed.
Group 1, A point advancement > 4 mm; Group 2, A point advancement < 2 mm; SD, standard deviation.
See Table 2 for definitions of each landmark or measurement.

maxillary and mandibular lengths (EMxL, 2.6 mm and EMnL, 8.3 mm, all $p < 0.01$), increase in labioversion of the upper incisors (U1-FH, 7.2°, $p < 0.05$; U1-SN, 7.4°, $p < 0.01$), and increase in the pharyngeal airway spaces (SPAS, 2.3 mm, $p < 0.001$; MAS, 1.9 mm, $p < 0.01$; PNS-ad1, 4.4 mm and PNS-ad2, 4.2 mm, all $p < 0.001$).

Table 4. Comparison of the treatment changes in skeletodental and airway variables between groups 1 and 2 (T1–T0)

Variable			Group 1			Group 2			p-value‡
			Mean	SD	p-value†	Mean	SD	p-value†	
Skeletodental		ΔA-VRP (mm)	6.07	1.77	0.002**	1.29	0.85	0.001**	0.000***
		ΔSNA (°)	2.53	1.22	0.000***	0.54	0.75	0.330	0.000***
		ΔA-N perp (mm)	2.70	1.14	0.000***	1.04	0.92	0.874	0.000***
		ΔPNS-HRP (mm)	4.52	1.79	0.000***	2.86	1.72	0.000***	0.030*
		ΔPNS-VRP (mm)	4.76	0.82	0.000***	1.14	0.80	0.070	0.000***
		ΔSNB (°)	0.18	2.13	0.771	0.64	2.35	0.365	0.377
		ΔB-N perp (mm)	1.31	2.23	0.067	1.62	2.79	0.070	0.767
		ΔSN-Pog (°)	0.37	2.34	0.598	0.13	2.39	0.860	0.805
		ΔPog-N perp (mm)	0.31	2.35	0.660	1.42	2.91	0.119	0.313
		ΔANB (°)	3.35	2.09	0.003**	1.18	2.21	0.090	0.008**
		ΔEMxL (mm)	5.97	2.81	0.000***	2.59	1.59	0.002**	0.014*
		ΔEMnL (mm)	8.80	5.62	0.000***	8.32	5.72	0.002**	0.590
		ΔPP-FH (°)	−0.70	0.77	0.109	0.22	0.79	0.364	0.143
		ΔMP-FH (°)	−0.62	0.96	0.300	0.14	2.34	0.838	0.597
		ΔLFH (°)	0.23	4.07	0.851	0.63	2.79	0.448	0.777
		ΔOverjet (mm)	4.32	2.87	0.000***	2.83	1.53	0.110	0.662
		ΔU1-SN (°)	7.54	8.53	0.011*	7.44	8.16	0.009**	0.977
		ΔU1-FH (°)	7.43	8.52	0.012*	7.19	8.12	0.011*	0.944
		ΔL1-MP (°)	−1.54	6.05	0.762	−2.74	4.49	0.215	0.155
Airway space	Hyoid bone	ΔH-RGN (mm)	2.71	4.94	0.038*	0.67	4.86	0.644	0.112
		ΔMP-H (mm)	0.55	4.00	0.430	0.74	3.55	0.483	0.897
		ΔH-PTV (mm)	1.01	6.29	0.347	2.02	3.13	0.047*	0.052
		ΔH-C3Me (mm)	0.26	3.03	0.769	0.96	2.76	0.252	0.560
	Tongue	ΔTGL (mm)	12.80	5.22	0.000***	3.54	5.15	0.137	0.000***
		ΔTGH (mm)	2.44	3.02	0.317	2.09	3.82	0.085	0.803
		ΔTd-PP (mm)	0.44	2.42	0.538	0.57	3.01	0.527	0.374
		ΔTT-PTV (mm)	5.79	3.36	0.002**	2.03	2.92	0.245	0.001**
	Soft palate	ΔSPL (mm)	1.56	3.44	0.145	−0.85	2.10	0.192	0.051
		ΔSPT (mm)	0.39	2.08	0.532	0.52	1.81	0.340	0.869
		ΔSPA (°)	−3.81	2.76	0.002**	−2.23	3.32	0.340	0.219
	Pharyngeal airway	ΔSPAS (mm)	4.92	3.01	0.002**	2.25	1.19	0.000***	0.002**
		ΔMAS (mm)	3.63	2.31	0.000***	1.86	1.76	0.004**	0.046*
		ΔIAS (mm)	2.00	2.72	0.027*	0.29	3.58	0.786	0.200
		ΔVAL (mm)	8.87	2.83	0.000***	7.13	5.23	0.001**	0.326
		ΔPNS-ad1 (mm)	5.96	2.29	0.000***	4.43	1.26	0.000***	0.056
		ΔPNS-ad2 (mm)	7.41	1.73	0.000***	4.23	1.36	0.000***	0.000***

Group 1, A point advancement > 4 mm; Group 2, A point advancement < 2 mm; SD, standard deviation.
See Table 2 for definitions of each landmark or measurement.
$^{*}p < 0.05$, $^{**}p < 0.01$, $^{***}p < 0.001$.
†Paired *t*-test was performed.
‡Independent *t*-test was performed.

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Comparison of the changes in cephalometric variables between groups 1 and 2 (Table 4)

Group 1 exhibited greater advancement of the anterior maxilla (A-VRP, $p < 0.001$), greater amount of forward and downward displacements of the posterior maxilla (PNS-VRP, $p < 0.001$; PNS-HRP, $p < 0.05$, respectively), greater increase in ANB angle ($p < 0.01$), greater forward tongue position (TT-PTV, $p < 0.01$) with longer tongue length (TGL, $p < 0.001$), greater increase in SPAS ($p < 0.01$), MAS ($p < 0.05$), and upper nasopharyngeal space (PNS-ad2, $p < 0.001$) than did Group 2.

In contrast, no significant differences were observed in the amount of changes in the anteroposterior position of the mandible (SNB, B-N perp, SN-Pog, and Pog-N perp), effective mandibular length (EMnL), palatal plane angle (PP-FH), mandibular plane angle (MP-FH), lower facial height, inclination of the upper and lower incisors (U1-FH, U1-SN, and L1-MP), sagittal and vertical positions of the hyoid bone (H-RGN, MP-H, H-PTV, and H-C3Me), shape and inclination of the soft palate (SPL, SPT, and SPA), IAS, and vertical airway length (VAL) between groups 1 and 2 (all $p > 0.05$).

Correlation between skeletodental and upper airway variables (Table 5)

The results of the correlation analysis between skeletodental variables and airway-related variables are presented in Table 5. The airway-related variables that correlated with the amount of maxillary advancement (A-VRP and PNS-VRP) were the increase in upper nasopharyngeal area (PNS-ad2, $R = 0.67$, $p < 0.01$), upper oropharyngeal area (SPAS, $R = 0.57$, $p < 0.01$), and lower oropharyngeal area (MAS, $R = 0.48$, $p < 0.05$), in relation to the increase in tongue length (TGL, $R = 0.54$, $p < 0.01$) and forward tongue position (TT-PTV, $R = 0.57$, $p < 0.01$). In addition, downward displacement of the PNS correlated with an increase in lower nasopharyngeal area (PNS-ad1, $R = 0.41$, $p < 0.05$) and a decrease in VAL ($R = -0.56$, $p < 0.01$). Mandibular forward displacement correlated with an increase in PNS-ad1 ($R = 0.45$, $p < 0.05$) and MAS ($R = 0.46$, $p < 0.05$), and the decrease in mandibular plane angle correlated with a decrease in MAS ($R = -0.47$, $p < 0.05$), as well as the upward (MPH, $R = 0.59$, $p < 0.01$) and forward (H-PTV, $R = -0.44$, $p < 0.05$) displacements of the hyoid bone.

Inversely in terms of pharyngeal changes, skeletal variables correlated with an increase in upper nasopharyngeal variables (PNS-ad2) including the amount of anterior and posterior maxillary protraction. The increase in lower nasopharyngeal variables (PNS-ad1) correlated with the advancement of the posterior maxilla and forward displacement of the mandible. The increase in upper oropharyngeal variables (SPAS) correlated with the downward displacement of the posterior maxilla as well as advancement of the maxilla. The increase in lower oropharyngeal variables (MAS) correlated with maxillary advancement, mandibular forward displacement, and decrease in mandibular plane angle. Neither skeletal nor dental variables showed any correlations with hypopharyngeal airway (IAS) changes.

DISCUSSION

FM-MP therapy has several advantages over the conventional tooth-borne anchored facemask therapy. First, the facemask appliance is independent of tooth

Table 5. Correlation between the skeletodental and airway-related variables

Variable			Pharyngeal airway					Hyoid			Tongue	
			PNS-ad2 (mm)	PNS-ad1 (mm)	SPAS (mm)	MAS (mm)	VAL (mm)	MPH (mm)	H-PTV (mm)	H-C3Me (mm)	TGL (mm)	TT-PTV (mm)
Maxilla	A point	A-VRP (mm)	0.667**	0.297	0.569**	0.476*	0.159	–0.047	–0.101	–0.042	0.544**	0.573**
		SNA (°)	0.518**	0.282	0.591**	0.550**	0.194	–0.103	–0.253	–0.070	0.545**	0.488*
		EMxL (mm)	0.219	0.357	0.680**	0.452*	0.478*	0.002	–0.147	–0.028	0.550**	0.625**
	PNS	PNS-HRP (mm)	0.461*	0.408*	0.551**	0.470*	–0.559**	–0.028	–0.070	–0.068	0.579**	0.568**
		PNS-VRP (mm)	0.654**	0.342	0.510*	0.397	0.118	–0.142	–0.046	–0.176	0.546**	0.652**
Mandible		SNB (°)	0.414*	0.421*	0.276	0.435*	–0.166	–0.294	0.284	–0.417*	–0.022	–0.021
		SN-Pog (°)	0.226	0.449*	0.278	0.463*	–0.109	–0.322	0.226	–0.439*	–0.006	–0.030
		EMnL (mm)	0.015	0.247	0.309	0.363	0.441*	0.073	–0.091	–0.115	0.396	0.446*
		MP-FH (°)	–0.292	–0.349	–0.318	–0.466*	0.038	0.585**	–0.436*	0.361	0.216	–0.083

Pearson's correlation analysis was performed.
See Table 2 for definitions of each landmark or measurement.
*$p < 0.05$, **$p < 0.01$.

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movement resulting from fixed orthodontic treatment. Second, the FM-MP can apply more orthopedic force directly to the circummaxillary sutures. Third, fixed orthodontic treatment can be performed simultaneously in the maxillary arch during maxillary protraction. Therefore, the increase in ANB caused by FM-MP therapy and labioversion of the maxillary incisor during decrowding caused by the fixed appliance (Table 4) could occur simultaneously, as confirmed by previous studies.[17-19]

This study elucidated the effect of the long-term application of bone-anchored maxillary protraction throughout adolescence on pharyngeal airway development in operated patients with CLP. The most clinically relevant finding of our study was that the FM-MP resulted in significant therapeutic outcomes representing extensive levels of pharyngeal enlargement from the nasopharynx to lower oropharynx, with no increase in total upper airway length in relation to FM-MP-dependent differences in skeletal changes even in patients with CLP.

As for the maxillary skeletal effects of FM-MP therapy in patients with CLP, the mean advancements of the anterior maxilla (A point) were significantly greater in Group 1 than in Group 2 ($p < 0.001$). When we evaluated the maxillary skeletal effects on the posterior maxillary area (PNS), it revealed lesser amount of advancement than did the anterior maxilla with downward displacement; however, no significant counterclockwise rotation of the palatal plane occurred thereafter. The orthopedic effect of FM-MP therapy on the posterior maxillary area, where the pharyngeal airway muscles are attached, was exclusively focused on in our study that also investigated the underlying mechanism of pharyngeal airway enlargement. Forward and downward displacements of the PNS resulting from the therapeutic acceleration by the FM-MP in addition to natural growth might contribute to significant enlargement of nasopharyngeal airway dimensions behind the posterior maxilla.

More interestingly, the FM-MP resulted in not only nasopharyngeal (PNS-ad2) but also oropharyngeal airway enlargement (SPAS and MAS), with no changes in the hypopharyngeal space (IAS) and total upper airway length (VAL), which is different from the effect of the conventional facemask reported in previous studies.[23] The possible mechanisms underlying the opening of larger levels of pharyngeal airway spaces when using the FM-MP are as follows. First, with advancement of the anterior maxilla, forward repositioning of the tongue and increase in tongue length could be accompanied by an increase in the oropharyngeal spaces behind the tongue base, which corresponded to the finding of a previous study.[24] Second, the therapeutic effect of the FM-MP on the mandible could not be clearly identified from the growth change in this study because of the large interindividual variations; nonetheless, the mandibular plane was slightly decreased even with 6.13-fold greater maxillary advancement. Considering that clockwise rotation of the mandible occurs with conventional maxillary protraction treatment, which may induce pharyngeal narrowing,[25] and that patients with CLP have a more vertical growth pattern than do patients without CLP,[26] the achievement of a well-controlled vertical dimension with sufficient maxillary protraction can be a great benefit of FM-MP therapy in patients with a risk of airway impairment. Third, mandibular growth throughout adolescence might advance the tongue position and open the oropharyngeal airway, and accordingly, the increase in MAS could be correlated with mandibular advancement (SNB and SN-Pog). Lastly, forward and upward displacements of the hyoid bone concomitant with mandibular advancement without an increase in the mandibular plane might contribute to oropharyngeal opening (MAS).

Noticeably, the treatment response of the soft palate to the FM-MP was not significant in our CLP population, different from what was observed in previous studies investigating the effect of the conventional facemask on the soft palate and pharyngeal morphology.[13,27] The soft palate, which is attached to the posterior maxilla and communicates with the tongue via the palatoglossus muscles,[27] plays an important role in regulating oropharyngeal patency. Accordingly, the soft palate as well as the tongue or hyoid are important therapeutic targets of craniofacial orthopedic reconstruction, especially when targeting airway development. Although palatal surgery seems to have little effect on oropharyngeal development in operated patients with CLP in spite of the anatomic relationship to the soft palate,[28] an abnormal soft palate with velopharyngeal insufficiency or a history of velopharyngeal surgery in patients with CLP may reduce the responsiveness of the soft palate to protraction treatment of the posterior maxilla. Owing to a possibility of poor response to maxillary protraction treatment in terms of the forward movement of the posterior maxilla in patients with velopharyngeal insufficiency treated using pharyngeal flap surgery, examining the history of velopharyngeal surgery in patients with CLP is important. Soft palate variables indicating the shape and inclination to the palatal plane showed no significant intergroup differences and no correlation with either skeletal changes or pharyngeal airway changes in our study. Nonetheless, FM-MP therapy could improve the pharyngeal dimension in growing patients with CLP.

Controversies still exist regarding the initiation time and total treatment duration of maxillary skeletal protraction. Moreover, no evidence shows that patients with repaired CLP have strongly resistant scar tissue affecting

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the treatment outcome and stability. In terms of early intervention for maxillary growth modification, the optimal patient age is 6–10 years old when using the conventional facemask.[29,30] More recently, however, the FM-MP has been recommended on the basis of its greater and more favorable skeletal effects over those of the conventional facemask at the age of 10–13 years old to avoid the risks of damaging developing teeth germs in the bone and poor quality of the bone used as a skeletal anchorage.[16] Despite delayed intervention for maxillary growth modification, the superior skeletal and upper airway effects of the FM-MP over those of the conventional facemask make delayed application a worthy option even in patients with CLP.

The limitations of the present study were as follows. (1) A baseline control group should be established for differentiating the effects of FM-MP therapy from the effects of growth in patients with CLP. Therefore, future studies should aim to include patients with CLP with a similar skeletal pattern and patients not treated using FM-MP therapy (positive control group) to investigate the exclusive effects of FM-MP therapy. (2) Lateral cephalometric assessment of pharyngeal airway dimensions had some fundamental limitations. Nonetheless, lateral cephalometry is the most critical tool for analyzing the relationships between craniofacial skeletal changes and parapharyngeal tissue changes like soft palate, tongue, and hyoid to pharyngeal airway changes. (3) We could not perform any respiratory functional evaluations to support our morphologic findings. Nevertheless, further studies using three-dimensional evaluation in association with respiratory functional analysis could yield more practical information supporting the extended application of the FM-MP in patients with CLP as well as in the non-CLP population with skeletal Class III malocclusion. In addition, future studies must investigate the effects of patient compliance to FM-MP therapy, the thickness and density of the cortical bone in the infrazygomatic crest, and the degree and quantity of scar tissue.

CONCLUSION

Since Group 1 showed more positive effects on the oropharyngeal and nasopharyngeal airway spaces without any increase in VAL than did Group 2, the amount of maxillary protraction with the FM-MP was significantly related with the improvements in these airway spaces. However, further study is necessary to compare the effects of FM-MP therapy on the airway spaces in an untreated CLP control group.

CONFLICTS OF INTEREST

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

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