

Dentoskeletal effects of facemask therapy in skeletal Class III cleft patients with or without bone graft

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Introduction: The association between maxillary protraction and bone graft in patients with cleft lip and palate remains unclear. The purpose of this study was to investigate whether a secondary alveolar bone graft influences dentoskeletal effects of facemask therapy in unilateral cleft lip and palate patients with a skeletal Class III relationship. **Methods:** In this prospective nonrandomized clinical trial, 61 consecutive boys with unilateral cleft lip and palate and skeletal Class III malocclusion were divided into 3 groups: grafted facemask group (n = 21), ungrafted facemask group (n = 20), and untreated control group (n = 20). Sixteen dentoskeletal measurements on lateral cephalometric radiographs were compared before and after therapy or observation with 1-way analysis of variance or the Mann-Whitney U test. **Results:** After facemask therapy, the grafted group showed a statistically significantly greater advancement of Point A (S-Vert-A, 4.18 ± 1.94 mm; SNA, $3.51^\circ \pm 2.21^\circ$) than did the ungrafted group (S-Vert-A, 2.64 ± 1.58 mm; SNA, $1.92^\circ \pm 1.05^\circ$). Furthermore, significant SNB changes were found in the grafted group when compared with those in the ungrafted group ($-0.38^\circ \pm 1.77^\circ$ vs $-1.69^\circ \pm 1.34^\circ$; $P < 0.05$). The changes in the mandibular plane angle (MP-SN, MP-FH) in the grafted group were less pronounced than in the ungrafted group by approximately 2° ($P < 0.05$). Flaring of the maxillary incisors was more pronounced in treated subjects than in untreated subjects. The mandibular incisors proclined in both grafted ($1.54^\circ \pm 4.21^\circ$) and control ($0.97^\circ \pm 3.71^\circ$) patients, and were retroclined in the ungrafted group ($-2.13^\circ \pm 3.68^\circ$). **Conclusions:** Facemask therapy performed after an alveolar bone graft produced more anterior maxillary migration (90%) and less pronounced mandibular clockwise rotation (10%) than those in the ungrafted group (50%, 50%, respectively). (Am J Orthod Dentofacial Orthop 2018;153:542-9)

Skeletal Class III malocclusion with maxillofacial growth dysplasia is common in patients with operated cleft lip and palate and results in personal, social, functional, and psychological problems.¹ The management of this craniofacial malformation is challenging, primarily because of the maxillary retrusion coupled with potentially unfavorable mandibular growth.²⁻⁴

By exerting directed, constant anterior force on the maxilla, facemask therapy can foster balanced skeletal harmony and a favorable occlusion.⁵⁻¹² It is widely implemented in the mixed or early permanent dentition and before the peak pubertal growth to alleviate the need for future orthognathic surgery.¹³⁻¹⁵

Kim et al⁵ concluded that the optimal timing for anterior protraction in Class III children may involve initiating maxillary protraction before age 10. Early mixed dentition is also favored over late, presumably because of the closure of the sutures in the vicinity of the nasomaxillary complex.^{16,17}

In the meantime, a secondary alveolar bone graft, which is optimally carried out between 9 and 11 years of age, before the eruption of the permanent canines, has become the state of the art.¹⁸⁻²⁰ Its purpose is to reconstruct the anatomy of the maxillary alveolar process and restore the integrity of the maxillary dental arch to benefit the orthodontic tooth movement in the cleft area.²¹

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With the proximity of timing of maxillary protraction and secondary alveolar bone graft, the treatment sequencing lacks clinical evidence, and the patient is often subject to hospitalization. In addition, the synergistic effects of bone graft and maxillary protraction remain apparently unexamined *in vivo*. It is unknown whether a secondary alveolar bone graft influences the outcomes of facemask therapy. Up to now, 2 studies of 3-dimensional finite element analysis are available, suggesting the advantage of secondary alveolar bone graft before maxillary protraction.^{22,23}

We conducted a prospective clinical trial to compare the dentoskeletal effects of preadolescent boys with unilateral cleft lip and palate (UCLP) treated with facemask before and after secondary alveolar bone graft. The null hypothesis was that skeletal and dental differences do not exist between the treated groups with these protocols.

MATERIAL AND METHODS

This clinical trial was approved by the ethics committee of the Peking University School of Stomatology, People's Republic of China. All clinical investigations were carried out according to the guidelines of the Declaration of Helsinki. Informed consent from the subjects and their guardians was obtained in written format.

This study was designed as a prospective nonrandomized clinical trial to determine the effect of secondary alveolar bone graft on facemask therapy in growing patients with UCLP. In a northern Chinese population, boys with skeletal Class III UCLP were enrolled according to the following inclusion criteria: (1) operated nonsyndromic UCLP; (2) concave profile with anterior crossbite; (3) palatoplasty surgery before 3 years of age; (4) no pharyngeal flap surgery; (5) $-4^\circ \leq \text{ANB} \leq 0^\circ$; and (6) cervical vertebral maturation stage between CS1 and CS3.²⁴ The exclusion criteria were additional congenital anomaly, temporomandibular disorder, or previous orthodontic treatment.

In each group, a sample size of 16 subjects was estimated at power of 80% and 0.05 level of significance, which would enable significant detection between the protracted and unprotracted groups in the distance from Point A to the y-axis line of 1 mm with a standard deviation of 0.98 mm.²⁵ To allow for a 20% loss, 61 patients in total participated in this study initially.

Based on hospitalization and family preference, 61 boys with UCLP were enrolled in 3 groups: (1) a grafted facemask group containing 21 patients with hypoplastic maxilla, who had undergone secondary alveolar bone graft at least 5 months previously to allow for clinically and radiographically successful osseointegration; (2)

an ungrafted facemask group containing 20 patients with a history of complete UCLP, without alveolar bone grafting; and (3) an unprotracted control group containing 20 patients who had not been treated because of loss of anchor teeth, matched to the treated subjects with regard to sex, age, skeletal structure, and cleft type, and subsequently received treatment after the eruption of the maxillary permanent first premolars.

Subjects in the protracted groups were treated with facemask by an orthodontist (W.L.) at the Department of Orthodontics, Peking University Hospital of Stomatology, Beijing, China. All surgical procedures including the secondary alveolar bone graft (cancellous bone graft from the iliac crest) were performed in the Cleft Lip and Palate Treatment Center, Peking University Hospital of Stomatology. Before protraction, all patients in the grafted group had attained interdental septum of category I or II according to the standard system of Bergland et al.¹⁸

All patients successfully finished the treatment except for 3 in the grafted group and 2 each in the ungrafted group and the control group, who dropped out because of poor compliance. Consequently, 18 boys remained in each group for analysis: the grafted group (age, 9.98 ± 1.10 years), the ungrafted group (age, 9.54 ± 1.30 years), and the control group (age, 9.76 ± 1.43 years).

In both treatment groups, the Hyrax appliance was banded on the maxillary permanent first molars and deciduous first molars or permanent first premolars. Protraction hooks were soldered bilaterally to the buccal aspects of the permanent first molar bands and extended anteriorly to the canine area.^{8,26} The protraction elastics were 30° down the occlusal plane, and the protraction force was 450 to 500 g per side.^{27,28} Maxillary expansion was not conducted. Bite-block appliances in the mandibular arch were inserted to prevent incisor interference. All patients were instructed to wear the facemask (Tiantian Dental Equipment, Hunan, China) for a minimum of 12 to 14 hours per day. Facemask therapy was continued until a positive overjet was achieved.²⁹⁻³¹ Radiographic observations after about one year were performed in the control group.

Lateral cephalometric radiographs were obtained on all experimental subjects before treatment or observation and after completion of protraction treatment or observation using the same cephalostat. A horizontal reference line that angulated 7° clockwise from the SN line passing through S point was registered as the x-axis, and a perpendicular line was subsequently constructed through S point as the y-axis. The cephalometric landmarks and measurements are shown in the Figure and Table 1. Sixteen dentoskeletal variables

were measured on the cephalograms; landmarks were traced by an experienced investigator (Y.Z.) and reconfirmed by another investigator (R.G.). Software (version 11.7; Dolphin Imaging and Management Solutions, Chatsworth, Calif) was used for evaluation of the cephalograms. All variables were reassessed by the same operator (Y.Z.) 2 weeks later.

Statistical analysis

First, a 1-sample Kolmogorov-Smirnov test showed all the variables to be normally distributed. Second, after the Levene test of equality of variance, a Mann-Whitney U test was performed on the SN-PP at baseline, the treatment changes in SNA, U1-L1, overbite, and overjet, all of which were labeled as variance-unequal. Third, all remaining cephalometric variables, ages, and durations of treatment or observation were analyzed with 1-way analysis of variance (ANOVA). Pairwise comparison was performed with post hoc least significant difference test. All statistical analyses were performed with the SPSS software package (version 20.0; IBM, Armonk, NY). The significance level was set at $P < 0.05$ for all tests. To calculate the intraexaminer difference, 5 randomly selected pairs of data from each group were measured twice by the same investigator (Y.Z.) 2 weeks later. Correlation coefficients of each measurement were then calculated.

RESULTS

The age distributions and treatment durations among the 3 groups were well matched (Table II). The intraclass correlation coefficients calculated for the repeatability test (Table III) were all above 0.9, indicating high reliability.

Table IV shows a comparison of baseline dentoskeletal characteristics among the 3 groups. One-way ANOVA and the Mann-Whitney U test detected no statistically significant differences before treatment or observation.

The dentoskeletal changes of the 3 groups during facemask protraction treatment or observation were listed in Table V.

The grafted protracted group had a significantly greater (58.3%) increase in A-point advancement than did the ungrafted group (S-Vert-A, 4.18 ± 1.94 mm vs 2.64 ± 1.58 mm; $P < 0.05$). An additional 1.59° increase in SNA angle was achieved in the grafted group ($3.51^\circ \pm 2.21^\circ$ vs $1.92^\circ \pm 1.05^\circ$; $P < 0.05$). The control group demonstrated Point A advancement of 0.52 mm and reduction in SNA of 0.65° , which was significantly less than the treated groups ($P < 0.001$).

Both the grafted and ungrafted groups exhibited markedly enhanced maxillary growth (Ptm-A/PP, 2.06

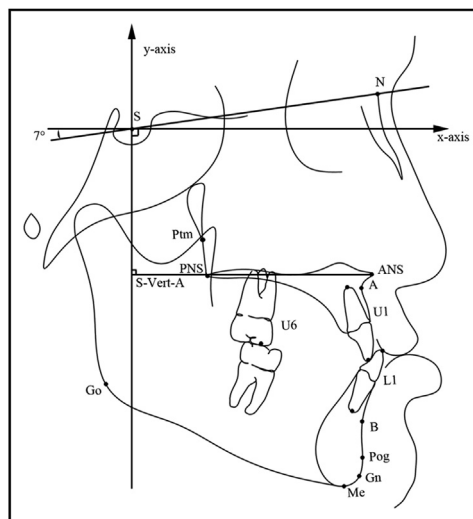


Fig. A horizontal reference line angulated 7° clockwise to the SN line passing through sella was registered as the x-axis, and a perpendicular line was then constructed through sella as the y-axis (S-Vert-A, the horizontal distance of A-point to the y-axis).

and 1.81 mm, respectively; $P > 0.05$) vis-à-vis the control group (Ptm-A/PP, -0.08 mm; $P < 0.001$). No difference in the length increment of the maxilla was detected among the grafted and ungrafted groups.

All 3 groups showed mild counterclockwise rotations of the palatal plane.

The grafted group exhibited less clockwise rotation of mandible. After facemask therapy, significant SNB changes were found between the grafted and ungrafted groups ($-0.38^\circ \pm 1.77^\circ$ vs $-1.69^\circ \pm 1.34^\circ$; $P < 0.05$). The changes in the angle of the mandibular plane (MP-SN, MP-FH) were less pronounced in the grafted group than in the ungrafted group, by approximately 2° ($P < 0.05$). Furthermore, the grafted group did not show significant differences from the control group with respect to changes in SNB, MP-SN, MP-FH, or y-axis angle ($P > 0.05$).

Both protracted groups had improved sagittal jaw relationships. At the end of the treatment or observation, all protracted groups demonstrated increases in the ANB angle ($P < 0.001$) and Wits appraisal ($P < 0.001$) compared with the control group. After therapy, overjets were similar between the 2 protracted groups.

Both protracted groups had protrusion of the maxillary incisors as well as better overjet than did the untreated control subjects ($P < 0.05$). The mandibular incisor to mandibular plane angle was increased in the grafted group and decreased in the ungrafted group (IMPA, $1.54^\circ \pm 4.21^\circ$ vs $-2.13^\circ \pm 3.68^\circ$; $P < 0.01$).

Table I. Definitions of cephalometric variables used in this study

Variable	Definition
SNA (°)	Angle between subspinale and sella at nasion, indicating the horizontal position of the maxilla relative to the cranial base
S-Vert-A (mm)	Horizontal distance from subspinale to a plane drawn perpendicularly to SN-7 plane (horizontal plane angulated 7° clockwise to the SN plane) at S
Ptm-A/PP (mm)	Distance between subspinale and Ptm projected on the palatal plane, respectively
SN-PP (°)	Angle between the SN plane and the palatal plane
SNB (°)	Angle between supramental and sella at nasion, indicating the horizontal position of the mandible relative to the cranial base
MP-SN (°)	Angle between the mandibular plane and SN plane, representing mandibular inclination
MP-FH (°)	Angle between the mandibular plane and Frankfort horizontal plane, representing mandibular inclination
y-axis (°)	Angle between the y-axis (line connecting sella to gnathion) and Frankfort horizontal plane
ANB (°)	Angle between subspinale and supramental at nasion, indicating the relative positions of the maxilla and mandible in relation to the cranium
Wits (mm)	Distance between the points of perpendiculars tracing from Points A and B contact on the occlusal plane, indicating the relative positions of the maxilla and mandible anteroposteriorly
U1-SN (°)	Angle between the long axis of the maxillary central incisor and the SN plane, determining the inclination of the central incisor relative to the anterior cranial base
IMPA (°)	Angle between the long axis of the mandibular central incisor and the mandibular plane, determining the axial inclination between the mandibular incisor and the inferior border of the mandible
U1-L1 (°)	Angle between the long axis of the maxillary central incisor and the mandibular central incisor, determining the degree of labial inclination of the incisors
SN-FOP (°)	Angle between the SN plane and FOP plane (occlusal plane)
Overjet (mm)	Distance between the maxillary anterior teeth ridges and the mandibular anterior teeth ridges in the anteroposterior axis
Overbite (mm)	Distance between the maxillary anterior teeth ridges and the mandibular anterior teeth ridges in the vertical axis

Table II. Ages and durations of treatment/observation

	<i>Grafted</i>	<i>Ungrafted</i>	<i>Control</i>	<i>Grafted vs ungrafted</i>	<i>Grafted vs control</i>	<i>Ungrafted vs control</i>
	Mean (SD)	Mean (SD)	Mean (SD)	P*	P*	P*
T0 (y)	9.98 (1.10)	9.54 (1.30)	9.76 (1.43)	0.563	0.861	0.868
T1 (y)	11.24 (0.99)	10.88 (1.33)	10.81 (1.25)	0.647	0.529	0.980
Duration (mo)	15.06 (5.83)	16.06 (5.91)	12.50 (4.63)	0.848	0.350	0.137

Eighteen subjects in each group.

One-sample Kolmogorov-Smirnov test of normality.

Levene test of equality of variance.

T0, Before treatment or observation; T1, after protraction treatment or observation.

*One-way ANOVA and post hoc least significant difference test.

And the IMPA of the grafted group also showed no difference from the control group ($1.54^\circ \pm 4.21^\circ$ vs $0.97^\circ \pm 3.71^\circ$; $P > 0.05$).

DISCUSSION

Close collaboration between orthodontists and oral surgeons is essential in cleft management.³² However, the clinical sequencing of secondary bone graft and facemask therapy remains unclear. This led us to question whether the graft procedure influences the outcome of protraction.

After maxillary protraction therapy, the hypoplastic maxilla was advanced, and a more harmonious maxillo-mandibular relationship was realized in both protracted groups compared with the untreated controls, indicating

that facemask protraction is an effective strategy to correct or improve a skeletal Class III relationship in UCLP patients. Localized to the anterior portion of the maxilla in these patients, a transverse discrepancy was solved after maxillary protraction, without expansion. It has been reported that alveolar density remained stable between 3 and 6 months after the alveolar bone graft.¹⁸⁻²¹ To be on the safe side, a latent period of at least 5 months was stipulated for the grafted group to allow osseointegration.

The efficacy of maxillary protraction is mainly evaluated with the positional changes measured at Point A.^{5,28,31} With the application of the facemask, the grafted group had a significantly greater increase, 58.3%, in Point A advancement relative to the

Table III. Intraclass correlations (ICC)

Variable	Mean	SD	ICC
Maxillary			
SNA (°)	-0.11	0.53	0.985
S-Vert-A (mm)	0.23	0.61	0.990
Ptm-A/PP (mm)	0.31	0.73	0.969
SN-PP (°)	-0.26	0.72	0.964
Mandibular			
SNB (°)	0.15	0.85	0.965
MP-SN (°)	-0.14	0.73	0.987
MP-FH (°)	0.27	0.61	0.988
y-axis (°)	0.04	0.84	0.952
Maxillomandibular			
ANB (°)	-0.13	0.58	0.918
Wits (mm)	0.03	0.73	0.946
Dental			
U1-SN (°)	0.09	0.64	0.994
IMPA (°)	0.15	0.52	0.995
U1-L1 (°)	0.21	0.70	0.996
SN-FOP (°)	0.03	0.63	0.992
Overjet (mm)	0.13	0.51	0.925
Overbite (mm)	-0.09	0.43	0.984

The intraclass correlation coefficients calculated for the repeatability test were all above 0.9, indicating high reliability.

ungrafted group (S-Vert-A increment, grafter vs ungrafted, 4.18 vs 2.64 mm). This can be explained by the effect of the secondary alveolar bone graft, which unifies the alveolar ridge and consolidates the maxillary dental arch. Stress under protraction is supposed to be evenly distributed between the segments after bone grafts.^{22,23} However, the control group showed a slight anterior migration of Point A, 0.52 mm, during the observation period. This contrasts with findings by So,⁶ who reported that Point A moved back 0.40 mm in untreated Class III cleft patients. Such diversity could be attributed to a difference in the choice of the reference plane. Sagittal maxillary growth typically ceases at the age of 8 years in normal populations. In a systematic review, Kim et al⁵ reported a range of 0.9 to 2.9 mm advancement of Point A in noncleft Class III patients treated with facemasks. Sample heterogeneity and inconsistency in severity of the skeletal discrepancy may explain this variation.

The grafted group showed an increase in the SNA angle 82.8% greater than that in the ungrafted group. According to Brodie,³³ SNA remains unchanged among normal growing subjects after approximately 7 years of age. Our control UCLP group had a decrease in SNA angle, which was consistent with the results reported by Bishara et al,³⁴ who found that SNA normally decreases in UCLP patients who have had surgery. Greater increases in SNA angle in the grafted groups suggested a more favorable outcome than in the ungrafted subjects and controls.

As far as the maxilla is concerned, the graft procedure promotes anterior repositioning of the maxilla by face-mask therapy, as evidenced by the larger S-Vert-A and SNA increments in the grafted facemask group. Nevertheless, no significant differences in maxillary length (Ptm-A/PP) changes were discovered between the 2 treated groups (grafted vs ungrafted, 2.06 vs 1.81 mm; $P > 0.05$); this confirmed that it was anterior repositioning of the body of the maxilla in the grafted group, rather than growth in the sagittal dimension, that led to greater A Point advancement compared with the ungrafted group.

Downward and backward rotation of the mandible, a common consequence and corollary of maxillary protraction, was significantly less pronounced in the grafted group than in the ungrafted group. More clockwise rotation of the mandible during maxillary protraction was associated with a more horizontally than vertically directed mandibular growth pattern and a subsequent relapse of reverse overjet.^{35,36} Hägg et al³⁷ confirmed a positive correlation between mandibular plane angle opening during treatment and future relapse. Therefore, we predict higher odds of stability in the grafted group, although further follow-up is necessary to confirm this speculation.

Changes in ANB were comparable between the 2 protracted groups, but they were utterly qualitatively different. The SNA increment contributed 90% to the overall ANB increment in the grafted group, whereas only half of that in ungrafted group was contributed by the SNA increment. The absence of significant alteration of SNB in the grafted group stood in sharp contrast to the untoward 1.69° opening in the ungrafted group; this constituted almost half of its ANB increment, a pattern that might incur a higher rate of relapse.

The maxillary incisors were proclined in both protracted groups compared with those in the untreated control ($P < 0.05$). Overjet was similar between the 2 protracted groups, but the contributions of the maxilla and the mandible to dentoskeletal changes were different. In the grafted group, the maxillary advancement contributed 90% to the overall sagittal skeletal relationship improvement, with only half of that in the ungrafted group. Clockwise rotation of the mandible was significantly less pronounced in the grafted group (10%) than in the ungrafted group (50%). The grafted group demonstrated 2.29° more proclination of the maxillary incisors than the ungrafted group. The mandibular incisors proclined by 1.54° in the grafted group but retroclined by 2.13° in the ungrafted group, dentally camouflaging the adverse rotation of the mandibular opening. Furthermore, we found that the angle of U1-L1 and overbite after therapy in the grafted

Table IV. Baseline cephalometric characteristics of patients in each group

Variable	Grafted	Ungrafted	Control	Grafted vs ungrafted	Grafted vs control	Ungrafted vs control
	Mean (SD)	Mean (SD)	Mean (SD)	P*	P*	P*
Maxillary						
SNA (°)	75.83 (3.36)	74.53 (2.33)	74.59 (4.01)	0.242	0.266	0.952
S-Vert-A (mm)	52.74 (3.43)	51.72 (2.55)	50.96 (4.13)	0.376	0.125	0.509
Ptm-A/PP (mm)	39.07 (2.42)	38.85 (2.10)	38.62 (2.06)	0.763	0.542	0.757
SN-PP (°)	10.35 (2.52)	10.59 (2.39)	10.69 (1.24)	0.673 [†]	0.767 [†]	0.815 [†]
Mandibular						
SNB (°)	78.14 (3.60)	76.46 (2.97)	75.89 (3.90)	0.155	0.059	0.630
MP-SN (°)	36.26 (3.84)	37.13 (4.73)	39.29 (5.31)	0.575	0.056	0.171
MP-FH (°)	29.68 (3.55)	29.71 (4.52)	31.14 (4.60)	0.984	0.309	0.318
y-axis (°)	63.86 (2.03)	63.16 (3.11)	64.02 (2.96)	0.447	0.866	0.354
Maxillomandibular						
ANB (°)	-2.27 (1.23)	-1.93 (1.77)	-1.28 (1.72)	0.526	0.068	0.226
Wits (mm)	-4.37 (2.74)	-4.65 (2.77)	-4.02 (2.61)	0.759	0.695	0.486
Dental						
U1-SN (°)	95.39 (5.38)	94.58 (4.97)	91.97 (7.03)	0.682	0.086	0.186
IMPA (°)	82.88 (7.13)	82.86 (6.59)	82.78 (5.95)	0.992	0.964	0.972
U1-L1 (°)	142.51 (8.18)	145.42 (9.97)	145.97 (9.07)	0.342	0.259	0.857
SN-FOP (°)	10.88 (5.22)	13.82 (5.69)	13.45 (6.08)	0.127	0.181	0.847
Overjet (mm)	-3.00 (1.11)	-3.41 (1.16)	-3.31 (1.28)	0.309	0.434	0.812
Overbite (mm)	3.41 (1.94)	3.30 (2.51)	2.87 (1.84)	0.882	0.449	0.542

Eighteen subjects in each group.

One-sample Kolmogorov-Smirnov test of normality.

Levene test of equality of variance.

*One-way ANOVA and post hoc least significant difference test; [†]Mann-Whitney U test.**Table V.** Cephalometric changes occurred during the treatment/observation

Variable	Grafted	Ungrafted	Control	Grafted vs ungrafted	Grafted vs control	Ungrafted vs control
	Mean (SD)	Mean (SD)	Mean (SD)	P [§]	P [§]	P [§]
Maxillary						
SNA (°)	3.51 (2.21)	1.92 (1.05)	-0.65 (1.77)	0.034 ^{*‡}	<0.001 ^{†‡}	<0.001 ^{†‡}
S-Vert-A (mm)	4.18 (1.94)	2.64 (1.58)	0.52 (2.50)	0.029 [*]	<0.001 [†]	0.003 [†]
Ptm-A/PP (mm)	2.06 (1.17)	1.81 (1.70)	-0.08 (1.14)	0.585	<0.001 [†]	<0.001 [†]
SN-PP (°)	-1.28 (2.54)	-0.12 (2.13)	-0.48 (1.22)	0.214	0.323	0.542
Mandibular						
SNB (°)	-0.38 (1.77)	-1.69 (1.34)	0.32 (1.62)	0.016 [*]	0.192	<0.001 [†]
MP-SN (°)	0.53 (2.58)	2.81 (1.82)	-0.79 (2.11)	0.003 [†]	0.077	<0.001 [†]
MP-FH (°)	0.65 (2.44)	2.66 (2.07)	-0.01 (3.07)	0.023 [*]	0.446	0.003 [†]
y-axis (°)	1.76 (1.67)	2.70 (1.89)	0.48 (2.54)	0.179	0.068	0.002 [†]
Maxillomandibular						
ANB (°)	3.89 (1.62)	3.61 (1.08)	-0.97 (1.20)	0.636	<0.001 [†]	<0.001 [†]
Wits (mm)	4.38 (3.55)	4.55 (3.24)	-1.06 (1.85)	0.863	<0.001 [†]	<0.001 [†]
Dental						
U1-SN (°)	6.68 (5.18)	4.39 (4.02)	1.07 (4.53)	0.142	0.001 [†]	0.035 [*]
IMPA (°)	1.54 (4.21)	-2.13 (3.68)	0.97 (3.71)	0.006 [†]	0.663	0.020 [*]
U1-L1 (°)	-9.03 (8.05)	-5.06 (5.46)	-1.27 (6.23)	0.129 [‡]	0.008 ^{†‡}	0.052 [†]
SN-FOP (°)	2.23 (5.93)	0.59 (8.25)	-0.49 (3.65)	0.436	0.197	0.604
Overjet (mm)	4.80 (1.60)	5.19 (2.05)	-0.62 (0.79)	0.367 [‡]	<0.001 ^{†‡}	<0.001 ^{†‡}
Overbite (mm)	-3.01 (1.82)	-2.52 (2.55)	0.63 (1.22)	0.506 [‡]	<0.001 ^{†‡}	<0.001 ^{†‡}

Eighteen subjects in each group.

One-sample Kolmogorov-Smirnov test of normality.

Levene test of equality of variance.

*P < 0.05; [†]P < 0.01; [‡]Mann-Whitney U test; [§]One-way ANOVA and post hoc least significant difference test.

group were less than those in the ungrafted group, so it may provide more clues for the similar overjet of the 2 protracted groups.

To date, few clinical reports have addressed this issue and considered the relationship between maxillary protraction and secondary alveolar bone graft. Authors of a recent 3-dimensional finite element study concluded that it would be more advantageous to implement maxillary protraction after secondary alveolar bone graft.²² Chen et al²³ suggested that graft resorption in the lower region has a better maxillary protraction outcome than in the higher region. Nonetheless, finite element analysis constructs computational mechanical models from real-world objects and higher levels of evidence from clinical series or clinical trials are still wanting.

We concluded that coupling maxillary protraction with preceding secondary alveolar bone graft enhances maxillary advancement and minimizes adverse effects such as rotation of the mandibular opening and incisor retroclination. To minimize subgroup heterogeneity, this study was designed around a homogeneous group to eliminate confounding factors: all patients had the same type of cleft (UCLP), were all of the same sex (boys), were of similar ages, and had skeletal discrepancies of similar severity.

Nonetheless, this study design could have been improved if the subjects had been randomly allocated to the 2 protracted groups. We did not include girls because there were much fewer female patients in our clinical practice. Furthermore, we evaluated the effects immediately after the facemask treatment but did not perform adequate follow-up. Therefore, longitudinal observations until completion of growth are needed to assess long-term stability.

CONCLUSIONS

1. Maxillary protraction is an effective treatment modality for mild-to-moderate skeletal Class III relationships in growing patients with UCLP.
2. Facemask therapy after an alveolar bone graft procedure led to pronounced maxillary advancement (90%) and less pronounced mandibular clockwise rotation (10%) than those in the ungrafted group (50%, 50%, respectively).

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