Original Article - Analytical Study

The effects of face mask therapy in cleft lip and palate patients

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ABSTRACT

Background and Aim: Children treated with cleft lip and palate often develops mid-facial retrusion. In this study 20 patients with unilateral cleft lip and palate (UCLP) were treated with face mask and studied for the effect of growth. **Materials and Methods:** The patients were treated by the same orthodontist using the same techniques and appliances. Mean pre- and posttreatment ages were 8.7 and 9.5 years, respectively. Each child was matched by ethnicity, age, sex, and the SN/MP angle to an untreated (noncleft) control. The treatment period with face mask was approximately 7 months and 5 days. **Result:** The study showed definite protraction of the maxilla for UCLP group ($P < 0.001$). The posterior maxilla of the UCLP group underwent anterior displacement while the maxillary incisors showed greater anterior movement than expected for untreated control group ($P < 0.01$). Vertical changes of the maxilla showed no significant differences in cleft group. The mandible of the UCLP group was rotated inferiorly and posteriorly ($P < 0.05$) while control group showed inferior and anterior changes. The lower incisors were stable in the two groups. **Conclusion:** From this study, it can be inferred that the UCLP group show significantly anterior maxillary movements when compared with the control group when face mask is used as per prescription.

Keywords: Cleft Lip, cleft palate, face mask, RME, cephalometrics

INTRODUCTION

Growing cleft patients with dentofacial deformities are characterized by a midfacial growth deficiency generally caused by primary surgeries. Skeletal discrepancies between the maxilla and mandible, frequently create an anterior and/or posterior crossbite and these are the most challenging cases for the clinician to manage.[1–7]

To correct the transverse discrepancies in patients with cleft lip and palate, orthodontists may use rapid maxillary expansion (RME) and to correct the sagittal discrepancies, face mask is used to obtain effective maxillary protraction and improve the Class III skeletal pattern. Maxillary protraction was the most effective method to correct or reduce maxillomandibular discrepancies in patients with unilateral cleft lip and palate.[8–15]

The purpose of the present study was to evaluate the dental and skeletal effects of maxillary protraction with face mask in patients with complete unilateral cleft lip and palate (UCLP), after the correction of maxillary transverse discrepancies with RME.

MATERIALS AND METHODS

The sample consisted of 20 individuals (12 male and 8 female) with unilateral complete cleft lip and palate patients treated with face mask. The records of these Class III patients were compared with 20 Class I (10 male and 10 female) untreated controls. All patients presented only sagittally constricted maxilla, anterior crossbite, and a Class III skeletal pattern with skeletal maxillary retrusion and all subjects had mixed dentition. Distribution of the patients according to gender, and skeletal age are summarized in Table 1. The patients were treated by the same orthodontist using the same techniques and appliances. Each child was matched by ethnicity, age, sex, and the Sella-Nasion/Mandibuler Plane angle

angle to an untreated (noncleft) control. The treatment period with face mask was approximately 7 months 5 days.

Appliance design

All of the patients had RME treatment for maxillary transversal discrepancy before face mask therapy. After the completion of the RME treatment, the same appliance was used for protraction. It was an acrylic splint with expansion screw and traction hooks were soldered at the mesial aspect of the maxillary canines on both sides. The extraoral appliance was a Delaire type face mask, with a force of 800 *g* applied to each hook with vector force about 25º downward and forward to the occlusal plane [Figures 1 and 2]. Patients were instructed to wear the face mask for 16 hours a day and they changed the elastics every other day. Each patient received a timing record to register the number of hours of face mask therapy per day, which was useful to evaluate patient compliance. They were seen every 4 weeks for to control the adjustment of the face mask.

All radiographs used in the study were taken using the same cephalostat. For each patient radiographs were taken after the removal of RME appliance (T1), and at the end of the face mask treatment after the removable of the appliance (T2). All cephalometric measurements were marked by the same operator (SD) with the help of Dolphin Imaging v11.5 (Chatsworth, CA, USA).

Reference lines and cephalometric landmarks for linear and angular measurement for skeletal and soft tissue changes are shown in Figures 3 and 4.

Statistical analysis

Cephalometric data were evaluated at the Computer Department of Ege University, with paired *t* tests to determine significant differences (SPSS 15.0), in UCLP group. Analyses of covariance were conducted to evaluate the differences between the UCLP and control groups. To assess repeatability, Dahlberg test was used. A *P* value less than or equal to 0.05 was taken as significant. Ten cephalograms were traced and digitized twice with a time interval of 1 week. None of the variables showed significant differences between the two assessments ($P < 0.05$).

Table 1: Distribution of the patients in the study group according to gender and mean age in each measured in years (mean±standard deviation)

Unilateral cleft lip and palate cases *N*=20		Control *N*=20	
Male *N*=12	Female *N*=8	Male *N*=10	Female *N*=10
8.70 ± 2.64	8.69 ± 1.64	8.22 ± 1.54	8.14 ± 2.04

RESULTS

Comparison of the mean differences between UCLP and control group are shown in Table 2. The data obtained from the

Table 2: Comparison of the mean differences between UCLP and control group in the baseline measurements

Cephalometric measurements	Unilateral cleft lip/palate Mean ± SS	Control Mean ± SS	*P*
SNA (°)	0.21 ± 1.64	0.40 ± 1.74	0.775
SN-PP (°)	0.15 ± 2.55	0.23 ± 2.44	0.035*
Co-A (mm)	0.53 ± 3.21	0.65 ± 3.19	0.022*
A-HR (mm)	0.30 ± 3.81	0.60 ± 2.39	0.032*
A-VR (mm)	0.03 ± 2.8	0.02 ± 2.84	0.775
SNB (°)	0.05 ± 2.34	0.42 ± 2.49	0.173
SN-MP (°)	0.30 ± 3.50	0.42 ± 2.61	0.006**
Co-Gn (mm)	0.40 ± 5.70	0.83 ± 4.94	0.008**
B-HR (mm)	0.13 ± 10.27	0.32 ± 10.07	0.042*
B-VR (mm)	0.60 ± 10.50	0.05 ± 10.48	0.038*
ANB (°)	-0.30 ± 1.76	0.95 ± 2.35	0.006**
PP-MP (°)	0.80 ± 5.58	0.88 ± 5.97	0.178
1/SN (0)	0.70 ± 2.78	0.65 ± 2.78	0.006**
1/MD (0)	0.10 ± 1.48	0.11 ± 1.00	0.231
N-ANS (mm)	0.80 ± 2.45	0.40 ± 3.13	0.353
ANS-Me (mm)	0.50 ± 3.30	0.67 ± 3.19	0.004**
N-Me (mm)	0.60 ± 8.59	0.10 ± 8.67	0.003**
S-PNS (mm)	0.21 ± 2.98	0.15 ± 2.68	0.342
S-Go (mm)	0.10 ± 2.78	0.09 ± 3.52	0.253
PNS-Go (mm)	0.47 ± 5.03	0.40 ± 4.70	0.345
Ls-EL (mm)	-0.00 ± 1.55	-0.75 ± 1.06	0.345
Li-EL (mm)	-0.02 ± 2.46	-0.02 ± 2.27	0.060
NST-SN-LS (°)	0.80 ± 12.47	0.18 ± 11.37	0.614
Ns-PRN-PG (°)	0.35 ± 5.22	0.18 ± 5.21	0.745
SS-Ns-SM (°)	0.75 ± 66.39	0.87 ± 60.71	0.877
SS-Ns-PG (°)	0.42 ± 68.23	0.60 ± 63.28	0.998
Li-SM-PG (°)	0.40 ± 35.07	0.05 ± 34.97	0.395
Ns-PRN-SN (°)	0.98 ± 10.60	0.20 ± 11.23	0.482

*$P<0.05$, **$P<0.01$

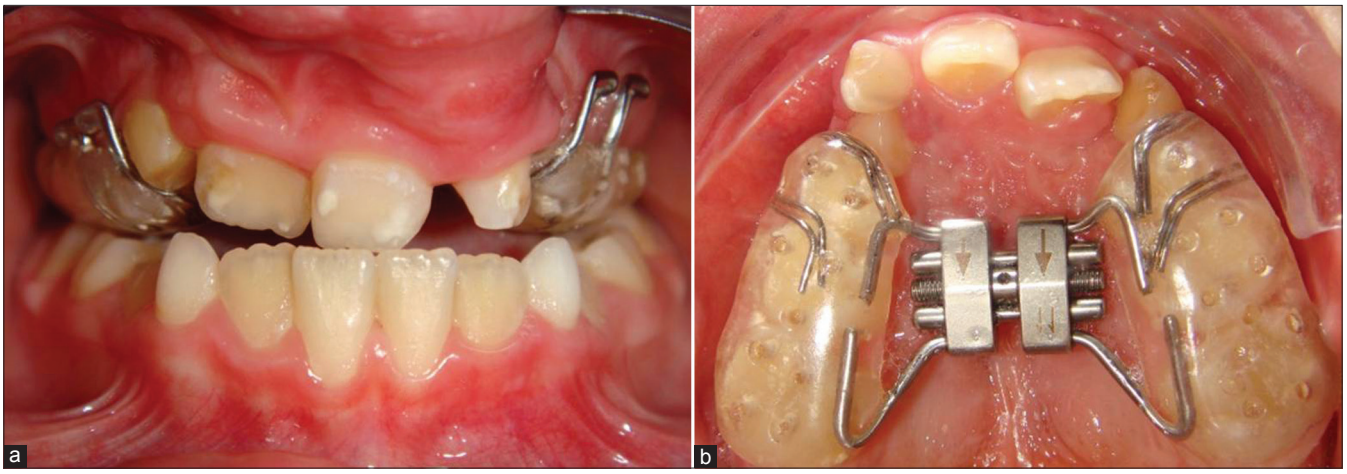

Figure 1: (a, b) Intraoral view of the acrylic splint with hooks for elastics

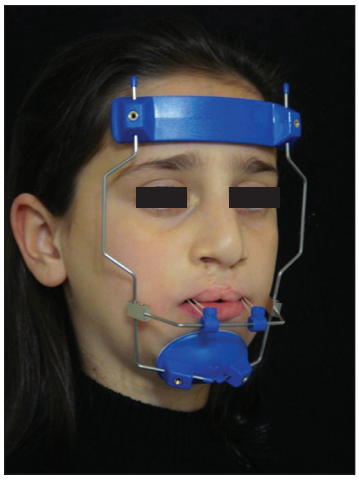

Figure 2: Patient wearing the face mask for anterior protraction with elastics from the intraoral hooks

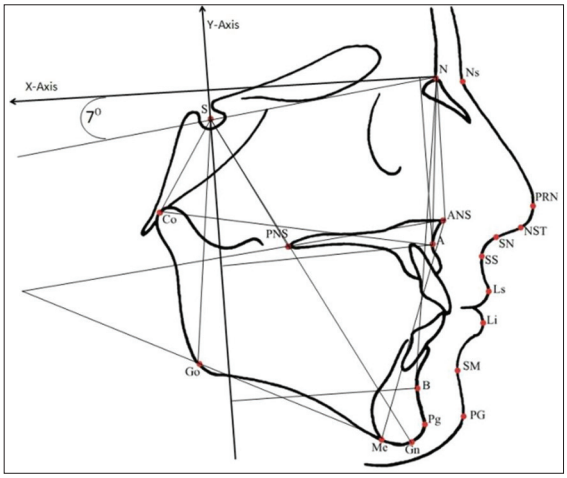

Figure 3: Reference lines and cephalometric landmarks for linear and angular measurement for skeletal changes. SNA (0), SN-PP (0), Co-A (mm), A-HR (mm), A-VR (mm), SNB (0), SN-MP (0), Co-Gn (mm), B-HR (mm), B-VR (mm), ANB (0), PP-MP (0), 1/SN(0), 1/MD (0), N-ANS (mm), ANS-Me (mm), N-Me (mm), S-PNS (mm), S-Go (mm), PNS-Go (mm)

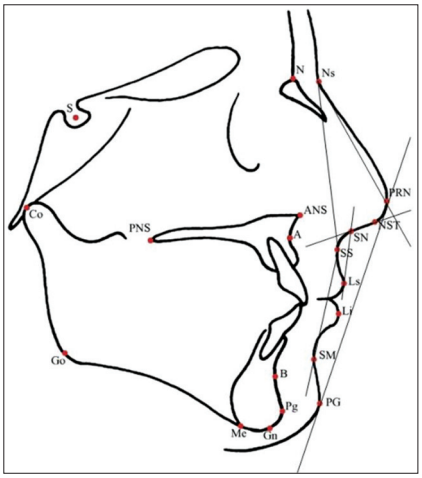

Figure 4: Reference lines and cephalometric landmarks for linear and angular measurement for soft tissue changes. Ls-EL (mm), Li-EL (mm), NST-SN-LS (0), Ns-PRN-PG (0), SS-Ns-SM (0), SS-Ns-PG (0), Li-SM-PG (0), Ns-PRN-SN (0)

cephalographs before (T1) and after (T2) face mask therapy are shown in Table 3.

Cephalometrically, the patients had a skeletal Class III relationships (A-Nasion-B Angle -3.30 ± 1.76 degrees) with a maxillary growth deficiency. The maxillary incisors were retroclined (U1-SN, 98.80 ± 0.27 degrees). The SN/MP angle was 38.80 ± 6.50 degrees. Table 2 shows that during protraction, the maxilla was moved significantly forward ($P < 0.001$). After maxillary protraction, the maxilla was more forward and the mandible more posterior. ANB angle increased significantly by an average of 2.95 ± 2.35 degrees ($P < 0.001$). Vertical changes in lower anterior facial height, observed by measurement of the distance between ANS and Me, showed a significant increase (72.67 ± 6.195.7 mm) ($P < 0.05$). Significant changes were observed in the mandibular plane angle (41.80 ± 6.50 degrees) and B point moved significantly downward ($P < 0.01$), ($P < 0.05$). Changes in the angle between the anterior part of the mandible and the base of the skull (SNB) showed downward and backward rotation of the mandible ($P < 0.01$). The SNB angle decreased significantly ($P < 0.01$). Angular and linear changes indicated a significant clockwise rotation of the mandible. The maxillary incisors moved forward significantly ($P < 0.01$), whereas the mandibular incisors moved backward, although not significantly. Table 3 shows that the UCLP group showed significantly anterior maxillary movements when compared with control group. The mandible of the UCLP group was rotated inferiorly and posteriorly while control group showed inferior and anterior changes ($P < 0.05$). The maxillary incisors showed greater anterior movement than expected for untreated control group ($P < 0.01$).

Table 3: Comparison of the cephalometric changes in UCLP patients before and after face mask therapy

Cephalometric measurements ($n=20$)	T1 Before treatment X ± SS	T2 After Treatment X ± SS	*P*
SNA (°)	73.62 ± 2.64	78.40 ± 2.74	0.001***
SN-PP (°)	11.25 ± 3.55	10.23 ± 3.44	0.038*
Co-A (mm)	84.13 ± 4.21	87.65 ± 4.19	0.001***
A-HR (mm)	55.50 ± 4.81	57.60 ± 4.39	0.886
A-VR (mm)	61.13 ± 3.8	64.02 ± 3.84	0.001***
SNB (°)	74.95 ± 2.34	72.42 ± 2.49	0.037*
SN-MP (°)	38.80 ± 6.50	41.42 ± 6.61	0.001***
Co-Gn (mm)	111.40 ± 5.70	110.83 ± 4.94	0.368
B-HR (mm)	98.13 ± 10.27	99.32 ± 10.07	0.172
B-VR (mm)	56.60 ± 11.50	55.05 ± 11.48	0.001***
ANB (°)	-3.30 ± 1.76	2.95 ± 2.35	0.001***
PP-MP (°)	33.80 ± 5.58	34.88 ± 5.97	0.178
1/SN(0)	98.80 ± 0.27	115.80 ± 0.78	0.007**
1/MD (0)	92.00 ± 1.53	88.80 ± 1.22	0.258
N-ANS (mm)	51.80 ± 4.45	52.40 ± 5.13	0.353
ANS-Me (mm)	71.50 ± 6.30	72.67 ± 6.19	0.026*
N-Me (mm)	115.60 ± 7.59	120.10 ± 7.67	0.006**
S-PNS (mm)	45.91 ± 2.98	47.15 ± 3.68	0.007**
S-Go (mm)	70.60 ± 2.78	71.07 ± 3.52	0.253
PNS-Go (mm)	41.87 ± 5.03	45.90 ± 4.70	0.008**
Ls-EL (mm)	-5.00 ± 2.55	-1.75 ± 2.06	0.001***
Li-EL (mm)	-0.72 ± 2.46	-0.02 ± 2.27	0.060
NST-SN-LS (°)	118.95 ± 13.47	118.18 ± 13.37	0.614
Ns-PRN-PG (°)	139.75 ± 5.22	136.18 ± 5.21	0.001***
SS-Ns-SM (°)	129.95 ± 66.39	127.87 ± 60.71	0.100
SS-Ns-PG (°)	135.42 ± 68.23	132.60 ± 63.28	0.006**
Li-SM-PG (°)	129.40 ± 35.07	126.05 ± 34.97	0.205
Ns-PRN-SN (°)	103.98 ± 12.60	103.20 ± 13.03	0.202

*$P<0.05$, **$P<0.01$, ***$P<0.001$

DISCUSSION

Improving facial aesthetics is one of the objectives of orthodontic treatment. Especially, in early childhood, soft tissue profile improvement is of obvious importance. Individuals born with cleft lip and/or palate often have personal, social, and psychological problems, along with functional difficulty. The face mask is a most effective tool for treating skeletal Class III malocclusion with a retrusive maxilla especially in a hypo-divergent growth pattern. If the patient is motivated enough to wear a face mask, treatment is likely to be successful. Downward and forward movement of the maxilla, an increase in overjet, and a backward rotation of the mandible with increased anterior facial height have all been documented with face mask therapy. Although, face mask therapy can induce advancement of the maxilla and the circummaxillary complex depending on the force generated at the sutures. In the deciduous or early mixed dentition period, more favorable outcomes might be expected in patients than late mixed dentition.[7,13,14,16–18] In this study, we applied face mask in early mixed dentition (mean pre-treatment ages—8.7 years old) with moderate maxillary deficiency.

The RME was primarily used to disrupt the circummaxillary sutural system, increasing the effect of the orthopedic face mask and initiating downward and forward movement of the maxillary complex.[4,5,12–14,16,17] In this study, after the completion of RME, we applied face mask and evaluated the results. The patients were instructed to wear the face mask full time, except during meals.[8,13,14] In this study, the mean duration of face mask wear was 16 hours per day.

To transmit the orthopedic force from the face mask to the maxilla, tooth-borne anchorage with a labiolingual arch, a quad-helix appliance, and RME have been used. However, usage of the maxillary dentition as anchorage does not avoid unwanted side effects such as labioversion of the maxillary incisors, extrusion of the maxillary molars, counter clockwise rotation of the palatal plane, and eventual clockwise rotation of the mandible. To minimize the effect of a counter clockwise rotation of the maxilla with the protraction headgear treatment, the force was applied from the canine area rather than the molar area and at an angle of 30 degrees downward from the occlusal plane using extra oral elastics ranging 500-1000 *g* of force per side.[6,8,11,12,15–17] In this study, we applied maxillary expansion and maxillary protraction together by means of a tooth-borne anchorage appliance with expansion screw. Traction forces were applied from the distal aspects of the lateral incisor on each side. The force vector angle was 25 degrees from the occlusal plane to a downward direction. Extraoral elastics with 800 *g* of force per side, were applied from the hooks to the pre-labial arch of the face mask.

It was recommended that it would be more advantageous to perform maxillary protraction with a miniplat placed in the infrazygomatic crest area in severe class III patients who need more advancement in the middle part of the zygomaticomaxillary complex, and maxillary protraction with a miniplate in the lateral nasal wall area in patients who need more advancement in the paranasal area and the lower part of zygomaticomaxillary complex. Several studies showed that, the maximum stresses were seen at frontonasal, frontomaxillary, zygomaticomaxillary, zygomaticotemporal, and pterygomaxillary suture. Some of the investigators claimed, that the infrazygomatic area could transfer the orthopedic force more effectively to the sutures than the lateral nasal wall and cause a slight tendency for counter clockwise rotation of the nasomaxillary complex. In contrast, some of them suggest that the lateral nasal wall might be favorable to minimize the counter-clockwise rotation of the maxilla and the lateral nasal wall of the maxilla might be a proper site for miniplate placement because it is anterior to the center of resistance of the nasomaxillary complex, allowing the force vector to be near the centre of resistance. Therefore, changing the force application point to a more forward position and the force vector to a more downward direction might be recommended to minimize the unwanted counter-clockwise rotation tendency of the nasomaxillary complex.[19–27] In this study, we applied face mask in early mixed dentition with moderate maxillary deficiency so we applied maxillary protraction by means of a tooth-borne anchorage appliance.

The effect of face mask therapy on patients with unilateral cleft lip and palate was studied by several investigators. Their results showed that anterior movement of the maxilla change from 1.0 to 4.0 mm, and the increase of Sella-Nasion-A (SNA) angle was 1.0–2.0 degrees. On the contrary, evaluating the children in whom the mean age of treatment was 9 years and up, the Sella-Nasion-A angle, showed little or no change.[2–8,11–15,27] In this study, protraction of the maxilla was obtained ($P < 0.001$) and vertical changes of the maxilla showed no significant differences in cleft group ($P < 0.01$).

The lack of alveolar bone in cleft lip and palate patients had produced many problems in comprehensive orthodontic treatment. Orthodontic treatment in permanent dentitions with the residual alveolar cleft cannot align the teeth in the cleft region and stabilize the alveolar segment. Secondary bone grafting of the residual alveolar cleft in the mixed dentition is a well-established mode of treatment for these patients.[7,13,14,27,28] In this study face mask was applied in early mixed dentition stage before secondary alveolar bone grafting procedure.

The forward displacement of the maxilla varied considerably as a result of face mask therapy. Early treatment with face mask created a better basis for conventional orthodontic treatment during the permanent dentition period, ideally eliminating, or reducing severe skeletal discrepancies.

CONCLUSIONS

The present study demonstrated that:

1. The UCLP group showed significantly anterior maxillary movements when compared with control group. The results showed definite protraction of the maxilla while the posterior part underwent anterior displacement for UCLP group ($P < 0.001$). The maxilla was displaced forward with a force of 800 *g* applied to each hook with vector force about 25 degrees downward and forward to the occlusal plane. Vertical changes of the maxilla showed no significant differences in cleft group.
2. There was a clockwise rotation of the mandible with an increase in the mandibular plane angle and movement of menton downward and backward in UCLP group. The mandible of the UCLP group was rotated inferiorly and

posteriorly while control group showed inferior and anterior changes ($P < 0.05$).
3. The maxillary incisors showed greater anterior movement than expected for untreated control group ($P < 0.01$). Overjet was improved, mainly as a result of skeletal changes rather than dental changes. The lower incisors were stable in the two groups.
4. Treatment results showed increasing convexity of the facial profile from anterior displacement of the maxilla and clockwise rotation of the mandible.

It can be concluded that face mask is a safe and effective method for the orthopedic intervention of unilateral CLP patients before autogenous bone grafting in early mixed dentition.

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