



Three dimensional comparison of facial soft tissue changes between face mask and modified tandem appliances in unilateral cleft lip and palate cases

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Abstract: Introduction: Correction of the three dimensional maxillary collapse in cleft lip and palate patients is considered as an extreme challenge to orthodontists. Growth modification including maxillary expansion and protraction is mandatory at an early age to adjust maxillary hypoplasia and enhance the facial esthetics. **Aim:** The aim of this study was to use CBCT to compare the facial soft tissue changes between the facemask and modified tandem appliances in the treatment of unilateral cleft lip and palate children with skeletal Class III malocclusion. **Materials and Methods:** 34 growing children suffering from surgically repaired unilateral complete cleft lip and palate with maxillary hypoplasia were randomly divided into 2 equal groups. The first group included 9 boys and 8 girls (9.1±1.2 years old) treated with hyrax expander and facemask. The second group included 7 boys and 10 girls (8.7±1.1 years old) treated with hyrax expander and modified tandem appliance. CBCT images were taken at the beginning of the treatment (T1) and after 1mm overjet was attained (T2) to compare the soft tissue profile changes between both groups. **Results:** In each group, there were significant decreases in the nasolabial angle and the facial convexity angle with significant increases in the H angle and the upper lip protrusion ($P < 0.05$). However, the lower lip protrusion showed insignificant change ($P > 0.05$). There was insignificant difference in all parameters between both groups ($P > 0.05$). **Conclusions:** Both the facemask and the modified tandem appliances are effective in improving the facial soft tissue profile in unilateral cleft lip and palate patients.

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Key Words: Cleft lip and palate; Face mask appliance; Modified tandem appliance; Facial soft tissue profile.

1. Introduction:

Clefts of the lip and palate are common craniofacial defects occurring in approximately one in each 500 to 1000 live births worldwide [1,2]. The multifactorial inheritance of these deformities could involve both genetic and acquired factors. They could also be distinguished as signs of numerous genetically determined syndromes [3].

Enhancing various functions and esthetic appearance in cleft patients involve various treatment modalities. The scar tissues resulting from the surgical interventions for closure of these defects at a very young age mostly result in cosmetic and functional problems [4-6]. Also, the combined midface retrognathia, nasolabial angle change and facial height alteration are extensively detrimental to the facial esthetics [7].

The psychological drawbacks caused by these dentofacial deformities induce patients and their parents to target for correction of these deformities to enhance both functional and esthetic complications [8]. Undesirable self-esteem in early adolescent

children mostly persists. Early adolescents who are rejected by their colleagues could get a negative attitude as this is an age of alteration and of problems with the self-concept [7].

Also, there is a developing attention to the influence of dentofacial status on patients' quality of life [9,10]. More attention is given not only to the clinicians' evaluation of treatment effects, but also to the patients' perception of alterations to their quality of life [11].

Enhancement of facial esthetics is one of the most important aims of contemporary orthodontic treatment. The esthetic outcomes of orthodontic therapy could be of greater significance to the patient than the attained occlusal modifications. Accordingly, both effective occlusion and facial esthetics are considered parallel objectives of orthodontic therapy [7]. Because of the intimate relation between the facial soft tissues and underlying bony structures, orthodontic treatment could result in favorable effects on facial soft tissues [12-14].

Cleft lip and palate patients usually suffer from

maxillary deficiency caused by postsurgical scar tissues accompanied by unilateral or bilateral posterior crossbite caused by maxillary constriction. Accordingly, a combination of maxillary expansion with protraction is required [15,16].

Therefore, the aim of this study was to compare the facial soft tissue profile changes of the facemask and modified tandem appliances when both are accompanied by rapid maxillary expansion for treatment of unilateral cleft lip and palate children with skeletal Class III malocclusion. The null hypothesis was that the facial soft tissue profile was not affected whether maxillary protraction was performed by the facemask appliance or the modified tandem appliance in these patients.

2. Materials and methods:

This retrospective study was approved by the ethical committee of the Faculty of Dentistry, Minia University. Thirty four growing children suffering from surgically repaired unilateral complete cleft lip and palate were included in this study according to the subsequent inclusion criteria:

- 1- Absence of syndromes and craniofacial deformities other than clefts.
- 2- Skeletal Class III caused by underdeveloped maxilla ($SNA \leq 77$ degrees). 3- Anterior crossbite with unilateral or bilateral posterior crossbite.
- 3- Absence of history of preceding orthodontic treatment.

Patients were randomly divided into 2 equal groups. The first group included 9 boys and 8 girls (9.1 ± 1.2 years old) treated with combined hyrax expander and face mask therapy. The second group included 7 boys and 10 girls (8.7 ± 1.1 years old) treated with hyrax expander and modified tandem appliance.

Expansion and Protraction protocol:

In the first group, hyrax expander (Leone, Firenze, Italy) was soldered to the palatal aspects of the maxillary first permanent molar bands in each patient. 0.45" stainless steel projections were extended anteriorly and adapted to the palatal sides of the premolars or the deciduous molars on both sides. Occlusal surfaces of the teeth were coated with acrylic resin (1 mm thickness) to enlarge the surface area of the appliance for improved cement adhesion and to eradicate occlusal interferences in the anterior region. Facemask hooks were soldered bilaterally opposite to the maxillary canine region projecting upwards for effective attachment of elastics. The appliance was subsequently cemented (Figure 1) and activated by opening the midline expansion screw twice daily (0.25 mm per turn) till the palatal cusp tips of the maxillary posterior teeth occluded with the buccal cusp tips of the mandibular posterior ones.



Figure 1: Bonded hyrax appliance with posterior occlusal coverage

The facemask appliance (Hubit Co., Ltd, Gyeonggi-do, South Korea) was then modified to be comfortable for every patient (Figure 2) and to render the angle between the elastics and the occlusal plane close to 30 degrees to offset the rotation of the maxilla in a counterclockwise direction [17,18]. The maxillary protraction was subsequently initiated utilizing 5/16" elastics extending from the hooks to the facemask (Figure 2). The forces produced by elastics were quantified using a force tension gauge (Dentaurum, Pforzheim, Germany).

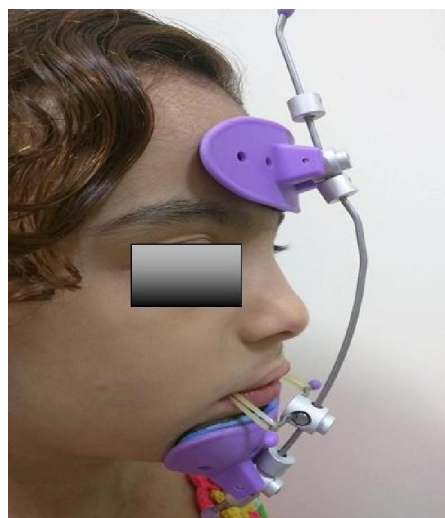


Figure 2: The face mask appliance adapted to the patient's face

In the second group, modified tandem appliance was fabricated for each patient, which consisted of 3 main components (Figure 3):

- 1- An upper fixed appliance that consisted of hyrax expander with buccal arms that were soldered to upper molar bands and extended anteriorly distal to the canine region for attachment of protraction elastics.

- 2- A lower fixed appliance that consisted of

lingual holding arch soldered to lower molar bands, fixed occlusal covering bite plane to eliminate interferences in the incisor region and buccal face bow tubes. A pin head clasp was added to the tube between the molar and the canine to enhance the stability of lower appliance and avoid upward rocking of the anterior segment during elastic traction.

3- A headgear face bow that was inserted in the lower tubes. Its outer bow was modified for elastic attachment.



Figure 3: Elastics attached to the modified tandem appliance for maxillary protraction

The upper appliance was cemented and activated in the same way as the first group till the palatal cusp tips of the maxillary posterior teeth occluded with the

buccal cusp tips of the mandibular posterior ones. The lower part of the appliance was then cemented and the orthopedic protraction was started using 5/16" elastics attached from the hooks distal to upper canines to lower traction bow. The force level was measured and the angle between the elastics and the occlusal plane was adjusted in the same technique as the first group.

Patients in both groups were instructed to wear the appliances for a minimum period of 14 hours daily and to substitute the elastics once daily or when they were lost. An assessment chart was presented to each patient to register the daily duration of elastics wear. Patients were followed-up monthly to assess the treatment advancement and patients' compliance.

Three dimensional cone beam computerized tomographic imaging:

CBCT scans (Scanora 3Dx Soredex, Finland) were taken for all patients in both groups before the insertion of the appliances (T1) and after a positive overjet of 1 mm was reached (T2). Exposures were performed at 10 mA and 90 kV using the same standardized technique. Data were then exported and transferred to DICOM format (Digital Imaging and Communications in Medicine) and OnDemand3D App software (Cybermed, South Korea) was utilized for localization of landmarks determination of linear and angular measurements (Figure 4).



Figure 4: OnDemand3D App software

At the software, 3D Ceph module was utilized for superimposition of pre and postoperative scans (Figure 5) using the anterior cranial base as a reference. This was planned to confirm recognizing landmarks in similar approach between sequential

scans. After identifying the landmarks and planes, a list of the required measurements was formulated and the software could selectively perform and generate these measurements automatically (Tables 1-3).

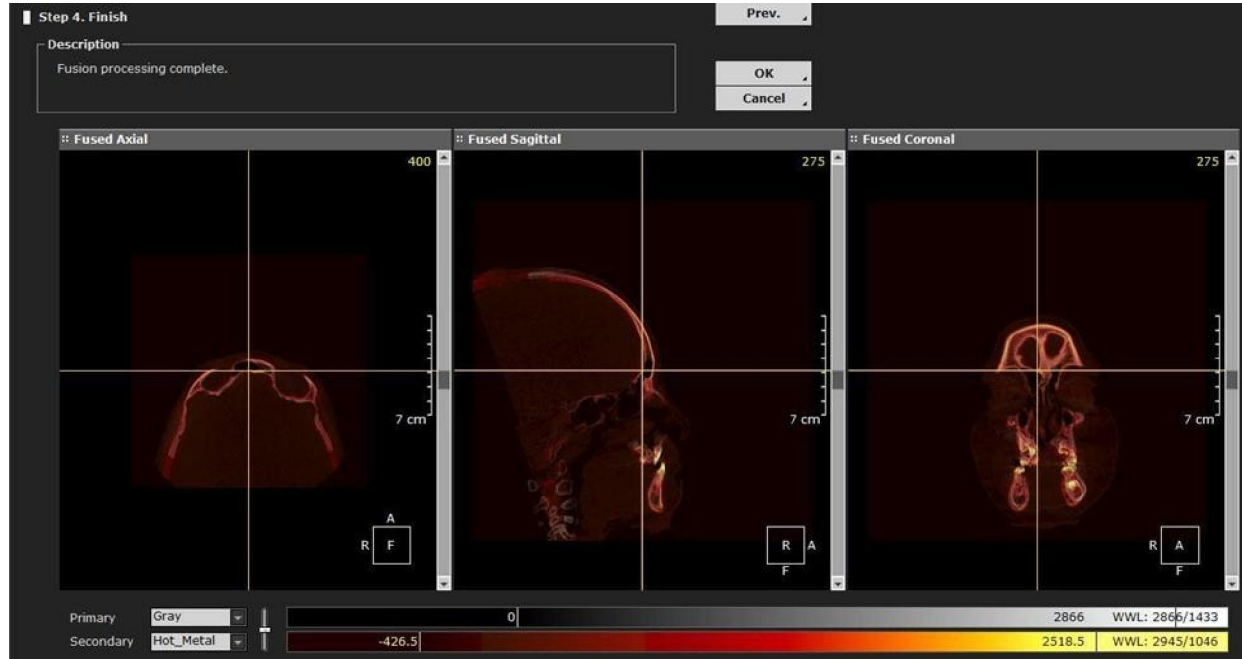


Figure 5: superimposition of pre and postoperative scans using the 3D Ceph module of the OnDemand3D App software

Table 1: List of the reference landmarks

Point	Definition
Glabella (G)	The most anterior point on the soft tissue of the forehead
Soft tissue Nasion (N')	The most concave point on the curvature between soft tissue contour of the head and the nose
Pronasale (Pn)	The most prominent point on the tip of the nose
Subnasale (Sn)	The point of joining of the base of the columella with the upper lip
Columella (Col)	The point of curvature of the base of the nose
Labrale Superius (Ls)	The point of junction of the vermilion border and the skin of the upper lip
Labrale Inferius (Li)	The point of junction of the vermilion border and the skin of the lower lip
Soft tissue Pogonion (Pog')	The most anterior point on the soft tissue outline of the chin

Table 2: List of the reference lines and planes

Line	Definition
Esthetic Line	The line connecting pronasale (Pn) and soft tissue pogonion (Pog').
H line	The line connecting labrale superius (Ls) and soft tissue pogonion (Pog').

Table 3: List of the three dimensional measurements

Measurement	Definition
Upper lip protrusion	The linear horizontal distance between Ls and E line
Lower lip protrusion	The linear horizontal distance between Li and E line
Angle of facial convexity	The angle G-Sn-Pog
H angle	The angle between N'-Pog line and H line
Nasolabial angle	The angle Col-Sn-Ls

Error of the method:

All references landmarks were detected and all measurements were taken by 3 different operators. Reliability of the measurements was assessed by Cronbach's Alpha.

Statistical method:

The collected data were statistically analyzed using SPSS program (Statistical Package for Social Sciences) version 25. Determination of the normality of data was done by Shapiro-Wilk test which revealed normal distribution of all variables in both groups. Descriptive statistics were done by mean \pm standard deviation.

Analyses were done using paired samples T test between T1 and T2 in each group. Analyses were done by independent T test between both groups. The level of significance was taken at (P value < 0.05).

3. Results:

Cronbach's Alpha was greater than 0.9 for all measurements in both groups indicating excellent method reliability.

Positive overjet was achieved in all patients of both groups. There was insignificant difference in the treatment duration for both groups (1.7 \pm 0.4 years for

the first group and 1.5 \pm 0.3 years for the second group with P value=0.254).

There was an insignificant difference in the magnitude of the forces produced by elastics in both groups (421 \pm 23 grams for the first group and 428 \pm 27 grams for the second group with P value=0.498). There was also an insignificant difference in the duration of appliance wear per day in both groups (14.2 \pm 1.5 and 14.9 \pm 1.8 hours per day respectively with P value=0.082).

Four patients in the first group and three in the second group showed mobility of the appliance during the course of treatment. For these patients, the appliances were re-cemented, and the treatment was continued with the same protocol. The period of interruption was added to the entire treatment duration.

Regarding the changes between T1 and T2, both groups showed significant decreases in both the nasolabial angle and the angle of facial convexity after treatment with significant increase in the H angle. The upper lip showed significant protrusion, while lower lip showed insignificant retrusion in both groups (Tables 4 and 5).

Table 4: Soft tissue profile changes between T2 and T1 in the first group

	T1	T2	T2-T1	P value
H angle	3.8 \pm 1.7	9.5 \pm 3	5.8 \pm 2.1	0.005*
Nasolabial angle	131.5 \pm 6.8	125.1 \pm 3.8	-6.2 \pm 2.1	0.001*
Angle of facial convexity	170.5 \pm 6.2	164.4 \pm 6.7	-6.1 \pm 1.7	<0.001*
Upper Lip/ E line	-4.1 \pm 1.5	-1.6 \pm 0.9	2.6 \pm 1	0.005*
Lower Lip/ E line	-1.8 \pm 1.1	-1.9 \pm 1.2	-0.1 \pm 0.1	0.064

*: Significant level at P value < 0.05

Table 5: Soft tissue profile changes between T2 and T1 in the second group

	T1	T2	T2-T1	P value
H angle	4.1 \pm 1.5	9.2 \pm 2.6	5.1 \pm 2.2	0.004*
Nasolabial angle	131.5 \pm 6.8	125.1 \pm 3.8	-6.4 \pm 2.1	0.002*
Angle of facial convexity	167.9 \pm 3.1	162.3 \pm 5.5	-5.6 \pm 2	<0.001*
Upper Lip/ E line	-3.7 \pm 1.3	-0.7 \pm 0.9	2.9 \pm 1.6	0.008*
Lower Lip/ E line	-1.1 \pm 0.9	-1.2 \pm 1.1	-0.1 \pm 0.2	0.195

*: Significant level at P value < 0.05

Comparing between both groups, there were insignificant changes in all soft tissue measurements (Table 6).

Table 6: Comparison of the changes in the soft tissue profiles between both groups

	Group 1	Group 2	P value
H angle	5.8 \pm 2.1	5.1 \pm 2.2	0.969
Nasolabial angle	-6.2 \pm 2.1	-6.4 \pm 2.1	0.814
Angle of facial convexity	-6.1 \pm 1.7	-5.6 \pm 2	0.758
Upper Lip/ E line	2.6 \pm 1	2.9 \pm 1.6	0.621
Lower Lip/ E line	-0.1 \pm 0.1	-0.1 \pm 0.2	0.939

*: Significant level at P value < 0.05

4. Discussion:

Treatment of cleft lip and palate patients is considered as an extreme challenge to orthodontists due to the variety and difficulty of the orthodontic problems they suffer from which include the skeletal structures, the dentition and the facial soft tissues [19]. Three-dimensional maxillary collapse is a common character for these patients. Accordingly, growth modification at an early age is mandatory, to adjust maxillary hypoplasia and enhance the facial esthetics [20].

Rapid palatal expansion could disarticulate the circummaxillary sutures and assist the orthopedic outcome in these patients [21-24]. Accordingly, maxillary expansion was carried on in this study till the palatal cusp tips of the maxillary posterior teeth occluded with the buccal cusp tips of the mandibular posterior ones in both groups. Subsequently, maxillary protraction was initiated.

Both the facemask and the modified tandem appliances are indicated for children suffering from skeletal Class III malocclusion with an underdeveloped maxilla. Both appliances are effective in maxillary protraction, overjet increase and correction of molar relation [25,26]. As the main challenge with extraoral appliances is the poor patient's compliance caused by their physical appearance, the modified tandem appliance is considered superior to the facemask as it limits the cooperation of the patient to the replacement of elastics and the preservation of effective oral hygiene [27].

Using cone beam computed tomography could overcome the limitations of 2 dimensional cephalograms, since the landmarks determined in the conventional cephalometries are 2D projections of 3D structures [28]. CBCT could present the distinct advantage of one to one geometry and could provide the possibility for using more anatomical landmarks that were not obvious in the two dimensional cephalograms, allowing visualization of the detailed complicated anatomy of cleft lip and palate patients [29,30]. Moreover, it was possible to enhance the effectiveness of image utilization by removing the superimposition of structures that were not related to the needed landmark determination and three dimensional measurements [31].

In this study, there was insignificant difference in the angle of facial convexity between both groups. There was a significant reduction in each group (-6.1° in the first group and -5.6° in the second). This was similar to the results of other studies [32,33] and can be attributed to the gradual correction of the intermaxillary sagittal skeletal relation accompanied by a significant maxillary advancement [34,35].

Regarding the nasolabial angle, there was insignificant difference between both groups. There was a significant reduction in each group (6.2° in the first group and 6.4° in the second). Forward movement of upper lip during maxillary protraction improves the concave profile with the nasolabial angle becoming more reduced [36].

There was also an insignificant difference between both groups regarding the H angle and a significant increase in each group (5.8° in the first group and 5.1° in the second). This was similar to the results of another study that showed significant increase of 3° [7].

There was insignificant difference between both groups in the upper lip protrusion. There was a significant protrusion in each group (2.6 mm in the first group and 2.9 mm in the second). This could be a direct consequence to the definite maxillary protraction in both groups [37].

5. Conclusion:

Both the facemask and the modified tandem appliances are effective in improving the facial soft tissue profile in unilateral cleft lip and palate patients.

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