

Soft-Tissue Changes in Unilateral Cleft Lip and Palate Patients after Non-surgical Maxillary Advancement with Face Mask Therapy - A Prospective Cohort Study

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Abstract

Introduction: The aim of this study was to evaluate soft-tissue changes in Egyptian cleft lip/palate (CLP) patients after conservative non-surgical maxillary advancement using face mask therapy. **Methods:** This prospective cohort study included 20 Egyptian patients with unilateral CLP, six females and 14 males, ranging in age from 10 to 15 years and suffering from moderate maxillary deficiency. These patients had been chosen randomly from the Oro-dental Genetics Clinic at the National Research Centre, Egypt. For lateral cephalometry tracing and superimposition of pre-operative and post-treatment data, this study used Dolphin 11.0 software. Subnasal (Sn), pronasal (Pn), soft tissue pogonion (Pg), labial superior (Ls), stomion superioris (Ss), labiale inferior (Li), stomion inferioris (Si) and soft tissue Menton (Me) were the soft tissue points used in this analysis. **Results:** All of the cases were successful and demonstrated a positive response to the orthodontic traction. All post-operative linear measurements of the measured soft-tissue points showed statistically significant advancement ($P = 0.05$) except for pronasal linear measurements, which did not show a significant difference post-treatment ($P = 0.84$). **Discussion:** With the use of the face mask procedure, both upper and lower lip soft-tissue points improved significantly, but nasal points remained unchanged, requiring more management.

Keywords: Cleft, Egypt, face, masks, maxilla

INTRODUCTION

Dentofacial orthopaedics have traditionally focused on restoring occlusion and jawbone relationship, but there has been a lot of emphasis on soft-tissue improvements as well as the optimal location.^[1,2] Patients with cleft lip and palate typically have a maxillary deficiency, which necessitates whole maxillary arch advancement in the majority of instances.^[3,4] Face mask therapy has been commonly used for maxillary advancement along with rapid maxillary expansion (RME).^[5-7]

Maxillary retrusion and soft-tissue concavity characterise Class III occlusion. Since orthodontic treatment begins at a young age, it yields better results, as it becomes more complicated after pubertal development.^[8-10] The enhancement of soft-tissue profile is strongly linked to skeletal changes in both arches as a result of face mask traction. Protrusion of maxillary incisors and retrusion of mandibular incisors result in correction of Class III incisal relationship by forward and downward positioning of the maxilla, combined with

open rotation of the mandible.^[11-13] Patients with a retruded maxilla and a Class III malocclusion are more likely to have an undesirable facial appearance as well as psychological insecurity about their appearance. Long-term studies have shown that some relapse can occur after treatment is completed, particularly when retainers are used.^[14-16] The importance of digital imaging and lateral cephalometry in tracing hard-tissue anatomical landmarks and soft-tissue points before beginning treatment and during the follow-up period for proper

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Received: 14-01-2023

Last Revised: 30-04-2023

Accepted: 07-09-2023

Published: 30-10-2023

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How to cite this article: Mossaad AM, Abdelrahman MA, Ghanem WA, Elsayed SA. Soft-tissue changes in unilateral cleft lip and palate patients after non-surgical maxillary advancement with face mask therapy - A prospective cohort study. *Ann Maxillofac Surg* 2023;13:179-83.

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DOI:
10.4103/ams.ams_10_23

evaluation of treatment progress cannot be overstated.^[17,18] For orthodontics and orthognathic procedures, cephalometry is a vital method. It was first introduced in 1931.^[16] Software is used to examine both bone and soft-tissue landmarks. In comparison to manual tracing methods, digital tracing has been shown to be more accurate.^[19-23]

Most Egyptian cleft patients are poor and unable to afford orthognathic surgery, which includes the costs of general anaesthesia and hospitalisation in addition to the expense of plates and screws. As a result, face mask therapy may be a viable choice for their treatment, but cosmetic results and soft-tissue profile analysis should be included when comparing these methods to the outcomes of other surgical techniques. In Egypt, there is scarce data on the results of these interventions. The aim of this study was to evaluate soft-tissue changes in Egyptian cleft patients after using this conservative face mask therapy for maxillary advancement.

METHODS

Twenty unilateral Egyptian cleft lip/palate (CLP) patients with minor maxillary deficiency, aged 10–15, were involved in this prospective cohort study. Participants in the study sample consisted of 14 men (70%) and 6 females (30%). These patients were selected at random from Oro-Dental Genetics Clinic at the National Research Centre between December 2020 and December 2022. Expert surgeons and orthodontists chose all cases of patients with unilateral complete cleft lip and palate. Primary lip closure was performed at two months and primary palate closure at nine months before the end of the first year of life. Before being studied, the participants did not receive any orthopaedic or orthodontic treatment. The current study followed the Helsinki Declaration of Clinical Research Principles and received ethical approval from the National Research Centre (MERC19255/2019). Before being included in the study, all patients and their guardians signed an informed consent form and were informed about the study's goals.

Study participants criteria

- Anterior crossbite with angle Class III molar relationship
- Negative ANB angle
- Concave soft-tissue profile
- No systemic or craniofacial disease
- No prior orthodontic procedure
- Age range of 10–15 years (pre-pubertal and pubertal stage).

Exclusion criteria included

- Syndromic or bony disorders
- Previous surgery for advancement
- Severe Class III malocclusion.

The face mask therapy group was the independent variable and the cephalometric measurements were the dependent variables. Pre-operative assessment included clinical examination, intraoral as well as extraoral photographs and

lateral cephalometry tracing followed by 6-month follow-up post-treatment assessment. Soft-tissue analysis with landmark points was compared pre-operatively and post-operatively using Digital Dolphin 11.0 software (Dolphin Imaging and Management Solutions, Chatsworth, CA, USA). The maxillary permanent first molars were banded with the Hyrax appliance. Protraction hooks were soldered to the buccal aspects of the permanent first molar bands on both sides, and they were extended anteriorly to the canine region. Face masks were fitted to each patient, and intraoral elastics of 5/16 inch, 14 oz were applied from the palatal appliance hooks to the face mask. The elastics' force vectors were modified to develop a 20°–30° angle with the occlusal plane. The applied forces per side ranged from 300 to 400 g. Patients were instructed to change their elastics on a regular basis and to wear their appliances for at least 16–18 h/day. Treatment was continued until a positive overjet of 2 mm was achieved [Figure 1].

The E line of Holdaway technique was used to perform lateral cephalometry linear tracing (Because the E line is commonly used in lateral cephalometry to measure soft-tissue profiles by soft-tissue tracing through the nasal tip, upper lip and chin), which included the following eight soft-tissue points: subnasal (Sn), pronasal (Pn), soft-tissue pogonion (Pg), labial superior (Ls), stomion superioris (Ss), labiale inferior (Li), stomion inferioris (Si) and soft-tissue Menton (Me). The 20 cephalometric radiographs were scanned into digital format with a HP scan G4050 and exported to the Dolphin Imaging 11.0 program (Dolphin Imaging and Management Solutions, Chatsworth, CA, USA) (Dolphin Radiographic Film Calibration Ruler) [Figure 2].

Statistical analysis

Within subjects comparison, design between pre-and post-treatment soft-tissue profile analysis was conducted as we have single group of unilateral cleft lip and palate patients using paired sample *t*-test and significance was set at <0.05.

RESULTS

Twenty unilateral Egyptian CLP patients with minor maxillary deficiency, aged 10–15, were involved in this prospective cohort study. There were six female and 14 male participants. All patients tolerated the device well and there was no complication reported. Except for the Pn linear measurements, which did not improve post-operatively ($P = 0.84$), all post-operative linear measurements of points (Sn, Pg, Ls, Ss, Li, Si and Me) show considerable advancement and statistically significant difference ($P < 0.05$). The nasal tips shifted forward and slightly downward in all of the patients in our sample, but this movement was not significant [Table 1]. All of the cases were successful, and the orthopaedic traction had a good response. The amount of forward soft-tissue movement was much greater than predicted and was primarily caused by the forward displacement of the maxilla and anterior nasal spine caused by the device's protraction forces [Figures 3 and 4].

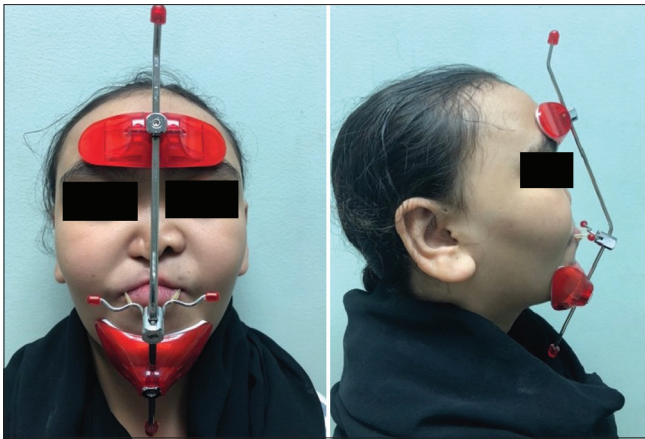


Figure 1: Frontal (Left) and lateral profile (Right) clinical photograph showing face mask device attached to the maxilla

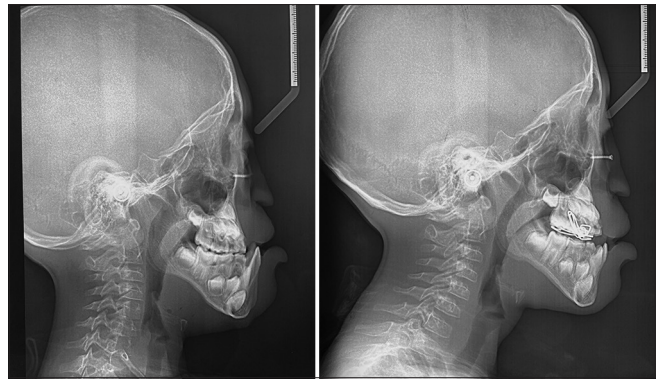


Figure 2: Pre- (Left) and post-treatment (Right) lateral cephalograms showing the advancement of maxilla



Figure 3: Pre-treatment (left) and Six months post-treatment (Right) profile photographs

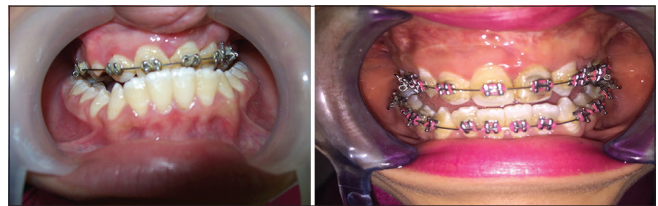


Figure 4: Pre- (left) and post-treatment (Right) intraoral photographs

DISCUSSION

Patients with cleft lip and palate who may have a retruded maxilla may have psychological and functional issues as a result of their appearance.^[24] The participants in this study were 20 pubertal patients who underwent non-surgical maxillary advancement using an orthopaedic face mask with elastic traction. The results of this study demonstrated that when the face mask approach was used, both upper and lower lip soft-tissue points improved significantly, while nasal soft-tissue points remained unaltered, necessitating more management in the future.

Dogan^[25] investigated the impact of face mask therapy in addition to RME in 20 unilateral cleft patients and found that combining the transverse and anteroposterior expansion for the maxilla produced better results. According to Zhang *et al.*,^[26] the earlier face mask therapy is started, the better the result will be, and it might also remove the need for potential orthognathic surgery. They included 60 pre-pubertal patients with mixed dentition and concluded that alveolar cleft grafting is needed before maxillary advancement, which is consistent with our findings.

Table 1: Descriptive mean and standard deviation and t-test analysis results of the study soft-tissue points variables

Study variables	Mean	SD	SEM	Significant (two-tailed)
Pn				
Pre-operative	1.05	0.35	0.08	0.84
Post-operative	1.06	0.41	0.09	
Sn				
Pre-operative	11.55	0.86	0.19	0.001
Post-operative	5.86	0.42	0.09	
Ls				
Pre-operative	9.73	0.84	0.19	0.001
Post-operative	3.86	0.42	0.09	
Ss				
Pre-operative	8.64	0.84	0.19	0.001
Post-operative	2.86	0.42	0.09	
Li				
Pre-operative	2.36	0.49	0.11	0.001
Post-operative	1.86	0.42	0.09	
Si				
Pre-operative	3.26	0.57	0.13	0.001
Post-operative	2.86	0.42	0.09	
Pg				
Pre-operative	5.03	0.90	0.20	0.019
Post-operative	4.76	0.71	0.16	
Me				
Pre-operative	7.16	0.49	0.11	0.006
Post-operative	6.91	0.37	0.08	

Pn: Pronasal, Sn: Subnasal, Ls: Labiale superior, Ss: Stomion superioris, Li: Labiale inferior, Si: Stomion inferioris, Pg: Soft-tissue pogonion, Me: Soft-tissue Menton, SD: Standard deviation, SEM: Standard error of mean

According to Kurt *et al.*,^[27] the face mask therapy with elastic traction causes downward and forward positioning in the

maxilla, resulting in proclination of the upper incisors, while the clockwise rotation effect occurs in the mandible due to the chin cup effect, reducing class III malocclusion. Face mask therapy, sometimes referred to as the Dr. Jean Delaire mask, is a non-invasive method for treating deficient maxilla. It is designed to deliver forward and downward traction to the upper jaw and has a direct influence on the maxilla and an indirect effect on the mandible. As a result, a balanced intermaxillary relationship promotes jaw growth as well as having a forward functional shift force on the lower jaw which avoids irreversible changes in dental and skeletal alignment^[28,29] and reverse relative mandibular prognathism, however, most patients, especially females, dislike it because of its appearance. Patients often avoid it because it takes a long time to complete, ranging from six months to a year, and it must be worn for the majority of the day; however, it eliminates the possibility of surgery. All of the cases were successful, and the orthodontic traction had a good response. In terms of assessment, lateral cephalometry is a valuable instrument. As shown by Dogan and Zhang *et al.*,^[25,26,30] hard and soft-tissue points tracing can now be easily applied with digital tracing by software such as Dolphin 11.0, which was chosen in our study and gives more reliable results than manual tracing while also saving time and effort for the doctor.

In the present study, the significant difference was mostly observed in the upper and lower lip soft-tissue points. Previous studies have shown that protraction forces cause increased forward displacement of the nasal tip, which contradicts our findings.^[5,31] The Pronasal (Pn) point refers to the position of the nose, which did not significantly improve after Face Mask (FM) maxillary advancement, necessitating additional intervention for rhinoplastic surgeries. However, soft tissue advancement after Face Mask provided superior outcomes when anchorage was done on maxillary and nasal bone rather than only dental bone. Patients will still require further nasal tip deformity correction, which is usually planned after maxillary advancement and orthodontic treatment after puberty.^[32]

Several previous studies on soft-tissue modifications using a conservative face mask method have been done and revealed comparable results to the current study. However, there is still a gap in our knowledge in Egypt when it comes to the treatment of cleft lip and palate patients, thus adding and displaying the findings of our population is necessary for these individuals who deserve a better quality of life.

Limitation of the study

Despite the fact that this is a single-centre study, it was carried out at Egypt's largest research national centre and provided impressive results for patients in the pubertal age group who benefit from the advances made possible by the conservative face mask technique.

CONCLUSION

With the use of the face mask procedure, both upper and lower lip soft-tissue points improved significantly, but nasal points remained unchanged, requiring more management.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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