

## Profile Changes and Stability following Distraction Osteogenesis with Rigid External Distraction in Adult Cleft Lip and Palate Deformities

### Abstract

**Objectives:** The objective of this study is to analyze the hard and soft-tissue profile changes as well as the upper airway changes after distraction osteogenesis (DO) using rigid external distraction device in adult cleft lip and palate (CLP) patients. The study also evaluates the stability of the surgical result. **Materials and Methods:** Three lateral cephalometric radiographs were taken: Predistracted (T1), postdistracted (T2), and 1 year after distractor removal (T3). The treatment changes (T1 vs. T2) and the stability (T2 vs. T3) were analyzed. The overall treatment changes after 1 year were also evaluated (T1 vs. T3). The lateral cephalograms were digitally analyzed with the help of software named Dolphin. **Statistical Analysis Used:** Wilcoxon Signed-Ranks test was used, and the probability value ( $P$  value) of 0.05 was considered as statistically significant level. **Results:** Eleven adult patients with CLP were retrospectively analyzed. After distraction, there was a significant mean maxillary advancement of 14 mm ( $P < 0.01$ ) from a T1 value of  $73.54 \pm 10.38$  to a T2 value of  $88.2 \pm 10.49$ . The lower facial height and the incisor exposure were significantly increased. The nasolabial angle had a significant improvement of  $24.5^\circ$  ( $P < 0.01$ ) from a T1 value of  $56.6 \pm 21.03$  to a T2 value of  $81.18 \pm 14.4$ . The upper airway was significantly improved by 3.7 mm ( $P < 0.01$ ) with a T1 value of  $13.5 \pm 3.8$  to a T2 value of  $17.2 \pm 3.66$ . After 1-year follow-up, there was a significant maxillary relapse of 3.20 mm ( $P < 0.05$ ) from a T2 value of  $8.29 \pm 6.84$  to a T3 value of  $5.09 \pm 5.59$ . However, the soft-tissue profile and upper airway remained stable. **Conclusion:** The clinician should have an understanding of the related hard and soft tissues as well as airway changes which may assist him when planning for maxillary advancement for CLP patients with DO. There were significant improvements immediately after distraction, but during the 1-year follow-up, some relapse was seen. This stressed on the need for overcorrection of about 35%–40% for adult CLP patients.

**Keywords:** Cleft palate, distraction osteogenesis, profile, rigid external distraction, stability

### Introduction

The deficiency of maxillary growth is a long-term negative effect of early cleft lip and palate (CLP) repair.<sup>[1]</sup> Cleft maxillary hypoplasia used to be managed by an orthopedic treatment with the help of an anteriorly directed extraoral force.<sup>[2]</sup> However, Ross in a 1987 review of 100 adults unilateral CLP reported that 27% of cleft maxillary hypoplasia patients did not respond to orthodontic procedures alone.<sup>[1]</sup> In 1997, Delaire stated that, in cleft patients, functional orthodontic therapy is often insufficient, and surgery is required.<sup>[3]</sup>

It is known that 25%–60% of all patients born with CLP will require maxillary advancement to correct maxillary hypoplasia and improve esthetic facial proportions.<sup>[1,4]</sup> Orthognathic surgery and

distraction osteogenesis (DO) are the most favored surgical treatment modalities for cleft maxillary hypoplasia.

When large skeletal movements are required, the associated soft tissue often cannot adapt to the acute changes. This failure of tissue adaptation results in several problems including surgical relapse and excessive loading of the temporomandibular joint structures. Le Fort I osteotomy in cleft patients have a relapse rate varied from 4% to 40%, with much higher rates with longer-term follow-up.<sup>[5]</sup> The primary causes of relapse for conventional Le Fort I procedures are large discrepancies between the bony segments, palatal scarring, tightness of the upper lip, and interference with the nasal septum are present.<sup>[6]</sup>

The technique of distraction has now become a standard tool in the hands

**Jaeson M. Painatt,  
Ravi Veeraraghavan,  
Ushass Puthalath,  
Sherry Peter<sup>1</sup>,  
Latha P. Rao<sup>1</sup>,  
Maria Kuriakose<sup>2</sup>**

*Department of Oral & Maxillofacial Surgery, Amrita School of Dentistry, Amrita University, <sup>1</sup>Department of Craniofacial Surgery, Aster Medcity, <sup>2</sup>Department of Orthodontics, Amrita School of Dentistry, Amrita University, Kochi, Kerala, India*

**Address for correspondence:**  
Dr. Jaeson Mohanan Painatt,  
Department of Oral and Maxillofacial Surgery,  
Amrita School of Dentistry,  
Kochi - 682 024, Kerala, India.  
E-mail: jaes\_m@hotmail.com

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of craniofacial and oral and maxillofacial surgeons. Distraction has various benefits such as evading bone grafting and donor site morbidity, its availability for use in surgery on younger patients and the concurrent expansion of the soft-tissue envelope.<sup>[7]</sup> Maxillary DO improves the soft-tissue profile by increasing nasal projection, normalizing the nasolabial angle, and making the upper lip more prominent.<sup>[8]</sup> One of the greatest advantages of maxillary DO is that the maxilla can be lengthened to a greater extent, and the lengthened maxilla is found to be more stable than the conventional maxillary advancement.<sup>[9]</sup> Relapses in maxillary DO in the long term are reported to be minimal because the maxilla is gradually advanced as compared to orthognathic surgery.

This study is a cephalometric follow-up analysis to determine the effects of maxillary DO on the hard and soft-tissue profile as well as the nasopharyngeal airway. We have also attempted to assess the stability of the result after a year.

### Materials and Methods

The cleft maxillary hypoplasia patients treated with DO using rigid external distraction (RED) device [Figure 1] in our institution were retrospectively analyzed. The study included eleven adult CLP patients (15–30 years). Incomplete treatment of distraction with RED, syndromic patients as well as those treated with internal distractors was excluded from the study to maintain its homogeneity.

### Surgical technique

After endotracheal intubation, a Frankfort's horizontal (FH) line was drawn on the face to orient the RED device [Figure 2a]. Following aseptic protocols, a maxillary vestibular incision was given, and mucoperiosteal dissection was carried out on to the posterolateral aspect of maxillary sinus and down to the pterygoid plates. A long titanium plate of 1.5 mm was adapted on the buccal surface just below the planned osteotomy [Figure 2b]. Twenty-six gauge-twisted stainless steel wires were passed through the holes of the plate on both sides. Following Le Fort 1 osteotomy, the preadapted plate was fixed on the osteotomized maxilla, and the wires were brought out through a stab incision placed in the alar crease bilaterally. The maxilla was positioned back to its original anatomical position, and the vestibular incision was sutured. The RED device was anchored onto the skull by positioning it parallel to the FH plane. The free ends of the wire were fixed to the RED device.

### Distraction protocol

After a latency period of 5–7 days, active distraction was initiated at the rate of 1 mm/day. Distraction was continued till an overjet of 2–4 mm. The distraction device was kept for 3 months for rigid retention after activation. The distractor along with the long titanium plate was removed

after 3 months, and mini-plates were fixed on the distracted segment so as to achieve stability.

### Cephalometric examination

Three lateral cephalometric radiographs were recorded: predistraction (T1), postdistraction (T2), and 1 year after distractor removal (T3). The treatment changes were analyzed when T1 was compared with T2 (T1 vs. T2), and the stabilities were evaluated when T2 was compared with T3 (T2 vs. T3). The overall treatment changes after 1 year were evaluated when T1 was compared with T3 (T1 vs. T3). These radiographs were recorded in natural head position and the patient's lips in repose [Figure 3a-c]. The cephalograms were digitally analyzed with the help of a Dolphin software (Dolphin Imaging and Management

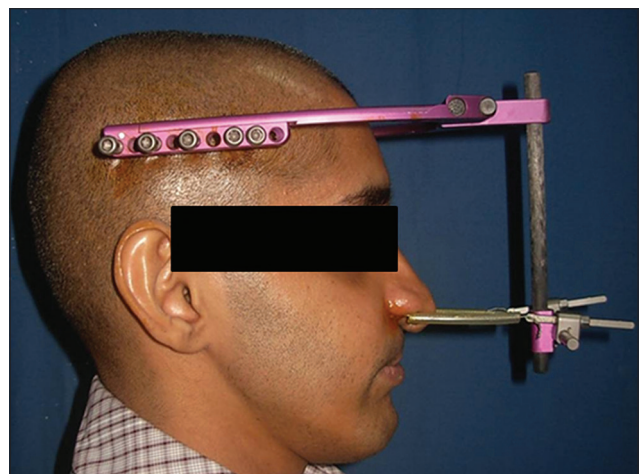


Figure 1: Patient wearing rigid external distraction

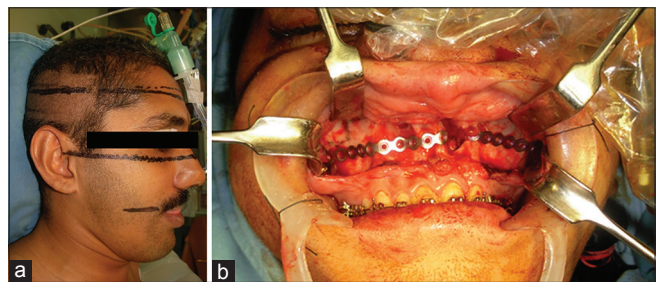


Figure 2: (a) Frankfort's horizontal line drawn. (b) Long titanium miniplate adapted

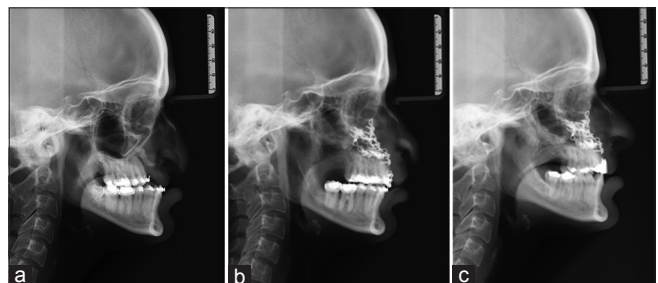


Figure 3: (a) Predistraction, T1 (b) Distractor removal, T2. (c) One year after distractor removal, T3

Solutions software (Patterson Dental®) as some of the lateral cephalograms were digital, and the rest were film based. Forty-six anatomical landmarks were used for the analysis [Figure 4a and b]. Eighteen parameters were digitally analyzed on all the lateral cephalograms.

All the statistical analysis were performed with Statistical Product and Service Solutions (SPSS, Statistical Product and Service solutions software by IBM) software. The data were subjected to descriptive analysis for mean, range, and standard deviation of all variables. Wilcoxon-signed ranks test was used, and the *P* value of 0.05 was considered statistically significant level.

## Results

The study population included 11 CLP patients who underwent midface DO with RED device in our institution between January 2007 and December 2012. However, only 7 patients reported for the follow-up after 1 year. Out of 11 patients, six were male and five were female. The age of the patients at the time of surgery ranged from 15 to 30 years with a mean age of 19.2 years. All these patients underwent surgical repair of CLP in the first 2 years of life followed by surgical repair of alveolar cleft using iliac crest.

On comprehensive cephalometric evaluation of predistracted (T1), postdistracted (T2), and 1 year after the removal of distractor (T3) lateral cephalograms, the following results were obtained [Table 1].

### Immediate surgical result (T1 vs. T2)

On comparing T1 and T2, there was an improvement in the facial curvature from concave to convex with a T1 value of  $-17.6^\circ \pm 8.77^\circ$  to a T2 value of  $12.81^\circ \pm 6.52^\circ$  with a significant mean difference of  $30.4^\circ$  ( $P < 0.01$ ). Cleft maxillary hypoplasia is mainly manifested by a decreased SNA angle, reduced maxillary length (Co-A), and a negative overjet. After

distracting the maxilla, the mean effective maxillary length significantly increased from a T1 value of  $73.54 \pm 10.38$  mm to a T2 value of  $88.2 \pm 10.49$  mm ( $P < 0.01$ ) leading to a significant increase in SNA angle from  $78.6^\circ \pm 5.9^\circ$  to  $92.5^\circ \pm 5.8^\circ$  ( $P < 0.01$ ) with a mean change of  $13.9^\circ$ . The maxilla in reference to the true horizontal plane (N-A) was significantly increased by 13.5 mm from  $-3.78 \pm 5.8$  mm to  $9.79 \pm 6.10$  mm ( $P < 0.01$ ). The distraction was continued till there was a significant positive overjet of mean 4 mm and an incisor exposure of 3.2 mm.

As the maxilla was brought forward, there was a mild increase in the upper facial height (N-ANS) with a mean change of 2 mm. Thus, there was an autorotation of the mandible backward which contributed to a decrease of SNB angle with a mean difference of  $1.3^\circ$ . Due to the backward movement of the mandible, there was an increase in the lower facial height (ANS-Me) with a mean difference of 2 mm. These changes led to an overall improvement in the anterior facial height (Na-Me) of mean 115.8 mm from 112.9 mm.

On removal of the RED device (T2), there were significant improvements in the nasomaxillary complex. There was a significant increase in the nasolabial angle with a mean change of  $24.5^\circ$  ( $P < 0.01$ ) from a T1 value of  $56.6^\circ \pm 21.03^\circ$  to a T2 value of  $81.1^\circ \pm 14.4^\circ$ . The upper lip length significantly increased from  $18.26 \pm 2.4$  mm to  $20.89 \pm 3.99$  mm ( $P < 0.01$ ). The upper lip thickness at the vermilion border had significantly decreased, from 13.1 mm to 10.7 mm, by 2.3 mm ( $P < 0.05$ ). The lower lip had moved behind significantly from  $8.9 \pm 3.35$  mm to  $4.3 \pm 1.8$  mm ( $P < 0.01$ ) from the H-line (Harmony line of Holdaway), thus contributing to a normal facial profile.

Postdistracted, there had been a striking improvement in the upper airway. The nasopharyngeal airway had significantly increased by 3.7 mm ( $P < 0.01$ ) from T1 value of  $13.52 \pm 3.84$  mm to a T2 value of  $17.26 \pm 3.6$  mm.

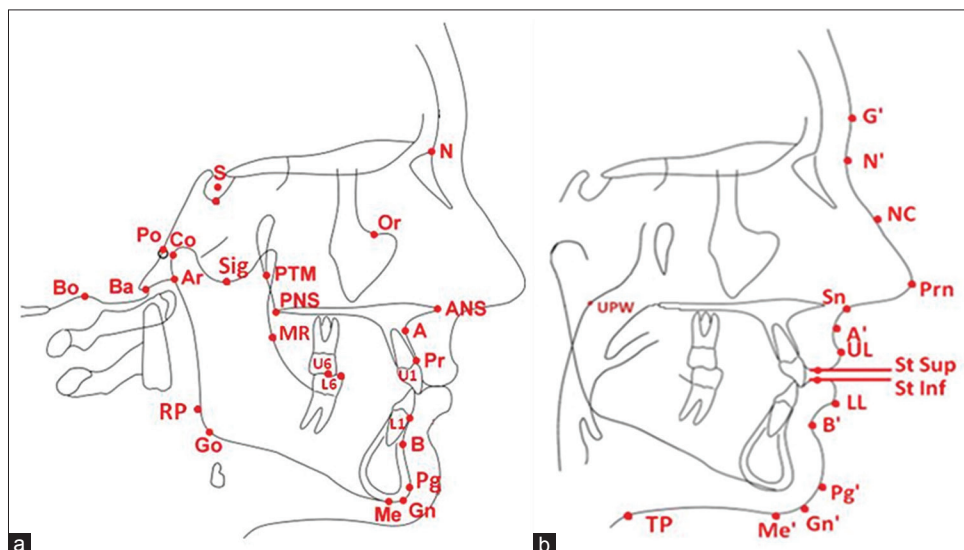


Figure 4: (a) Hard-tissue landmarks. (b) Soft-tissue landmarks



**Table 1: Immediate surgical result**

Parameters	T1 (n=11)		T2 (n=11)		Mean difference	P
	Mean	SD	Mean	SD		
<b>Hard tissue</b>						
N-A (HP) (mm)	-3.782	5.8738	9.791	6.1024	13.573	*
N-B (HP) (mm)	5.509	9.0415	4.482	7.7913	-1.027	NS
N-Pg (HP) (mm)	8.518	10.0531	7.373	8.3631	-1.145	NS
N-A-Pg (°)	-17.609	8.7781	12.818	6.5219	30.427	*
SNA (°)	78.6	5.9724	92.518	5.8338	13.9	*
SNB (°)	86.409	5.9111	85.027	4.5198	-1.382	NS
ANB (°)	-7.791	3.8438	7.464	2.8612	15.255	*
Lower face height (ANS-Me) (mm)	68.5	11.5739	70.582	10.8223	2.082	*
Upper face height (N-ANS) (mm)	44.464	7.164	46.491	7.857	2.027	NS
Anterior face height (NaMe) (mm)	112.936	16.769	115.882	18.0405	2.946	NS
Midface length (Co-A) (mm)	73.545	10.3842	88.2	10.4971	14.65	*
<b>Soft tissue</b>						
Nasolabial angle (Col-Sn-UL) (°)	56.664	21.0397	81.182	14.4844	24.518	*
Lower lip to H-line (mm)	8.991	3.3519	4.309	1.8014	-4.682	*
U-lip thickness at vermilion border (mm)	13.109	2.3339	10.736	1.8304	-2.373	*
Upper lip length (Sn-StSup) (mm)	18.264	2.4945	20.891	3.9906	2.627	*
<b>Dental</b>						
Overjet (mm)	-8.97	5.056	4.036	1.9397	13.006	*
Incisor edge to upper lip	1.464	3.573	3.218	1.9646	1.754	*
<b>Airway</b>						
Upper airway: Naso-pharyngeal	13.527	3.8474	17.264	3.6609	3.737	*

\* $P < 0.05$ . NS: Not significant; SD: Standard deviation

The treatment changes revealed that there was marked improvement in the hard and soft tissues, as well as airway post, DO in adult CLP patients.

### Stability of the result (T2 vs. T3)

On comparing the lateral cephalograms of postdistraction (T2) and 1 year after distraction (T3), there was some amount of skeletal relapse. The angle of convexity (N-A-Pg) was significantly decreased by  $3.46^\circ$  from a T2 value of  $10.53^\circ \pm 7.15^\circ$  to a T3 value of  $7.07^\circ \pm 10.39^\circ$  ( $P < 0.01$ ). There was a mild relapse of the anteroposterior maxilla-mandibular relationship (ANB) by  $3.34^\circ$  from  $6.34^\circ \pm 3^\circ$  which was significant ( $P < 0.01$ ) [Table 2].

The maxilla in relation to the true horizontal plane (N-A) was significantly decreased from a mean of  $8.29 \pm 6.84$  mm to  $5.09 \pm 5.59$  mm with a mean difference of 3.20 mm ( $P < 0.05$ ). There was a 38% significant maxillary relapse. The effective maxillary length (Co-A) was decreased by 4.4 mm, and the SNA angle was decreased by  $1.96^\circ$ . Thus, there was a decrease in the upper facial height (N-ANS) by 1.01 mm and a lower facial height (ANS-Me) by 2.86 mm. This led to the overall decrease in the anterior facial height (Na-Me) of 3.66 mm. However, the mandible remained stable with a distance of 0.4 mm (N-Pg). N-B showed stable measurements with a mean difference of 0.29 mm. The overjet had a mild relapse of 1.19 mm, but the incisor exposure remained stable.

The soft-tissue changes were relatively stable 1 year after distraction (T3). The thickness of the upper lip at the vermilion border had a mean difference of 2.3 mm, and the length of the upper lip had a mean difference of 0.63 mm. The upper airway also remained stable with a mean difference of 0.93 mm.

These results signify that there is a skeletal relapse after maxillary distraction with RED after 1 year. However, the soft-tissue profile of the midface region and nasopharyngeal airway remained stable.

### Stability of outcome after 1 year (T1 vs. T3)

To appreciate the overall surgical outcome after 1 year, the predistraction phase (T1) was compared with the 1-year postdistraction phase (T3). The angle of facial convexity (N-A-Pg) has significantly improved from a mean of  $-17.81^\circ \pm 10.73^\circ$  to  $3.71^\circ \pm 7.38^\circ$  with a mean difference of  $21.3^\circ$  ( $P < 0.01$ ). The anteroposterior skeletal relationship of the maxilla and mandible was improved from a mean of  $-7.61^\circ \pm 4.54^\circ$  to  $3^\circ \pm 3.13^\circ$  with a  $P < 0.01$  [Table 3].

One year after distraction, the maxillary length (Co-A) had significantly increased from a T1 value of  $74.37 \pm 9.98$  mm to a T3 value of  $81.14 \pm 9.04$  mm by 6.77 mm ( $P < 0.01$ ). The maxilla in relation to the true horizontal plane (N-A) was significantly increased by 9.66 mm from a T1 value of  $-4.57 \pm 7.31$  mm to a T3 value of  $5.09 \pm 5.59$  mm ( $P < 0.01$ ). The SNA angle was

**Table 2: Stability of the result**

Parameters	T2 (n=7)		T3 (n=7)		Difference	P
	Mean	SD	Mean	SD		
<b>Hard tissue</b>						
N-A (HP) (mm)	8.29	6.84	5.09	5.59	3.20	*
N-B (HP) (mm)	4.17	9.46	4.46	9.96	-0.29	NS
N-Pg (HP) (mm)	6.66	9.83	7.07	10.39	-0.41	NS
N-A-Pg (°)	10.53	7.15	7.07	10.39	3.46	*
SNA (°)	91.66	6.61	89.70	7.41	1.96	NS
SNB (°)	85.30	5.30	86.69	6.79	-1.39	NS
ANB (°)	6.34	2.89	3.00	3.13	3.34	*
Lower face height (ANS-Me) (mm)	70.09	10.48	67.21	9.60	2.87	NS
Upper face height (N-ANS) (mm)	46.24	8.35	45.23	8.75	1.01	NS
Anterior face height (NaMe) (mm)	115.57	18.34	111.91	17.66	3.66	NS
Midface length (Co-A) (mm)	85.63	9.36	81.14	9.04	4.49	NS
<b>Soft tissue</b>						
Nasolabial angle (Col-Sn-UL) (°)	76.97	15.25	84.31	14.89	-7.34	NS
Lower lip to H-line (mm)	4.47	2.03	5.33	3.05	-0.86	NS
U-Lip thickness at vermilion border (mm)	11.30	1.31	8.96	2.69	2.34	NS
Upper lip length (Sn-StSup) (mm)	20.91	4.15	20.29	4.83	0.63	NS
<b>Dental</b>						
Overjet (mm)	3.49	1.79	2.30	4.78	1.19	NS
Incisor edge to upper lip	3.77	2.12	3.16	1.26	0.61	NS
<b>Airway</b>						
Upper airway: Naso-pharyngeal	17.54	4.03	16.61	4.15	0.93	NS

\*P<0.05. NS: Not significant; SD: Standard deviation

**Table 3: Stability of outcome after 1 year**

Parameters	T1 (n=7)		T3 (n=7)		Difference	P
	Mean	SD	Mean	SD		
<b>Hard tissue</b>						
N-A (HP) (mm)	-4.57	7.31	5.09	5.59	-9.66	*
N-B (HP) (mm)	3.99	10.23	4.46	9.96	-0.47	NS
N-Pg (HP) (mm)	6.73	11.06	7.07	10.39	-0.34	NS
N-A-Pg (°)	-17.81	10.73	3.71	7.38	-21.53	*
SNA (°)	77.39	7.33	89.70	7.41	-12.31	*
SNB (°)	85.03	6.68	86.69	6.79	-1.66	NS
ANB (°)	-7.61	4.54	3.00	3.13	-10.61	*
Lower face height (ANS-Me) (mm)	67.54	10.19	67.21	9.60	0.33	NS
Upper face height (N-ANS) (mm)	46.69	8.03	45.23	8.75	1.46	NS
Anterior face height (NaMe) (mm)	114.20	16.97	111.91	17.66	2.29	NS
Midface length (Co-A) (mm)	74.37	9.98	81.14	9.04	-6.77	*
<b>Soft tissue</b>						
Nasolabial angle (Col-Sn-UL) (°)	53.49	22.23	84.31	14.89	-30.83	*
Lower lip to H-line (mm)	9.09	3.73	9.09	3.05	3.76	NS
U-lip thickness at vermilion border (mm)	12.39	2.34	8.96	2.69	3.43	NS
Upper lip length (Sn-StSup) (mm)	18.33	3.05	18.33	4.83	-1.96	NS
<b>Dental</b>						
Overjet (mm)	-8.06	5.98	2.30	4.78	-10.36	*
Incisor edge to upper lip	1.41	3.87	1.41	1.26	-1.74	NS
<b>Airway</b>						
Upper airway: Naso-pharyngeal	14.10	4.67	14.10	4.15	-2.51	*

\*P<0.05. NS: Not significant; SD: Standard deviation

significantly increased, from a mean of 77.39° to 89.70°, by a mean difference of 12.31° (P < 0.01). The upper

facial height (N-ANS) had a mild decrease with a mean difference of 1.4 mm, consequently, there was a decrease

in the anterior facial height (Na-Me) by 2.29mm. The mandible remains stable with N-B and N-Pg showing mean differences of around 0.4 mm. There was a marked significant improvement in the overjet, from a reverse overjet to a positive overjet, by a horizontal distance of 10.36 mm from a T1 value of  $-8.06 \pm 5.98$  to a T3 value of  $2.30 \pm 4.78$  mm ( $P < 0.01$ ) as a result of which the incisor exposure improved by 1.7 mm.

The soft tissues of the nasomaxillary complex showed very obvious improvements. The nasolabial angle was significantly improved by  $30.8^\circ$  from a T1 value of  $53.49^\circ \pm 22.23^\circ$  to a T3 value of  $84.3^\circ \pm 14.89^\circ$  ( $P < 0.05$ ). The upper lip length (Sn – St Sup) had increased by 1.96 mm. The upper lip thickness at the vermilion border was significantly reduced by 3.43 mm. The lower lip had moved behind the H-line by 3.76 mm, thus adding to the normal facial profile. The nasopharyngeal airway has significantly increased by 2.51 mm from a T1 value of  $14.1 \pm 4.67$  mm to a T3 value of  $14.10 \pm 4.15$  mm ( $P < 0.01$ ).

The significant relapse advocates for a need of overcorrection of distraction in adult CLP patients.

## Discussion

DO has opened a new perspective for the treatment of various skeletal anomalies, particularly since its introduction for patients with CLP in 1995.<sup>[10]</sup>

It has been reported that the majority of the CLP patients who underwent maxillary DO (70.65%) were aged between 11 and 15 years.<sup>[11]</sup> In this study, an attempt was made to select patients whose maxillary growth and development had been diminished. The mean age of the patients in this study was 19.2 years. Although there might be significant variation in the timing of completion of growth because of the unique growth pattern of each person, the patients in this study were assumed to be nongrowing.

A study has reported the use of miniplates as skeletal anchorages in combination with RED devices because they provided an excellent stable anchorage for maxillary distraction, thereby allowing direct distraction force transfer to the bone.<sup>[12]</sup> In another study, the traction force was delivered to the bone through dental anchorage. After distraction, there was a significant sagittal movement of the upper incisors, showing a 4.5 mm labial displacement. This suggests that the traction force may cause undesirable labial movement of upper incisors.<sup>[13]</sup> In all our cases, skeletal anchorage has been implemented to avoid undesirable movement of maxillary incisors.

An advancement of more than 10 mm is beyond the limit of conventional Le Fort I osteotomy. In this study, the significant advancement of the maxilla was achieved with a mean of 14 mm. The mean horizontal movement at A-point was between 10 and 15 mm in many studies.<sup>[6,14-17]</sup>

The nose in cleft patients shows a marked retrusion and retroclined configuration.<sup>[18]</sup> In our cases, after maxillary advancement through DO, the nasolabial angle increased. All the patients in this study underwent a high Le Fort I osteotomy just inferior to the infraorbital level. Thus, the effect on the nasomaxillary complex was more favorable. In a randomized controlled clinical trial by Chua and Cheung,<sup>[19]</sup> performed DO and conventional osteotomy (CO) on 42 CLP patients (21 each). The nasolabial angle increased more in the DO group than in the CO group. A few studies by Jena *et al.* revealed stable and improved soft-tissue profile of the nasomaxillary complex in CLP patients who underwent DO with 2 years follow-up.<sup>[20,21]</sup>

The maxillary advancement with RED aided in substantial advancement of the upper lip and a reduction in the thickness of the vermilion border of upper lip. Similar upper lip changes have been reported after facial mask treatment<sup>[18,22]</sup> and Le Fort I advancement.<sup>[23,24]</sup>

The maxilla is small and retruded in operated CLP patients. The dimensional pharyngeal airway changes are also smaller in CLP patient than in normal individuals.<sup>[25]</sup> In our study, the nasopharyngeal airway increased to 3.7 mm immediately after distraction and remained stable for a year. A similar finding was seen in a study by Jena *et al.*<sup>[26]</sup> and Abuzinada and Alyamani.<sup>[27]</sup>

During the follow-up period (T3), the maxilla in reference to the true horizontal plane (N-A) significantly reduced to a mean difference of 3.2 mm, approximately 38% skeletal relapse. It has been reported that the maxillary advancement decreased gradually during the postdistraction period.<sup>[11,28]</sup> In a study by Aksu *et al.*<sup>[13]</sup> where 7 adult CLP patients were treated with DO, after 3 years, a 22% relapse rate was seen in the maxilla. Cho and Kyung<sup>[17]</sup> found a relapse rate of approximately 23% during the 1 to 6-year period after distraction whereas Kanno *et al.*<sup>[29]</sup> found less relapse of 8% over 2.8 year follow-up period. In this study group, the relapse tendency of the maxillary advancement might be because of the possibility of the strong resistance of the soft tissues as a result of scar formation rather than the growth deficit of the maxilla. The magnitude of maxillary advancement could also be considered as another factor causing more relapse in our patients because many previous studies also found a positive correlation between the magnitudes of relapse with the magnitude of advancement.<sup>[16,30]</sup> In a similar study, Kumar *et al.* reported good stability after 1-year postdistraction with RED in CLP patients, but that could be due to a lesser magnitude of maxillary advancement of mean 9.9 mm.<sup>[31]</sup>

Since most of the studies on cleft maxillary hypoplasia in adult patients treated with DO showed some amount of skeletal relapse,<sup>[13,31-34]</sup> the need for overcorrection should be anticipated. This study revealed around 35%–40% overcorrection may be required which can be correlated with another study by Singh *et al.* (2013),<sup>[33]</sup> who concluded

that an overcorrection of 30% should be considered. The soft tissue changes after 1 year showed stable results. This correlated with a study by Ko *et al.* (2000),<sup>[9]</sup> where CLP patients who underwent DO, showed stable soft-tissue profile changes after 1 year.

The limitations of this study, particularly the small sample size, should be taken into consideration. However, because a homogenous sample is preferred for a research study and is one of the very few to evaluate hard and soft tissues as well as airway of adult CLP patient after distraction with RED (skeletal anchorage) at 1-year follow-up. We believe that our results are of importance in reflecting distraction and postdistraction effects.

This protocol was approved by an appropriate Institutional Review Board according to the Declaration of Helsinki.

### 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.

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### Conflicts of interest

There are no conflicts of interest.

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