

# **APOS Trends in Orthodontics**



# Original Article

# Effect of maxillary distraction osteogenesis and LeFort-1 advancement orthognathic surgery on soft-tissue thickness and anterior soft-tissue to hard-tissue movement ratios among patients with complete unilateral cleft lip and palate

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# ABSTRACT

**Objectives:** The objective of this study was to compare the soft-tissue thickness and anterior soft-tissue to hard-tissue movement ratios in patients with unilateral cleft lip and/or palate (UCLP) following maxillary distraction osteogenesis using rigid external distractor device and maxillary advancement at LeFort I level using lateral cephalograms.

**Material and Methods:** This retrospective study was conducted on 20 patients with UCLP who underwent either LeFort I maxillary advancement or maxillary distraction osteogenesis. Non-syndromic patients with complete UCLP anomalies and skeletal class III patterns due to maxillary hypoplasia were included in the study. The patients with a pre-surgical negative overjet of  $\geq$ 5 mm were treated by maxillary distraction osteogenesis, while a negative overjet of <5 mm was managed with maxillary advancement orthognathic surgery. The growth completion in all the patients was assessed using the cervical vertebrae maturation index (CS 6) on a lateral cephalogram. The lateral cephalograms taken before surgery at (T0) and after a minimum interval of six months (T1) of surgery were assessed for changes in soft-tissue thickness and hard-tissue to soft-tissue movement ratios among the two groups. Paired *t*-test was used to compare the mean values obtained within the same group at two different time intervals. Unpaired *t*-test was used to compare mean values between the Groups 1 and 2. Pearson's correlation coefficient (r) test was used to assess the associations between the mean changes in hard- and soft-tissue variables.

**Results:** Group 1 showed significantly greater maxillary advancement compared to Group 2 with a mean difference of 5.80 mm at Point A and 7.65 mm at the upper incisal edge. Soft-tissue thickness decreased significantly after advancement in Group 1 at subnasale (P < 0.05), labrale superius, stomion, and labrale inferius (P < 0.01) and at subnasale (P < 0.05), stomion and labrale inferius (P < 0.01) in Group 2. There was a significantly strong correlation between the hard- and soft-tissue movement in sagittal plane in both Group 1 and Group 2. In Groups 1 and 2, a statistical highly significant strong positive correlation was found between vertical change in dU1 to soft-tissue dLs and dStms. In Group 2, a statistical highly significant strong positive correlation was found between vertical change in dA to soft-tissue dC and dStms.

**Conclusion:** The soft-tissue thickness reduced in patients with UCLP after maxillary advancement in both groups. The soft tissue followed the hard tissue in both groups. There was a greater downward movement of the maxillary base and soft-tissue lengthening in Group 1 compared to Group 2.

Keywords: Cleft lip and palate, Distraction osteogenesis, Soft-tissue thickness, LeFort I advancement, RED

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# INTRODUCTION

Midface hypoplasia, impaired growth, and a collapsed maxillary dental arch are some of the cardinal features of patients with cleft lip and palate (CL±P) anomaly. Conventional orthopedic/orthodontic approaches to treatments are sometimes successful in achieving stable occlusal relationships. However, sometimes they often fall short of expectations with respect to facial balance and esthetics. About one-quarter of patients with CL±P develop maxillary hypoplasia that cannot be corrected by orthodontic or orthopedic treatment alone and require orthosurgical intervention.<sup>[1]</sup>

The restoration of facial balance and occlusion in severe skeletal discrepancy due to hypoplastic maxilla requires LeFort 1 advancement. In CL $\pm$ P patients, due to the post-operative difficulties caused by the palatal scar contracture, maxillary advancement of >5–6 mm requires distraction osteogenesis for stable results.<sup>[2-4]</sup>

Distraction osteogenesis technique has the advantage that allows a more gradual adaptation of surrounding soft-tissue drape and the palatal scar tissue, whereas this change is more acute in osteotomy cases, resulting in muscle imbalance and contractures.<sup>[5]</sup> When gradual distraction forces are applied across the osteotomy site, not only does the callus elongates, but also the soft tissues grow in response to mechanical stress. Not mere stretching, but hyperplasia of soft tissue occurs, and this is termed as *Distraction Histogenesis*, and the outcome achieved with this treatment modality is believed to be more stable than LeFort-1 maxillary advancement.<sup>[6]</sup>

The soft-tissue morphology and underlying hard tissue are closely related, and it is the soft-tissue profile of the patient that dictates the limits and esthetic outcomes of the treatment.<sup>[7]</sup> The soft-tissue thickness in patients with unilateral cleft lip and/or palate (UCLP) has been evaluated using cone-beam computed tomography<sup>[8]</sup> and lateral cephalogram.<sup>[9]</sup>

Ewing and Ross<sup>[9]</sup> found that soft-tissue changes following LeFort-1 maxillary advancement surgery in patients with UCLP were highly correlated with horizontal movement of the underlying skeletal bases with minimal changes in mandibular soft-tissue thickness. A systematic review conducted by Cheung and Chua<sup>[10]</sup> (2006) concluded that there were no significant changes in soft-tissue thickness of patients with UCLP who underwent maxillary osteotomies.

A significant number of patients with  $CL\pm P$  anomalies are treated with an interdisciplinary approach for the comprehensive cleft care in our center. There is controversy between the results of the previous studies regarding the effect of maxillary advancement on lip thickness. Furthermore, due to the difference in the mechanism of maxillary advancement using single-stage advancement and distraction, there may be differences in the soft-tissues changes in the two procedures. Thus, it is important to study the effects of the two procedures for future treatment planning.

Hence, the purpose of this study was to compare the softtissue thickness and anterior soft-tissue to hard-tissue movement ratios in patients with UCLP following maxillary distraction osteogenesis using a rigid external distractor device and maxillary advancement at LeFort I level.

#### MATERIAL AND METHODS

This retrospective study was conducted following the guidelines of the Declaration of Helsinki for medical protocol and ethics and approved by the Institutional Ethics Committee (NK/6890/MDS/775). A prior sample size was calculated using G\* Power statistical software based on the study of Chua and Cheung<sup>[11]</sup> at alpha ( $\alpha$ ) value of 0.05, power of 90%, and 95% confidence interval. Power analysis showed a minimum of eight patients was required in each group.

A sample of 20 patients with complete UCLP with ten patients in each group were categorized into two groups. Group 1 comprised of seven male and three female patients with a mean age of  $16.9 \pm 3.11$  years who underwent maxillary distraction osteogenesis at LeFort 1 level using Rigid External Distraction (RED) device; Group 2 comprised five males and five females with a mean age of  $20 \pm 4.29$  years who underwent LeFort-1 maxillary advancement. The surgical procedures for all the subjects were performed by a single maxillofacial surgeon under general anesthesia. CL $\pm$ P closure all the patients were done at the same institute, though the surgeons were different, following the same protocol.

The patients with a pre-surgical negative overjet of  $\geq 5 \text{ mm}$ were treated by maxillary distraction osteogenesis, while a negative overjet of <5 mm was managed with maxillary advancement orthognathic surgery. Non-syndromic patients with complete UCLP anomalies who underwent either maxillary distraction osteogenesis using a rigid external distraction device or maxillary advancement orthognathic surgery and skeletal class III pattern due to maxillary hypoplasia were included in the study. The growth completion in all the patients was assessed using the cervical vertebrae maturation index (CS 6) on lateral cephalogram.<sup>[12]</sup> All the patients received isolated maxillary surgery only. Those with bilateral CL±P, isolated clefts of the palate or lip, craniofacial syndromes, and faulty or incomplete records were excluded from the study. The lateral cephalograms were taken before surgery (T0) and at six-month (T1) post-surgery were assessed with manual tracing.

The investigator was calibrated for registration, landmark identification, and measurement of soft-tissue thickness on lateral cephalogram. The intraexaminer reliability was assessed by repeating the measurement of selected parameters on 10% of all the lateral cephalograms selected randomly after an interval of three weeks. The value of intra class correlation (ICC) ranged from 0.938 to 0.999, which indicated an excellent reliability between 1<sup>st</sup> and 2<sup>nd</sup> measurements.

Soft-tissue thickness<sup>[13]</sup> was calculated from hard tissue to corresponding soft-tissue landmarks, as shown in [Figure 1]. The changes in sagittal and vertical positions of the landmarks were assessed as perpendicular distances with respect to the horizontal reference line and vertical reference line reference planes at time interval (T0-T1), as shown in [Figure 2a and b]. Correlation between the anterior movement ratio of soft-tissue and hard-tissue landmarks was derived and compared between Group 1 and Group 2 patients.

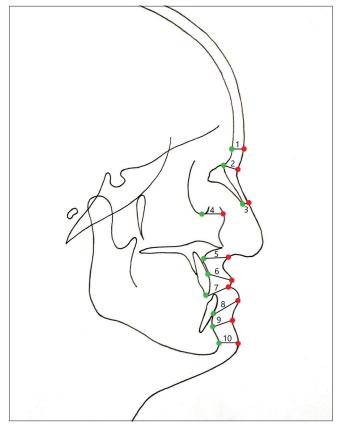
#### Statistical analysis

Statistical analysis were performed using the Statistical Package for the Social Sciences version 25.0 and MedCalc software. The data followed normal distribution as analyzed by Shapiro–Wilk test. Paired *t*-test was used to evaluate intragroup differences at two different time-intervals. Pearson's correlation coefficient test was used to assess the associations between the mean change in hard- and soft-tissue variables. The level of significance was set at P < 0.05.

# RESULTS

The pre-surgical comparison of skeletal dysplasia (Wits appraisal) and overjet between Group 1 and Group 2 was statistically significant; however, the differences among various soft-tissue thickness parameters were statistically insignificant [Table 1]. In Group 1, soft-tissue thickness decreased (T0-T1) significant at subnasale, labrale superius, stomion, and labrale inferius (P < 0.05). Group 2 also showed significant decrease in soft-tissue thickness at subnasale, labrale inferius, and stomion (P < 0.05). The intergroup comparison showed a significantly greater decrease in soft-tissue thickness in Group 1 at labrale superius, stomion, and labrale superius, stomion, and labrale inferius [Table 2].

Comparison of sagittal movement of various hard- and softtissue landmarks in Group 1 and Group 2 is shown in [Table 3]. The intragroup mean maxillary advancement in Group 1 and Group 2 was statistically significant at point A and upper incisal edge (P < 0.01). The intergroup comparison showed significantly greater maxillary advancement in Group 1 at Point A and upper incisal edge (P < 0.01). Group 1 showed greater advancements at Subnasale (P < 0.05), Labrale Superius, and Stomion (P < 0.01) as compared to Group 2. Downward displacement of Point A (P < 0.01), pogonion (Pog), labrale inferius, labiomentale, and soft-tissue pogonion (P < 0.05) was



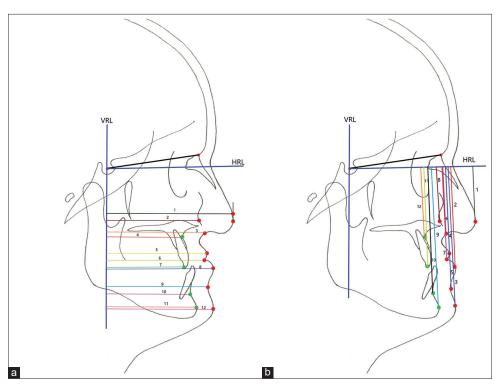
**Figure 1:** Cephalometric landmarks and various soft-tissue thickness measurements; 1: Glabella-Soft-tissue glabella, 2: Nasion-Soft-tissue Nasion, 3: Rhinion-soft-tissue rhinion, 4: Orbitale to Soft-tissue Orbitale, 5: Point A-Subnasale, 6: Prosthion-Labrale Superius, 7: Upper incisor tip-Stomion, 8: Infradentale-Labrale Inferius, 9: Point B-Labiomentale, 10: Pogonion to soft-tissue Pogonion. Green dots: Hard tissue landmarks Red dots: Soft tissue Landmarks.

also greater in Group 1 when compared to Group 2 [Table 4].

The sagittal change in the hard-tissue parameters at dA, dU1, dB, and dPog was found to be positive and strongly correlated with the respective soft-tissue parameters except dC for Group 1 and dSn and dPog' in Group 2 [Table 5]. In Group 1, a statistically highly significant strong positive correlation was found between vertical change in dU1 to soft-tissue dLs and dStms. In Group 2, change in hard-tissue point A was positively correlated with soft-tissue point dC and dStms and dU1 with dLs and dStm [Table 6].

# DISCUSSION

The treatment modality for maxillary retrognathism in adult patients with CL±P is based on the extent of the deformity, degree of desirable jaw movement, and anticipated softtissue changes following surgical intervention.<sup>[14]</sup> Traditional orthodontic and or orthopedic approaches, such as Facemask therapy to treat these patients in growing stage, often fall



**Figure 2:** (a) Horizontal distance from vertical reference line to hard-tissue (Green dot) and soft-tissue (Red dot) landmarks: Horizontal distance from VRL to: 1: Pronasale (Point located on a tangent drawn perpendicular to HRL from Pn to avoid overlapping of 1 and 2), 2: Cheek point, 3: Subnasale, 4: Point A, 5: Labrale superius, 6: Stomion, 7: Upper incisor tip, 8: Labrale inferius, 9: Labiomentale, 10: Point B, 11: Pogonion, 12: Soft-tissue Pogonion. (b): Vertical distance from HRL to hard-tissue (Green dot) and soft-tissue (Red dot) landmarks: Vertical distance from HRL to: 1: Pronasale, 2: Labrale Inferius, 3: Soft-tissue Pogonion, 4: Labrale superius, 5: Labiomentale, 6: Subnasale, 7: Stomion, 8: Cheekpoint, 9: Pogonion, 10: Point B, 11: Upper incisor tip, 12: Point A, VRL: Vertical reference line, HRL: Horizontal reference line.

Table 1: Baseline characteristics of the sture	dy sample.			
	Group 1	Group 2		Total
Male	7 (70%)	5 (50%)		12 (60%)
Female	3 (30%)	5 (50%)		8 (40%)
Age (Range)	14-21	16-24		14-24
Age (Mean±SD)	16.9±3.11	20±4.29	1	$7.6 \pm 4.38$
				P-value
Wits appraisal (mm)	$-7.3 \pm 2.95$	$-3.5\pm2.47$		0.0052**
Negative overjet (mm)	$-7.15 \pm 1.93$	$-2.1\pm0.57$	<	0.0001***
Soft-tissue thickness (mean±SD)	Group 1	Group 2	MD	<i>P</i> -value
Glabella (G-G') (mm)	$5.90 \pm 1.54$	5.80±1.03	-0.10	0.866 (NS)
Nasion (N-N') (mm)	5.75±1.84	6.20±2.39	0.45	0.642 (NS)
Rhinion (Rh -Rh') (mm)	$3.45 \pm 1.44$	2.90±0.61	-0.55	0.280 (NS)
Subnasale (Point A-Sn) (mm)	13.40±2.58	$14.80 \pm 2.81$	1.40	0.261 (NS)
Labrale superius (Pr-Ls) (mm)	13.45±2.60	$14.30 \pm 2.81$	0.85	0.491 (NS)
Stomion (U1-St) (mm)	15.00±2.35	14.65±3.49	-0.35	0.795 (NS)
Labrale inferius (Id-Li) (mm)	10.90±2.67	8.45±3.16	-2.45	0.077 (NS)
Labiomentale (Point B-Lm) (mm)	$15.40 \pm 1.07$	15.80±1.96	0.40	0.578 (NS)
Orbitale (Or-C)	11.50±1.55	11.10±1.73	-0.40	0.592 (NS)
Pogonion (Pog-Pog') (mm)	$12.20 \pm 2.54$	$11.95 \pm 2.75$	-0.25	0.835 (NS)
NS: Non significant (P>0.05), SD: Standard dev	viation, MD: Mean difference,	**Highly significant (P<0.01)	), ***Very high significan	tt ( <i>P</i> <0.001)

Parameters	Mean±SD								
(mm)		Gro	up 1						
	T0	T1	T0-T1	P-value	T0	T1	T0-T1	P-value	P-value
Glabella (G-G')	$5.90 \pm 1.54$	5.80±1.57	$0.10 \pm 0.32$	0.343 (NS)	$5.80 \pm 1.03$	5.55±0.69	0.25±0.72	0.299 (NS)	0.552 (NS)
Nasion (N-N')	$5.75 \pm 1.84$	5.75±1.53	$0.00 \pm 0.91$	1.000 (NS)	6.20±2.39	$6.25 \pm 2.47$	$-0.05\pm2.17$	0.943 (NS)	0.947 (NS)
Rhinion (Rh -Rh')	$3.45 \pm 1.44$	$3.55 \pm 1.40$	$-0.10 \pm 0.21$	0.168 (NS)	$2.90 \pm 0.61$	$3.50 \pm 0.85$	$-0.60 \pm 0.84$	0.051 (NS)	0.086 (NS)
Subnasale (Point	$13.40 \pm 2.58$	$11.75 \pm 2.60$	$1.65 \pm 1.70$	0.013* (NS)	$14.80 \pm 2.81$	$11.60 \pm 2.92$	$3.20{\pm}2.07$	0.001**	0.084 (NS)
A-Sn)									
Labrale Superius	$13.45 \pm 2.60$	$11.10 \pm 2.45$	$2.35 \pm 2.04$	0.005**	$14.30 \pm 2.81$	$14.20 \pm 3.05$	$0.10 \pm 1.71$	0.858 (NS)	0.016*
(Pr-Ls)									
Stomion (U1-St)	$15.00 \pm 2.35$	11.35±2.68	$3.65 \pm 2.38$	0.001**	$14.65 \pm 3.49$	13.75±3.32	$0.90 \pm 1.15$	0.035*	0.004**
Labrale Inferius	$10.90 \pm 2.67$	$5.65 \pm 2.57$	$5.25 \pm 2.88$	0.001**	8.45±3.16	$7.15 \pm 2.90$	$1.30 \pm 1.32$	0.012*	0.001**
(Id-Li)									
Labiomentale	$15.40 \pm 1.07$	$16.05 \pm 1.48$	$-0.65 \pm 1.65$	0.245 (NS)	$15.80 \pm 1.96$	15.25±1.96	$0.55 \pm 0.98$	0.111 (NS)	0.064 (NS)
(Point B-Lm)									
Orbitale (Or-C)	$11.50 \pm 1.55$	$12.15 \pm 2.44$	$-0.65 \pm 1.68$	0.253 (NS)	$11.10 \pm 1.73$	$10.80 \pm 1.32$	$0.30 \pm 0.63$	0.168 (NS)	0.112 (NS)
Pogonion	$12.20 \pm 2.54$	$12.30 \pm 2.02$	$-0.10 \pm 1.54$	0.842 (NS)	$11.95 \pm 2.75$	$11.89 \pm 1.90$	$0.06 \pm 1.40$	0.895 (NS)	0.811 (NS)
(Pog-Pog')									

Table 3: Comparison of sagittal soft- and hard-tissue changes in Group 1 and Group 2 at T0-T1 time interval. Gp1-Variable Group 1 Group 2 Gp 2 Mean±SD MD **P-value Mean±SD** MD **P**-value P-value (T1-T0) (T1-T0) T1 T0 T0 T1 Soft tissue VRL to C 60.85±5.89 63.75±7.00 -2.900.022\*  $57.45 \pm 9.18$ 59.90±10.09 -2.450.005\*\* 0.721 (NS) (cheek point) VRL to Pn 88.40±8.88 -3.65 0.003\*\*  $80.85 {\pm} 16.64$  $82.25 \pm 18.03$ -1.400.061 (NS) 84.75±8.52 0.063 (NS) VRL to Sn 0.001\*\* 69.10±7.60 75.85±8.33 -6.75 $65.90{\pm}10.84$  $67.60 {\pm} 12.28$ -1.700.420 (NS) 0.039\* 0.001\*\* VRL to Ls 0.003\*\*  $70.70 \pm 8.39$ 79.35±9.42 -8.65  $67.45 \pm 10.19$  $70.80 \pm 10.51$ -3.350.006\*\* 0.001\*\* VRL to Stms  $66.30 \pm 8.52$  $74.00 \pm 9.54$ -7.7062.75±9.82  $66.10 \pm 9.68$ -3.35  $0.018^{*}$ 0.030\* VRL to Li  $77.90 \pm 10.45$ 79.60±10.19 -1.700.249 (NS)  $73.00 \pm 10.31$  $72.05 \pm 9.80$ 0.95 0.341 (NS) 0.130 (NS) VRL to Lm 69.05±10.91 69.50±10.78 -0.450.769 (NS) 65.30±12.29 65.30±11.31 0.00 1.000 (NS) 0.791 (NS) VRL to Pog' 0.00 -0.35  $71.10 \pm 12.01$ 71.10±11.49 1.000 (NS)  $68.25 \pm 14.95$ 68.60±13.69 0.747 (NS) 0.853 (NS) Hard tissue 0.10 VRL to Point B  $57.90 \pm 10.64$  $57.80 {\pm} 10.36$ 0.943 (NS)  $55.80{\pm}14.40$ 0.05 0.945 (NS) 0.974 (NS) 55.75±13.68 0.15 0.50 VRL to Pog 59.70±11.65 59.55±11.27 0.928 (NS)  $59.40 \pm 17.91$ 58.90±18.07 0.712 (NS) 0.868 (NS) VRL to Point A  $55.85 \pm 6.56$ 65.25±7.61 -9.400.001\*\*\* 53.55±7.79 57.15±7.61 -3.600.001\*\*\* 0.001\*\* 0.001\*\*\* VRL to U1 55.65±8.58 68.85±9.51 -13.20 $55.30 \pm 9.81$  $60.85 \pm 8.32$ -5.550.002\*\* 0.001\*\*

VRL: Vertical reference line, SD: Standard deviation, MD: Mean difference, NS: Non significant (*P*<0.05), \*Significant (*P*<0.05), \*\*Highly significant (*P*<0.01), \*\*\*Very high significant (*P*<0.001), Pn: Pronasale; Sn: Subnasale; Ls: Labrale superius; Stms: Stomion superius; Li: Labrale inferius; Lm: Labiomentale; Pog: Pogonion; U1: Upper incisor tip.

short of expectations with respect to facial balance and esthetics, despite obtaining a stable occlusal relationship.

# Change in soft-tissue thickness and soft-tissue to hardtissue movement ratios in maxillary distraction group

In the present study, there was a significant difference of 5.80 mm in maxillary advancement between Group 1 and Group 2 as measured at Point A (U1), and the results were similar to the previous study by Markose *et al.*<sup>[15]</sup> and Chua and Cheung.<sup>[11]</sup>

Significant decrease in soft-tissue thickness was observed at subnasale (P < 0.05), labrale superius, labrale inferius, and stomion superius (P < 0.01) post-distraction in Group 1 patients. The decrease in soft-tissue thickness at

Variable		Grou	p 1			Group 1- Group 2			
	Mean±SD		MD	MD <i>P</i> -value	Mear	n±SD	MD	P-value	P-value
	Т0	T1	(T1-T0)		TO	T1	(T1-T0)		
Soft tissue									
HRL to C	34.65±3.70	$34.50 \pm 3.27$	0.15	0.671 (NS)	38.45±10.97	37.80±10.93	0.65	0.454 (NS)	0.584 (NS
(cheek point)									
HRL to Pn	36.15±4.09	35.30±3.77	0.85	0.212 (NS)	$41.50 \pm 18.75$	$40.50 \pm 18.81$	1.00	0.204 (NS)	0.878 (NS
HRL to Sn	$45.45 \pm 4.60$	$44.65 \pm 3.84$	0.80	0.196 (NS)	49.15±11.24	48.65±11.77	0.50	0.221 (NS)	0.668 (NS
HRL to Ls	$55.30 \pm 4.84$	56.95±3.95	-1.65	0.188 (NS)	59.85±10.27	$59.80 \pm 10.21$	0.05	0.931 (NS)	0.203 (NS
HRL to Stms	60.70±5.59	63.15±4.50	-2.45	0.049*	$64.60 \pm 9.34$	65.30±9.02	-0.70	0.200 (NS)	0.227 (NS
HRL to Li	68.80±5.76	$72.05 \pm 5.34$	-3.25	0.049*	72.15±9.85	$71.50 \pm 9.32$	0.65	0.477 (NS)	0.045*
HRL to Lm	79.25±6.34	81.80±6.35	-2.55	0.126 (NS)	79.95±10.55	79.55±11.26	0.40	0.443 (NS)	$0.048^{*}$
HRL to Pog'	89.10±7.05	92.65±7.39	-3.55	0.049*	90.15±13.36	90.45±12.46	-0.30	0.709 (NS)	0.041*
Hard tissue									
HRL to Point A	45.25±3.27	$45.70 \pm 4.60$	-0.45	0.700 (NS)	47.95±8.39	48.15±8.20	-0.20	0.705 (NS)	0.843 (NS
HRL to U1	61.35±4.93	$65.50 \pm 3.82$	-4.15	0.001**	$63.30 \pm 8.45$	63.25±8.20	0.05	0.907 (NS)	0.001**
HRL to Point B	81.60±7.58	82.45±7.85	-0.85	0.589 (NS)	79.85±12.97	79.00±13.17	0.85	0.101 (NS)	0.298 (NS
HRL to Pog	91.80±6.65	92.35±5.22	-0.55	0.063	92.10±16.53	91.35±16.90	0.75	0.224 (NS)	0.023*

HRL: Horizontal reference line, SD: Standard deviation, MD: Mean difference, NS: Non significant (*P*>0.05), \*\*\*Very high significant (*P*<0.001), \*Significant (*P*<0.05), \*\*Highly significant (*P*<0.01), Pn: Pronasale; Sn: Subnasale; Ls: Labrale superius; Stms: Stomion superius; Li: Labrale inferius; Lm: Labiomentale; Pog: Pogonion; U1: Upper incisor tip

Table 5: C	Correlation between h	hard-tissue movem	ent and soft-tiss	ue changes in sagit	tal plane in G	roup 1 and Grou	p 2 at T0-T1 tim	e interval.	
S. No.	Paran	neters		Group 1		Group 2			
	Hard tissue Soft tissue		R-value P-value S: H			R-value	P-value	S: H	
1.	dA	dC	0.499	0.142 (NS)	0.42:1	0.630	0.049*	0.54:1	
2.		dSn	0.900	0.001**	0.76:1	0.113	0.757	0.29:1	
							(NS)		
3.		dLs	0.824	0.003**	0.82:1	0.885	0.001**	1.07:1	
4.		dStms	0.815	0.004**	0.94:1	0.851	0.002**	1.29:1	
5.		dPn	0.788	0.007**	0.57:1	0.839	0.002**	0.72:1	
6.	dU1	dLs	0.911	0.001**	0.86:1	0.848	0.002**	0.61:1	
7.		dStms	0.884	0.001**	0.94:1	0.723	0.018*	0.65:1	

NS: Non significant (*P*>0.05), \*\*\*Very high significant (*P*<0.001), \*Significant (*P*<0.05), \*\*Highly significant (*P*<0.01). dA: Change in position of Point A (T0-T1), dU1:Change in position of Upper Incisor (T0-T1), dC: Change in position of Cheek point (T0-T1), dSn: Change in position of subnasale (T0-T1), dLs: Change in position of Labrale superius (T0-T1), dStms: Change in position of Stomion superius (T0-T1), dPn: Change in position of Pronasale (T0-T1), dLs: Change in position of Labrale superius (T0-T1), dStms: Change in position of Stomion superius (T0-T1).

subnasale (1.65mm) in the present study was slightly greater than Ko *et al.*<sup>[16]</sup> who reported a mean change in soft-tissue thickness of 1.05 mm. However, a decrease in soft-tissue thickness at lower lip of 5.25 mm in the present study was markedly greater than reported by Ko *et al.*<sup>[16]</sup> (0.83 mm). The marked change in thickness at the lower lip may have been contributed by the support provided by maxillary anterior teeth following maxillary distraction. The additional support provided to the nasal base and lower lip following maxillary advancement explains the decrease in soft-tissue thickness at subnasale and labrale inferius. The significant improvement in the nasal tip projection was explained by the direct effect of maxillary advancement on the ANS and subsequently on the nasal tip.

In the sagittal plane, except for Cheekpoint, other soft-tissue landmarks correlated well with the advancement of Point A. Change in subnasale, labrale superius, stomion superius, and pronasale correlated significantly with the movement at Point A with soft-tissue to hard-tissue ratios of 0.76:1, 0.82:1, 0.94:1, and 0.57:1, respectively. Chua and Cheung<sup>[11]</sup> also reported similar significant correlations between movement of Point A and the respective soft-tissue landmarks postdistraction using an internal distractor,unlike the present study. Correlations between anterior movement of U1 and

S. No.	Parameters			Group 1		Group 2			
	Hard tissue	Soft tissue	<b>R-value</b>	P-value	S:H	R-value	P-value	S:H	
1.	dA	dC	-0.555	0.096 (NS)	-0.16:1	0.655	0.040*	1.06:1	
2.		dSn	-0.011	0.976 (NS)	-0.00:1	0.157	0.665 (NS)	0.12:1	
3.		dLs	0.156	0.668 (NS)	0.16:1	0.503	0.138 (NS)	0.55:1	
4.		dStms	0.265	0.459 (NS)	0.30:1	0.625	0.045*	0.62:1	
5.		dPn	-0.189	0.601 (NS)	-0.10:1	0.490	0.150 (NS)	0.70:1	
6.	dU1	dLs	0.826	0.003**	0.60:1	0.822	0.004**	1.11:1	
7.		dStms	0.904	0.001**	1.40:1	0.727	0.017*	0.88:1	

NS: Non significant (*P*>0.05), \*\*\*Very high significant (*P*<0.001), \*Significant (*P*<0.05), \*\*Highly significant (*P*<0.01), dA: Change in position of Point A (T0-T1), dU1:Change in position of Upper Incisor (T0-T1), dC: Change in position of Cheek point (T0-T1), dSn: Change in position of subnasale (T0-T1), dLs: Change in position of Labrale superius (T0-T1), dStms: Change in position of Stomion superius (T0-T1), dPn: Change in position of Pronasale (T0-T1), dLs: Change in position of Labrale superius (T0-T1), dStms: Change in position of stomion superius (T0-T1).

labrale superius and stomion superius were also found to be significant in the present study (P < 0.01) with movement ratios of 0.86:1 and 0.94:1, respectively. Results on the anterior movement ratio for soft- to hard-tissue in the distraction group share a tendency similar to the study by Ko *et al.*,<sup>[16]</sup> one-year after maxillary advancement using a rigid external distractor.

There was a significant downward movement of the upper incisal edge by 4.15 mm, stomion superius by 2.45 mm, and labrale inferius by 3.25 mm in Group 1 patients (P < 0.01). Figueroa and Polley<sup>[17]</sup> reported a non-significant downward displacement of maxilla at incisal edge by 1.3 mm and Sahoo et al.<sup>[18]</sup> (2015) also reported a significant downward displacement of the upper incisor by 7.7 mm. This maxillary downward displacement may be due to the alignment of the force vector using the RED that passed above the center of resistance of the maxillary base that resulted in the downward advancement of the maxilla. The lengthening of the soft-tissue drape at Stms and Li in Group 1 was similar to the findings of Harada et al.[19] who also reported subnasal and lip lengthening following maxillary distraction. This can possiblybe attributed to the histogenesis that accompanies maxillary distraction.

## Change in soft-tissue thickness and soft-tissue to hard-tissue movement ratios in LeFort-1 maxillary advancement group

Significant decrease in soft-tissue thickness was observed at subnasale (P < 0.01) by 3.02 mm, labrale inferius by 1.30 mm, and at stomion superius by 0.90 mm (P < 0.05) post LeFort 1 maxillary advancement in Group 2 patients. According to Ewing and Ross,<sup>[9]</sup> only maxillary advancements of >4 mm produced significant thinning of the upper lip. Thus, a mean maxillary advancement of 3.60 mm in the present study may explain the non-significant decrease in soft-tissue thickness at labrale superius by 0.10 mm. Furthermore, it had also

been hypothesized by Epker *et al.*<sup>[20]</sup> (1978) that previous lip surgery might leave patients with cleft with lips that were less compressible during LeFort-1 advancement. Heliövaara *et al.*<sup>[21]</sup> observed upper lip thinning by 1.6 mm, and Susarla *et al.*<sup>[22]</sup> reported upper lip thinning by 5.8  $\pm$  2.5 mm. Such variable results may be due to variations in patient posture or forceful lip closure/strain while taking the lateral cephalograms.

In the sagittal plane, significant correlation was found between advancement at Point A and changes at C point, labrale superius, stomion superius, and pronasale in the ratios of 0.54:1, 1.07:1, 1.29:1, and 0.72:1, respectively. Lines and Steinhauser<sup>[23]</sup> found that there was a change in the nasal shape and the nasal tip position in a ratio of 2:3 compared to hard-tissue movement based on the finding of three cleft patients treated with maxillary advancement. Freihofer's analysis of changes in nasal profile after maxillary advancement in 25 cleft cases showed a mean ratio of soft- to hard-tissue change of 0.3,<sup>[24]</sup> less than half the value reported earlier by Lines and Steinhauser<sup>[23]</sup>. Other values reported are 0.13 by Hui et al.<sup>[25]</sup> and 0.3 by Araujo et al.<sup>[26]</sup> (1978). The changes in upper lip position following LeFort I osteotomy also show significant variation from one author to another. The ratio of soft- to hard-tissue advancement at Ls ranges from 0.4:1 to 0.66:1 for the majority of authors like Lines and Steinhauser,<sup>[23]</sup> Freihofer,<sup>[24]</sup> Araujo et al.<sup>[26]</sup> (1978), McCarthy et al.,<sup>[6]</sup> Ewing and Ross,<sup>[9]</sup> and Hui et al.<sup>[25]</sup>

Vertical lengthening of soft-tissue drape observed in Group 1 was not observed in Group 2, which was similar to the findings of Heliövaara *et al.*<sup>[21]</sup> This is possibly explained by the one-step advancement of the cleft maxilla, unlike the gradual advancement during distraction and the subsequent soft-tissue adaptation.

It may be inferred from this study that both the surgical interventions for maxillary advancement produce significant changes in the soft and hard tissue. It may be further implied that the soft tissue follows the hard tissue postsurgically. The ratios obtained from the study may be useful in the prediction of profile changes and treatment planning for maxillary advancement or distraction.

#### Limitations of the study

The primary limitation was the smaller sample size in the study. Therefore, future studies with larger sample size are recommended. In future, prospective studies and clinical trials are thus recommended with a larger sample size.

# CONCLUSION

- 1) In both groups, soft-tissue thickness was significantly reduced at subnasale, stomion, and labrale inferius (lower lip); however, reduction in thickness was not significant at labrale superius after LeFort 1 advancement surgery.
- 2) The sagittal movement of all soft-tissue landmarks strongly correlated with movement of the corresponding hard-tissue landmarks in both Group 1 and Group 2.
- 3) A marked positive and strong correlation was found between labrale superius and stomion points to the downward movement of the upper incisal edge in both Group 1 and Group 2.
- 4) There was significant soft-tissue lengthening at subnasale and the upper lip following maxillary distraction in Group 1.

# Ethical approval

The research/study approved by the Institutional Review Board at PGIMER, Chandigarh, number NK/6890/MDS/775, dated 11-01-2021.

# Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

# **Conflicts of interest**

There are no conflicts of interest.

# Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that they have used artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript or image creations.

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