A COMPARATIVE STUDY OF SOFT TISSUE CHANGES OF MIDFACE FOLLOWING CONVENTIONAL LEFORT I OSTEOTOMY VERSUS DISTRACTION OSTEOGENESIS IN CLEFT PATIENTS

Aung RONNY[1] and Danaiya SUPAKANJANAKANTI[1]
1 Faculty of Dentistry, Prince of Songkla University, Thailand;
ronnyaungdr@gmail.com (A. R.); danaiya.s@psu.ac.th (D. S.)

ABSTRACT
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 and bilateral cleft lip and/or palate (UCLP and BCLP) following maxillary distraction osteogenesis (DO) using internal distractor device and Conventional maxillary advancement at Lefort I osteotomy (CO) using lateral cephalograms. This retrospective study was conducted on 22 patients with UCLP or BCLP who underwent either maxillary distraction osteogenesis (Group 1) or Lefort I maxillary advancement (Group 2) with 5-10 mm in maxillary advancement. The lateral cephalograms were taken before surgery at (T0) and after a minimum interval of six months (T1) and 1 year (T2) of surgery. Significant differences were not found between the DO and CO patients in soft tissue thickness at 6 months and 1 year. A statistical significance of sagittal advancement and downgrafting of soft tissue was not observed between the two groups at 6 months and 1 year. There were better correlations of hard and soft tissue changes with maxillary advancement. There were much more consistent hard to soft tissue ratios in maxillary advancement with DO than with CO. In conclusion, this study found no statistically significant differences in soft tissue thickness, sagittal advancement, or vertical downgrafting between distraction osteogenesis (DO) and conventional Le Fort I osteotomy (CO) in cleft patients at 6 months and 1 year postoperatively. Both techniques produced comparable soft tissue changes of the upper lip and nose, with soft tissue following hard tissue movement in both groups. However, DO demonstrated more consistent hard-to-soft tissue ratios in maxillary advancement than CO, suggesting a more predictable soft tissue response despite equivalent overall outcomes.
Keywords: Distraction Osteogenesis, Lefort 1 Osteotomy, Clefts, Maxillary Hypoplasia

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INTRODUCTION

Maxillary hypoplasia is a common developmental sequela in patients with cleft lip and palate. Hypoplastic midface, impaired growth and a collapsed maxillary dental arch are some of the cardinal features of the patients with cleft lip and palate anomaly. Retrusive and retroclined configuration of nose shows markedly in cleft patients, contributing to the facial disharmony (Rachmiel et al., 1998). In the study of Ross, 1987 and Rachmiel, 2007, It is estimated that 25% to 60% of all cleft patients need maxillary advancement to correct hypoplastic maxilla and improve esthetics facial proportions (Anjana et al., 2024). Conventionally, Advancement of hypoplastic maxilla has been done by conventional Le Fort I osteotomy (LFIO) since the 1970s by McCarthy (Hannah et al., 2012). However, advancement with LFIO usually faces difficulties to correct in very extreme discrepancy cases in which greater advancement is required (Eldho et al., 2013). Moreover, the risk of post-surgical relapse and potential velopharyngeal incompetence usually happens following maxillary advancement (Adi et al., 2007). In the late 1990s, maxillary distraction osteogenesis (DO) has been developed as a new perspective (Austin et al., 2015). Maxillary distraction osteogenesis is an alternative method of surgical correction in midface hypoplasia. DO is a process of generating new bone through gradual traction between two surgically separated segments fixed to a mechanical distractor (Hannah et al., 2012). Focusing on facial aesthetics has become a main concern in orthognathic surgery in the 21st century. A major factor of the decision-making process for orthodontic or surgical orthognathic treatment is soft tissue changes after treatment (Rais et al., 2015). Since the relation of soft tissue morphology and underlying hard tissue exists, the soft tissue profile dictates the limits and esthetic outcome of treatment (Anjana et al., 2024). Every clinician needs to understand the facial soft tissue changes brought about by DO and conventional LFIO when the patients with cleft lip and palate are planned for surgery of maxillary movements (Cheung et al., 2006).

Since the beginning of the early 1970s, soft tissue changes after conventional LFIO have already been studied (Bell and Dann, 1973; Lines and Steinhauser,1974; Rais et al., 2015). However, there have been only a few studies comparing soft tissue changes in patients with cleft lip and palate. The reason is that most researchers excluded the patients with cleft lip and palate in the criteria of their study. Reliable correlations of the soft tissue and hard tissue movement showed surprisingly more than in non-cleft cases from the finding of early studies. It is postulated that the presence of scar tissue in the lip may cause the forward push of the underlying advancement of maxilla with less lateral displacement of tissues. The firmer structure of the lip may transmit the force better. Therefore, the soft tissue response is more predictable and more consistent (Hui et al., 1994). Andersen et al., 2015 reported that appropriate surgical correction technique is still uncertain, especially in terms of clinical indications, patient-related outcomes, stability, quality of life and long-term influence on growth. Furthermore, since the mechanism of maxillary advancement between conventional technique and distraction osteogenesis is not the same, there may be different soft tissue responses significantly (Anjana et al., 2024). Therefore, this study aimed to compare the soft tissue changes of the midface following LFIO with conventional technique and DO in cleft patients with maxillary hypoplasia.

LITERATURE REVIEW

Since the past 30 years, conventional orthognathic surgery provides the patients with dramatic improvements in soft tissue profile. However, there has been rising soft tissue improvement stability as questions whether it will be stable in the long term. Moreover, there has still been uncertainty about the soft tissue drapes whether it is able to adapt easily to newly arranged bony structures. In the 1990s, distraction osteogenesis, an alternative approach, has been existing to correct soft tissue adaptation to immediately positioned skeletal structure, especially

in maxillary advancement procedures in orthognathic surgery (Rais et al., 2015). The soft tissue morphology and underlying hard tissue are closely related. Anjana Rajagopalan et al., 2024 concluded that both DO and conventional techniques produce significant changes in the soft and hard tissue for advancement of maxilla. Their study further reported that the soft tissue follows the hard tissue. The soft tissue changes of the upper lip significantly vary from another to another. The ratio of soft- to hard-tissue advancement at labrale superius ranges from 0.4:1 to 0.66:1 in the studies of Lines and Steinhauser, Freihofer, Araujo et al. (1978), McCarthy et al., Ewing and Ross, and Hui et al (Anjana et al., 2024). Ewing and Ross (1993) found that there was high correlation between soft tissue changes postop LFIO advancement and underlying hard tissue in patients with unilateral cleft lip. They also found that significant thinning of the upper lip may happen only if maxillary advancement is greater than 4mm.In a retrospective study of Hui at el. 1994, the results reported that statistically significant correlations were found between soft and hard tissue movement in the cleft group following LFIO. Lines and Steinhauser (1974) observed that there was a ratio of 2:3 of a change in the nasal shape and the nasal tip position compared to hard tissue movement in finding of their study of 25 cleft cases treated by LFIO (Hui et al.,1994). In Harada's study of comparing maxillary DO and conventional technique LFIO, the conclusion was that DO produced significantly greater soft tissue changes than conventional group. Moreover, they found out that soft tissue to hard tissue ratios were also higher than conventional technique (Harada et al. 2002). In Chua and Cheung's study, they found that DO produced a more consistent hard and soft tissue ratio, and the amount of soft tissue changes of DO was more than conventional LFIO (Rais et al., 2015).

The systematic review of Austin et. (2014) reported that a statistically significant difference was not observed between DO and conventional LFIO in terms of nasolabial angle. However, it demonstrated that sagittal advancement of maxilla treated with either DO and conventional osteotomy can produce soft tissue improvement of the nose and upper lip. Moreover, the study showed that DO can generate more consistently in hard to soft tissue ratios than conventional osteotomy. The meta-analysis of Cheung and Chua (2007) concluded that an obvious improvement in facial aesthetics was observed in both DO and conventional osteotomy (Cheung et al., 2006). DO can change more soft tissue parameters than conventional osteotomy after treatment of sagittal advancement of maxilla. However, in conclusion of their study, they concluded that there was inconclusiveness in treatment of DO and conventional LFIO. (Austin et al., 2014).

Research Hypothesis

There is a difference of soft tissue response in the midface following LFIO advancement between conventional technique and distraction osteogenesis.

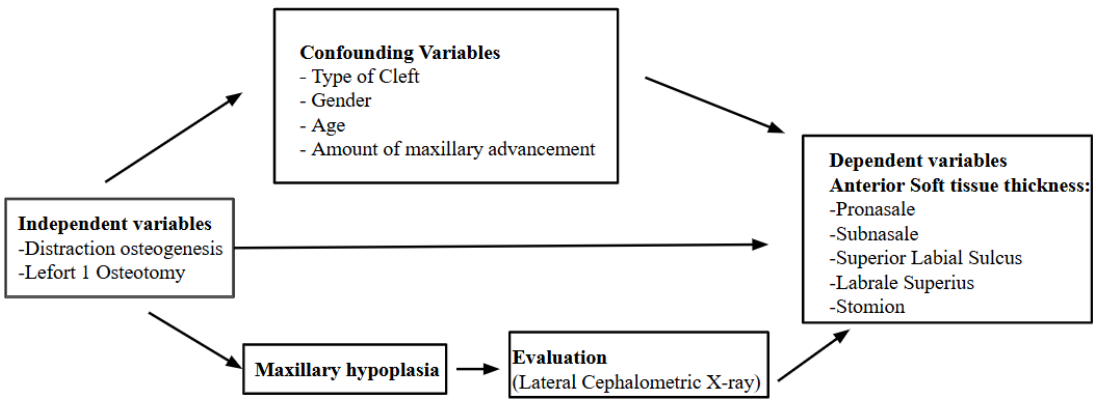


Figure 1 Conceptual Framework

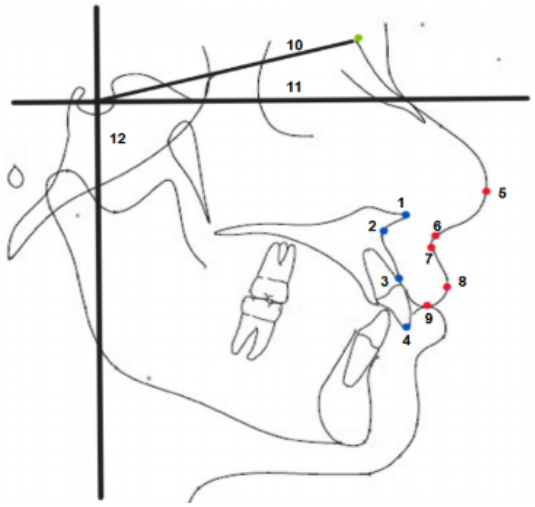
RESEARCH METHODOLOGY

This is a retrospective study using the lateral cephalometric radiographs in cleft maxillary hypoplasia patients after treatment of DO and conventional LFIO. This research was approved by The Human Research Ethical Committee of the Faculty of Dentistry, Prince of Songkhla University (PSU), Hatyai, Thailand (EC6809-040) on October 1, 2025. All patients were treated in the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Prince of Songkla university, Thailand from January 2013 to December 2024. Inclusion criteria were as follows: Patients with unilateral or bilateral cleft lips and palate diagnosed skeletal class III and maxillary hypoplasia who underwent maxillary advancement with either conventional technique or distraction osteogenesis with or without mandibular procedure, age of the patient from 14 to 35 years and the degree of maxillary advancement between 5-10 mm. Exclusion criteria were as follows: Patients with craniofacial syndromes such Treacher-Collin syndrome, Pierre-Robin syndrome and DiGeorge syndrome, patients with systemic diseases affecting bone and soft tissue healing such as Type 1 Diabetes Mellitus, systemic lupus, osteogenesis imperfecta, hyperthyroidism, chronic anemia, prolonged steroid users, lateral cephalometric X-ray with artifacts and poor quality and faulty or incomplete records. We calculated the sample size using formula based on data from the study by Hannab Daile P. Chua, et al. in 2012 titled "Soft tissue changes from maxillary distraction osteogenesis versus orthognathic surgery in patients with cleft lip and palate - A Randomized Controlled Clinical Trial." The total calculated sample size was 22. The sample was calculated with an alpha (α) value of 0.05, power of 80%, and 95% confidence interval and effect size 1.29. The patients were categorized equally into two groups. Group 1 (DO group) was the patients who underwent maxillary distraction osteogenesis at Le Fort I level using a rigid internal distraction device (DePuy Synthes; Johnson & Johnson MedTech, Raynham, Massachusetts, USA). Group 2 (CO group) was the patients who underwent LFIO maxillary advancement. A few numbers of patients treated with distraction osteogenesis and conventional lefort 1 osteotomy were available. Since the samples for conventional Lefort 1 osteotomy were few in number at our hospital, we could not include the sample of conventional Lefort 1 group according to inclusion criteria (within Maxillary advancement 5 - 10 mm). However, the samples of the distraction osteogenesis group were included within the maxillary advancement of 5-10 mm.Our study relied on existing records and lateral cephalometric radiographs, which made the study limit control over confounding variables.

In all patients, lateral cephalograms were obtained using the same orthopantomography machine (Gendex GXDP-700 3D panoramic and cone beam system; USA) in natural head position and centric occlusion. Standardized lateral cephalograms were assessed by comparing serial lateral cephalograms taken at different postoperative points. Timeline for Cephalometric analysis: before surgery(T0), after 6 months post-surgery (T1) and after 1-year post-surgery (T2). All measurements were carried out by two operators to ensure consistency. Lateral cephalometric radiographs were printed on the X-ray paper. After setting up, acetate tracing papers (Delta, Tracing paper, Germany) were adapted on each of the X-ray papers. 2B Lead pencil and eraser were used in tracing landmarks and outlines. For accuracy of tracing on X-ray film, the first operator located the landmarks and measured the lines. And then, the second operator checked and confirmed the location of landmarks and measurements. Three separate readings were done in each variable of each sample. After three separate measurements had been completed, the arithmetic mean from these three measurements were used to be a representative value for each variable. To accurately measure lateral cephalometric radiographs, it is necessary to account for magnification error. We used the magnification ruler reference. Linear and angular measurements were collected by using the same millimeter ruler and protractor with the help of the nearest 0.5 mm and 0.5 degrees, respectively. All measurements were recorded in a Google Excel spreadsheet and two decimal forms. Five soft

tissue landmarks (Pronasale (Prn), Subnasale (Sn), Superior labial sulcus (SLS), Labrale superius (LS), Stomion (St)) and four hard tissue landmarks (Anterior nasal spine (ANS), Point A (A), Labial bone of upper incisor (LBUI), Upper incisor tip (UIT)) were located on lateral cephalometric radiograph. Two reference lines were constructed and used for analysis. A horizontal (X) reference line was constructed at 7 degree clockwise from a linear line connecting the sella (S) and nasion (N) points (SN line). The vertical (Y) reference line was a line drawn perpendicular to the horizontal (X) reference line passing through the sella. These two reference lines were used to measure the vertical and horizontal changes, respectively. Soft tissue thickness was calculated from hard tissue to corresponding soft-tissue landmarks. 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 three-time intervals (T0, T1 and T2). Correlation between the anterior movement ratio of soft tissue and hard tissue landmarks was derived and compared between Group 1 and Group 2 patients. All the parameters were retraced and re-measured for a second time by the same examiner at an interval of more than one month after the first measurement to ensure the intra-examiner accuracy. The intraclass correlation coefficient test based on 95% confident interval was applied. Intraclass correlation coefficient was used to determine the intra-examiner variance. Data was analyzed by categorizing participants into DO and CO groups. Data was analyzed using SPSS version 23 (IBM Corporation; Armonk, NY, USA). The normality of the data distribution was assessed by the Shapiro-Wilk test ($n < 50$).

Descriptive statistics were presented as mean of standard deviation (SD) for normally distributed data and median for non-normally distributed data. For inferential statistics, normally distributed data were analyzed using the independent t-test and Two-way ANOVA, whereas non-normally distributed data were analyzed using the Mann–Whitney U test. A p-value < 0.05 was considered statistically significant.



Description of cephalometric reference points and lines for soft tissue and hard tissue evaluation; 1: Anterior nasal spine (ANS), 2: Point A (A), 3: Labial bone of upper incisor (LBUI), 4: Upper incisor tip (UIT), 5: Pronasale (Prn), 6: Subnasale (Sn), 7: Superior labial sulcus (SLS), 8: Labrale superius (LS), 9: Stomion (St), 10: SN line, 11: X reference line, 12: Y reference line.

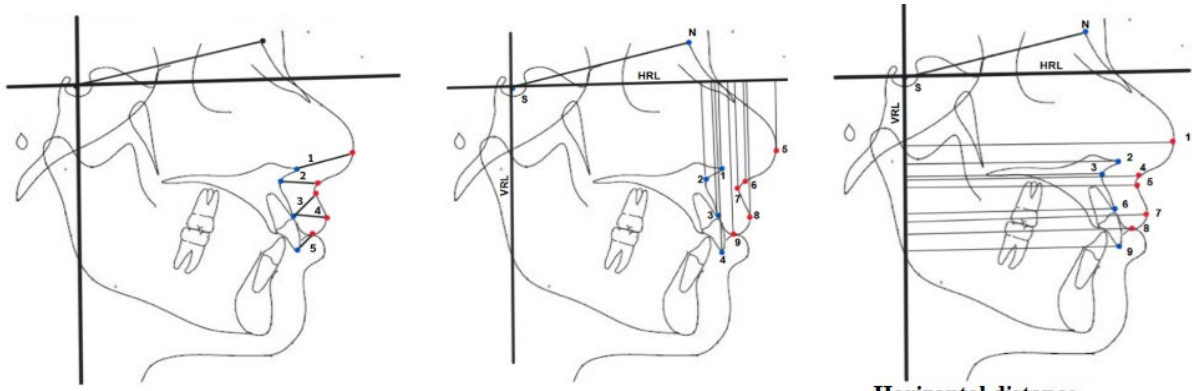


Figure (2) Measurements of soft tissues and hard tissues

RESEARCH RESULTS

A total of 22 cleft patients with maxillary hypoplasia who underwent maxillary advancement surgery were included in this study. The sample was divided into two equal groups: the conventional LFIO (CO) group (n = 11) and the distraction osteogenesis (DO) group (n = 11). Consequently, there were no statistically significant differences were observed in baseline characteristics such as age, gender distribution, cleft type and type of surgery performed between the two groups ($p > 0.05$) except amount of maxillary advancement (Table 1). Intraclass correlation coefficient (ICC) was 0.809 (95% CI: 0.598-0.909), indicating good reliability.

Table 1 Demographic data of the study sample (Mean ± SD)

Variable	DO Group (n=11)	CO Group (n=11)	P-value
Gender			
Male	3 (27.3%)	4 (36.4%)	0.65
Female	8 (72.7%)	7 (63.6%)	
Age			
14-18	5 (45.5%)	4 (36.4%)	0.76
19-22	1 (9.1%)	2 (18.2%)	
23-26	-	2 (18.2%)	
27-30	3 (27.3%)	2 (18.2%)	
31-35	2 (18.2%)	1 (9.1 %)	
Type of surgery			
Maxillary advancement	8 (72.7%)	6 (54.5%)	0.38
Maxillary advancement + BSSRO	3 (27.3%)	5 (45.5%)	
Cleft type			
Unilateral Cleft Lip	8 (72.7%)	7 (63.6%)	0.65
Bilateral Cleft Lip	3 (27.3%)	4 (36.4%)	
Amount of Maxillary Advancement	7.01 (±1.23)	4.27 (±2.52)	0.01*

Soft Tissue Thickness Changes

Soft tissue thickness was measured from five hard tissue landmarks to their corresponding soft tissue points. No statistically significant differences were found between the DO and CO

groups for soft tissue thickness parameters at baseline (T0) (P-value > 0.05) except soft tissue thickness of LBUI-SLS (*P-value = 0.01). (Table 2)

Table 2 Preoperative soft tissue thickness (mm) between DO and CO at T0

Parameters	Soft -tissue thickness (mm)			
	DO Mean (SD)	CO Mean (SD)	Difference	P-value
SNA to Prn	22.42 (3.19)	21.49 (1.31)	0.92	0.39
Point A to Sn	12.34 (2.68)	11.46 (2.16)	0.87	0.41
LBUI to SLS	11.31 (2.63)	8.63 (1.18)	2.68	0.01 *
LBUI to LS	13.84 (2.93)	12.29 (3.01)	1.54	0.24
UIT to St	10.41 (3.09)	8.20 (2.44)	2.21	0.06

*Significant difference (P-value<0.05), DO: Distraction Osteogenesis, CO: Conventional osteotomy

No statistically significant differences were found between the DO and CO groups for any soft tissue thickness parameter at 6 months (T1), or 1 year (T2) postoperatively (P-value > 0.05 for all comparisons), suggesting that both surgical techniques produced similar effects on soft tissue thickness. The intergroup comparison showed a lesser decrease in soft tissue thickness of Group 1 than group 2 at T1, but soft tissue parameters were statistically insignificant. (Table 3)

Table 3 Soft tissue changes (mm) Between DO and CO at T1 and T2

Parameters	Soft tissue thickness (mm)							
	T1 (Post Op 6 months)				T2 (Post op 1 year)			
	DO Mean (SD)	CO Mean (SD)	Difference	P-value	DO Mean (SD)	CO Mean (SD)	Difference	P-value
SNA to Prn	18.75 (2.03)	20.00 (2.85)	-1.26	0.25	19.23 (2.76)	20.5 (2.59)	-1.27	0.28
Point A to Sn	11.58 (2.35)	12.64 (1.59)	-1.06	0.43	10.88 (2.16)	11.33 (2.87)	-0.46	0.68
LBUI to SLS	10.76 (2.52)	10.23 (2.26)	0.53	0.61	9.63 (1.70)	8.41 (1.24)	1.22	0.07
LBUI to LS	13.13 (2.67)	13.72 (2.99)	-0.59	0.63	11.92 (3.00)	11.37 (2.28)	0.55	0.63
UIT to St	5.96 (1.88)	6.27 (2.25)	-0.30	0.74	6.18 (2.04)	5.06 (1.86)	1.12	0.19

*Significant difference (P < 0.05), DO: Distraction Osteogenesis, CO: Conventional osteotomy

Sagittal Soft Tissue Changes (Advancement)

The horizontal positions of soft tissue landmarks relative to the vertical reference line (VRL) were measured to assess sagittal advancement.

Table 4 Comparison of sagittal soft-tissue changes (mm) in Group 1 and Group 2 at T0, T1 and T2

Parameters	Mean Advancement (mm)										
	DO Mean (SD)			CO Mean (SD)			P-value (Time)			P-value (Time, Treatment, Time-Treatment)
Variables	T0	T1	T2	T0	T1	T2	(T0-T1)	(T0-T2)	(T1-T2)	(T0-T1-T2)
VRL to Prn	81.89 (6.40)	87.37 (4.65)	84.59 (6.80)	85.37 (5.71)	87.51 (5.60)	86.26 (13.69)	0.11	0.61	0.52	0.12 (Time) 0.23 (Treatment) 0.64 (Time-Treatment)
VRL to Sn	66.44 (6.99)	74.44 (4.03)	72.84 (6.64)	70.02 (6.40)	74.96 (5.29)	71.94 (5.52)	0.03*	0.07	0.44	0.01 (Time)* 0.46 (Treatment) 0.44 (Time-Treatment)
VRL to SLS	67.27 (7.57)	75.64 (4.71)	73.62 (6.87)	70.83 (7.09)	75.00 (5.61)	73.35 (5.31)	0.06	0.07	0.63	0.01 (Time)* 0.57 (Treatment) 0.47 (Time-Treatment)
VRL to LS	70.64 (8.07)	78.21 (5.48)	76.18 (8.19)	74.66 (8.27)	78.81 (6.99)	76.90 (6.97)	0.03*	0.21	0.67	0.03 (Time)* 0.32 (Treatment) 0.68 (Time-Treatment)
VRL to St	65.64 (7.52)	70.32 (5.21)	69.43 (7.33)	70.25 (7.83)	70.75 (7.11)	71.00 (6.36)	0.47	0.56	0.99	0.48 (Time) 0.20 (Treatment) 0.59 (Time-Treatment)

At three timepoints (T0, T1 and T2), no statistically significant differences were observed between the two groups (Time-Treatment comparison) for the sagittal positions of any soft tissue landmarks (*p > 0.05), suggesting that both surgical techniques produced similar effects on soft tissue advancement. However, There were statistically significant differences in three timepoints (Time comparison) for the advanced position of some soft tissue landmarks such as Subnasale (*p = 0.01), Superior Labial Sulcus (*p = 0.01) and Labrale superius (*p = 0.03) .Post Hoc test for timepoint showed that only T0-T1 timepoint of Subnasale and Labrale superius had statistically significance of 0.03 (p < 0.05).At T1-T2 timepoint, there was no significant relapse of any soft tissue, indicating that the advancement was relatively stable at 12 months. (Table 4)

Vertical Soft Tissue Changes (Downgrafting)

The vertical positions of landmarks relative to the horizontal reference line (HRL) were measured to assess downgrafting effects. At three timepoints (T0, T1 and T2), no statistically significant differences were observed between the two groups (Time-Treatment comparison) for the vertical positions of any soft tissue landmarks (*p > 0.05), suggesting that both surgical techniques produced similar effects on soft tissue downgrafting. However, There was a statistically significant difference in vertical position of Superior Labial Sulcus between DO and CO group at treatment comparison. Post hoc tests were not performed for DO and CO because there were fewer than three groups. (Table 5)

Table 5 Comparison of vertical soft-tissue changes (mm) in Group 1 and Group 2 at T0, T1 and T2

Parameters	Mean Downgrafting (mm)										
	DO Mean (SD)			CO Mean (SD)							
Variables	T0	T1	T2	T0	T1	T2	P-value (Time) (T0-T1)	(T0-T2)	(T1-T2)	P-value (Time, Treatment, Time-Treatment) (T0-T1-T2)	
HRL to Prn	37.94 (4.65)	37.39 (4.23)	38.61 (5.08)	37.47 (3.11)	37.07 (4.10)	35.70 (2.53)	0.93	0.91	0.99	0.89 (Time) 0.22 (Treatment) 0.49 (Time-Treatment)	
HRL to Sn	48.02 (5.20)	47.96 (3.07)	49.29 (4.23)	47.18 (3.03)	46.93 (3.10)	46.17 (2.55)	0.99	0.99	0.97	0.97 (Time) 0.07 (Treatment) 0.52 (Time-Treatment)	
HRL to SLS	54.26 (5.66)	55.57 (4.95)	55.71 (5.39)	51.12 (2.74)	51.71 (3.08)	51.28 (2.65)	0.76	0.83	0.99	0.73 (Time) 0.01 (Treatment)* 0.88 (Time-Treatment)	
HRL to LS	61.43 (6.21)	63.88 (6.89)	63.40 (6.49)	59.18 (2.84)	60.91 (2.78)	59.51 (2.72)	0.39	0.75	0.83	0.39 (Time) 0.02 (Treatment)* 0.86 (Time-Treatment)	
HRL to St	69.01 (7.62)	72.29 (7.14)	71.06 (6.63)	66.20 (3.93)	70.48 (4.59)	66.76 (4.31)	0.11	0.77	0.39	0.12 (Time) 0.05 (Treatment) 0.78 (Time-Treatment)	

Correlation Between Hard and Soft Tissue Changes

The relationship between the movement of corresponding hard and soft tissue landmarks was analyzed for both sagittal advancement and vertical downgrafting.

Sagittal Correlations and Soft-to-Hard Tissue Ratios

Table 6 presents the correlation coefficients and soft-to-hard (S:H) tissue movement ratios for the sagittal plane. In the DO group, statistically significant moderate to strong positive correlations were observed for most parameters at both T1 and T2. The S:H ratios were from 0.4:1 to 0.9:1, indicating a wider response depending on regions of midface. In the CO group, statistically significant correlations were also observed, but the S:H ratios showed greater variability, ranging from 0.2:1 to 0.9:1, suggesting that soft tissue movement often was not consistent with the underlying hard tissue movement. (Table 6)

Table 6 Correlation between hard-tissue movement and soft-tissue changes in sagittal plane in Group 1 and Group 2 at T0-T1 and T0-T2 time interval

Saggital Advancement	DO Group			CO Group		
Variable	R-value	P-value	S: H	R-value	P-value	S: H
dANS - dPrn						
T1	0.66	0.03*	0.64:1	0.25	0.47	0.62:1
T2	0.66	0.03*	0.39:1	0.59	0.06	0.45:1
dA - dSn						
T1	0.62	0.04*	0.91:1	0.66	0.03*	1.4:1
T2	0.55	0.08	0.85:1	0.52	0.09	0.70:1
dLBUI - dSLS						
T1	0.78	0.01*	0.97:1	0.66	0.03*	1.4:1
T2	0.86	0.01*	0.86:1	0.89	0.01*	0.83:1
dLBUI - dLS						
T1	0.57	0.07	0.88:1	0.61	0.04*	1.5:1
T2	0.65	0.03*	0.73:1	0.84	0.01*	0.71:1
dUIT - dSt						
T1	0.63	0.04*	0.49:1	0.49	0.13	0.20:1
T2	0.44	0.18	0.41:1	0.69	0.02*	0.18:1

Vertical Correlations and Soft-to-Hard Tissue Ratios

Table 7 presents the correlations for vertical movements. Both groups showed significant correlations for few parameters, moreover most S:H ratios were generally lower than those in the sagittal plane, ranging from 0.1:1 to 0.9:1. This suggests a less pronounced vertical soft tissue response. (Table 7)

Table 7 Comparison of vertical soft- and hard-tissue changes in Group 1 and Group 2 at T0-T1 time interval

Downgrafting	DO Group			CO Group		
Variable	R-value	P-value	S: H	R-value	P-value	S: H
dANS-dPrn						
T1	0.08	0.81	0.38:1	0.41	0.21	0.28:1
T2	0.29	0.39	0.15:1	0.48	0.14	0.65:1
dA-dSn						
T1	0.04	0.91	0.08:1	0.21	0.53	0.01:1
T2	0.16	0.65	0.79:1	0.65	0.03*	0.86:1
dLBUI-dSLS						
T1	0.05	0.88	0.37:1	0.01	0.99	0.19:1
T2	0.55	0.08	0.32:1	0.42	0.19	0.33:1
dLBUI-dLS						
T1	0.58	0.06	0.77:1	0.29	0.37	0.52:1
T2	0.66	0.03*	0.65:1	0.28	0.40	0.28:1
dUIT-dSt						
T1	0.45	0.17	0.74:1	0.19	0.57	0.92:1
T2	0.68	0.02*	0.72:1	0.51	0.11	0.32:1

DISCUSSION AND CONCLUSION

The thinning of soft tissues was observed after advancement of hypoplastic maxilla with distraction osteogenesis or conventional Lefort 1 osteotomy in this study. This phenomenon explains that stretching the soft tissue envelope appears during the advancement of hard tissue framework. The DO group showed a slightly lesser decrease in thickness compared to CO at T1 but the soft tissue thickness of DO reduced in only two parameters such as SNA to Prn and Point A to Sn than CO at T2. However, there were no statistically significant differences between two groups at T1 and T2 timepoints. In the study of Rajapopalan et al., 2024, they found that a significantly greater decrease in soft tissue thickness in the DO group at Labrale superius, stomion. They concluded that soft tissue thickness decreased significantly after maxillary advancement in both distraction osteogenesis and Lefort 1 osteotomy group (Rajagopalan et al.,2023). In the DO group, a greatly decrease in soft tissue thickness was observed at stomion after maxillary advancement. The mean of UIT -St thickness reduced obviously from 10.42mm to 5.96 mm after post op 6 months but the soft tissue thickness at stomion of CO group decreased from 8.20 mm to 6.27mm after 6 months. After 1 year of advancement, soft tissue thickness at stomion of DO showed consistency than CO group. However, most soft tissue parameters showed reduced thickness in both groups after 1 year of maxillary advancement. In the study of Markose et al.,2013, both groups produced significant soft tissue and hard tissue changes although more consistency showed in distraction osteogenesis compared to conventional osteotomy (Markose et al., 2013).

The degree of maxillary advancement between Group 1 and Group 2 was statistically significant; however, the soft tissue changes were quite like each other. This finding suggests that DO may be more effective than CO to produce soft tissue changes proportionally.

Among the pre-surgical comparison of soft-tissue thickness parameters, there was statistically significant in thickness of LBUI-SLS between DO and CO group at T0. Since the samples for conventional Lefort 1 osteotomy were few in number at dental hospital (PSU), It was not possible to include the samples according to inclusion criteria. This study relied on existing

records and lateral cephalometric radiographs, which made the study limit control over confounding variables.

In sagittal soft tissue advancement, no statistical differences were observed between distraction osteogenesis (DO) and conventional osteotomy (CO) at three timepoints (T0, T1 and T2). However, the DO group produced more soft tissue advancement compared to the CO group at T1 and T2. This finding aligns with Harada et al. (2002) and Chua and Cheung (2012), who reported that DO generates larger and more consistent soft tissue changes. However, statistically significant differences were found in subnasale and Labrale superius at T0-T1. These findings were similar to the study of Hannab et al, 2012. They also showed that significant differences were observed in the changes of subnasale and labrale superius after advancement of 6 months. After advancement of 1 year (T1-T2), there was stable soft tissue advancement, and no major relapse of all soft tissue was observed. This suggests that both DO and CO have effective surgical technique in achieving and maintaining sagittal soft tissue changes in cleft patients (Harada et al. 2002, Chua and Cheung et al.,2012). In a study of systematic reviews of Austin et al., 2014, their findings showed that there were no major differences in sagittal soft tissue improvement between DO and CO group (Austin et al., 2014). Rais et al., pointed out that none of the two procedures were found to be superior to each other for mild to moderate cases (Rais et al., 2015).

In vertical soft tissue downgrafting, no statistical differences were observed between distraction osteogenesis (DO) and conventional osteotomy (CO) at T0, T1 and T2 (Time-Treatment comparison) Hannab et al, 2012 also told that no significant differences were noted in all the soft tissue landmarks between the CO and DO groups after 6 months of treatment. However, the vertical position of superior labial sulcus between DO and CO had a statistically significant difference at treatment comparison, suggesting DO has downgrafting properties in treatment of hypoplastic maxilla.

Both the CO and DO group of our study showed that there was a much stronger significant correlation of the hard to soft tissue response in maxillary advancement than in downgrafting of maxilla in cleft patients with maxillary hypoplasia. In the present study, we found that the DO group had a more reliable correlation of hard to soft tissue response in maxillary advancement than the CO group. The correlation of hard to soft tissue response in maxillary advancement and more strong correlation of advancement than downgrafting that we found is quite similar to the findings of Hannab et al., 2012.This finding may be possible to guide presurgical prediction of soft tissue changes after treatment of DO or CO. However, there still need to more investigate and compare with soft tissue changes of non-cleft patients.The ratio of the upper incisor to the upper lip in the DO group obtained in this study was 1:0.73 at postoperative 1 year (T0). The soft to hard tissue ratio we obtained from the DO group was not quite different from the study of Hui et al, Hanna Et al and Ewing et al, with the ratios of 0.629:1 and 0.66:1 respectively (Hui et al.,) Most parameters of the DO group had similar soft to hard tissue ratios of the CO group in our study at T1 and T2. The A point to subnasale ratio was 0.91:1 in DO group and 1.4:1 in CO group at 6 months after advancement. This ratio is not similar to the ratio obtained by Hui et al. A different soft tissue response can be expected from different types of cleft lip (Hannab et al., 2012).

The correlation of hard to soft tissue response in downgrafting was not strong and well in both CO and DO groups in our study. This finding we obtained is the same as the study of Hannab et al., 2012. They discussed that the hard and soft tissue ratios of maxillary downgrafting in both DO and CO groups were not well correlated in their study. There was only correlation in the DO group, of which the upper incisor to labrale and the stomion at T2 in our study. Hannah et al found out the same findings in their study. Therefore, It needs to be cautious to use these values of correlation of soft tissue downgrafting for surgeons in planning of maxillary downgrafting.

The result of statistically insignificant difference between conventional Lefort 1 osteotomy and distraction osteogenesis in cleft patients should not be determined as a conclusive outcome. It was actually a reflection of convergence of biological and surgical mechanisms that adapt soft tissue response of midface. Biologically, the perioral musculature has a potential inherent adaptability to homogenize soft tissue responses across both techniques.In adults, the skeletal maturity makes the growth-related remodelling potential reduces the likelihood of divergent outcomes. Surgically, the rigid osteosynthesis after conventional Lefort 1 osteotomy and gradual consolidation and careful vector control of internal distractor after distraction achieved parallel remodelling of soft tissue in both techniques. These standardized operative protocols, coupled with surgeons expertise, minimize technique-dependent variability.The relatively small sample size may have limited statistical power to detect subtle differences, and also the reliance of this study on two-dimensional cephalometric analysis makes the detection to be obscured differences seen in three dimensional changes. Long term follow-up intervals may be essential to capture the differences of soft tissue changes between two groups as long-term divergence.

The smaller sample size was the primary limitation in the study. Therefore, larger sample size needs to be used in future studies. Moreover, type of cleft was another limitation in this study. It was not possible to separate the type of cleft (Unilateral or bilateral cleft) due to available small sample size. The different cleft type may affect the soft tissue changes especially upper lip and nose. Besides, the secondary operation for internal devices of DO need to be done after the consolidation phase of treatment. Secondary surgeries make the soft tissue profile changes additionally.

Further prospective studies using 3-dimensional analysis with larger sample size and multicenter approach are needed to fully understand the soft tissue changes after CO and DO in patients with Clef.

Both DO and CO can produce the same soft tissue changes of the upper lip and nose. The soft-tissue thickness reduced in cleft patients after maxillary advancement in both groups. The soft tissue followed the hard tissue in both groups with maxillary advancement. But there was lesser correlation in downward movement of soft -tissue lengthening in both groups except Subnasale, Labrae superius and Stomion.

In conclusion, this study found no statistically significant differences in soft tissue thickness, sagittal advancement, or vertical downgrafting between distraction osteogenesis (DO) and conventional Le Fort I osteotomy (CO) in cleft patients at 6 months and 1 year postoperatively. Both techniques produced comparable soft tissue changes of the upper lip and nose, with soft tissue following hard tissue movement in both groups. However, DO demonstrated more consistent hard-to-soft tissue ratios in maxillary advancement than CO, suggesting a more predictable soft tissue response despite equivalent overall outcomes.

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