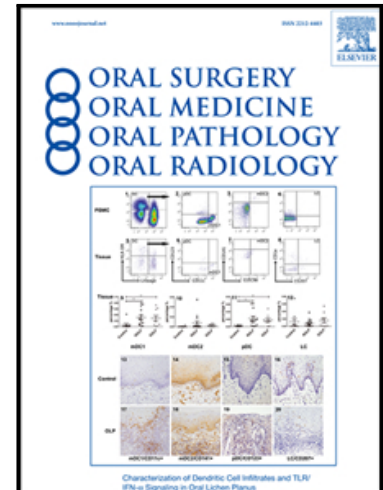


Nasolabial angle and nasal tip elevation changes in profile view following a Le Fort I osteotomy with and without the use of an alar base cinch suture: A long-term cohort study

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Abstract

Objectives: Cinch sutures attempt to counteract alar base widening, but may lead to unintended increases in the nasolabial angle and nasal tip elevation. This investigation assessed nasolabial angle changes following maxillary osteotomies with and without alar base cinch sutures in the short and long-term.

Design: 78 patients were assessed, 51 in the cinch group (38F, 13M; age range: 16-39 years), 27 in the no cinch group (12F, 15 M; age range 17-27 years). The upper component (nasal tip elevation), lower component (lower lip inclination) and overall nasolabial angle were measured on pre-operative, post-operative and long-term follow-up lateral cephalometric radiographs.

Results: Overall nasolabial angle ($p=0.006$) and its upper component ($p<0.001$) increased significantly in the cinch group immediately post-operatively, but resolved by 6-12 month for overall nasolabial angle and by 12+ months (up to 5.7 years) for the upper component. There were no significant changes in the no cinch group.

Conclusions: In the short-term, the alar base cinch suture increases nasal tip elevation and overall nasolabial angle. In the long-term there was no significant difference, suggesting that the initial nasal tip elevation resolves over time, and that the cinch suture may have limited effect on nasal tip elevation in the longer term.

Keywords: Osteotomy; cinch suture; nasolabial angle; stability

Introduction

Orthognathic surgical moves are accurately planned to ensure a reliable hard tissue result. However, the overlying soft tissue change is less predictable, which can negatively affect the overall patient satisfaction with treatment.¹⁻³ Being able to accurately predict not just the underlying skeletal changes but the complex soft tissue changes will enhance patient understanding of what can be achieved. It will also demonstrate the limitations of these procedures ensuring effective management of patient expectations and allowing informed consent.⁴

Soft tissue changes in Le Fort I osteotomies concentrate around the nasolabial complex, including the nasolabial angle. It is generally agreed that the alar base will widen with advancement or impaction of the maxilla due to stretching of the soft tissues.⁵ The benefit of these changes is dependent on the initial facial appearance and may be desirable or not. Intra-operative surgical techniques such as the alar base cinch suture can aid the control of soft tissue changes. The alar base cinch suture was described by Millard,⁶ for cleft lip and palate patients and adapted by Collins and Epker,⁷ for use in Le Fort I osteotomy patients to control unwanted alar base widening. The technique involves placing a non-resorbable suture through the right and left alar bases through the pre-existing circumvestibular incision made for the osteotomy. This is tightened until the desired width is achieved. In a recent retrospective study, the alar base cinch suture has been shown to effectively control unwanted alar base widening following a Le Fort I osteotomy at 3 years post-operative.⁸ However, the effect on the nasolabial angle is unclear and may cause an unwanted nasal tip elevation.⁹

The nasolabial angle is defined as the angle formed between the upper lip and the base of the nasal columella in profile view. It may be divided into two component angles by

drawing a true horizontal line intersecting through subnasale when the patient is in natural head position (Figure 1).¹⁰ If changes occur to the nasolabial angle, dividing it into upper and lower component parts will demonstrate which structure has contributed to the change. Variations in the upper component of the nasolabial angle would suggest a change in nasal tip elevation. Variations in the lower component of the nasolabial angle suggest a change in upper lip inclination. Better understanding of the changes to the upper and lower components of the nasolabial angle would aid surgical treatment planning.

Although research focussing specifically on nasolabial angle changes is limited, the overall angle is commonly quoted as increasing following a Le Fort I osteotomy.^{5,11} Westermarck et al.⁵ are the only group to have compared the overall nasolabial angle changes with and without the cinch suture. The retrospective cephalometric data of 123 patients undergoing Le Fort I osteotomies were subdivided according to maxillary moves. The results demonstrated an overall increase in nasolabial angle in both the cinch and no cinch groups (5.2° and 1.4° respectively) but the cinch group had a statistically significantly greater increase. They attributed this to the cinch suture crossing the midline and compressing the nasolabial soft tissues. There was no significance in relation to type of maxillary movements. Of note, they suggested that the cinch suture has a greater effect on the nasolabial angle than it had on the alar base. The study appears to be well designed with comparatively large sample size although with a short follow up period of only 6 months. They only assessed the effects on the entire nasolabial angle, with no separation of the effects on the nasal columella (upper component) and upper lip inclination (lower component).

However, one of the original papers investigating soft tissue changes with Le Fort I osteotomies suggests the nasolabial angle decreases or stays the same. Betts et al.¹² examined 32 patients in a prospective study based on cephalometric data and nasal casts. The authors state 65% of their patients experienced a decrease or no change in nasolabial angle after a 12 month follow up period. Surgical adjuncts such as the cinch suture were used in seven patients in this study but the impact on the results was statistically insignificant, most likely due to low numbers. More recently, Metzler et al.¹³ performed a retrospective 3D photogrammetry study that demonstrated there was no change to the nasolabial angle with Le Fort I osteotomies. 44 patients were examined over a period of 6 months with no predictable trend following maxillary advancement. Two operators were involved in data collection but reliability studies were not included. The operators were blinded to intervention decreasing the risk of bias.

The existing literature is unclear on changes to the nasolabial angle following orthognathic surgery, therefore the primary aim of this prospective cohort study was to assess the changes to the nasolabial angle following a Le Fort I osteotomy with and without the use of the alar base cinch suture, immediately post-operative and at greater than 6 months post-operative. The null hypothesis was that the cinch suture has no effect on the nasolabial angle following a Le Fort I osteotomy in the short and long-term.

Materials and methods

Ethical approval was obtained through the National Research Ethics Service (NRES), REC reference 14/LO/1957. The patients had undergone a Le Fort I osteotomy or bimaxillary surgical procedure at St George's Hospital by one surgeon (HW) between March 2006 and March 2017. Patient analysis was carried out by one researcher (RM).

Participants were included if they had undergone a maxillary osteotomy (advancement +/- impaction +/- rotation) and were aged 16 years or above at the time of surgery with the capacity to consent. Good quality lateral cephalometric radiographs were required at:

- T0 - pre-operative.
- T1 - less than 30 days post-operative.
- T2 - 6-12 months post-operative.
- T3 - greater than 12 months post-operative; (in this investigation the eventual range was from 12 months to 5.7 years, with a median of 2.0 years).

Participants were excluded if they had cleft lip, cleft palate or other congenital abnormalities or had a post-operative rhinoplasty or secondary procedures which may affect the nasolabial angle in the long-term analysis.

All the surgical procedures were undertaken by the same surgeon (HW) using the technique of submental intubation, thereby avoiding any nasolabial distortion from the nasotracheal tube traditionally used for orthognathic surgery. Treatment planning for each patient was undertaken clinically, based on achieving improvement in facial aesthetics and dental occlusion. The direction and amount of maxillary movement was decided clinically, based on patient examination, and verified using traditional model surgery techniques and wafer splint construction in the laboratory. Intra-operatively, the

sagittal and vertical position of the maxilla was also assessed directly on the patient, which is permitted due to the submental intubation technique not distorting the upper lip and nasal regions.

Intra-operatively, the cinch suture was placed subcutaneously using 3-0 prolene. Small incisions of 1-2 mm at the ala were made using a number 11 blade and the suture passed from intra-oral to extra-oral. The needle was then passed back through the incision in the alar groove into the mouth. The suture was directed across the septum to the opposite side and moved from intra-oral to extra-oral through the alar base incision. The suture was passed back to intra-oral, tightened to create the desired alar-base width and tied below the nasal septum. To ensure the pull of the suture was across the alar base, a small notch at the caudal end of the septum was made to prevent anterior displacement.

The nasolabial angle was measured using the lateral cephalometric radiographs taken throughout treatment and follow up in accordance with the British Orthodontic Society and British Association of Oral and Maxillofacial Surgeons minimum required dataset for treatment of orthognathic patients.¹⁴ The images were assessed in a random order and the assessor was blind to whether a cinch suture had been placed. An angular difference of 4° was considered to be clinically significant; this was based on a previous paper examining changes to the nasolabial angle.¹⁰

Most lateral cephalograms were available for analysis on the hospital's radiographic images viewing software (IntelliSpace PACS Enterprise. Version 4.4.516.15). All of these images were analysed in a darkened room on the same computer to ensure the screen resolution (1440 by 900 pixels) was standardised. For 11 pre-operative images, digital radiography was unavailable and film radiographs were analysed instead using a lightbox in a darkened room. The nasolabial angle was measured using protractor

software (Ondesoft Screen Rulers V1.12.1) (Figure 2). The horizontal reference line was constructed using the Nasion horizontal plane (S-N plane minus 7°) due to ease of landmark identification.¹⁵ The raw data was recorded on a Microsoft Excel (Microsoft Corporation, USA) spreadsheet.

To ensure the measurements were reliable, intra-rater repeatability testing was undertaken. Twenty randomly selected digital lateral cephalometric radiographs from both pre-operative and post-operative time periods were selected using a computer random number generator. These images were traced and following a two-week wash-out period traced for a second time.

Statistical analysis

Minitab v18 (Minitab Inc., USA), statistical package was used for analysis of the results. To test for intra-rater reliability, the Bland and Altman method and Lin's concordance correlation coefficient (CCC) were used. Data were tested for consistency with a normal distribution using the Ryan-Joiner test in Minitab. The tables show significance levels with no changes applied for multiple testing; in cases of multiple testing the Benjamini-Hochberg procedure¹⁶ was applied with the value for false discovery rate of 0.25 and p values remaining significant are indicated.

Results

Sample Demographics

Seventy-eight patients were included in this investigation. The age range for females was 16-45 years and for males was 17-52 years, with a mean age of 21 years for both groups (Table 1). To ensure the cinch and no cinch groups could be analysed equally, they were assessed for differences in age, sex and maxillary move. Sex data was compared using the Fisher's exact test. Age and maxillary moves were compared using Mann Whitney tests.

Repeatability Testing

Intra-rater reliability was analysed using two methods: Lin's Concordance Correlation Coefficient (CCC) and the Bland and Altman method. Lin's calculations demonstrate almost perfect agreement in the majority of measurements Table 2. The Bland-Altman analysis also confirmed high levels of agreements.

Nasolabial Angle Changes with and without the Cinch Suture

Data were assessed at:

1. Each stage, e.g. pre-operatively in the cinch group (T0) and pre-operatively in the no cinch group (T0) with a Mann Whitney test.
2. Each change in time point, e.g. post-operatively compared to pre-operatively in the cinch group (T1 – T0) and post-operatively compared to pre-operatively in the no cinch group (T1 – T0) with a Wilcoxon signed rank test.

Descriptive statistics at each time point are shown in Table 3.

The effect of the cinch suture on the nasolabial angle at each time point and the change in measurements compared to pre-operative values were compared with no cinch suture measurements (Table 4).

The Mann-Whitney tests show wide confidence intervals and no significant changes ($p < 0.05$) to the nasolabial angle after a Le Fort I osteotomy with or without the cinch suture in the long-term. In the short-term, there is a suggestion of a difference between the cinch and no cinch group immediately post-operatively however, after applying the Benjamini-Hochberg procedure this does not reach significance. The post-operative change in the upper component angle is higher in the cinch group with a median change of 8° and estimated difference of 5° compared with the no cinch group. Both the T2 and T3 analyses demonstrate no statistically significant differences.

To assess the effect of the cinch suture over time following a Le Fort I osteotomy, the Wilcoxon signed rank test was used on paired samples (Table 5). There was an increase post-operatively (T1) compared with pre-operatively (T0) in the overall and upper components in the cinch group with an estimated median change of 4.5° and 7° respectively. However, there is no such significant change for the overall angle in the 6-12 months follow-up measurements and the difference was only just significant for the upper component at that time with an estimated median change of 4° . There was no significant change for the 12+ months measurements (T3 measurements ranging from 12 months to 5.7 years, with a median of 2.0 years).

Discussion

The nasal alar base cinch suture, used by some clinicians to reduce the unwanted alar base widening resulting from maxillary advancement, also has the effect of elevating the nasal tip, which may also be detrimental to nasal aesthetics in patients with an already obtuse nasolabial angle. The aim of this investigation was to assess the changes to the nasolabial angle upper component, lower component and overall angle after a Le Fort I osteotomy with and without the use of the alar base cinch suture. This suture is used intra-operatively to preserve the alar base width and has been shown to be effective in the short and long-term.⁸ The nasolabial angle was assessed at three time points: immediately post-operatively (T1), 6-12 months post-operatively (T2) and at more than 12 months post-operatively (T3). The results show that the overall nasolabial angle and upper component increased immediately post-operatively (median increase in angle of 4.5° , $p = 0.006$) and for the upper component with an estimated median increase of 7° ($p < 0.001$). This difference persisted at the 6-12 month follow up for the upper component (estimated median increase in angle of 4° , $p = 0.024$) but was not apparent for the overall angle at that stage. The lower component demonstrates a reduction in angle (estimated median reduction of 3.5°) but this was not statistically significant. The significance for upper component was lost by the 12+ month follow up. There were no significant differences in the no cinch group.

The results of this study show that immediately following a Le Fort I osteotomy, patients will experience an increase in the overall nasolabial angle and upper component with a cinch suture. The lower component undergoes a reduction in angle, although this was not statistically significant. These angles change in the way anticipated following a Le Fort I osteotomy with an increase in nasal tip elevation and upper lip inclination

immediately post-operatively. With healing, the overall angle reduces by the 6-12 month follow up and the upper component by the 12+ month follow up.

A limitation to the study is that the spread of T3 radiographs is extensive, ranging from 12 months to 5.7 years with a median of 2.0 years. As this group was analysed together, it is difficult to pinpoint when the upper component starts to reduce back to the pre-operative value. Patients are informed that swelling has largely resolved by 6 months post-operative and complete by 12 months post-operative.¹⁷ The results of this study suggest nasal changes should be expected past this point.

It can be assumed that the reduction in the upper component of the nasolabial angle is related to a drop in nasal tip elevation with further post-operative healing. In addition, patient numbers were higher at the long-term analysis providing a more reliable result. From a surgical perspective, the magnitude of septoplasty could also play a role in the immediate appearance of the nasolabial angle. With further post-operative healing and reduction of swelling, this change fades with time. An alternative theory to explain the reduction in the upper component angle could be that the cinch suture is loosening over time. This would be accompanied by an increase in alar base width. Raithatha et al.⁸ confirmed the stability of the alar base with the use of the cinch suture in a 3 year follow up study. This reinforces that the cinch suture itself appears to remain stable up to this point.

The results of this study are in line with Vasudavan et al. and Metzler et al.^{1,13} They assessed nasolabial angle changes following a Le Fort I osteotomy without a cinch suture at 6 months and with a cinch suture at 12 months respectively. Neither assessed nasolabial angle by dividing into component parts. However, both studies found that the nasolabial angle did not change significantly following a Le Fort I osteotomy.

Comparing the results to Westermarck et al.⁵ where the effect of the cinch suture was formally assessed, a clinically significant increase in the overall nasolabial angle was found in both groups.

In this current investigation, as the period of review spans a significantly longer term, up to 5.7 years post-operatively, the results indicate that the nasal tip elevation and overall nasolabial angle may revert to the pre-operative measurement over a longer time frame. This information is important both for the planning surgeon and in terms of informed consent for patients.

This observational cohort study was designed to assess the impact of the alar base cinch suture on the upper component, lower component and overall nasolabial angle following a Le Fort I osteotomy. The changes were assessed immediately post-operatively, 6-12 months post-operatively (short-term) and 12 months to 5.7 years post-operatively (long-term). The conclusions from this study are:

1. The overall nasolabial angle and the upper component (nasal tip elevation) of the nasolabial angle increased significantly from pre-operative to immediately post-operative with the use of the cinch suture (median increase in angle of 4.5° ($p = 0.006$) and 7° ($p < 0.001$) respectively).
2. The pre-operative to post-operative change in the upper component of the nasolabial angle appeared to be higher in the cinch group compared to the no cinch group, suggesting that the cinch suture leads to greater elevation of the nasal tip in the immediate post-operative period and short term (<6 months).
3. There was no significant change in the overall angle with respect to the pre-operative value by the 6-12 month follow up and no significant change in upper

component by the 12+ month follow up suggesting that the nasal tip elevation changes resolve in the long-term.

4. The lower component of the nasolabial angle (i.e. the inclination of the upper lip) in the cinch suture group decreased but this was not statistically significant.
5. There are no significant differences in nasolabial angle in the no cinch suture group following a Le Fort I osteotomy.

Statement of clinical relevance

The alar base cinch suture increases nasal tip elevation and overall nasolabial angle following maxillary osteotomy, but this effect appears to resolve over time, therefore the cinch suture appears to have limited effect on nasal tip elevation in the long-term.

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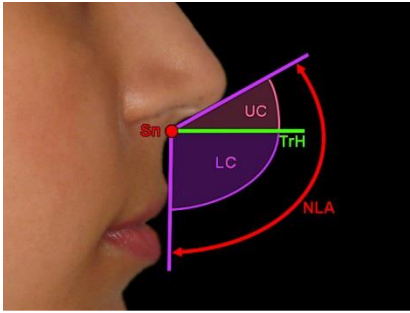
Figure captions

Figure 1 The nasolabial angle (NLA) may be separated into an upper component (UC, which represents the nasal columellar angle and thereby nasal tip elevation), and a lower component (LC, which represents upper lip inclination). TrH, true horizontal line; Sn, subnasale.

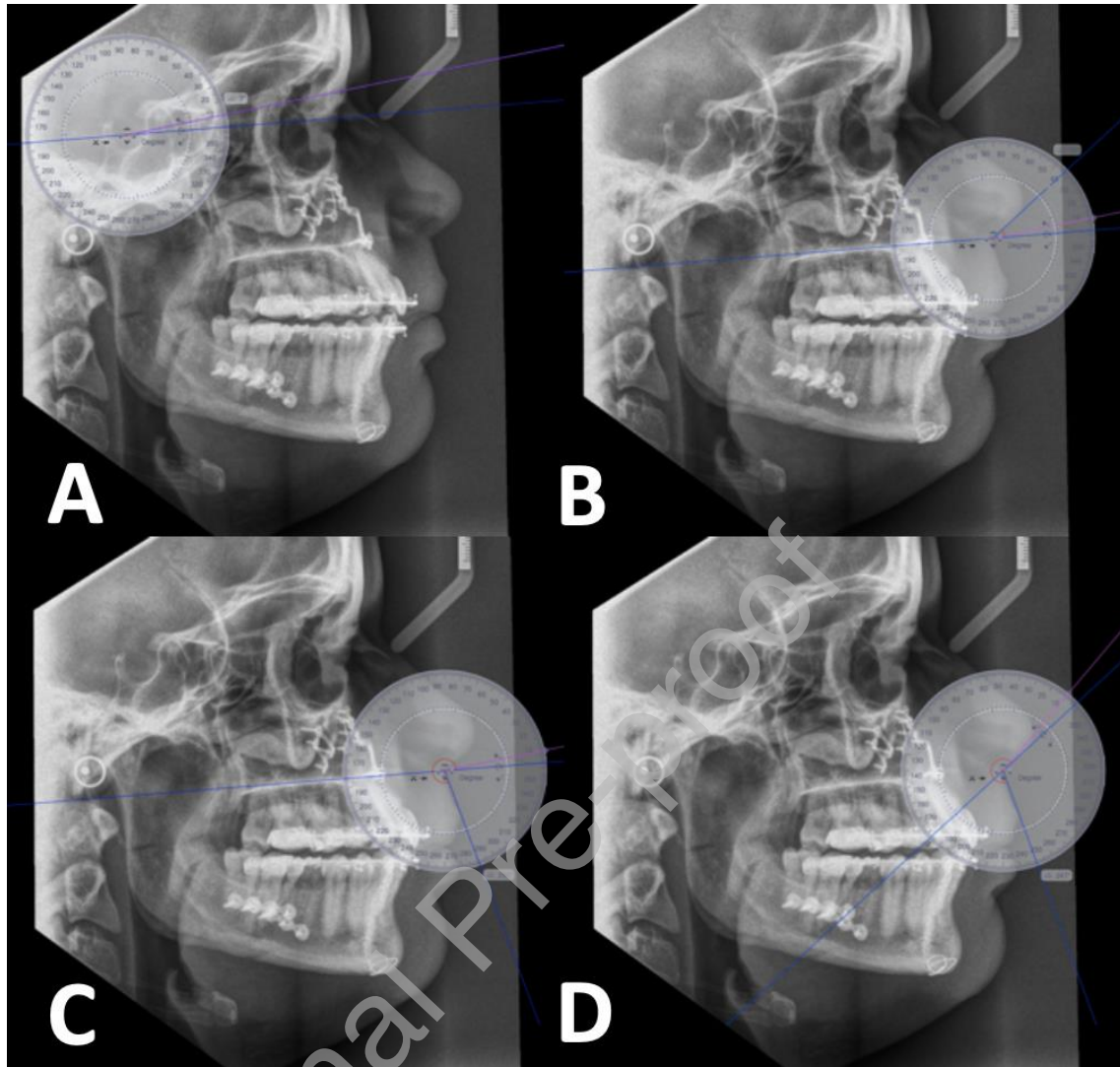


Figure 2 Examples of nasolabial angle measurements using the Ondesoft Screen Rulers. Image A: Nasion horizontal plane was identified. Image B: upper component of the nasolabial angle was measured. Image C: lower component of the nasolabial angle was measured. Image D: overall nasolabial angle was measured.

Table 1. Demographics of patients included in the study. The p-values indicate there is no significant difference ($p < 0.05$) between the groups aside from a higher proportion of females in the cinch group.

Demographic	Cinch Group (n=51)	No Cinch Group (Control, n=27)	p-value
Sex (F:M)	38:13	12:15	0.013
Median (range) age	20 years (16 – 39 years)	20 years (17 – 27 years)	0.916
Median (range) maxillary advancement	4 mm (0 to 12 mm)	4 mm (0 to 8 mm)	0.838
Median (range) maxillary impaction	2 mm (0 to 7 mm)	2 mm (0 to 8 mm)	0.681

Table 2. Intra-rater reliability testing demonstrating high levels of concordance

	Angle	Mean difference	95% limits	Lin's CCC	95% confidence interval of Lin's CCC	Strength of Agreement
Digital	Overall NLA	1.5	-8.8	0.991	0.980 - 0.996	Almost perfect
	Upper component	0.2	-9.4	0.99	0.980 - 0.996	Almost perfect
	Lower component	1.5	-12.1	0.998	0.996 - 0.999	Almost perfect
Film	Overall NLA	-0.25	-5.3	0.991	0.980 - 0.996	Almost perfect
	Upper component	0	-6.6	0.97	0.939 - 0.985	Substantial

	Lower component	-0.2	-8.4	0.984	0.966 - 0.994	Substantial
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Table 3. Descriptive statistics for the overall NLA, upper and lower components in both the cinch and no cinch groups at each stage of analysis and the changes occurring in between. Values are given in degrees. T0: pre-operative, T1: post-operative, T2: 6-12 months follow up, T3: more than 12 months follow up. The results demonstrate the pre-operative values for all three angles are similar, confirming pre-treatment equivalence.

Min: minimum value and Max: maximum value. NLA, nasolabial angle.

Value	Time point	Cinch suture	Sample size	Min	Median	Max
Overall NLA	T0	No	27	78	105	131
		Yes	51	68	104	121
	T1	No	13	82	108	120
		Yes	38	75	104.5	129
	T2	No	10	86	110	125
		Yes	18	80	104	124
	T3	No	17	75	100	124
		Yes	36	72	99	118
	Change in T1 – T0	No	13	-45	4	19
		Yes	38	-19	3.5	35
	Change in T2 – T0	No	10	-11	3	19
		Yes	18	-20	0	23
	Change in T3 – T0	No	17	-19	-2	11
		Yes	36	-20	0	8
Upper component NLA	T0	No	27	10	26	40
		Yes	51	6	25	41
	T1	No	13	15	26	39
		Yes	38	8	31.5	50
	T2	No	10	11	29.5	46
		Yes	18	16	30	44
	T3	No	17	9	25	35
		Yes	36	2	22.5	39
	Change in T1 – T0	No	13	-13	4	10
		Yes	38	-33	8	16
	Change in T2 – T0	No	10	-9	-1	20
		Yes	18	-10	4	16
	Change in T3 – T0	No	17	-11	-2	10
		Yes	36	-32	-2	16
Lower component NLA	T0	No	27	59	76	99
		Yes	51	47	77	105
	T1	No	13	65	73	94
		Yes	38	47	73	97
	T2	No	10	60	81	99
		Yes	18	52	78	94
	T3	No	17	60	80.5	99
		Yes	36	53	79	94
	Change in T1 – T0	No	13	-32	-1	19
		Yes	38	-20	-3	43
	Change in T2 – T0	No	10	-17	0	24
		Yes	18	-17	-4	18
	Change in T3 – T0	No	17	-10	-2	12
		Yes	36	-11	-0.5	20

Table 4. Results of the Mann-Whitney tests used to assess estimated differences between the cinch and no cinch groups. Significant p value after applying the Benjamini-Hochberg procedure shown in red. NLA, nasolabial angle.

Value	Time Point	Difference	95% confidence	p-value
Overall NLA	T0	3	(-3, 10)	0.334
	T1	0	(-10, 8)	0.948
	T2	7	(-4, 16)	0.172
	T3	5	(-3, 12)	0.23
	T1 – T0	-2	(-9, 4)	0.574
	T2 – T0	3	(-6, 10)	0.472
	T3 – T0	0	(-4, 4)	0.939
NLA Upper Component	T0	2	(-1, 6)	0.209
	T1	-6	(-10, 0)	0.037
	T2	-2	(-10, 5)	0.615
	T3	3	(-3, 8)	0.299
	T1 – T0	-5	(-9, -1)	0.01
	T2 – T0	-5	(-10, 1)	0.103
	T3 – T0	0	(-4, 5)	0.939
NLA Lower Component	T0	2	(-4, 8)	0.532
	T1	4	(-4, 12)	0.393
	T2	7	(0, 14)	0.072
	T3	2	(-4, 7)	0.746
	T1 – T0	1	(-6, 8)	0.787
	T2 – T0	6	(-3, 13)	0.144
	T3 – T0	-1	(-4, 4)	0.746

Table 5. Wilcoxon signed rank tests with the paired estimated median changes in nasolabial angle following a Le Fort I osteotomy over time. The overall nasolabial angle and upper component are significantly higher immediately post-operatively in the cinch group, however, this was not seen in the follow up

measurements. Significant p values after applying the Benjamini-Hochberg procedure are shown in red. NLA, nasolabial angle.

	Value	Time Point	N	Median	p-value
NO CINCH	Overall NLA	T1 – T0	13	2.5	0.594
		T2 – T0	10	3	0.415
		T3 – T0	17	-0.5	0.653
	NLA Upper Component	T1 – T0	13	2	0.224
		T2 – T0	10	-1	0.799
		T3 – T0	17	-1	0.492
	NLA Lower Component	T1 – T0	13	-1	0.78
		T2 – T0	10	3	0.61
		T3 – T0	17	-0.5	0.85
CINCH	Overall NLA	T1 – T0	38	4.5	0.006
		T2 – T0	18	0.5	0.755
		T3 – T0	36	-0.5	0.551
	NLA Upper Component	T1 – T0	38	7	<0.001
		T2 – T0	18	4	0.024
		T3 – T0	36	-1.5	0.318
	NLA Lower Component	T1 – T0	38	-2	0.169
		T2 – T0	18	-3.5	0.136
		T3 – T0	36	0	0.864

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