



Effect of infant surgical orthopedic treatment on facial growth in preadolescent children with unilateral and bilateral complete cleft lip and palate

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Objective. To examine the impact of dentofacial infant orthopedic treatment (DFIO) on facial growth in preadolescent children with unilateral complete cleft lip and palate (UCCLP) and bilateral complete cleft lip and palate (BCCLP).

Methods. This is a retrospective study of patients with UCCLP and BCCLP treated at a single center. The treatment group had DFIO, and the control group did not have DFIO. Regression models were used to compare outcomes between the study and control groups.

Results. The study sample comprised 81 patients (54 had DFIO and 27 did not have DFIO). Among those with UCCLP, those who had DFIO had a shorter maxillary length (-2.12 mm; $P = .04$) and shorter lower anterior facial height (-2.77 mm; $P = .04$) compared with controls. Among those with BCCLP, there were no significant differences between the treatment and control groups.

Conclusions. DFIO treatment could result in shorter maxillary length and lower anterior facial height in those with UCCLP. (Oral Surg Oral Med Oral Pathol Oral Radiol 2015;120:291-298)

In 1950, McNeil¹ introduced the concept of orthopedic treatment for infants with complete cleft lip/palate before primary surgical repair. The underlying premise was that dentofacial infant orthopedic (DFIO) treatment would improve the esthetic outcome of primary nasolabial repair by repositioning the alar base through the anterior movement of the bony platform supporting it.²⁻⁵ Since then, however, there has been conflicting evidence regarding the efficacy of DFIO in improving surgical outcomes and concern about the long-term impact on skeletal maxillary growth. Millard and Latham⁶ stated that preoperative

repositioning of the maxillary segments provided a more symmetric, improved platform for closure of the alveolar clefts as well as a reduction in the width of the alveolar cleft. Additional reported benefits of DFIO treatment include improved feeding efficiency, improved psychosocial development of the child, and added parental support.⁷

Some reports suggest that there is no conclusive evidence that the use of DFIO treatment facilitates primary nasolabial repair or that it provides a more esthetic outcome.^{8,9} Others have opined that in patients with unilateral complete cleft lip/palate, the combination of osseous defects in the alveolus and palate will contribute to the instability of the arch and sometimes to medial movement of the lateral lesser segments. Therefore, DFIO treatment may be less effective for the lesser segment.¹⁰ More importantly, other investigators argue that DFIO treatment impairs facial growth.^{8,9,11} Henkel stated that patients with unilateral cleft lip/palate treated with the Latham appliance and gingivoperiosteoplasty (GPP) exhibit decreased maxillary length,

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Statement of Clinical Relevance

Dentofacial infant orthopedic treatment in preadolescent patients with unilateral complete cleft lip and palate appears to be associated with shorter maxillary lengths and shorter lower anterior facial height compared with those who did not have dentofacial infant orthopedic treatment.

as well as an increased incidence of anterior open bite (vertical growth disturbance) and anterior crossbite (horizontal growth disturbance).¹¹ Berkowitz et al., although acknowledging an aesthetic benefit to using dentofacial infant orthopedic treatment, also reported a higher incidence of anterior crossbites in patients treated with the Latham device.⁹

Currently, many teams continue to use DFIO treatment, including surgically placed Latham-type appliances (e.g., the dentomaxillary appliance [DMA] for patients with unilateral complete cleft lip/palate [UCCLP] and the elastic chain premaxillary retraction appliance [ECPR] for patients with bilateral complete cleft lip/palate [BCCLP]), nasoalveolar molding appliances, and facial tapings, whereas others use passive appliances or none at all.¹² The objective of the present study is to examine the impact of DFIO (by use of surgically placed DMA and ECPR) on facial growth in preadolescent children with UCCLP and BCCLP. The present study tests the hypothesis that there could be differences in facial growth in children with UCCLP and BCCLP who underwent DFIO (DMA or ECPR) compared with those children who did not undergo DFIO.

MATERIALS AND METHODS

Institutional review board approval

The present study was approved by the Office of Clinical Investigations — Boston Children's Hospital (Institutional Review Board protocol # is M06-12-0560).

Study design

This study was designed to be a retrospective cohort study of midfacial growth in nonsyndromic patients with UCCLP and BCCLP. Inclusion criteria were patients with UCCLP or BCCLP who had a lateral cephalogram between age 7 years and the time of alveolar bone grafting. We excluded patients if they underwent prior orthodontic treatment, had no lateral cephalogram at the time of review, or were diagnosed with a syndrome. This cohort of patients had DFIO (either with DMA or ECPR) and surgical repair of the lip by the same surgeon. The control group consisted of patients who had UCCLP or BCCLP, were born before 1991, and had the same surgeon but were not treated with DFO before nasolabial repair. One dentist supervised or performed all uses of DFIO.

In 1991, the treatment protocol at our institution changed, and from then to the present, all patients with UCCLP or BCCLP were treated with preoperative DFIO initiated at 5 to 10 weeks of age (treatment group). The DFIO and non-DFIO groups underwent the same surgical procedures for cleft lip and palate repair. Patients with UCCLP were repaired in 2 stages: In the

Table I. Description of cephalometric variables

Variables	Description
Facial convexity (skeletal)	Convexity (Nasion—A point —Pogonion)
Facial convexity (soft tissue)	Subnasale—soft tissue Pogonion —Soft tissue Glabella
S-A	Distance from S to A in mm
Ba-A	Distance from Ba to A in mm
S-ANS	Distance from S to ANS in mm
Ba-ANS	Distance from Ba to ANS in mm
SNA angle	Anterior-posterior position of point A in relation to the cranial base
SNB angle	Anterior-posterior position of point B in relation to the cranial base
ANB angle	The relative position of point A and B to each other
N-ANS	Distance from N to ANS in mm
Ar-Gn	Distance from Ar to Gn in mm
ANS-PNS	Distance from ANS to PNS in mm
ANS-Me	Distance from ANS to Me in mm

S, Sella; A, A-point; Ba, Basion; ANS, anterior nasal spine; N, nasion; Ar, articulare; Gn, gnathion; Me, menton.

first stage, a labionasal adhesion was performed, followed 6 to 8 weeks later by nasolabial repair using the rotation advancement surgical technique. GPP was performed at the time of nasolabial adhesion in the DFIO group, if possible, but not in the non-DFIO group.

Facial growth

The primary outcome variable of interest was facial growth. The treatment (DFIO) and control (non-DFIO) group cohorts were followed up at Boston Children's Hospital Cleft Center on an annual basis. This patient cohort has a comprehensive set of diagnostic records just before alveolar bone grafting. As part of the comprehensive records, lateral cephalometric radiographs were exposed. The lateral cephalometric radiographs exposed just before alveolar bone grafting were used to evaluate facial growth. The cephalograms for each patient were scanned, and selected landmarks were digitized using Dolphin Imaging software (Chatsworth, CA). Reliable and reproducible landmarks were selected as described by Riolo et al., and 13 cephalometric measurements were analyzed (Table I).¹³ These linear and angular measurements were selected on the basis of the need to evaluate maxillary size and position in the sagittal plane, both vertically and horizontally; from these, an assessment of midfacial growth was made.

Analytical approach

Simple descriptive statistics were used to summarize the data. The baseline characteristics (age, gender, type of cleft lip/palate, and side of cleft lip/palate) of those

Table II. Characteristics of patients who had cleft lip and palate

Characteristic	Infant orthopedic treatment		P value*
	Did not have infant orthopedic treatment (N = 27)	Had infant orthopedic treatment (N = 54)	
Age in years at the time of exposure of lateral cephalometric radiograph			
Mean	8.69	8.54	.54
Standard deviation	1.24	.97	
25th percentile	7.79	7.78	
Median	8.81	8.54	
75th percentile	9.57	9.22	
Gender			
Female	14 (51.9%)	21 (38.9%)	.27
Male	13 (48.1%)	33 (61.1%)	
Type of cleft			
Unilateral	20 (74.1%)	37 (68.5%)	.80
Bilateral	7 (25.9%)	17 (31.5%)	
If unilateral cleft – side of cleft			
Left	13 (65%)	18 (48.6%)	.24
Right	7 (35%)	19 (51.4%)	

*Independent sample *t* test was used for comparing age, and Chi-square tests were used for comparing gender, type of cleft, and side of unilateral cleft between the two groups.

patients who had DFIO and those who did not were examined by independent sample *t* test (for age) and Chi-square tests (for gender, type of cleft, and side of cleft). Intraexaminer reliability for all the cephalometric variables examined in the present study was assessed by computing Cronbach Alpha values (intraclass correlation coefficients). Comparisons of cephalometric variables between those who had DFIO and those who did not have DFIO were computed by Man-Whitney tests (nonparametric tests were used because the data were skewed). Separate analyses were conducted for those UCCLP and BCCLP.

Multivariate linear regression models were used to examine the simultaneous association between the independent variables (age, gender, and performance of DFIO) and outcomes (different cephalometric variables for facial growth). Separate models were used for each cephalometric variable. Ordinary least-squares approach was used to fit the regression models. Estimates of change for each level of independent variables and the associated 95% confidence intervals were computed. All statistical tests of associations were 2-sided and a *P* value of < .05 was deemed to be statistically significant. All statistical analyses were conducted using SPSS Version 22.0 software (IBM Corp, New York City, NY).

RESULTS

We identified 187 consecutive patients with UCCLP and BCCLP (born between 1980 and 2000) who were treated at Boston Children’s Hospital. Of these, 106 patients were excluded due to loss of follow-up, no

Table III. Intra-examiner reliability of lateral cephalometric radiograph variables

Variable name	Cronbach Alpha values
Facial convexity NA–Apo (Pogonion)	.976
Facial convexity (soft tissue) Subnasale–soft tissue Pogonion–soft tissue Glabella	.9
Sella–A point (mm)	.999
Basion–A point (mm)	.991
Sella–ANS (mm)	.998
Basion–ANS (mm)	.976
SNA	.968
SNB	.977
ANB	.964
Upper face height (Nasion–ANS) (mm)	.966
Articulare–gnathion (mm)	.996
Maxillary length (ANS–PNS) (mm)	.954
LAFH (ANS–Menton) (mm)	.989

NA–Apo, Nasion–A point to A-point pogonion; ANS, anterior nasal spine; SNA, sella-nasion-A point; SNB, sella-nasion-B point; ANB, A point-nasion-B-point angle; PNS, posterior nasal spine; LAFH, lower anterior facial height.

cephalometric radiograph from the appropriate time point, or nondiagnostic (unreadable) radiographs due to positioning, processing, or preservation. The final sample comprised 81 patients. This included 54 who had DFIO (37 unilateral and 17 bilateral complete cleft lip/palate) and 27 (20 unilateral and 7 bilateral complete cleft lip/palate) who did not have DFIO. The characteristics of the study sample are summarized in Table II. The mean age of those who had DFIO was 8.5 years (compared with 8.7 years for those who did not have

Table IV. Lateral cephalometric measurements for patients with unilateral clefts

	Infant orthopedic treatment										P value*
	Did not have infant orthopedic treatment					Had infant orthopedic treatment					
	Mean	SD	Percentiles			Mean	SD	Percentiles			
			25	50	75			25	50	75	
Facial convexity NA–Apo (Pogonion)	4.960	9.8092	–1.000	7.000	12.400	3.083	7.9043	–3.050	2.200	8.475	.20
Facial convexity (soft tissue)	6.300	10.5471	–1.450	4.950	14.950	5.120	6.6495	.300	4.000	9.800	.46
Subnasale–soft tissue											
Pogonion–soft tissue											
Glabella											
Sella–A point (mm)	78.350	5.3947	76.050	78.600	82.025	76.144	4.8432	72.100	77.600	79.300	.20
Basion–A point (mm)	89.185	5.2570	85.200	90.000	93.100	86.863	5.0335	81.700	87.400	91.100	.13
Sella–ANS (mm)	79.360	5.4503	76.000	79.800	82.600	76.870	4.7018	73.200	78.000	80.000	.10
Basion–ANS (mm)	93.065	5.3220	89.475	94.050	96.450	90.322	4.9918	86.200	90.900	94.100	.07
SNA	79.185	4.5331	75.075	79.800	82.300	78.158	4.5535	74.825	77.500	81.000	.27
SNB	76.300	3.9656	73.000	75.250	79.800	76.203	4.1210	73.950	76.300	78.575	.92
ANB	2.890	4.6445	.200	3.600	6.125	1.953	3.4724	–.775	1.750	3.500	.17
Upper face height (Nasion–ANS) (mm)	49.270	3.1600	48.125	49.050	50.750	47.544	3.6264	45.000	47.400	50.200	.11
Articulare–gnathion (mm)	98.795	6.4456	95.150	97.750	102.750	96.504	5.1562	93.825	96.950	100.050	.35
Maxillary length (ANS–PNS) (mm)	50.505	3.1938	47.425	51.050	53.950	48.393	3.2637	46.400	48.600	51.000	.055
LAFH (ANS–Menton) (mm)	62.170	4.3132	59.100	61.300	65.075	59.781	4.5135	56.800	60.900	62.800	.15

NA–Apo, Nasion–A point to A-point pogonion; ANS, anterior nasal spine; SNA, sella-nasion-A point; SNB, sella-nasion-B point angle; ANB, A point-nasion-B point angle; PNS, posterior nasal spine; LAFH, lower anterior facial height.

*Mann-Whitney U test.

DFIO). Males comprised the majority of patients (61.1%) who had DFIO, whereas females comprised the majority of patients who did not have DFIO. Overall, there were no statistically significant differences in distribution of age, gender, type of cleft, and side of cleft (for patients with unilateral cleft lip/palate).

A total of 13 different cephalometric variables were examined in the present study. The Cronbach Alpha values (intraclass correlation coefficients) assessing the intraexaminer reliability for the cephalometric variables are presented in Table III. All the cephalometric variables had high internal consistency (intraexaminer reliability) as indicated by the Cronbach Alpha values (≥ 0.9 for all cephalometric variables).

The distributions of the lateral cephalometric measurements for those with unilateral complete cleft lip/palate (by DFIO) are summarized in Table IV. For all 13 examined cephalometric variables, those who did not have DFIO had higher values compared with those who had DFIO. However, none of these variables was statistically significant (as indicated by the Mann-Whitney tests).

The results of the multivariable linear regression analyses examining the effects of DFIO treatment in those with unilateral complete cleft lip/palate following adjustment for the effects of age and gender are summarized in Table V. Estimates from the multivariable

linear regression models indicated that following adjustment for age and gender, those who had DFIO had a shorter maxillary length (-2.12 mm; 95% CI = -4.12 to -0.12 ; $P = .04$) and shorter lower anterior facial height (-2.77 mm; 95% CI = -5.42 to -0.12 ; $P = .04$) compared with those who did not have DFIO.

The distributions of the lateral cephalometric measurements for those with bilateral complete cleft lip/palate (by DFIO) are summarized in Table VI. The mean values for facial convexity (soft tissue), sella–nasion–B angle, upper face height, articulare–gnathion distance, and lower anterior facial height were higher for those who did not have DFIO treatment, whereas the rest of cephalometric variables had higher mean values for those who had DFIO treatment. However, none of these cephalometric variables was statistically significantly different between these two groups (as indicated by the Mann-Whitney tests).

The results of the multivariable linear regression analyses examining the effects of DFIO treatment in those with bilateral complete cleft lip/palate following adjustment for the effects of age and gender are summarized in Table VII. Estimates from these models indicated that following adjustment for age and gender, there were no significant differences between those who had DFIO and those who did not have DFIO treatment in the patients with BCCLP.

Table V. Effects of infant orthopedic treatment on cephalometric measurements after adjustment for age and sex in patients with unilateral clefts: Summary of estimates from multivariable linear regression analysis)

Variables	Age (1 unit increase)	Males	Had infant orthopedic treatment
Facial convexity NA–Apo			
Estimate (95% CI)	-.062 (-2.45 to 2.32)	-2.52 (-7.58 to 2.53)	-1.65 (-6.55 to 3.25)
P value	.96	.32	.50
Facial convexity (soft tissue)			
Estimate (95% CI)	-.532 (-2.84 to 1.78)	-.097 (-5.01 to 4.81)	-1.038 (-5.80 to 3.72)
P value	.64	.97	.66
Sella–A point			
Estimate (95% CI)	.006 (-1.50 to 1.51)	1.56 (-1.70 to 4.81)	-2.35 (-5.45 to .75)
P value	.99	.34	.13
Basion–A point			
Estimate (95% CI)	-.545 (-2.07 to .98)	.266 (-3.04 to 3.57)	-2.143 (-5.29 to 1.01)
P value	.48	.87	.18
Sella–ANS			
Estimate (95% CI)	.064 (-1.43 to 1.56)	1.261 (-1.97 to 4.49)	-2.63 (-5.71 to .45)
P value	.93	.44	.09
Basion–ANS			
Estimate (95% CI)	-.371 (-1.91 to 1.16)	.035 (-3.28 to 3.35)	-2.61 (-5.77 to .56)
P value	.63	.98	.10
SNA			
Estimate (95% CI)	-.335 (-1.60 to .93)	0.139 (-2.55 to 2.83)	-0.948 (-3.55 to 1.66)
P value	.60	.92	.47
SNB			
Estimate (95% CI)	-.195 (-1.32 to .93)	1.246 (-1.14 to 3.63)	-.149 (-2.46 to 2.16)
P value	.73	.30	.90
ANB			
Estimate (95% CI)	-.137 (-1.22 to .95)	-1.12 (-3.41 to 1.18)	-.807 (-3.03 to 1.42)
P value	.80	.33	.47
Upper face height			
Estimate (95% CI)	.278 (-.74 to 1.30)	-.852 (-3.06 to 1.36)	-1.751 (-3.86 to .36)
P value	.59	.44	.10
Articulare–gnathion			
Estimate (95% CI)	.402 (-1.22 to 2.02)	3.10 (-.39 to 6.59)	-2.766 (-6.10 to 0.57)
P value	.62	.08	.10
Maxillary length			
Estimate (95% CI)	-.02 (-.99 to .95)	.133 (-1.96 to 2.23)	-2.12 (-4.12 to -.12)
P value	.97	.90	.04
LAFH			
Estimate (95% CI)	.823 (-.46 to 2.11)	.779 (-2.00 to 3.56)	-2.77 (-5.42 to -.12)
P value	.20	.57	.04

NA–Apo, Nasion–A point to A-point pogonion; ANS, anterior nasal spine; SNA, sella-nasion-A point angle; SNB, sella-nasion-B point angle; ANB, A point-nasion-b point angle; LAFH, lower anterior facial height.

DISCUSSION

The present study was a retrospective cohort study of the impact of DFIO before surgical repairs on preadolescent facial growth in patients with UCCLP and BCCLP. Patients were not selected for the DFIO cohort; rather, this treatment modality was introduced into the protocol in 1991 at the request of the surgical leadership. Since that time, all patients with complete cleft of the lip and palate have undergone DFIO and alveolar GPP whenever possible, depending on the post-DFIO proximity of the cleft segments. We compared children treated with the pre-1991 protocol with those who underwent DFIO in the post-1991 protocol. The results of this study suggest that among patients with UCCLP, those in the DFIO group have

shorter maxillary lengths (2.12 mm short) and shorter lower anterior facial height (2.77 mm shorter) compared with those who did not have DFIO. Among patients with BCCLP, there were no significant differences between those who had DFIO and those who did not have DFIO treatment.

We found a decreased maxillary length in UCCLP children treated with DFIO; however, the clinical significance of this finding may be questionable. It should be interpreted with caution because the horizontal location of the landmark posterior nasal spine on a cephalogram can be difficult to locate in patients with a cleft palate, particularly if the posterior nasal spine is absent or obscured by the shadow of the second molar. Performance of GPP is also a possible confounding

Table VI. Lateral cephalometric measurements for patients with bilateral clefts

Cephalometric variables	Infant orthopedic treatment										P value*
	Did not have infant orthopedic treatment					Had infant orthopedic treatment					
	Mean	SD	Percentiles			Mean	SD	Percentiles			
			25	50	75			25	50	75	
Facial convexity NA—Apo (Pogonion)	7.914	6.9808	1.800	6.600	12.000	9.381	8.3498	3.375	8.100	16.850	.74
Facial convexity (soft tissue)	9.686	7.1971	8.100	11.000	13.500	7.864	6.5893	3.275	7.400	10.075	.16
Subnasale—soft tissue Pogonion—Soft tissue Glabella											
Sella—A point (mm)	79.671	6.2083	75.300	76.500	87.200	82.900	3.3882	81.000	83.900	84.900	.16
Basion—A point (mm)	88.329	7.4442	80.000	88.400	96.200	93.467	4.9888	90.100	93.400	97.400	.08
Sella—ANS (mm)	80.971	6.6668	75.900	78.100	87.900	83.520	3.5045	82.300	83.300	85.700	.19
Basion—ANS (mm)	92.529	8.0618	84.700	91.200	100.200	97.413	5.2070	93.000	98.500	100.800	.15
SNA	79.200	5.7680	75.800	77.600	81.100	79.488	5.0475	74.425	80.050	83.525	.64
SNB	75.271	4.4184	70.900	76.600	79.500	74.506	3.9132	70.850	75.200	76.350	.50
ANB	3.914	3.5503	.900	3.300	6.600	5.100	3.8273	2.225	4.450	7.775	.46
Upper face height (Nasion—ANS) (mm)	51.157	1.9789	50.200	51.200	52.400	50.987	3.3643	49.200	51.000	54.100	.89
Articulare—gnathion (mm)	98.786	6.6271	93.400	98.100	103.000	98.013	4.9206	94.625	96.250	101.450	.64
Maxillary length (ANS—PNS) (mm)	51.471	5.7844	48.100	49.100	58.200	53.193	3.7465	51.400	53.800	56.700	.27
LAFH (ANS—Menton) (mm)	65.071	6.4856	60.600	63.500	70.200	63.287	3.3168	60.600	62.500	65.700	.83

NA—Apo, Nasion—A point to A-point pogonion; ANS, anterior nasal spine; SNA, sella-nasion-A point angle; SNB, sella-nasion-B point angle; ANB, A point-nasion-B point angle; PNS, posterior nasal spine; LAFH, lower anterior facial height.

*Mann—Whitney U test.

factor; at our institution, it has been done in all patients in whom we could achieve close approximation of the cleft segments. Width of the residual cleft and position of the premaxilla after orthopedics were some of the determining factors in the decision to perform GPP.

It is difficult to directly compare the present study results with those from prior studies because of differences in protocol.^{9,11,14-16} The effects of GPP on facial growth are unclear; some authors have reported no significant effects, and others have documented a negative influence.^{14,16} In a 2008 study, patients who underwent GPP after alveolar molding with a pin-retained Latham appliance in infancy showed decreased maxillary protrusion and height compared with those who had not undergone GPP.¹⁴ This report, however, may not be comparable with our study because of a difference in age at follow-up and the number of surgeons involved.

The controversy surrounding active infant orthopedics revolves around whether or not it has a detrimental effect on facial growth. The findings in this study are in agreement with previous reports showing no effects on facial convexity in preadolescent children treated with the Latham appliance.¹⁷⁻¹⁹ Bitter followed up patients longitudinally and found no deviation from a normal maxillary growth pattern in patients with bilateral cleft lip and palate.^{18,19} Chan et al. found no occlusal evidence of negative effects on maxillary growth in patients with unilateral complete cleft lip and palate.²⁰

There are, however, reports that have suggested disturbances in facial growth after the use of the Latham appliances.^{9,11} Henkel examined the relationship of upper jaw length to skull base length and observed significantly shorter maxillary lengths in patients who underwent DFIO, GPP, and nasolabial repair.¹¹ Consistent with this finding, in the present study, we also observed significantly shorter maxillary lengths and lower anterior facial heights. When the variable of surgical skill and experience is considered, it becomes challenging to isolate and compare the effects of DFIO.^{7,17} In the present study, a single surgeon performed all nasolabial adhesions/repairs, and thus it is not subject to operator bias. However, one should not discount the effects of clustering of outcomes with one the surgeon.

The present study has several limitations, which should be kept in perspective while interpreting the results and conclusions. As mentioned earlier, this study was a retrospective cohort analysis. The nature of the study design precluded us from establishing a definitive cause-and-effect relationship between the DFIO treatment and preadolescent facial growth. Consequently, the estimates presented in this study are only associations. The study evaluated preadolescent facial growth based on lateral cephalometric radiographs exposed before alveolar bone grafting. The long-term impact of DFIO on facial growth and need for possible orthognathic surgeries in this cohort were not evaluated. It is likely that

Table VII. Effects of infant orthopedic treatment on cephalometric measurements following adjustment for age and sex in patients with bilateral clefts: Summary of estimates from multivariable linear regression analysis

Variables	Age (1 unit increase)	Males	Had infant orthopedic treatment
Facial convexity NA–Apo			
Estimate (95% CI)	.057 (–4.05 to 4.17)	–3.026 (–10.78 to 4.72)	2.130 (–7.47 to 11.73)
P value	.98	.42	.65
Facial convexity (soft tissue)			
Estimate (95% CI)	1.820 (–1.54 to 5.18)	–4.917 (–11.72 to 1.88)	1.645 (–6.37 to 9.66)
P value	.27	.14	.67
Sella–A point			
Estimate (95% CI)	.175 (–2.19 to 2.54)	–.249 (–4.77 to 4.27)	3.486 (–1.99 to 8.96)
P value	.88	.91	.2
Basion–A point			
Estimate (95% CI)	–.07 (–3.18 to 3.04)	.560 (–5.39 to 6.51)	4.925 (–2.29 to 12.14)
P value	.96	.85	.17
Sella–ANS			
Estimate (95% CI)	.143 (–2.36 to 2.64)	–.055 (–4.84 to 4.73)	2.72 (–3.07 to 8.52)
P value	.91	.98	.34
Basion–ANS			
Estimate (95% CI)	–.106 (–3.40 to 3.19)	1.159 (–5.15 to 7.47)	4.489 (–3.15 to 12.13)
P value	.95	.70	.23
SNA			
Estimate (95% CI)	–1.082 (–3.76 to 1.59)	–.979 (–6.03 to 4.07)	–.817 (–7.07 to 5.44)
P value	.41	.69	.79
SNB			
Estimate (95% CI)	–1.282 (–3.27 to .71)	.060 (–3.68 to 3.79)	–2.356 (–7.08 to 2.36)
P value	.19	.97	.31
ANB			
Estimate (95% CI)	.146 (–1.81 to 2.10)	–.953 (–4.63 to 2.73)	1.548 (–3.01 to 6.11)
P value	.88	.59	.49
Upper face height			
Estimate (95% CI)	.632 (–.92 to 2.18)	.864 (–2.10 to 3.82)	.341 (–3.25 to 3.93)
P value	.4	.55	.84
Articulare–gnathion			
Estimate (95% CI)	1.06 (–1.66 to 3.79)	2.12 (–3.09 to 7.33)	–.076 (–6.49 to 6.34)
P value	.42	.40	.98
Maxillary length			
Estimate (95% CI)	–1.13 (–3.44 to 1.18)	.061 (–4.36 to 4.48)	.428 (–4.92 to 5.78)
P value	.32	.98	.87
LAFH			
Estimate (95% CI)	1.258 (–1.06 to 3.57)	.186 (–4.24 to 4.61)	–.403 (–5.77 to 4.96)
P value	.27	.93	.88

NA–Apo, Nasion–A point to A-point pogonion; ANS, anterior nasal spine; SNA, sella-nasion-A point angle; SNB, sella-nasion-B point angle; ANB, A point-nasion-B point angle; LAFH, lower anterior facial height.

the DFIO group continued to exhibit shorter maxillary lengths and lower anterior facial heights. At the present time, we are conducting a historical cohort longitudinal study to examine this effect.

The limited sample size we used could have precluded us from establishing statistically significant differences in facial growth variables between the DFIO and non-DFIO groups. It should be kept in perspective that the numbers of patients with cleft lip/palate that present and can be longitudinally followed up for a considerable period at a single center is usually few in number, and despite our best efforts, we could not include a larger number of patients who met all our

inclusion criteria. It is inevitable that some patients are lost to follow-up.

Finally, the present study presents results from a single center. Consequently, the external validity of the study findings is questionable, and an effort to generalize conclusions based on these results is limited. To address this issue, centers using similar protocols need to collaborate on multicenter studies to examine the long-term impact and efficacy of DFIO on multiple outcome measures. This would make the results more generalizable and would also minimize the effects of clustering of outcomes within the centers. This should be the focus of future efforts.

CONCLUSIONS

Results from this study suggest that among preadolescent patients with UCCLP, those who underwent DFIO have shorter maxillary lengths and shorter lower anterior facial height compared with those who did not have DFIO treatment. In patients with BCCLP, there were no significant differences between those who had DFIO and those who did not have DFIO treatment.

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