




3D Assessment of the Correlation between Neonatal Morphology and Occlusal Outcomes in 5-Year-Old Patients with Complete Unilateral Cleft Lip and Palate

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ABSTRACT

Objective: To exploit 3D measurement technology to determine any correlation between neonatal palate morphology and occlusal outcomes at five years in patients receiving surgery for unilateral cleft lip and palate (CLP). **Material and Methods:** Twenty-nine neonatal and 5-year models treated by the same surgeon using the same protocol for CLP correction were scanned using a high-resolution structured-light scanner and stored in stl format. Dedicated software was used to make linear and surface area measurements on the neonatal models, and each digitized 5-year model was assigned a Five-Year-Old (5YO) index score on three separate occasions by the same investigator. **Results:** Minimum, maximum, mean, standard deviation and standard error were calculated for each variable considered, and the Pearson coefficient was used to identify any correlations between neonatal variables and 5YO scores. Linear regression analysis showed that the only variable to approach significance was the posterior width of the cleft, which showed an R^2 equal to 0.111, indicating that it accounts for 11% of the variability of the 5YO index. There was no other appreciable correlation between linear measurements, surface areas, or their inter-relationships. **Conclusion:** There is no correlation between neonatal morphological characteristics and occlusal outcomes at 5 years in CLP patients treated via the surgical protocol considered.

Keywords: Jaw Abnormalities; Orthodontics; Child; Palate.

Introduction

In patients with cleft lip and palate (CLP), its width at birth and the extent of the tissue defect are factors that influence the surgical difficulties and, therefore, indirectly, the results of corrective surgery. Indeed, a wider cleft may require greater displacement of the palatal mucoperiosteal tissue. The more tissue involved, the greater the degree of scarring, and the more the palate narrows consequently.

Maxillary growth in patients with CLP has been investigated by numerous authors, and Liao and Mars [1] have published two reviews, both of which have highlighted that if left untreated during infancy, the upper jaw growth of individuals with CLP is normal, or even protrusive. This is because the maxilla is subject to both the centripetal force exerted by the upper lip [2] and the centrifugal force exerted by the tongue, which pushes the anterior sector forward during speech and swallowing. Hence, post-surgical contraction at the site of CLP repair may be the first link in a chain of events leading to secondary skeletal deformities in these patients.

Indeed, during wound closure, the palate undergoes contraction on all spatial planes, causing skeletal retrusion of the upper jaw, anterior and posterior transverse deficiency, and reduced vertical growth associated with changes in the direction of mandibular growth [3,4]. Upper jaw hypoplasia and the resulting tendency towards skeletal class III have long been the subject of debate [5-10] and have inspired numerous treatment protocols - EUROCLEFT [11]. However, despite efforts to standardize treatment, the great variability in the initial dimensions of the cleft and the resulting scarring after surgery means that there is similarly great variability in surgical outcomes, even in patients treated via the same protocol. Further complications arise from the reduced maxillary growth in patients with complete, as opposed to partial, CLP [3]. Therefore, it appears that the severity of the initial cleft may impact maxillary growth, and it is vital to evaluate morphological features and relationships at birth to assess their potential impact on surgical outcomes [12,13].

Several indices have been proposed for the categorization of inter-arch relationships in newborns with CLP, but the most often used to evaluate these patients today is the Goslon Yardstick [14,15]. This, however, is applied when patients have reached 9 years of age when skeletal issues are manifest. To investigate the same relationships in younger patients with deciduous dentition, in 1997, the Five-Year-Old Index (Figure 1 a-i) was proposed [16,17].

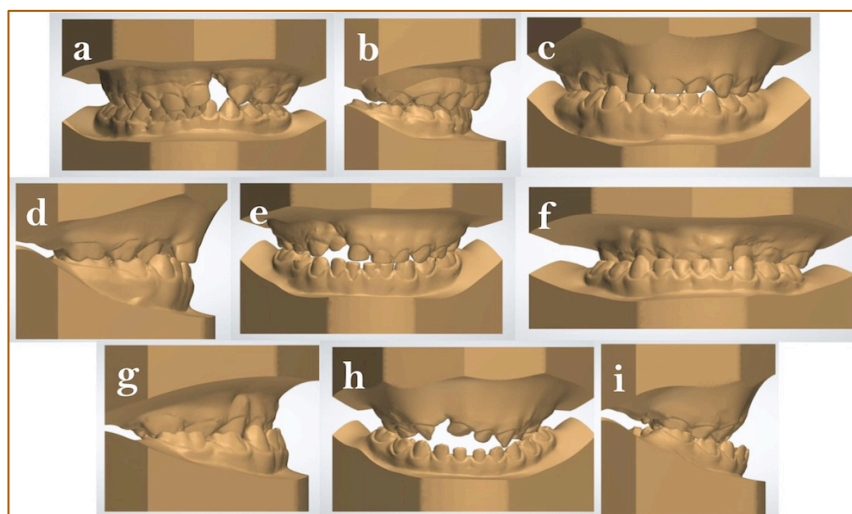


Figure 1. Graphical representation of 5-year-old index scores in frontal and lateral views.

The idea behind this index was to determine whether or not the outcomes of primary surgery could be predicted from occlusion models of patients taken at five years of age (+ or – 1 year).

When seeking to investigate possible relationships between the pathological picture at birth and the outcomes at five years, it is essential to adhere to a very rigorous scientific protocol with extremely precise measurement methods. However, most studies to date have relied on a variety of measurement methods involving 2D and 3D radiographs [18,19], manual or digital measurements on plaster casts, and microscopy. More recently, complex techniques such as stereophotogrammetry [20] have also been attempted. Nowadays, however, there is a consensus in the literature that 3D digital models are among the most reliable in comparing linear and superficial measurements. Furthermore, the use of 3D models to calculate the Five-Year-Old (5YO) index in patients with unilateral CLP has already been validated as reliable and reproducible [21]. Hence, this study aimed to exploit the advantages of 3D technology to determine whether there is any correlation between neonatal morphology and surgical outcomes at 5 years in a sample of patients with CLP who underwent the same treatment protocol.

Material and Methods

Study Design and Sample

In this retrospective study, samples were taken from among the plaster casts conserved at Vicenza Hospital, Italy – the regional center for diagnosing and treating craniofacial malformations. Selection criteria were as follows: non-syndromic complete unilateral CLP, Caucasian race, availability of both neonatal and 5-year (+ or – 6 months) plaster models (Figure 2).

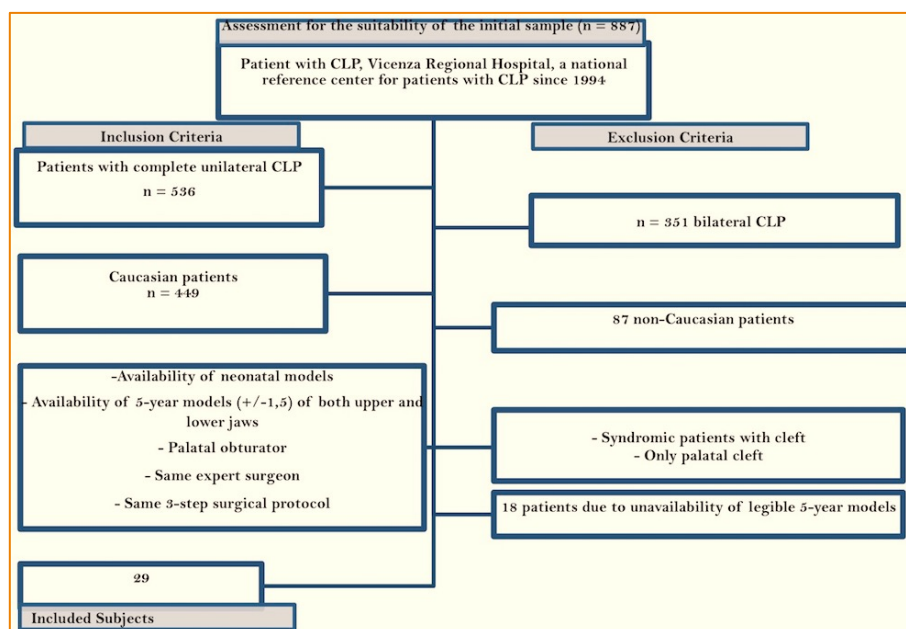


Figure 2. Flow diagram of selection process for study sample.

All patients had undergone the same treatment protocol involving passive palatal plate, soft palate repair at 3 months, rhinocheiloplasty at 6–9 months, hard palate repair at 18–24 months, and secondary graft at 9–11 years. All patients were treated by the same expert surgeon (roughly 200 cleft repairs in 2014). A power and sample size calculation was done: fixing the type I error to 5% for a two-tail Fisher’s Z

Transformation test and the type II error rate to 20% (power of 80), the total number of patients needed is 25. The criteria used led to the selection of 29 patients, each assigned a unique identification number [17]. Both neonatal and 5-year models were scanned using a high-resolution structured-light 3D scanner (Open Technology) and images were acquired in .stl format. Each digital 5-year model was assigned a 5YO index score by a fully trained investigator. 5YO assessments were performed three times by the same investigator at intervals of one week. Linear and surface area measurements of each digital neonatal model were performed by a sole investigator using dedicated software [17]. All points localization and measurements were repeated one month later by the same investigator under the same conditions. The means of each two sets of measurements were considered in the subsequent statistical analyses. Reference point identification and linear measurements were performed using 3Shape software (Copenhagen, Denmark), and the reference points identified are shown in Figure 3 and explained in Table 1 [22,23].

Table 1. Reference points used for measurements in horizontal projection of a neonatal digital model.

Point	Description
G	Most anterior point of Segment A
L	Most anterior point of Segment B
I	Intersection between anterior labial frenulum extension and the alveolar crest
C	Intersection between lateral labial frenulum extension and the alveolar crest
M	The point on the alveolar crest at the widest portion of the jaw
T	The junction between the maxillary tuberosity and alveolar crest
c	Intersection between C–C' and the lateral cleft margins
t	Intersection between T–T' and the lateral cleft margins
m	Intersection between M–M' and the lateral cleft margins

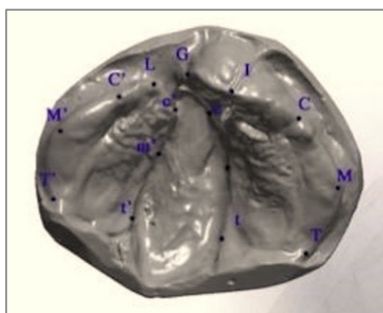


Figure 3. Horizontal projection of a neonatal digital model showing reference points used for measurements.

On the neonatal digital models, linear measurements were made (Table 2) with the model positioned in horizontal view and based on a virtual horizontal line tangential to the marginal crest through the most prominent (vertical) points (Figure 4).

Table 2. Linear distance measured on the digital neonatal model.

Points	Measures
G–L	Anterior Width of Cleft
t–t'	Posterior Width of Cleft
M–m'	Median Width of Cleft
c–c'	Width of Cleft at Inter-Canine Distance
T–T'	Posterior Width of Palate
M–M'	Central Width of Palate
C–C'	Anterior Width of Palate

I-G	Length of Anterior Crest, Segment A
I-C	Length of Anterior Crest, Segment A
L-C'	Length of Anterior Crest, Segment B
C-M	Length of Medial Crest, Segment A
C'-M'	Length of Medial Crest, Segment B
M-T	Length of Posterior Crest, Segment A
M'-T'	Length of Posterior Crest, Segment B
I perp T-T'	Length of Palate
G perp T-T'	Length of Palate

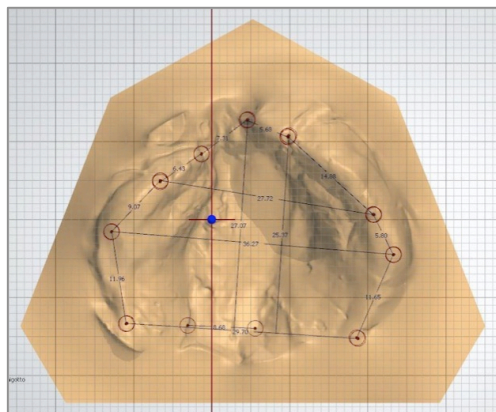


Figure 4. Horizontal view of digital neonatal model showing the linear distances measured.

Surface area measurements were performed using Rhinoceros software (Seattle, Washington, USA). In particular, the 3D rendering of the palate was divided into a larger segment (a) without the cleft and a smaller segment (b) affected by the cleft. The limits of the palate were considered the vestibular sulcus (deepest), the medial edge of the cleft (medial), the line uniting the two maxillary tuberosities (posterior, T-T'), and the line between the lateral and medial vestibular limits (anterior) (Figure 5 a-b and Figure 6 a-b). Cleft limits were considered as the borders of each maxillary segment (medial), the line uniting the terminal points of the two alveolar crests (anterior), and the line uniting the two maxillary tuberosities (posterior, t-t') (Figure 7 a-b and Figure 8 a-b). Once the limits of the palate (Segments A and B) and the cleft had been defined, the areas of both were calculated. The two sets of imaging data (neonatal and 5YO scores) were then subjected to correlation analysis, as reported in Table 3.

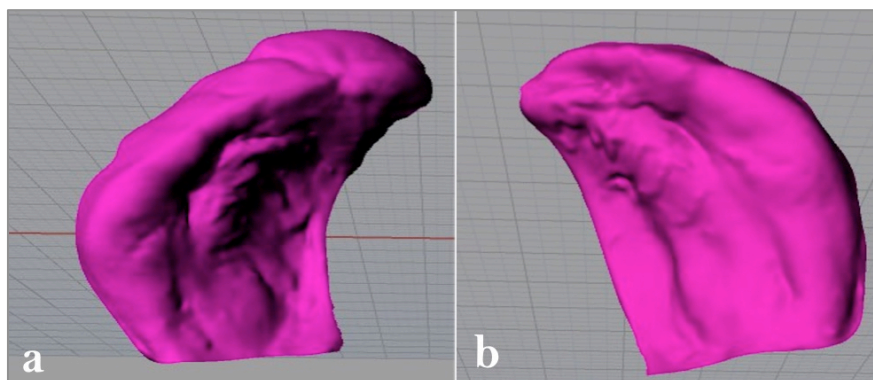


Figure 5. The larger (a) and smaller (b) segments of the cleft palate seen from a horizontal view.

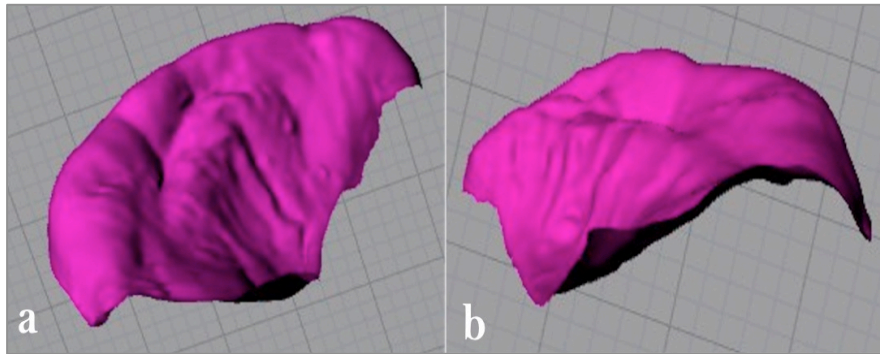


Figure 6. The larger (a) and smaller (b) segments of the cleft palate seen from a posterior view.

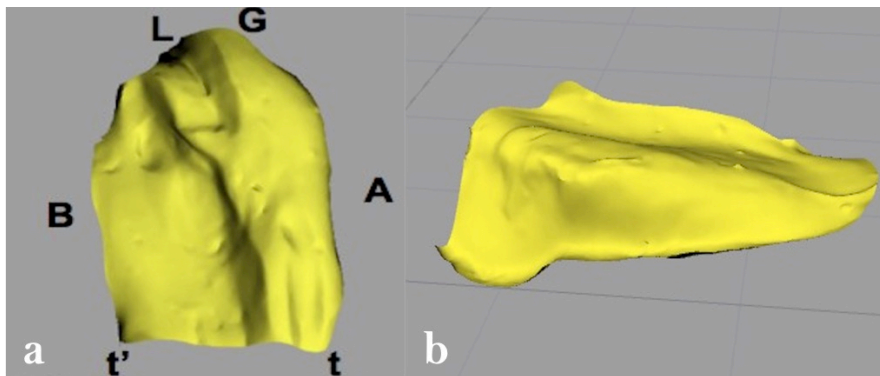


Figure 7. (a) The anterior (L-G), lateral (segment A, segment B) and posterior (T'-T) limits of the cleft; (b) Lateral view.

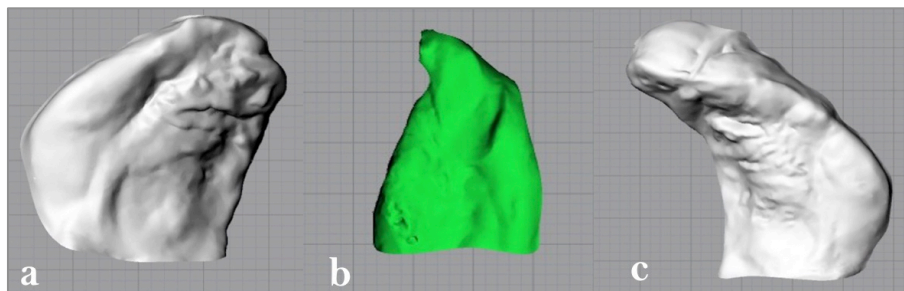


Figure 8. Representation of the three segments considered in patients with CLP: (a) Lower segment; (b) Cleft; and (c) Upper healthy segment.

Table 3. Surface area measurements.

Surface	Measures
GL / Palate Area	Relationship between anterior cleft width and area of palate
GL / Cleft Area	Relationship between anterior cleft width and area of cleft
GL / P	Relationship between anterior cleft width and maxillary perimeter
GL / GperpTT'	Relationship between anterior cleft width and length of palate
GL / IperpTT'	Relationship between anterior cleft width and length of palate (calculated from point I)
Cleft area / Palate area	Relationship between cleft area and palate area
t -t' / Palate area	Relationship between posterior cleft width and area of palate
t-t' / Cleft area	Relationship between posterior cleft width and area of cleft
GperpTT' / Palate Area	Relationship between palate length and palate area

IperpTT' / Palate Area	Relationship between palate length and palate area
GperpTT' / Cleft Area	Relationship between palate length and cleft area
IperpTT' / Cleft Area	Relationship between palate length and cleft area (calculated from point I)
P / Cleft Area	Relationship between palate perimeter and cleft area
P / Palate Area	Relationship between palate perimeter and palate area
Area B/ Palate Area	Relationship between area of segment B and palate area
Area A / Palate Area*	Relationship between area of segment A and palate area.

*A statistical investigation was performed to determine any correlations between the 5YO index and these relationships, G-L, t-t', and G-L/P, to evaluate any links between neonatal variables and 5-year occlusal outcomes, and consequently prognosis.

Data Analysis

All statistical analyses were performed using SPSS 17.0 software (IBM SPSS Inc., Armonk, NY, USA). The minimum, maximum, mean, standard deviation and standard error were calculated for each studied variable. 5YO and neonatal values were compared using the Pearson correlation coefficient (values between -1 and +1); in this test, a value of 0 indicates no correlation, < 0 a negative correlation, and > 0 a positive correlation. The sample's 5YO index distribution was comparable to those of other inter-centric study samples and, therefore, considered suitable for the planned correlation analysis [14,17]. Simple linear regression analysis was performed, taking the 5YO score as a dependent variable and the t-t' (posterior cleft width) as the independent variable (predictor). The aim was to calculate the extent to which the variance in the dependent variable was accounted for (i.e., predicted) by the independent variable. Significance values of $p < 0.05$ were considered statistically significant.

Ethical Clearance

The study was approved by the ethics committee of Postgraduate School of Orthodontics in Ferrara (approval number 15/2016). Informed consent on the treatment plan signed by parents was collected for all patients and then kept in the Vicenza Hospital's archive.

Results

Correlations between neonatal and 5YO models were calculated for 20 variables (Table 4): two linear, the anterior and posterior width of cleft (GL and t-t', respectively); two surface areas (of the cleft and palate); and 16 representing relationships between distance and area measurements, or among area measurements. The mean 5YO index value was 3. As shown in Table 5, there was no significant relationship detected, and the only relationship that tended towards significance was the t-t' variable (posterior cleft width) ($p = 0.078$).

Table 4. Descriptive statistics for each variable investigated (all linear measurements in mm and surface areas in mm²).

Variables	N	Minimum	Maximum	Mean	Std. Error	Std. Deviation
5 year index	29	1.00	5.00	3.0000	0.23278	1.25357
G_Lmean	29	1.20	15.40	9.5534	0.85136	4.58474
t_tmean	29	7.45	16.60	12.5190	0.46816	2.52114
area_cleft	29	116.00	605.80	353.2793	20.03030	107.86645
area_palate	29	931.20	1378.80	1103.0862	23.00999	123.91257
GL_areapalate	29	0.0011	0.0160	0.008834	0.0008398	0.0045224
GL_areacleft	29	0.0074	0.0420	0.025783	0.0018835	0.0101429
GL_P	29	0.0150	0.1961	0.115352	0.0107099	0.0576747
GL_GperpTT	29	0.0545	0.6162	0.367762	0.0320814	0.1727637
GL_IperpTT	29	0.0539	0.6848	0.390914	0.0360618	0.1941988
tt_area palate	29	0.0065	0.0162	0.011503	0.0005056	0.0027230

tt_area cleft	29	0.0244	0.0767	0.038324	0.0022303	0.0120105
area cleft_area palate	29	0.0841	0.5073	0.322528	0.0177994	0.0958529
GperpTT_area palate	29	0.0156	0.0291	0.023259	0.0005616	0.0030244
IperpTT_areapalate	29	0.0184	0.0269	0.022383	0.0003794	0.0020429
P_areacleft	29	0.1429	0.7496	0.272007	0.0253507	0.1365176
P_areapalate	29	0.0631	0.0927	0.076448	0.0011952	0.0064365
areaB_areapalate	29	0.3363	0.4274	0.380793	0.0050623	0.0272616
areaA_areapalate	29	0.5726	0.6637	0.619207	0.0050623	0.0272616
GperpTT_areacleft	29	0.0390	0.1849	0.080155	0.0057981	0.0312237
IperpTT_areaschisi	29	0.0405	0.2185	0.079076	0.0070783	0.0381179
Valid N (listwise)	29					

Table 5. Correlations tending towards significance.

Variables		5-year-old index
5YO index	Pearson Correlation	1
	Sig.	
G-Lmean	Pearson Correlation	0.037
	Sig.	0.850
T-t'mean	Pearson Correlation	0.333
	Sig.	0.078
Cleft area	Pearson Correlation	0.149
	Sig.	0.442
	N	29

Simple linear regression analysis (Table 6) was performed taking the 5YO score (dependent variable) and the t-t' (posterior cleft width) as the independent variable. A correlation coefficient of 0.333 expresses a positive relationship between the two variables; as the value of one variable increases so does the other. No other relationships were found to be significant. Linear regression analysis (Table 6) showed an R² for t-t' of 0.111, which indicates that the 11% of the variability in 5YO index was explained by the variability in the posterior width of the cleft (Figure 9).

Table 6. Linear regression.

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	Change Statistics			Sig. F Change
						F Change	df1	df2	
1	0.333 ^a	0.111	0.078	1.204	0.111	3.363	1	27	0.078

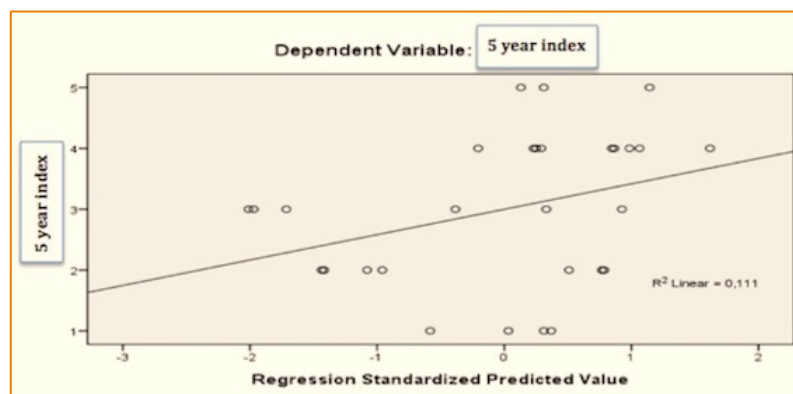


Figure 9. Scatter plot showing the regression line.

Discussion

Evidence-based information regarding the relationship between neonatal morphological characteristics of CLP patients and surgical outcomes would enable surgery to be better targeted and more predictable.

Multiple factors are whispered to be crucial cause of unfavorable dental arch relationship in cleft lip and palate (CLP): Haque et al. [24] suggested that family history of skeletal class III was significantly correlated with unfavourable dental arch relationship of Bangladeshi UCLP children. Moreover, by literature survey, the incidence of certain dental anomalies is strongly correlated with Cleft lip [25]. Therefore, predicting surgical outcomes as early as five years of age would allow procedures and variables that may compromise aesthetic outcomes in adulthood to be avoided. Furthermore, 5-year assessment of outcomes of primary surgery – before secondary procedures or orthodontic treatment has been initiated [26,27] – enables surgical outcomes to be evaluated in their ‘purest’ state, without the interference of such variables, which may affect results [28,29]. Moreover, as the genetic predisposition for skeletal growth patterns is not fully expressed until puberty, the influence of genetics is minimal at five years of age [30].

In this regard, our sample displayed a 5YO index distribution in line with the data reported in the literature. In particular, 41% of patients presented a greater 5YO score, indicating greater severity of the defect. Thus, even though the 3D technology we exploited enabled more precise calculation of distances and volumes than traditional methods, our measurements were also largely in agreement with those previously reported [21].

Based on these measurements, we found no particular correlation between neonatal variables and the occlusal outcomes at five years. The only variable that approached the significance was the t–t’ distance, i.e., the posterior width of the cleft, measured on the line between the two maxillary tuberosities ($p=0.078$). It may be that with a larger sample, this value could reach significance. That being said, these findings do reflect those in the greater part of the literature, as only Chiu et al. [31] have found a correlation, reporting that the cleft area has an effect on maxillary protrusion. Specifically, they found that maxillary protrusion is correlated with a smaller cleft area, while the width of the maxilla depends not on the cleft but on the palatal area. Nevertheless, their conclusion that the size of the cleft can predict the post-growth outcomes appears to contrast with our results

As mentioned, one of the strengths of our study concerning those previously published was the level of calculation precision afforded by the 3D technology we employed. Indeed, the software we used enabled each model to be rotated in the three spatial planes, rather than relying on the 2D plane alone used for measurement in other studies [20,32]. In fact, the limits of the palate can only be reliably traced accurately by stepwise rotation of the 3D model, as described by Chiu et al. [31]. The reliability of our findings is also bolstered by the method we used to calculate surface area; once again, thanks to the use of 3D technology, we did not have to rely on a single plane, but could instead measure in three dimensions, enabling us to calculate the real surface area of the palate, rather than a 2D projection of the same. Accordingly, our surface area figures were generally higher than those in the literature [30] ($1103.08 \pm 123.91 \text{ mm}^2$ vs. $131.75 \pm 46.45 \text{ mm}^2$). This comparison confirms that a 2D analysis of 3D anatomical morphology may lead to a considerable underestimation, especially if palatal segments are inclined [20,33,34].

What is more, we also took into consideration the depth of the cleft, which also influences its total area, as the deeper the cleft, the greater the surface area in the three spatial planes. Nonetheless, it is worth bearing in mind that the literature has not yet defined the vertical limit of the cleft, as it connects the oral and







nasal cavities, interrupting its floor. In theory, therefore, the cleft may reach the roof of the nasal cavity, even though this tissue is whole and undamaged. A valuation made on the models makes it impossible to reach the right height because the maximum height that can be estimated is that given by the depth at which the impression material is pushed upward during the takeover.

Unfortunately, the absence of correlations between neonatal and 5YO linear and surface area measurements does not allow us to contribute in any meaningful way to the debate on surgical times and techniques in CLP. However, as the severity in our neonatal sample did not correspond to the occlusal outcome at five years, it is important to note that our data appear to suggest that the primary CLP surgery protocol applied may correct the initial defect entirely satisfactorily.

Conclusion

There is no significant correlation between neonatal morphology and 5YO occlusal outcomes regarding the linear and surface area measurements we considered and correlated in CLP patients. Therefore, we may conclude that the initial variability in the defect and the degree of post-surgical scarring have a decisive influence on the occlusal outcomes of any surgical protocol.

Authors' Contributions

FC		https://orcid.org/0000-0002-4641-2196	Conceptualization, Methodology, Formal Analysis, Investigation, Writing - Original Draft, Writing - Review and Editing.
MC		---	Methodology, Validation and Writing - Review and Editing.
UB		---	Writing - Review and Editing.
FC		---	Writing - Review and Editing.
MP		https://orcid.org/0000-0001-6198-3053	Conceptualization and Writing - Review and Editing.
PA		https://orcid.org/0000-0002-4020-5065	Data Curation and Writing - Review and Editing.

All authors declare that they contributed to critical review of intellectual content and approval of the final version to be published.

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None.

Conflict of Interest

The authors declare no conflicts of interest.

Data Availability

The data used to support the findings of this study can be made available upon request to the corresponding author.

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