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RESEARCH AND EDUCATION

Comparison of silicone impressions with intraoral 3D scans in newborns with cleft lip and palate

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ABSTRACT

Statement of problem. Intraoral scanning is currently becoming the standard method for imaging the maxilla in patients with cleft lip and palate. However, the reliability of intraoral scans compared with traditional conventional impression methods has not yet been sufficiently described and examined in detail in newborns with severe types of cleft lip and palate.

Purpose. The purpose of this clinical study was to assess the reliability and agreement between intraoral scanning and traditional impression methods for maxillary measurements in newborns with unilateral and bilateral cleft lip and palate (U/BCLP). A secondary aim was to evaluate the consistency of maxillary measurements obtained with and without general anesthesia.

Material and methods. Six newborns with cleft lip and palate underwent 4 maxillary impression methods (silicone impression and 3-dimensional (3D) scan, with and without anesthesia). Intra- and inter-observer reliability was assessed by 3 clinicians using intraclass correlation coefficient, median absolute deviation, and median relative deviation (α=.05).

Results. The intraclass correlation coefficient values for both inter-observer and intra-observer reliability indicated excellent agreement (ICC>.90, P<.05) for maxillary dimension measurements. Acceptable variability was observed because of differences in reference point identification by clinicians and across data collection methods.

Conclusions. When assessing the maxilla in U/BCLP patients, both intraoral scanner and traditional impression techniques showed excellent reliability and agreement in measurements, whether performed while the newborns were awake or under general anesthesia. (J Prosthet Dent 2025;134:275-282)

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Clinical Implications

Long-term maxillary assessments in patients with clefts are required from the neonatal period. Individual cleft centers can decide whether to use intraoral scanning or standard impression techniques for preserving these records based on available equipment.

Cleft lip and palate represent some of the most common congenital developmental anomalies, affecting approximately 1 in 700 live births worldwide depending on the type of cleft.[1–3] Complete clefts can affect the lip, alveolus, and palate (CLP) and may manifest unilaterally (UCLP) or bilaterally (BCLP).[4] The management of children with clefts is multidisciplinary, involving a plastic surgeon who performs primary cleft lip surgery (either neonatally or by 3 months of age) and palate surgeries,[5–7] and an orthodontist who optimizes anatomical conditions for reconstructive procedures using nasoalveolar molding (NAM) from the neonatal period.[8,9]

For the ongoing monitoring of patients with clefts and to facilitate the creation of NAM,[10] obtaining an impression of the maxilla is essential even during the neonatal period. In recent years, intraoral 3-dimensional (3D) scanners have become a standard tool in orthodontics for virtual visualization of hard dental tissues and soft intraoral tissues.[11–14] However, the use of intraoral scanners in newborns, particularly those with anatomically deficient maxillae, remains less extensively documented.[15–18]

In patients with CLP, traditional practice involved using alginate impression material, but this carried a risk of material leakage into the open nasal cavity.[19–21] With contemporary silicone materials, this risk is reduced, albeit potentially at the expense of precision. In newborns, difficulties in cooperation and restlessness during impression-making, including the involvement of facial muscles pathologically attached to the cleft segments of the maxilla, may lead to variations in impressions obtained during crying versus at rest (Fig. 1). Furthermore, the pressure applied by the clinician's hands during standard silicone impression procedures may result in premaxillary displacement, especially in patients with BCLP, thus potentially misrepresenting the actual condition of the cleft alveolar segments.[22] An intraoral 3D scanner has been reported to be one the most accurate method for obtaining parameters of the maxilla[12,23,24]; however, challenges may arise in newborns with CLP because of difficulties in targeting the scanner precisely at the site of the cleft defect, shallow maxillary vestibule, small dimensions of the palate and alveolar arch and edentulous maxilla.

Although contemporary techniques, such as silicone-based impressions and intraoral 3D scanning, have reduced some of the risks associated with traditional methods, several questions remain regarding the reliability, and technical feasibility of these approaches in newborns with CLP. Given the challenges of working with such a delicate patient population, where anatomical constraints and patient restlessness can significantly affect outcomes, it is essential to explore whether current measurement techniques are reliable across different clinicians and methods. To address these uncertainties, the following research hypotheses were explored: that the use of an intraoral 3D scanner would be technically feasible and could provide reliable maxillary measurements in newborns with both UCLP and BCLP without significant technical difficulties, whether there would be significant differences in the measured maxillary dimensions based on the personal expertise of different clinicians, whether the measurements would be consistently reproducible across observers, whether the choice of measurement method (intraoral 3D scanning or silicone impressions, either under general anesthesia or without it) would lead to significant differences in the results, specifically whether measurements of maxillary dimensions obtained using different techniques on the same patient remained consistent or varied.

MATERIAL AND METHODS

Six newborns were enrolled in the study, 3 of whom were diagnosed with unilateral cleft lip and palate and 3

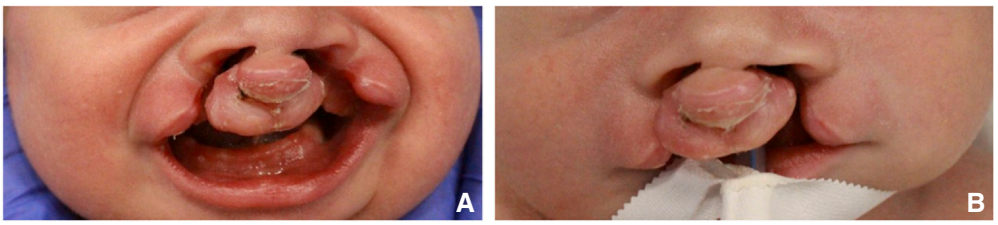

Figure 1. Patient with bilateral cleft lip and palate. A, Visible disfiguration of cleft segments because of tension of pathological attachments of facial muscles during crying. B, Same patient without muscle tone during general anesthesia.

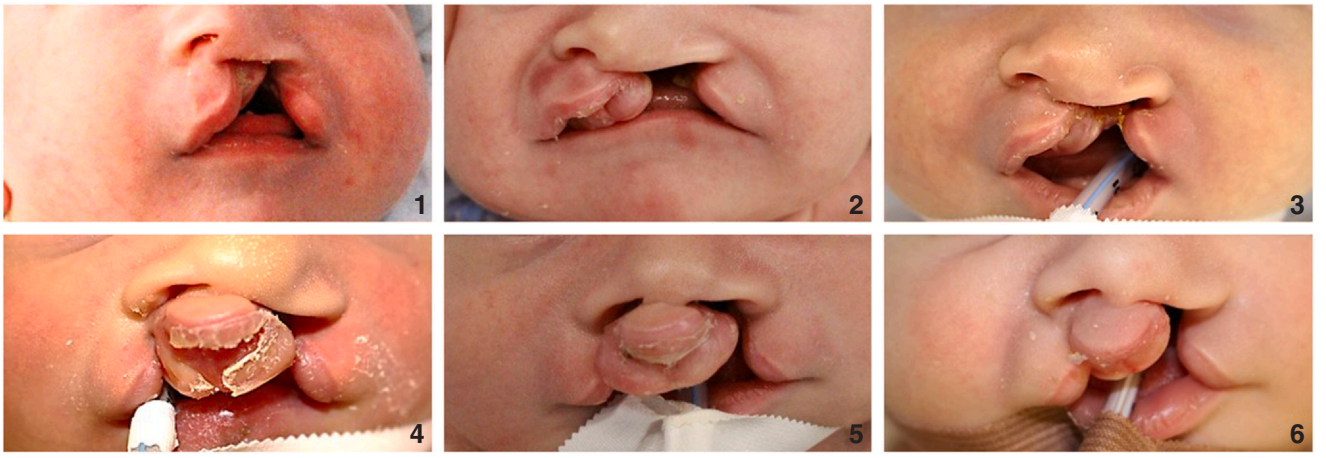

Figure 2. Patients in study. Patients No. 1 – 3: newborns with unilateral cleft lip and palate. Patients No. 4 – 6: newborns with bilateral cleft lip and palate.

with bilateral cleft lip and palate (Fig. 2). All 6 patients underwent primary cleft lip reconstruction in the neonatal period under general anesthesia (GA) and participated in a project investigating the improvement of intubation conditions in children with clefts,[25] during which the following 4 methods of making impressions were performed: silicone impression without GA, intraoral 3D scan without GA, silicone impression with GA, and intraoral 3D scan with GA. The study was approved by the Ethics Committee of the University Hospital Brno (Approval number: 08–220622/EK). All legal guardians of participants provided written informed consent.

For making silicone impressions, the material Zhermack Elite HD+ Putty Soft Fast was used. An intraoral 3D scanner (TRIOS 3 Wireless Pod; 3Shape A/S) was utilized not only for direct imaging of the maxilla but also for scanning the silicone impression and thereby converting it into digital format. The scan data were processed in a measuring software program (GOM Inspect; GOM GmbH).

To assess maxilla dimensions, a method described by Seckel et al[26] was used (Fig. 3). The digitized scans (whether obtained directly using an intraoral 3D scanner or by digitizing silicone impressions) were examined by the 3 clinicians, and 11 reference points according to Seckel were identified, provided the nature of the defect allowed. Based on the positions of these points in 3D space, following dimensions between selected pairs of points were calculated: The width of the alveolar arch was analyzed by measuring the distance between points C – C´ (canine points), Q – Q´ (lateral groove crossing the gingival notch), L – L´ (lateral segment margin of the cleft), and T – T´(tuberosity points). The width of the cleft fissure was analyzed by measuring the distance between point I (incisal point) and P (lateral point of premaxilla) with L, C, Q, and T. In addition, 8 angles

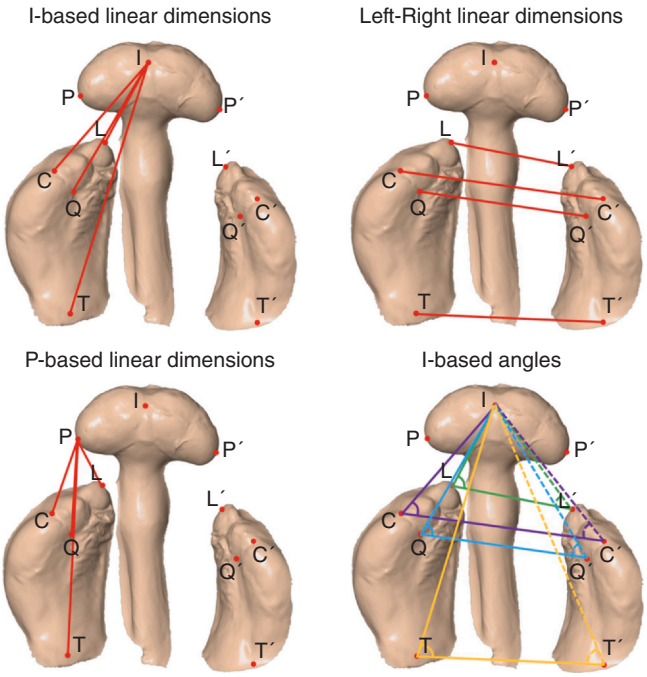

Figure 3. Bilateral cleft lip and palate with defined orthodontic points used in this study according to Seckel et al.[26].

defined by 3 selected points were calculated as well. The analyzed dimensions are indicated in Figure 3. Definition of the position of the premaxilla has been addressed by Heidbüchel et al[27] and Oosterkamp et al.[28] Figure 4 presents an example of reference points in Patient 6, along with a typical comparison of a specific dimension obtained using different methods. This figure also illustrates the differences between direct intraoral scanning of the patient and scanning a conventional impression. Because of the limited space within the oral cavity of a newborn, achieving a deep recording of the palate with an intraoral scanner can be challenging.

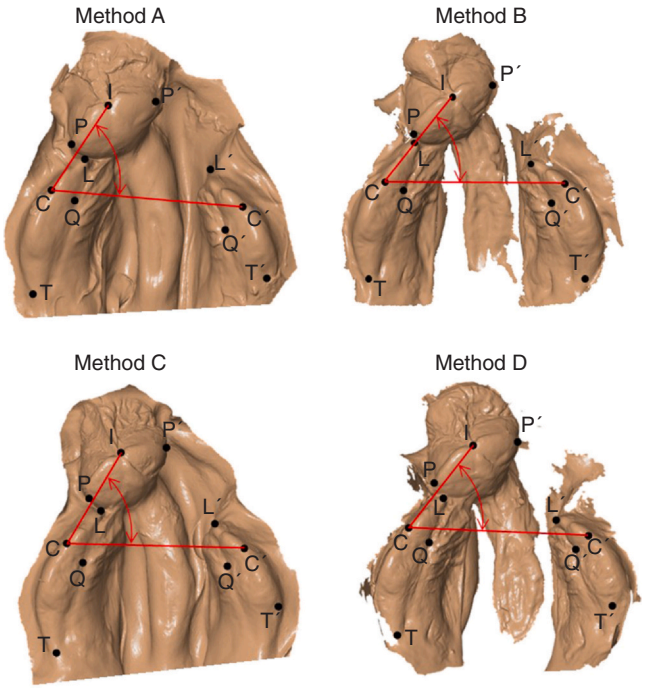

Figure 4. Comparison of angle ICC' in Patient No.6, defined using reference points as identified by one observer.

However, essential information regarding the alveolar geometry and cleft was still adequately captured. All reference points were evaluated independently by 3 experienced clinicians (observers) MN, WU and AB, each performing the assessment twice (in 2 sessions) with an interval of at least 1 week between them.

Measurements of each dimension on the same patient, conducted by different observers employing the same approach, were used to determine inter-observer reliability. Similarly, measurements of each dimension on the same patient, conducted by 1 observer employing different approaches, were used to determine intra-observer reliability. For this purpose, the reliability was assessed using the intraclass correlation coefficient (ICC), suitable for quantitative data such as linear distances between 2 reference points or angles formed by 3 points.[29] These data were subjected to the Kolmogorov-Smirnov test to verify normal distribution (α=.05). Furthermore, the median absolute deviation (MAD) and median relative deviation (MRD) were calculated to quantify variability in measurements across observers and methods. Linear distances and angles between the reference points were analyzed separately.

For the inter-observer reliability assessment, all combinations of patient, dimension, and method were numbered 1 through 288 for linear distances and 1 through 240 for angles, constituting the measured "subjects". Each subject underwent a single measurement by each of the 6 observations (conducted by 3 clinicians). To evaluate the reliability of measurements among the observers, the ICC(2,1) model was used. This model is suitable for assessing absolute agreement, taking into account 2-way random effects and single measurements.[30] Where observers could not measure dimensions satisfactorily or omitted them, the subject was excluded from ICC evaluation. The resulting intraclass correlation coefficient was interpreted according to the guidelines provided by Koo and Li[30] and summarized in Table 1.

Table 1. Intraclass correlation coefficient (ICC) interpretation

ICC	Agreement
0.000 – 0.499	Poor
0.500 – 0.749	Moderate
0.750 – 0.899	Good
0.900 – 1.000	Excellent

For the intra-observer reliability assessment, all combinations of patient and dimension were numbered 1 through 72 for linear distances and 1 through 60 for angles, constituting the measured "subjects". Each of the 3 observers conducted twice measurements of each subject using 4 different methods. To evaluate the reliability of the measurements among the methods, the ICC(1,1) model was used for each observer separately. This model is appropriate for evaluating absolute agreement, considering 1-way random effects and single measurements.[30] Where observers could not measure dimensions satisfactorily or omitted them, the subject was excluded from ICC evaluation. The resulting interclass correlation coefficients were interpreted using the guidelines outlined in Table 1.

To quantify and assess variability among observers, the median absolute deviation (MAD) defined as $MAD=Me(|X_i-\tilde{X}|)$, where X_i are measured data and $\tilde{X}=Me(X_i)$, was calculated for each dimension, method, and patient. A maximum of 288 and 240 MAD values could be calculated for the linear distances and angles, respectively. However, in certain instances, the observers were unable to measure certain dimensions satisfactorily or even omitted them. Combinations of dimension, method, and patient with less than 3 valid measured values were excluded from the calculation. Similarly, the variability because of method choice was assessed using MAD for each dimension, observer, and patient. A total of 432 and 360 MAD values could be calculated for the linear distances and angles, respectively. However, combinations of dimension, method, and patient with less than 3 valid measured values were excluded from the calculations. To consider dimension size, the median relative deviation (MRD) defined as $MRD=100\cdot MAD/\tilde{X}$ was also calculated. MRD values less than 10% were regarded as acceptable.

RESULTS

The resulting interclass correlation coefficient (ICC) values for models ICC(2,1) and ICC(1,1), used to assess inter-observer and intra-observer reliability, respectively, are

Table 2. Inter-observer reliability

Group	Interclass Correlation		F Test for ICC=0				Agreement
	ICC	CI95%	F-value	df1	df2	P	
Distances	0.974	[0.97, 0.98]	170.985	383	1149	<.001	Excellent
Angles	0.963	[0.96, 0.97]	106.696	290	870	<.001	Excellent

Table 3. Intra-observer reliability

Group	Observer	Interclass Correlation		F Test for ICC=0				Agreement
		ICC	CI95%	F-value	df1	df2	P	
Distances	AB, first session	0.975	[0.96, 0.98]	154.706	65	198	<.001	Excellent
	AB, second session	0.970	[0.96, 0.98]	131.306	65	198	<.001	Excellent
	MN, first session	0.979	[0.97, 0.99]	187.993	55	168	<.001	Excellent
	MN, second session	0.990	[0.99, 0.99]	411.668	57	174	<.001	Excellent
	WU, first session	0.961	[0.94, 0.97]	100.686	68	207	<.001	Excellent
	WU, second session	0.977	[0.97, 0.98]	173.359	68	207	<.001	Excellent
Angles	AB, first session	0.954	[0.93, 0.97]	83.209	50	153	<.001	Excellent
	AB, second session	0.946	[0.92, 0.97]	71.249	50	153	<.001	Excellent
	MN, first session	0.970	[0.95, 0.98]	132.489	39	120	<.001	Excellent
	MN, second session	0.976	[0.96, 0.99]	161.346	40	123	<.001	Excellent
	WU, first session	0.967	[0.95, 0.98]	118.435	53	162	<.001	Excellent
	WU, second session	0.972	[0.96, 0.98]	141.054	53	162	<.001	Excellent

presented in Tables 2 and 3. In all situations, excellent agreement was observed (ICC>.90) in the measurements of maxillary dimensions (distances and angles) and thus the related reference point positions. The strength of these findings was further emphasized by the lower bounds of 95% confidence intervals consistently exceeding 0.90, indicating robust reliability of the measurements. The F-tests performed within ICC evaluation for the null hypothesis ICC=0 confirmed that these excellent agreements were not because of chance (P<.001). Table 4 summarizes the variability in the measured distances and angles between reference points for individual patients. The calculated variability represents the spread of the median values of these measurements, caused by differences in reference point identification by different clinicians. Table 5 similarly summarizes the variability caused by differences in reference point identification when using different data collection methods (impression or scanner, GA or without GA).

Table 4. Observer-caused maximum median absolute and relative deviations

Dimension	Patient					
	1	2	3	4	5	6
I-C	0.21	0.19	0.33	0.60	0.48	0.61
I-Q	0.33	0.18	0.51	0.68	0.65	0.82
I-T	0.33	0.35	0.89	0.99	1.31	1.42
I-L	0.37	0.39	0.32	0.32	0.66	0.35
P-L	0.82**	0.49*	0.54*	1.20**	0.72*	0.41**
P-C	0.38	0.16	1.02	0.54*	0.31	0.25
P-Q	0.61	0.15	0.63	0.74*	0.35	0.66*
P-T	0.61	0.34	0.74	1.00*	1.97*	2.69**
L-L′	excl.	excl.	excl.	0.64	0.35	0.33
C-C′	0.56	1.12	0.57	0.98	0.68	0.59
Q-Q′	0.24	0.62	0.59	0.73	0.36	0.39
T-T′	0.76	0.54	2.01*	1.12	3.20*	1.54
C-L-P	2.00	3.88*	4.33*	9.17**	3.72	7.84*
T-C-L	4.94	3.10	3.27	21.50**	4.29	5.88
I-L-L′	excl.	excl.	excl.	5.42*	1.45	1.51
I-L′-L	excl.	excl.	excl.	0.77	2.01	0.93
I-C-C′	1.05	4.11**	1.72*	2.22	1.38	1.04
I-C′-C	1.21	0.99*	0.65	1.07	0.90	1.08
I-Q-Q′	1.14	3.90*	0.91	3.26	1.55	1.96
I-Q′-Q	0.97	0.65	1.21*	0.95	1.35	1.38
I-T-T′	2.64	1.04	3.81*	4.97*	2.17	2.76
I-T′-T	1.87	0.67	2.85*	1.80	3.24*	3.87*

Angular dimensions in degrees, linear dimensions in millimeters. Asterisks indicate high maximum relative deviations: *=MRD>5%; **=MRD>10%. Otherwise, MRD<5%. "excl." indicates excluded assessment because of low number of samples in calculation of median (< 3).

Table 5. Method-caused maximum median absolute and relative deviations

Dimension	Patient					
	1	2	3	4	5	6
I-C	0.80*	0.52	0.29	2.39**	0.36	0.58
I-Q	0.36	0.30	0.59*	1.94**	0.57	0.95*
I-T	2.21*	0.52	1.65*	4.74**	3.60*	2.67*
I-L	0.67*	1.90**	0.34	0.41	0.72	0.34
P-L	0.95**	1.71**	0.86**	1.01**	0.71*	0.79**
P-C	0.52	0.36	0.86	2.09**	0.45	0.58*
P-Q	0.69	0.38	0.82	0.68*	0.37	0.48*
P-T	2.39*	0.94	0.90	4.21**	4.25**	2.67**
L-L′	excl.	excl.	excl.	0.54	1.02*	0.31
C-C′	1.11	1.38	1.06	2.47*	1.16	0.38
Q-Q′	0.71	0.58	0.73	2.24*	0.49	0.37
T-T′	1.11	1.19	2.31*	1.52	1.33	0.85
C-L-P	4.51*	7.28**	4.43*	10.87**	4.38*	12.69**
T-C-L	3.75	3.72	3.81	24.95**	10.53*	5.38
I-L-L′	excl.	excl.	excl.	4.97*	2.86	3.50
I-L′-L	excl.	excl.	excl.	2.70*	4.83*	1.09
I-C-C′	1.99*	2.75*	3.30**	7.25*	2.63	3.74*
I-C′-C	1.01	0.47	1.76**	3.01*	2.11	1.10
I-Q-Q′	2.16	1.88	2.46	5.77*	3.00	3.53*
I-Q′-Q	1.24	1.27*	1.87*	2.65*	2.52	3.35*
I-T-T′	4.63*	2.17	6.48**	2.84	4.80*	3.52*
I-T′-T	4.29*	1.60	2.07*	6.17**	3.68*	2.63

Angular dimensions in degrees, linear dimensions in millimeters. Asterisks indicate high maximum relative deviations: *=MRD>5%; **=MRD>10%. Otherwise, MRD<5%. "excl." indicates excluded assessment because of low number of samples in calculation of median (< 3).

DISCUSSION

The results of this clinical study supported all the research hypotheses. Intraoral 3D scanning was found to be technically feasible in newborns with both UCLP and BCLP, providing reliable maxillary measurements without significant technical difficulties. The measurements remained consistent across different clinicians and techniques, regardless of whether performed under general anesthesia or not.

Long-term monitoring of maxilla growth is a standard procedure in the care of patients with cleft lip and/or palate. Documenting the baseline condition of this congenital defect before primary lip and palate reconstructions is a crucial, yet sometimes underestimated, factor for future assessment of treatment outcomes. However, making impressions of the maxilla in newborns can be technically challenging.[17] Traditional impression techniques using alginate or silicone materials require custom trays, particularly for the most severe types of BCLP, where individualized adjustments are necessary.[18] The selection of an appropriate impression material is also an important factor. Using soft alginate materials carries the risk of the material flowing into the nasopharynx and the risk of aspiration of its particles.[20,21] When using firmer silicone materials, concerns may arise about distortion of the impression because of pressure on the clefted alveolar segments of the maxilla (particularly in patients with BCLP, there may be concerns about premaxillary malposition during the impression process).

Recently, there has been a noticeable shift from traditional impression techniques toward the use of intraoral scanners, which manufacturers have also gradually adapted to fit the smaller dimensions of the maxilla,[13,14] including those of newborns.[9] Although most published studies report that the time of performing an intraoral scan in children with clefts is similar to that of standard impression techniques,[12] slight difficulties encountered during scanning in the area of pronounced alveolar defects in patients with UCLP or BCLP should be highlighted. The degree of distortion of the clefted alveolar segments is also unclear, both when the child is at rest and when crying (the facial muscles are pathologically connected to the lateral clefted segments).[7]

This clinical study found excellent agreement between maxillary standard silicone impression and 3D intraoral scan in newborns with severe types of unilateral or bilateral cleft lip and palate, whether made in the resting state (under general anesthesia with maximum relaxation of facial muscles) or while awake. This finding was consistent with a study that compared traditional impression techniques with intraoral scanners in older patients.[22] Similarly, excellent agreement was observed between the measurements conducted by different observers, indicating that the personal expertise of different clinicians did not result in significant differences in the measured maxillary dimensions. Therefore, the measurements were consistently reproducible across observers, confirming the practical applicability of the methods used for measuring the dimensions of the cleft maxilla prior to dentition eruption.

The evaluation of inter- and intra-observer reliability using ICC models did not allow for finer distinctions between differences in methods and observers, as it focused on general agreement and measurement reproducibility. For this reason, the analysis also included an assessment of absolute and relative deviations in distances and angles caused by different measurement methods and observers. Because of the varying dimensions of individual patients, comparing absolute deviations (MAD) was of limited value. For example, the I-C-C′ angle ranged from 1.99 degrees in Patient 1 to 7.25 degrees in Patient 4 (Table 5). However, by comparing the relative deviations (MRD) of dimensions and angles in individual patients, it was possible to approximately determine what had a greater influence on measurement variability. The results in Tables 4 and 5 suggest that the choice of measurement method contributed more to variability than the clinician's expertise. In the case of variability because of clinician expertise, approximately 5.8% and 5.6% of distance and angle deviations, respectively, were classified as significant (MRD>10%). In contrast, the variability because of the choice of method resulted in 18.8% and 14.8% of distance and angle deviations, respectively, being classified as significant (MRD>10%). In general, however, it can be concluded that the observed variability in measuring reference points represented by both distances and angles by different clinicians and methods was small for newborn patients and sufficient for clinical practice. Measurement of the opposing (left- and right-sided) angles using reference points was included in the study to determine whether the measurement method (or professional experiences) was more pronounced in patients with bilateral clefts, in whom the premaxilla may protrude more with an open mouth than in patients with other (more rigid) types of clefts. The assessment of the agreement of measurements using ICC models suggested no effect, as excellent agreement between methods and observers was constant for the distances of the reference points and the angles between them. A closer look at the relative deviations did not find differences between patients with unilateral and bilateral defects. For angles I-C-C′, I-C′-C, I-Q-Q′, and I-Q′-Q, for which there was sufficient data, and which were clearly identifiable in patients with unilateral (Patients 1–3) and bilateral (Patients 4–6) clefts, no significant differences in the measured values using different

methods (or when measured by different observers) were found. Although Table 4 indicates slightly more observer-caused variability for the 4 angles in patients with unilateral defects (once MRD>10%, 4-times MRD>5%) than in patients with bilateral defects (always MRD<5%), on average the 2 groups of patients were not significantly different, and the results cannot be considered conclusive. Even the variability caused by the method (Table 5) did not provide clear evidence for the claim that there were significant differences between the 2 groups of patients in terms of the applicability and reproducibility of the chosen methods.

In this study, the use of reference points for measuring the dimensions of the cleft defect had proven to be an effective method in newborns. In addition to the classical reference points and their distances, measurements of potential premaxillary distortion in BCLP were further supplemented by newly defined angles. Currently, it is also possible to assess and compare maxillary morphology through superimposition of 3-dimensional surfaces. However, the use of reference points identified on the maxilla for comparison between patients and measurement methods is preferable to the superimposition for several reasons. Primarily, it allows for precise and standardized identification of anatomical reference points that can be consistently located across different patients and methods. This enhances the reproducibility and objectivity of measurements. In contrast, superimposing entire surfaces may be influenced by variations in individual patient morphology and the quality of digitization, while point-based analysis is less prone to such deviations resulting in more consistent and comparable outcomes.

Assessment of maxillary development using an intraoral scanner represents the future in the field of orofacial clefts. However, it is simply an alternative method of obtaining maxillary dimensions, offering reliable equivalent to that of standard methods using traditional impression materials. Limitations of this study included the small sample size, but was mitigated by the inclusion of the most severe cleft types. Despite this, the study provided valuable insights into evaluating and comparing measurement methods. Larger cohorts could enhance future analyses.

CONCLUSIONS

Based on the findings of this clinical study, the following conclusions were drawn:

1. The use of both standard impressions and intraoral 3D scanner is technically feasible in newborns with UCLP and BCLP.
2. The results demonstrated high reliability and agreement between measurements obtained using standard impressions and 3D scans, whether performed under general anesthesia or while fully conscious, even in instances of severe, wide clefts of the lip and palate.
3. The results suggested that the measurement of reference points was consistent, independent of the clinician.
4. The reproducibility of the measurements was also demonstrated by comparing results obtained by different clinicians. Assessment of dimensions using reference points remains the standard in evaluating edentulous cleft maxillae.

PATIENT CONSENT

Legal guardians of each participant signed a written informed consent.

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