

# DIAGNOSTIC EVALUATION AND GUARDIAN ASSESSMENT OF USING DIGITAL IMPRESSION IN NEONATES VERSUS THE CONVENTIONAL TECHNIQUES

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## ABSTRACT

**INTRODUCTION:** Cleft lip and palate are common facial deformities, that can involve the lip only, lip and palate, or palate only. Dental casts are important tool in planning, documentation, and analysis of the dental arch forms. Impression taking in a neonate is a technique-sensitive procedure, but with the use of digital dental technologies and intraoral scanning, it become more safe, more effective, and more accurate.

**AIM:** This article aimed to evaluate the reliability of the use of conventional impressions versus digital ones to resemble the neonate's ULCLP oral defect. Assessing the attitudes of guardians with different educational backgrounds regarding impression registration techniques and their compliance with using feeding appliances for neonates.

**MATERIALS AND METHODS:** 7 ULCLP non-syndromic neonates of 0-28 days presented to the cleft center of the Maxillofacial department. Impressions were registered using conventional versus optical impressions using intraoral (3D) scanner. Data were generated by two impression system combinations through STL by scanning the impression using Geomagic software. As well as manual digital linear calibration of both the conventional stone model and the 3D printing the intraoral scanned one.

**RESULTS:** The validity of using intraoral digital impression technique as a viable alternative to conventional ones was statistically significant Regarding the PISO questionnaire, guardian's perception, and experience of the digital impression technique it showed a higher clinical significance in comparison to the conventional one.

**CONCLUSION:** Using 3D digital impressions reduces multiple risks for both neonates and their guardians. Digital data was utilized as records for further appliance planning and fabrication.

**KEYWORDS:** NAM, Unilateral cleft lip and palate (UCLP), Intraoral scanning, Conventional impressions, PISO Questionnaire.

**SHORT TITLE:** Neonates and guardian's assessment for digital ULCLP impressions.

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## INTRODUCTION

Lip, alveolus, and palatal clefts are the most frequent congenital anomalies of the head and neck, and the second most common congenital abnormality affecting the whole body. (1,2)

Neonates with cleft palate and lip (CLP) frequently have feeding and psychological impairment as well as craniofacial developmental problems. Speech difficulties and common dental anomalies are usually presented as long-term side effects of untreated CLP. (1,2)

CLP requires many surgical procedures and a lifetime of clinic visits, causing both emotional and physical stress for both the patients and their guardians. (3,4)

The help of a multidisciplinary team is required for the best treatment planning of CLP patients. (5) Presurgical CLP neonatal and infant appliances have been used as supplementary corrective surgery

that started in 1950. However, at any health care providing facility, impressions are registered using irreversible impression material as well as silicone impressions. The treatment is usually accompanied by accidental risks that may include ingestion, aspiration, and suffocation of the patient. (6,7)

With the advanced technologies of intraoral scanners and their wide use in the dental practice to register completely edentulous arches, digital impressions are registered using an intraoral scanner, in which it facilitates the production of a diagnostic model that can be required for presurgical newborn prosthetic approaches whether they are feeding appliances or naso-alveolar molds (NAMs). (8,9)

The success of any pre-operative appliances for neonates or infants is dependent on their parents' effective commitment and responses to the pre-planned treatment. (6)

With the lack of evidence-based data and uncertainty about parents' satisfaction nor the effective reproducibility of the cleft lip and palate for neonates using different impression techniques, the purpose of this study is to clinically assess the reliability of using conventional impression versus digital one to resemble the neonate's ULCLP oral defect. As well as assessing the behavior of guardians with variable educational backgrounds based on the technique of impression registration as well as the compliance on using feeding appliances for neonates.

The null hypothesis in this study is there were no significant differences between both impression techniques either in the diagnostic evaluation or guardian acceptance.

### Methodology

#### Study design, setting, and participants.

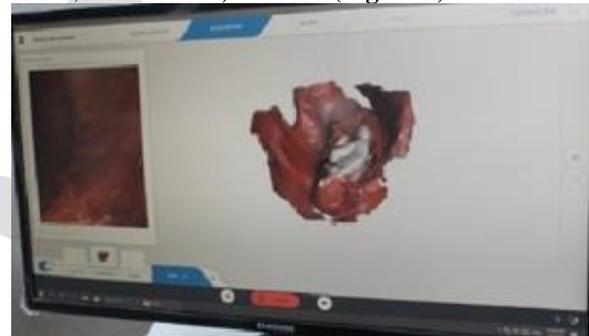
The present study evaluated using intraoral scanners to digitally register cleft defects for neonates who presented with their parents or caregivers at the Cleft Center of Maxillofacial and Plastic surgery department, Faculty of Dentistry, Alexandria University the duration from February 2023 till June 2023 where data was collected. Neonates aged from 0-28 days with non-syndromic, complete ULCLP were enrolled in the study. (Figure 1) Parents were informed about the risk factors that might be encountered in the aspiration of the impression material due to the vomiting reflex. The parents were instructed to let the neonates fast for 4 hours preceding the impression registration. In the current study, 7 neonates with UCLP (three females and four males: aged from 0-28 days; average age, 15 days) were enrolled. The study was performed according to the Declaration of Helsinki after approval acceptance from the local and Institutional Ethics Committee of the Alexandria University School of Dentistry (IORG0008839). The parents and caregivers declared written informed consent for their neonates regarding their enrollment in the study and to be aware of risks that might be encountered. All the neonates received a feeding appliance (till 1 month age) followed by NAM (1-6 months) appliance till the age of 6 months to improve the foundation area for palatal surgical correction.



**Figure 1:** Neonate with non-syndromic ULCLP.

### Impression registration

Upon registered impression, an anesthetist was present during the impression phase with an oxygen saturation oximeter and heart rate pulse monitor in case of any risk that can be encountered. Two impression registration techniques for 7 UCLP neonates were made as follows were neonates were being held by their caregivers or guardians or professional assistant to limit their body movement during conventional impression registration.: 1) Conventional impressions using an irreversible hydrocolloid impression material (Tropicalgin; Zhermack, Badia Polesine), and 2) intraoral digital impression registration technique was made using intraoral scanner I700 ((Medit i700, Medit Corp, Seoul, South Korea) scanner. (Figure 2)



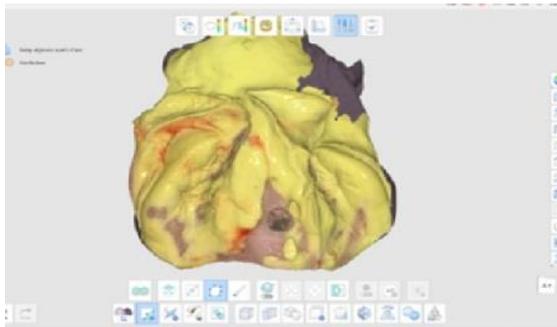
**Figure 2:** Digital impression scanning using IOS (Medit1700).

Stone models were poured for a conventional impression based on the manufacturer's instructions (Suprastone Ultra Hard™, Kavo, Kerr). On being set, the conventional Stone models were scanned using intraoral I700 Medit to produce a virtual 3D model. Subsequently, the scanned intra-oral impression was then saved as a 3D model scan.

The virtual 3D model obtained from scanned intraoral digital impressions was then exported as a standard triangulated language (STL) and printed using a 3D printer (Crealty HALOT-SKY 3D Printer, China).

### Evaluation methodology

**3D scanned Superimposed testing impressions.** (9) The scanned conventional impression and the digital impression that is directly obtained by the intraoral scanner for maxillary defect were transformed into STL data followed by superimposition using Geomagic software (Control X 2022; 3D Systems). The two 3D virtual models were compared depending on two reference areas, the alveolar arch width, and the alveolar cleft defect. (Figure 3)



**Figure 3:** Digital impressions and conventional impressions were superimposed.

**Model Measured methodology**

The stone models obtained from conventional methods and 3D printed models obtained from the intraoral digital scanning impression were measured 3 times clinically using Vernier Calipers (Westport Corporation, NY.), and the average data values were used. The measurement site is shown in (Figure 4) for both the maximum alveolar arch width as (and) the maximum distance between premaxillary segments.

**Questionnaire for guardian's assessment of different impression techniques**

By using the PISO questionnaire to assess the guardian's acceptance of both impression techniques, where 10 min were required to answer all questions.

Since neonates were incapable of providing responses to the questionnaire, Guardians or caregivers were charged, and it seemed to be problematic to evaluate the child's reaction to treatment.

Data were analyzed using IBM SPSS version 23, Armonk, NY, USA. Data were presented using frequency and percentage and compared using McNemar test. All tests were two-tailed, with a significance threshold at a p-value of 0.05.

**RESULTS**

Demographic data of the enrolled 7 neonates with their guardian education and enrollment in the treatment modality was registered. (Table 1)

**Table 1:** Demographic data of neonates and their guardians.

Table 1: Demographic data of neonates and their guardians

Patient no	Gender	Age	Cleft type	Guardians	Education level	Relatives
1	Male	9 days	LUCLP	Mother and father	High	Yes
2	Male	11 days	RUCLP	Mother	low	No
3	Female	14 days	LUCLP	Mother and father	None	Yes
4	Male	8 days	LUCLP	Mother and father	High	No
5	Female	17 days	LUCLP	Mother and father	None	Yes
6	Female	20 days	LUCLP	Mother and father	Low	No
7	Male	15 days	RUCLP	Mother	High	No

Education level scoring: High: refers to University education, Low: refers to School education only, and None: refers to no education at all.

**3D scanned Superimposed testing impressions.**

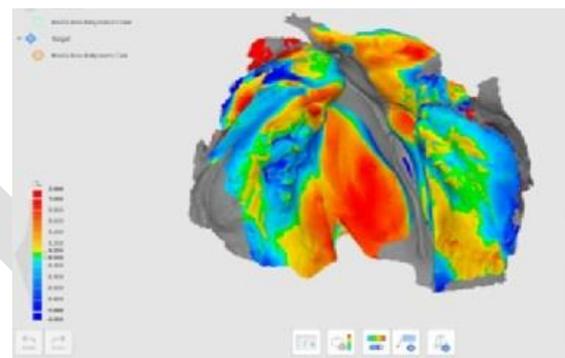
On comparing the overall deviation using color map % between models obtained from scanned

conventional impressions and digital intraoral impressions, the (STL) are being superimposed and deviation was calculated as follows: 85% or more of equal superimposition of two models showed an insignificant difference of two models, where less than 85% of superimposition models showed significance difference). The study showed that a significant difference was observed in three cases (less than 85%) while the rest four cases showed no significant difference between either technique. (Equal or more than 85) %As shown in (Table 2) and (Figure 5)

**Table 2:** 3D scanned Superimposed testing impressions using the overall deviation percentage of the colour map.

Table 2: 3D scanned Superimposed testing impressions using the overall deviation percentage of the color map.

Cleft patient	Superimposed area %	Significant
1	77.1	S
2	84.1	S
3	90.2	NS
4	80.9	S
5	91	NS
6	89.3	NS
7	87.5	NS



**Figure 5:** A color map for the superimposed impressions.

**Model measured methodology**

The values measured using a digital vernier caliper showed no significant difference in comparing both, the stone model and 3D-printed digital impression groups for both the maximum alveolar arch width as the maximum distance between premaxillary segments. (Figure 4).



**Figure 4:** The use of the vernier caliper to measure the maximum width of the alveolar arch and the maximum width between the premaxillae.

### Guardian's perception and experience related to impression technique for PISO treatment.

Regarding the guardian's perception and experience of the impression technique when using the intraoral scanners or the conventional method it was found that all answered questions showed no significant difference between the two impression techniques, however, the questions (Do you think your infant suffered during the impression method?) and (How invasive was the method of impression taking?) showed a significant difference with a p-value of 0.016 for both questions where all the guardians replied with the answer no in the intraoral scanner group and on the other hand they all replied with the answer yes in the conventional group for both questions as shown in (Table 3)

**Table 3:** Guardian's perception and experience related to impression technique for PISO treatment.

Table 3: Guardian's perception and experience related to impression technique for PISO treatment.

Items	IOS		Conventional		P value
	Yes	No	Yes	No	
	N (%)		N (%)		
How often have you been worried after the explanation of the impression-taking procedure?	3 (42.9%)	4 (57.1%)	7 (100%)	0 (0%)	0.125
Do you think your infant suffered during the impression method?	0 (0%)	7 (100%)	7 (100%)	0 (0%)	0.016*
Have you found any sign of intra- or extra-oral physical trauma after the impression procedure?	0 (0%)	7 (100%)	4 (57.1%)	3 (42.9%)	0.125
How invasive was the method of impression taking?	0 (0%)	7 (100%)	7 (100%)	0 (0%)	0.016*
Do you face any difficulties in following the instructions of the orthodontist, in regard to the insertion of the PSIO and/or taping the elastic band?	4 (57.1%)	3 (42.9%)	4 (57.1%)	3 (42.9%)	1.00
"Do you think that CLP infants always need PSIO treatment?"	5 (71.4%)	2 (28.6%)	5 (71.4%)	2 (28.6%)	1.00
"Did you search the web looking for information about PSIO treatment?"	2 (28.6%)	5 (71.4%)	2 (28.6%)	5 (71.4%)	1.00
"Did you find PSIO treatment useful for your infant?"	6 (85.7%)	1 (14.3%)	6 (85.7%)	1 (14.3%)	1.00
"Did it improve the infant's feeding?"	7 (100%)	0 (0%)	7 (100%)	0 (0%)	-
"Did it improve the esthetic of the infant's facial appearance, in regard to lip, nose, and profile of the face?"	5 (71.4%)	2 (28.6%)	5 (71.4%)	2 (28.6%)	1.00
"Did it make the appointment for surgical repair earlier?"	6 (85.7%)	1 (14.3%)	6 (85.7%)	1 (14.3%)	1.00
"Did you find it embarrassing that your infant was wearing the appliance?"	5 (71.4%)	2 (28.6%)	5 (71.4%)	2 (28.6%)	1.00
"How satisfied are you with the outcomes of the PSIO?"	6 (85.7%)	1 (14.3%)	6 (85.7%)	1 (14.3%)	1.00
"Would you encourage other parents to do the PSIO treatment?"	5 (71.4%)	2 (28.6%)	5 (71.4%)	2 (28.6%)	1.00
Do you think that the orthodontist is an important member of the cleft team?"	5 (71.4%)	2 (28.6%)	5 (71.4%)	2 (28.6%)	1.00
To what extent has the cleft influenced your family's life?"	7 (100%)	0 (0%)	7 (100%)	0 (0%)	-

\*Statistically significant at p value=0.05

## DISCUSSION

The null hypothesis of the study has been rejected. Patients and their families who suffer from orofacial anomalies usually suffer from a long journey in therapy measures. Any protocols to reduce risk and improve the final outcomes are important, specifically for early lifetime neonates. Therefore, any alternative techniques to encounter the risk of conventional impressions are needed. (10)

Complications and risks resulting from technical procedures such as impression material, dental expertise as well as adequate airway management should be eliminated. Therefore, with these

complications, conventional impressions are no longer favored in dental practice and are being replaced by digital impressions. (11)

The present study favored the use of simplified digital impressions not only to reduce the risk to neonates but also to relieve part of the burden that can be felt by their guardians. During the study, it was observed that parents with high or low levels of education were better candidates to understand the importance of using feeding appliances as well as being punctuated in their appointments. Therefore, parents, education had a significant impact to present their neonates in the early stages to seek treatment as well as showing compliance to risk and the importance of registering impressions for their neonates to proceed with the treatment protocol. (12-13)

In the presented study, the neonates required a lot of care during conventional impression registration, to keep their mouth open and limit their body movement. As for the digital impression, there was no adverse reaction or any problem that had been encountered during scanning involving any risk for the neonates. (14) Also, the accuracy of the 3D obtained image produced was not affected by the wetting of the saliva nor the neonate straining but significantly showed a prolonged imaging time. Even with the prolonged time duration of 2 to 2.30 mins of scanning, the guardians favored the digital impression over the conventional ones in the PISO questionnaire evaluation. On evaluating impression time, the results showed a faster registration of conventional impression modality than optical ones. (14) where the results were in accordance with Burzynski et al. (15) as well as depending on the neonates and infants' age, type of cleft, and parents' cooperation.

In the current study, the superimposed scanned stone model (STL) with the intraoral scanned image (STL), a significant difference in the premaxilla portion of the conventional impression versus that of the digital impression was observed. This finding was consistent with Patel et al. who stated that the segments of premaxilla had a degree of distortion, that was associated with the pressure applied from registered impression material. (16)

In the current study, those registered 3D digital morphometric model obtained from intraoral digital impressions was proven to be safe modality only but deemed valuable data to be archived with high accuracy as preoperative records in neonates with CLP giving the possibility of digitally designing other appliances as stated earlier in literature. (17)

Using the vernier digital caliper, to evaluate the efficacy of the produced 3D models generated from digital impression versus conventional stone-mold models. This study revealed no significant differences between the study groups. Results were equivalent to results obtained in other studies. (18,19)

All enrolled guardians were convinced that using the feeding appliance improved their neonate's health and replaced the need for special feeding bottles.

## CONCLUSION

The use of the 3D digital impression technique was successfully applied to neonates with unilateral Cleft Lip and Palate, as it reduces multiple risks for both neonates and their guardians. The guardian assessment questionnaire PISO favored the digitalized impression as well as the clinical significance of reliable models produced from digital imaging. Moreover, digital data can be utilized as records for further appliance planning and fabrication. Also, the use of digital images had a significant impact on parents to show them a virtual model for their infant's improvement during pre-surgical treatment. Within the limitations of this study, The use of the 3D digital impression technique was successfully applied to neonates with unilateral cleft lip and palate

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