

Evaluation of Two Computerized Methods for Presurgical Volumetric Analysis in Secondary Alveolar Cleft Bone Grafting: A Prospective Study

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ABSTRACT

Aim: The purpose of this study is to evaluate presurgical computerized volumetric analysis in secondary alveolar cleft bone grafting (SABG) and the time taken for calculation using cone-beam computed tomography (CBCT) via two different software programs.

Materials and methods: Twelve patients with unilateral alveolar clefts were investigated using CBCT. Two independent investigators did presurgical volumetric analysis for each patient's CBCT data using two different methods. Method A involved On-Demand 3D software (Cybermed Inc., Korea), while method B involved InVesalius 3 software (CTI, Brazil). The volume outcomes and time spent for measurements were compared between both software programs. Interobserver reliability and descriptive and *t*-test statistics were computed, and statistical significance was considered when $p \leq 0.05$.

Results: There was not a statistically significant difference between clefts' volumetric measurements by the two methods via both investigators ($p = 0.186$ and 0.069). However, the difference in time taken for these measurements between the two methods was statistically significant ($p < 0.001$). Intraclass correlation coefficient (ICC) values indicated excellent interobserver reliability for measurements by method A (ICC ~ 0.998), and moderate reliability for method B (ICC ~ 0.626).

Conclusions: Both software programs used in this study had comparable volumetric computation. Method B took much less calculating time than method A. The interobserver reliability was high for both methods.

Clinical significance: These both investigated software programs may show a clinical implication for presurgical alveolar cleft volume measurement, thus reducing the surgical operating time and adequately selecting a donor site with a congruent sufficient amount of bone grafts.

Keywords: Alveolar bone grafting, Alveolar cleft, Cone-beam computed tomography.

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INTRODUCTION

The incidence of cleft lip and palate was reported to be 1:700 of live births,¹ with existing variability according to geographic origin, race, ethnic groups, environmental variables, and socioeconomic status.¹ Alveolar cleft was found in 75% of patients with cleft lip and palate.² It was also stated that the alveolar cleft is the most common congenital bone defect.³

The objectives of alveolar cleft repair are to restore dental arch continuity, stabilize the maxilla, facilitate subsequent orthodontic treatment and permanent teeth eruption, and support soft tissue structures.^{3,4} Secondary alveolar cleft bone grafting, that is, in the mixed dentition stage, is considered superior to primary alveolar cleft bone grafting, that is, during infancy.⁵ Autogenous bone grafts are considered the gold standard for SABG.⁶ Moreover, the timing of orthodontic intervention is debated whether before or after SABG.^{7,8}

In SABG, individualized presurgical treatment planning plays a crucial role.⁹ The assessment of the volume and shape of the bone defect is important for accurate planning, yielding a more predictable procedure.⁹ Presurgical computerized planning allows for a more precise volume evaluation of required bone graft, with better postsurgical outcomes.¹⁰ The preoperative knowledge of the cleft volume may also result in reduced donor site morbidity, minimized hospitalization, and decreased overall cost.¹⁰

Many radiographic two-dimensional (2D) and three-dimensional (3D) methods of alveolar cleft volume have been investigated.¹¹

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The 2D assessment was quite popular using standardized scales.^{12,13} However, due to limitations of 2D modalities^{14,15} and the development of more precise multi-slice computed tomography (CT), micro-CT, and CBCT, 3D measurement methods are more commonly considered than 2D methods in SABG.¹⁶

Cone-beam computed tomography is preferred over CT for being more reachable, less expensive, having less radiation dose, and possessing a shorter exposure time.¹⁷⁻¹⁹ Studies reporting

on different methods of alveolar cleft assessment using CBCT are increasing.¹¹ Moreover, CBCT gives realistic data in various spatial diameters; therefore, it is utilized for the presurgical assessment using reconstructed images, and it is also used for the evaluation of postsurgical outcomes of SABG through volumetric and linear measurements.²⁰ The alveolar cleft boundaries definition in CBCT remains a problem.²¹ These boundaries were reported difficult-to-define without a well-established anatomical landmarks that should be stated by the assessor before analysis.¹¹

The race of digital analysis software programs draws attention in the medical literature. Many programs are available for volume assessment with different compatibility, availability, accuracy, and time took for analysis.^{3,22} Instances for such software programs are Mimics (Materialize, Belgium), Matlab (MathWorks Inc., USA), Romexis (Planmeca, Finland), and On-Demand 3D (Cybermed Inc., Korea). These software programs were investigated in different studies for their validation in alveolar cleft volumetric measurements, in particular.^{16,23,24} InVesalius 3 (CTI, Brazil) is an example of these softwares that could undergo volume measurements. It is an open-source program that generates 3D imaging reconstructions based on a sequence of 2D digital imaging and communications in medicine (DICOM) files acquired from CBCT, CT, and magnetic resonance imaging (MRI).²⁵

This study aimed to evaluate presurgical computerized volumetric analysis in SABG, and the time taken for calculation using CBCT by two different software programs; On-demand 3D (Cybermed Inc., Korea) and InVesalius 3 (CTI, Brazil).

MATERIALS AND METHODS

Twelve patients with unilateral alveolar clefts seeking treatment were admitted from the outpatient clinic of the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Mansoura University, Mansoura, Egypt. The study was done at the same department from August 2021 to January 2022. A prospective study was conducted in which all patients were exposed and tested for same variables.

An informed consent was obtained for each patient at study entry (written and verbal guidelines) and signed by their representative guardians. In addition, the study protocol was approved by the ethical committee of faculty of dentistry, Mansoura university, Mansoura, Egypt, Registration No. A08080920.

The inclusion criteria were non-contributory medical history, willingness to participate into the study, and aging from 8 to 14 years old. The exclusion criteria, on the other hand, were patients with syndromic alveolar clefts, inability to attend the recalls, previously operated alveolar clefts, and history of relevant orthodontic maxillary expansion.

Data Acquisition

A preoperative CBCT (iCAT FLX, ISI, PA, USA) was done for each patient using quick scan imaging protocol of 16 cm × 13 cm field of view (FOV) (120 kV, 5 mA, 2 seconds) and 0.3 mm voxel size. The CBCT scans were processed and produced into DICOM files.

Anatomical Landmarks

For standardizing the cleft definition in the CBCT, the anterior nasal spine (ANS) level was considered as the cleft superior limit (CSL). The cemento-enamel junction (CEJ) of the mesial tooth to cleft was considered as the cleft inferior limit (CIL). The labial limit of the cleft (CLL) was the continuity of the mesiolabial and distolabial dentoalveolar margins. The palatal limit of the cleft (CPL) was the continuity of the mesiopalatal and distopalatal bony margins. Whereas the mesial and distal boundaries were normally the axial cleft borders, cleft mesial limit (CML) and cleft distal limit (CDL), respectively.

Cleft Volume Calculation

The following two methods were implemented using two different software programs to calculate the cleft volume:

- Method A using On-Demand 3D software (Cybermed Inc., Korea) (Fig. 1).
- Method B using InVesalius 3 software (CTI, Brazil) (Fig. 2).



Fig. 1: A screenshot from On-demand 3D software program interface used in method A volume calculation

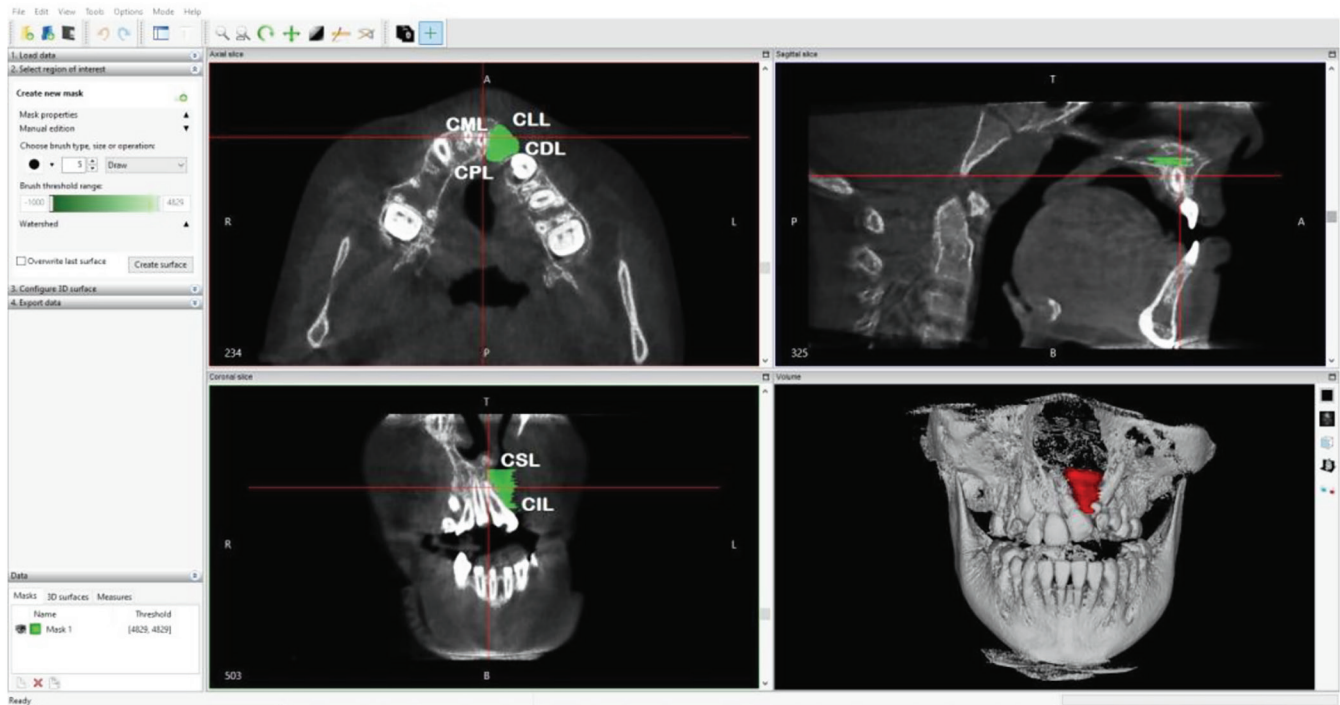


Fig. 2: A screenshot from InVesalius 3 software program interface used in method B volume calculation

Two well-trained independent investigators (X and Y) did the measurements in both methods.

In method A, DICOM data were imported into the software. Using the “area” tool under the “measure” tab, the surface area (SA) of the cleft was demarcated on every axial scan cut following the previously defined anatomical landmarks (Fig. 1). After each selection, the software automatically calculated the SA per scan cut. Then, the following formula was used to calculate the overall cleft volume:^{16,26}

$$\text{Volume} = \frac{\text{Sum of surface area on axial plane} \times \text{cleft vertical dimension on coronal plane}}{\text{Number of axial scan cuts}}$$

where the volume is measured in mm³ and the SA in mm².

The sum of SA was the total of SAs on every axial cut. The vertical dimension of the cleft was measured on the coronal plane from CSL to CIL using the “ruler” tool under “measure” tab. Number of axial cuts was calculated as the difference between the CSL axial cut order, and the CIL axial cut order.

In method B, DICOM data were imported into the software. Under “select region of interest” tab, “manual edition” was chosen. Then, the “choose brush type, size and operation” inputs were adjusted as follows: Circle, 5, and, draw, respectively. Afterward, the cleft was drawn on every axial cut by dragging this brush and following the aforementioned anatomical landmarks as in method A. After the cleft has been highlighted in all cuts within its boundaries, the “create new surface” tab was clicked. Under “data” tab, “3D surfaces” tab was selected, and now the overall highlighted cleft volume was calculated by the software (Fig. 2).

Volume Calculation Time

Time spent for volume calculation in both methods was calculated using a stop-watch. In method A, time started from first axial cut

cleft’s SA demarcation, passing by measuring the cleft’s vertical dimension in the coronal plane, and ended after calculating the volume formula. In method B, time started from the first axial cut cleft’s brush drawing and ended by clicking the “3D surfaces” tab in the software’s interface, where volume was automatically calculated.

Statistics

Data were collected and analyzed using statistical package for social science software (SPSS, v.23.0, IBM Inc., Chicago, USA). Statistical *t*-test was performed in which the statistical significance was considered if *p* ≤ 0.05. Interobserver reliability was calculated by means of ICC. The ICC values below 0.5 were indicative for poor reliability, greater than or 0.5 and below 0.75 indicated moderate reliability, greater than or 0.75 and below 0.9 indicated good reliability, and values greater than or 0.9 indicated excellent reliability.²⁷

RESULTS

Twelve patients were included in this study after the inclusion criteria have been met. Seven patients were males (58%) and 5 were females (42%). The mean age was 10.6 ± 2.1. Six patients had unilateral alveolar cleft in the right side (50%), and six patients had unilateral alveolar cleft in the left side (50%) (Table 1).

For investigator X, mean cleft volumes measured by methods A and B for the same sample were 1.19 ± 0.04 cm³ and 1.17 ± 0.04 cm³, respectively. The difference between volumes measured by both methods was not statistically significant (*t*-test, *p* = 0.186) (Table 2). The mean time spent in volume measurements and calculations in method A was 8.1 ± 0.54 minutes, while the mean time spent in volume calculations in method B was 5.7 ± 0.38 minutes. The difference between both times was statistically significant (*t*-test, *p* < 0.001) (Table 3).

Table 1: Descriptive statistics, and measurements used for method A by both investigators

Number of patients (n = 12)	Cleft side	Gender	Age (years) (mean = 10.6 ± 2.1)	Investigator X readings			Investigator Y readings		
				Sum of CBCT axial cuts SA in method A (mm ²)	Number of axial cuts in CBCT	Vertical dimension of cleft in CBCT (mm) (mean = 14.5 ± 0.97)	Sum of CBCT axial cuts SA in method A (mm ²)	Number of axial cuts in CBCT	Vertical dimension of cleft in CBCT (mm) (mean = 14.5 ± 0.94)
1	L	M	14	4,250	52	15.6	4,245	51	15.3
2	L	F	9	4,010	48	14.4	4,013	48	14.4
3	R	M	8	3,850	46	13.8	3,855	46	13.8
4	R	F	10	4,008	50	15	3,985	49	14.7
5	L	F	11	4,020	51	15.3	4,022	51	15.3
6	R	M	10	3,900	49	14.7	3,890	49	14.7
7	L	F	13	4,150	52	15.6	4,160	52	15.6
8	L	M	14	4,100	52	15.6	4,110	52	15.6
9	R	M	12	3,820	47	14.1	3,833	48	14.4
10	L	F	9	3,710	42	12.6	3,710	42	12.6
11	R	M	8	3,800	44	13.2	3,780	44	13.2
12	R	M	10	3,920	49	14.7	3,942	50	15

F, female; L, left; M, male; mm, millimeters; mm², square millimeters; n, sample size; R, right; SA, surface area

Table 2: Volume measurements by the two methods via both investigators (statistically significant if p ≤ 0.05)

Number of patients (n = 12)	Investigator X readings		Investigator Y readings	
	Cleft volume by method A (cm ³) (mean = 1.19 ± 0.04)	Cleft volume by method B (cm ³) (mean = 1.17 ± 0.04)	Cleft volume by method A (cm ³) (mean = 1.19 ± 0.05)	Cleft volume by method B (cm ³) (mean = 1.14 ± 0.07)
1	1.275	1.100	1.274	1.055
2	1.203	1.195	1.204	1.190
3	1.155	1.150	1.157	1.160
4	1.2024	1.198	1.196	1.020
5	1.206	1.210	1.207	1.226
6	1.170	1.168	1.167	1.046
7	1.245	1.240	1.248	1.246
8	1.230	1.200	1.233	1.203
9	1.146	1.150	1.150	1.149
10	1.113	1.101	1.113	1.099
11	1.14	1.135	1.134	1.141
12	1.176	1.168	1.183	1.175

p = 0.186 p = 0.069

cm³, cubic centimeters; n, sample size

For investigator Y, the mean cleft volumes measured by methods A and B for the same sample were 1.19 ± 0.05 cm³ and 1.14 ± 0.07 cm³, respectively. The difference between volumes measured by both methods was not statistically significant (t-test, p = 0.069) (Table 2). The mean time spent in volume measurements and calculations in method A was 11.3 ± 0.73 minutes, while the mean time spent in volume calculations in method B was 7.3 ± 0.47 minutes. The difference between both times was statistically significant (t-test, p < 0.001) (Table 3).

The ICC values indicated excellent interobserver reliability for measurements by method A [ICC average = 0.998, 95% confidence interval (CI), p < 0.001], it ranged from 0.994 to 1.000. While for method B, ICC values ranged from 0.159 to 0.888 and indicated moderate reliability (ICC average = 0.626, 95% CI, p = 0.049).

These results could infer that volume measurements were close between the two methods. On the other side, time difference exists between them. Also, readings were reliable between both investigators.

Table 3: Time spent in volume calculation for the two methods by both investigators (Statistically significant if $p \leq 0.05$)

Number of patients (n = 12)	Investigator X		Investigator Y	
	Time spent in volume measurements and calculations in method A (min) (mean = 8.1 ± 0.54)	Time spent in volume measurements in method B (min) (mean = 5.7 ± 0.38)	Time spent in volume measurements and calculations in method A (min) (mean = 11.3 ± 0.73)	Time spent in volume measurements in method B (min) (mean = 7.3 ± 0.47)
1	8.7	6.1	11.9	7.7
2	8	5.6	11.2	7.2
3	7.7	5.4	10.7	6.9
4	8.3	5.8	11.4	7.3
5	8.5	6	11.9	7.7
6	8.2	5.7	11.4	7.4
7	8.7	6	12.1	7.8
8	8.7	6	12.1	7.8
9	7.8	5.5	11.2	7.2
10	7	5	9.8	6.3
11	7.3	5.1	10.3	6.6
12	8.2	5.7	11.7	7.5
	$p < 0.001$		$p < 0.001$	

min, minutes; n, sample size

DISCUSSION

Presurgical three-dimensional evaluation of alveolar clefts not only orients surgeons with cleft's details like cleft extension and irregularities, but also aids in volumetric analysis for estimating the required amount of bone grafts.¹⁰ In this study, it is mentioned that the two investigated software programs showed comparable volumetric measurements of the alveolar clefts. However, time that was spent to measure the alveolar cleft volume showed a marked difference between both programs.

In this study, there was a male gender predilection for the investigated alveolar cleft patients. This agrees with Murray et al.²⁸ who stated that males are more affected than females. Dixon et al.¹ reported that left-sided unilateral alveolar clefts are more common than right-sided ones. However, in this study, an equal distribution between the two sides was found.

The mean cleft volumes that were measured in this study by both investigators using method A were $1.19 \pm 0.04 \text{ cm}^3$ and $1.19 \pm 0.05 \text{ cm}^3$. This is in agreement with Attar et al.²⁶ and Etemadi et al.¹⁶ who had the same measures, approximately, using the same formula utilized in this method. Using method B, the mean measured volumes by both investigators were $1.17 \pm 0.04 \text{ cm}^3$ and $1.14 \pm 0.07 \text{ cm}^3$. These measurements were very close to method A measures, and the difference between both methods' measurements was not statistically significant.

Many computer software programs were discussed in the literature with various accuracy and predictability. For instance, Du et al.³ investigated mirroring techniques for unilateral alveolar cleft volume measurement using a proprietary closed-source software, Mimics (Materialize, Belgium). However, the dentoalveolar complex is not believed to be symmetrical, and that, the sound side of the maxilla could not be relied on to reproduce the volume of the affected side.

Another example was Chen et al.,⁹ who reported another technical method using a the same proprietary closed-source

software as the study of Du et al.³ However, it took a lot of time; around 1 hour, for each cleft volume calculation. In this study, mean times spent for volume calculation in method B by both investigators were 5.7 ± 0.38 and 7.3 ± 0.47 minutes. These were much less than times spent in method A by the two investigators (means = 8.1 ± 0.54 minutes and 11.3 ± 0.73 minutes), and the difference between both methods' time was statistically significant. This latter difference could be justified in that, for every CBCT axial cut, SA demarcation in method A was done by surrounding the cleft from around its boundaries. This took more time than just drawing the cleft itself in the axial cuts using a brush tool as in method B. Moreover, the volume formula used, and the cleft's vertical dimension measurement in method A added more time for volume calculation, unlike the situation in method B where the software calculated the overall volume automatically by itself without any needed manual formula.

In this study, the interobserver reliability was quite high. For method A measurements, the ICC showed excellent reliability. The used formula, and the multiple analyzing factors; anatomical landmarks establishment, vertical dimension, cleft demarcation and total SAs calculation, were attributed to diminish the end result differences majorly. In method B, although the interobserver reliability was more than good, that is, moderate, this could be related to the only two factors affecting the volume measurement; anatomical landmarks establishment and cleft drawing. Therefore, differences were transported shortly to the end result of the volume measurement without further processing as in method A.

The advantages of On-Demand 3D software program (Cybermed Inc., Korea) includes its accuracy, simplicity and ability to import lots of DICOM files, thus producing high definition 3D images.²⁶ Attar et al.²⁶ used this program for presurgical alveolar cleft volume measurement as this study and highlighted its accuracy for such purpose. However, being a closed-source program, it is a relative disadvantage that may limit its use in many institutes.

InVesalius 3 software program (CTI, Brazil), on the other hand, has a marked advantage of being an open-source program. Hasan et al.²⁹ investigated this program in craniofacial measurements and proved it as accurate as another closed-source program; Mimics (Materialize, Belgium). Similarly, Serindere et al.³⁰ used InVesalius 3 for volumetric and morphological analysis of mandibular condyle and glenoid fossa, reporting its fast processing and open-source service. Moreover, Ruppert et al.²⁵ incorporated this program in producing a touchless user interface solution to enable a surgeon to toggle between computer-based CT images just using hand gestures, with proven functionality and accuracy.

To the authors' knowledge, the software used in method B; InVesalius 3, was not used in the literature before for such purpose; alveolar cleft volume calculation. This software is an open-source program that can be freely downloaded from the software's company website. This may help lots of researchers and clinicians to entail this volume calculation method in their daily practice, especially in relatively low-economic standards or with patients that could not afford proprietary software planning costs, with the advantage of a reasonably fast, apparently reliable, and easy procedure of calculation. Such entailment may lower patient's and health care provider's financial burden that were discussed before by Kesztyús et al.³¹

This study is not flawless. The boundaries of the alveolar bone defect were customized and uncertain, and may differ from one investigator to another, especially the palatal boundary (CPL). The same point was highlighted in the study of Stoop et al.¹¹ Moreover, the presurgical estimated cleft volume could not be confirmed to be the actual needed bone volume for alveolar cleft grafting. Further studies are deemed hopeful for probing this study's limitations.

CONCLUSIONS

Both software programs investigated in this study had comparable volumetric computation, but one of them; InVesalius 3 was relatively faster than the other, On-Demand 3D. The interobserver reliability was high for both programs, which indicated minimal subjective variance for well-trained practitioners.

These both presurgical volumetric analytical methods may participate in the regular work-up for SABG, in particular method B that used InVesalius 3 program. Thus, reducing the surgical operating time, as the surgeon would be clearly oriented with the cleft's volume and nature preoperatively, and adequately selecting a donor site with congruent sufficient amount of bone grafts.

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