

Human Cadaver Study Evaluating a New Measurement Technique for Graft Volumes after Sinus Floor Elevation

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ABSTRACT

Purpose: Volumetric data can be used as complementary information to characterize grafting materials. The aim of this cadaveric study was to analyze a noncommercial measurement technique based on the novel concept of an “interactive rigid registration algorithm” (IRRA). Parameters analyzed included the reproducibility of IRRA measurements and their reliability in comparison with the established measurement technique of “region growing segmentation thresholding” (RGST).

Materials and Methods: Three human skulls were used to simulate a total of 18 sinus grafts, using three incremental grafting procedures in each sinus (three skulls × two sinuses × three grafting increments). Radiopaque impression material was used for the simulated grafts, whose volumes were recorded by computed tomography from three different tilt angles. The reproducibility of IRRA measurements and the reliability of volumetric results obtained with both the IRRA and RGST techniques were evaluated by appropriate intraclass correlation coefficient (ICC) and Bland–Altman analysis.

Results: ICC greater than 0.9 indicated close to perfect agreement of the results obtained with both methods and good reproducibility of the IRRA measurements. Bland–Altman analysis demonstrated good inter-method and intramethod agreement.

Conclusions: The IRRA measurement technique can be recommended as a noninvasive tool to evaluate graft volumes in human maxillary sinuses.

KEY WORDS: computed tomography, sinus floor elevation, volumetric analysis

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INTRODUCTION

The stability of grafts used for sinus augmentation is an important concern in implant dentistry. Numerous different grafting materials and techniques have been proposed, two decisive factors for successful implant treatment in atrophic posterior maxillae being graft consolidation and sinus repneumatization. A number of volumetric techniques have been proposed to evaluate dimensional changes in the wake of these grafting procedures. Baseline volumetric data and nonlinear dimensional changes are therefore of great interest in clinical research dealing with sinus floor elevations.^{1–5} Unfortunately, processes inside the maxillary sinus are accessible neither to visual inspection nor to direct measurement or water displacement volumetry.⁶ Plain dental or panoramic radiographs are also unsuitable for volumetric analysis, as they can only give an approximation of the vertical dimension of grafts due to their two-dimensional nature.^{7–9}

For this reason, alternative devices and quantification techniques have been introduced to assess graft volumes in the maxillary sinus. The data records offered by three-dimensional imaging technologies such as magnetic resonance imaging, cone-beam computed tomography (CBCT) or computed tomography (CT) are known to yield reliable volumetric information in a nondestructive fashion for routine analysis.^{8,10–12}

Morphometric studies have shown that three-dimensional data can be segmented and analyzed depending on the field of application or spread and availability of the technology. One common and well-studied approach is manual perimeter tracing with three-dimensional imaging (CT/CBCT) to display the region of interest.^{13–18} After tracing this region slice by slice to obtain multiple surface areas, these areas are then multiplied by the thickness of each slice to calculate the three-dimensional volume. As a major constraint, this technique proved to be rather time-consuming and distinctly technique-sensitive, the latter being an issue notably in the hands of less experienced investigators.¹⁹

Another measurement technique is “region growing segmentation thresholding” (RGST) as described by Park and colleagues²⁰ Here an appropriate seed point with a defined Hounsfield unit (HU) value is selected by mouse click in the region of interest and is then three-dimensionally visualized by CT or CBCT. All neighboring contacting voxels located within a defined range (threshold) of similar HU values are conflated (region growing) for semiautomated volumetric assessment. However, due to the similar HU values of the grafting material and the surrounding bone, this approach cannot normally be used to assess graft volumes in the maxillary sinus, but its use remains confined to applications such as lung nodules that involve a suitable radiopacity difference.²¹ The present study was conducted to adapt a novel “interactive rigid registration algorithm” (IRRA) to this application. The IRRA technique relies on rigid structures that are present in every skull, such that two CT scans taken of the same skull at different times can be matched to detect dissimilarities, as for volumetric assessment of sinus grafts.²²

The IRRA technique used in this cadaveric study has been developed to offer swift results at high accuracy and irrespective of individual skills or material densities by aligning two volumetric data sets of the same patients obtained at different times and including the use of different tilt angles. The purpose of this human cadaver

study was to evaluate the usefulness of semiautomated three-dimensional IRRA measurements in quantifying simulated graft volumes in human maxillary sinuses. Use was also made of the RGST technique as an accepted reference method, which became possible thanks to the high radiopacity of the material used for simulated grafting in this experimental setting.

MATERIALS AND METHODS

Institutional approval was obtained from the local ethics commission (reference number 19–087 ex 07/08). Two examiners were trained by a radiologist prior to the investigation. The roadmap for data acquisition is presented in Figure 1. Four scanning stages can be distinguished, including one stage performed on the non-grafted skull and three stages performed after three consecutive grafting increments. All results are expressed in cubic centimeters (cm³).

Specimens

Twelve cadaveric human skulls were screened using a CT scanner (Somatom AR.T, Siemens, Bensheim, Germany) at the Medical University of Graz Division of Anatomy to find suitable skulls for simulated sinus floor elevations. Only skulls with edentulous maxillae could be included whose maxillary sinuses were bilaterally intact, had no history of surgical or grafting procedures, and did not contain any impacted teeth. Any additional defects related to the maxillary sinuses led to exclusion from the study. Three skulls were selected, cleared of soft tissue, and subjected to a desiccation procedure, such that dry skulls were obtained. The osseous structures dorsal to the oval foramen and cranial to the orbita were removed parallel and perpendicular to the frontal plane, respectively. Access to the maxillary sinuses was established by carefully preparing a cavity roughly 1 cm in diameter in each orbital base (Figure 2). The first increment of sinus floor elevation was performed in both cavities through an orbital access, using a radiopaque impression material that offered an HU value of 3017 (Elite Implant Medium, Zhermack, Badia Polesine, Italy). Afterwards, additional volumes of the radiopaque impression material were sequentially applied to obtain two more grafting increments. Thus a total of three different graft volumes were created in each sinus.

Acquisition of Raw Data

All scans were performed with a Somatom Plus 4 CT Scanner (Siemens) at the Medical University of Graz

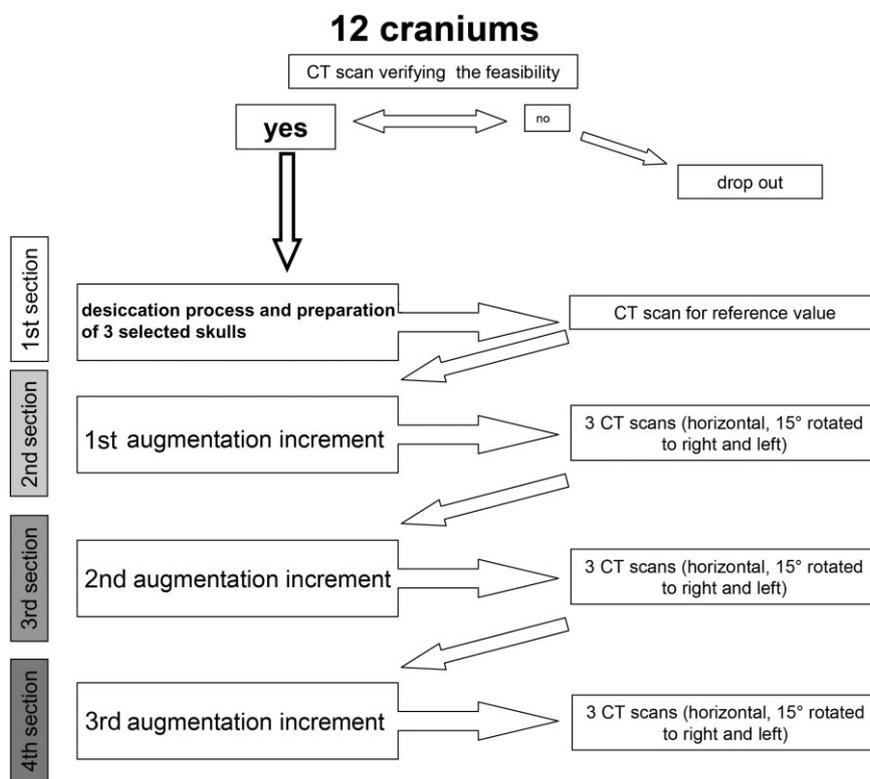


Figure 1 Study procedure involving four CT scanning stages, including a baseline stage and three grafting stages.

Department of Radiology. Data were acquired by taking 1.25 mm slices at 140 kVp and 240 mA in high-quality helical mode with a speed of 3.75 mm/rotation and a field of view of 20 cm. The first scanning session was performed on the non-grafted skull to obtain baseline data. Additional scans were obtained after the consecutive grafting sequences, thus representing the first, second, and third increment of sinus grafting, each procedure being performed on both sinuses. Three

scanning angles (0° and 15° from the left and right) were used in each scanning session to capture each skull (Figure 3).

Volumetric Analysis Using RGST as Reference Technique

The simulated graft volumes could be distinguished clearly from the surrounding bone thanks to the

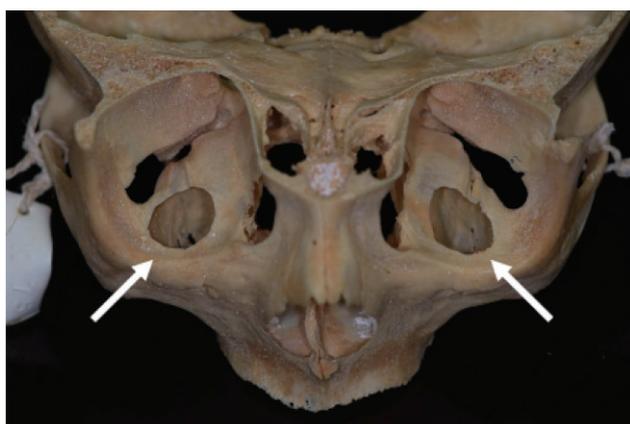


Figure 2 Desiccated skull with access cavities in the orbital plane.

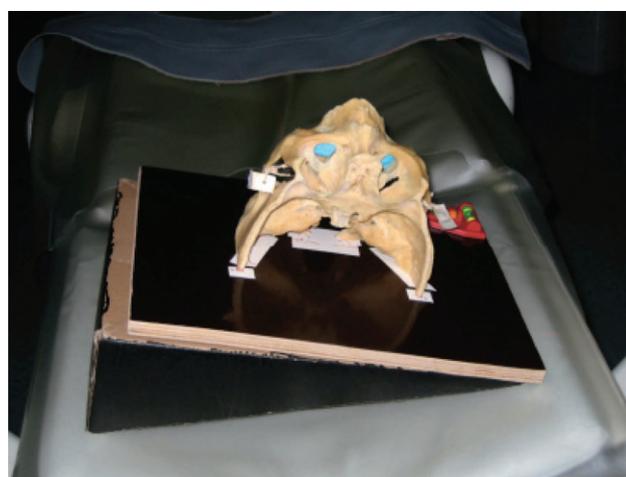


Figure 3 Rotation of skull for tilted CT scanning. The tilt angle of 15° was verified by a spirit level. Note the blue volumes of radiopaque impression material.

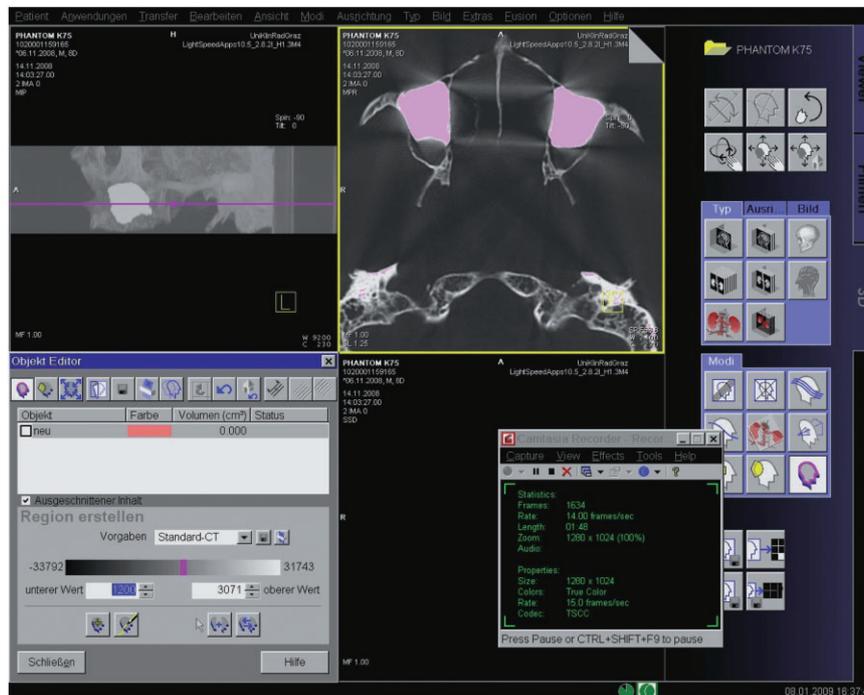


Figure 4 User interface of the Leonardo software. The selected graft area trough RGST is highlighted by the pink area, the actual plane is indicated by the pink line.

radiographic properties of the material employed. Using a Leonardo 3D Workstation (Siemens) with VD10B software on a Syngo VX49B platform (Figure 4), semi-automated volumetric calculation was performed using the RGST technique. Starting from a voxel in the center of the graft, the algorithm expanded this seed point gradually within the same density in the surroundings. The peak value of the cross-correlation curve was determined, and an empirical cutoff value near the peak value was used to separate the graft from its adjacent structures in order to calculate the volume of each graft on either side of the maxilla.

Volumetric Analysis Using IRRA as Study Technique

A dedicated system to define bone volume within human maxillary sinuses was developed in a collaborative effort at the Medical University of Graz School of Dentistry and the Graz University of Technology.²² The research software was implemented on a Microsoft Windows XP Professional platform (minimum hardware requirements: Intel Core 2-Quad CPU Q6700 2.66 GHz; 3.25 GB RAM; NVIDIA GeForce 280GTX). The IRRA process consists of preprocessing, manual masking, and registration as major steps (Figure 5, A–C). All volumetric data were first acquired and

transformed to “analyze” format. Manual masking was applied to exclude nonrigid bone structures like the cervical spine and mandible. The complete process of registration is performed automatically in the form of an iterative optimization approach for spatial transformation, using an intensity-based method to map one volume into another. After obtaining a positive match of two CT data sets, the volume of the graft area was automatically displayed by visually representing the resultant differences (see Figure 5B).

Body of Values Analyzed

An overview of the scanning information captured for analysis is presented in Figure 6. A total of 12 scans were performed per skull (four scanning sessions \times three scanning angles). This included one baseline scan performed on the non-grafted skull and three scans performed after each of the consecutive grafting increments, each scan being taken horizontally (0°) and from left/right tilt angles ($15^\circ/15^\circ$). Thus a total of 24 values were obtained per skull (four scanning sessions \times three scanning angles \times two sinuses). For the RGST technique, a total of 18 values were assessed based on the mean value of each grafting increment (three mean values \times two sinuses \times three skulls). For the IRRA technique, statistical analysis was based on a total of 162 values. This included

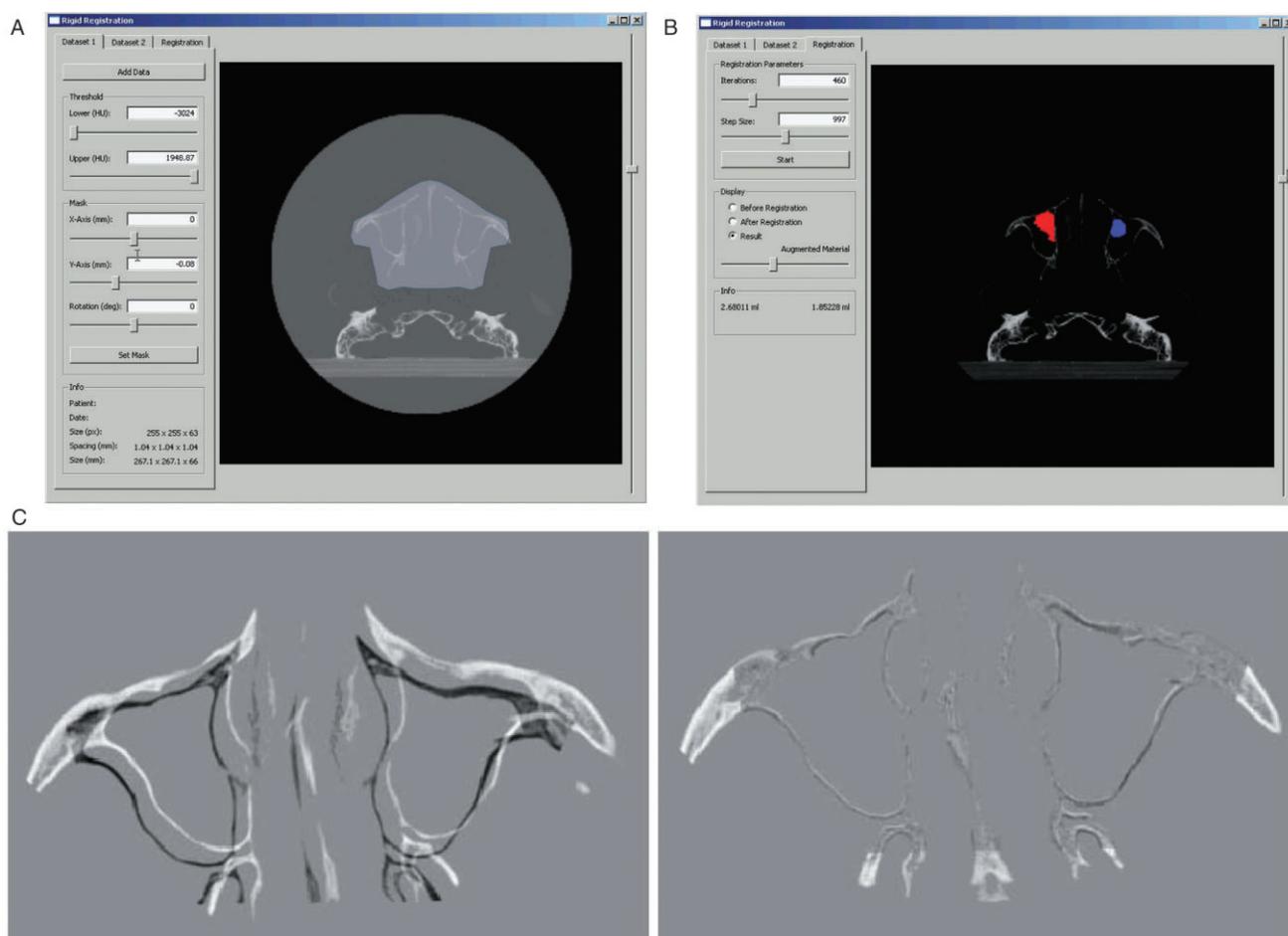


Figure 5 A–C, User interface of the IRRA software. A registration procedure is shown, including (A) mask adjustment, (B) the calculated volumes highlighted in red/blue, and (C) the data sets before and after registration.

each value obtained from the various scanning angles used on each grafting increment compared to each value obtained from the various scanning angles previously used on the non-grafted skull (i.e., nine angle combinations \times three grafting increments \times two sinuses \times three skulls). The reader is referred to Table 1 for an overview. Once the reliability of IRRA had been demonstrated, the detailed measurements obtained from the various scanning angles were averaged to obtain 18 values for direct comparison with the 18 RGST values.

Statistical Analysis

Statistical analysis was performed using SPSS 18.0 (SPSS Inc., Chicago, IL, USA) and Excel 2003 (Microsoft Corporation, Redmond, WA, USA). IRRA measurements were analyzed for reliability by comparing the data sets of identical graft volumes that had been taken from three different angles. Accuracy of the IRRA measurements (i.e., the graft volumes) was assessed in compari-

son with the RGST technique, calculating the mean value of nine IRRA measurement combinations within each graft volume. Accuracy and reliability were assessed based on the intraclass correlation coefficient, two-way random model (ICC [2,1] concept) as described by Shrout and Fleiss.²³ In accordance with Landis and Koch,²⁴ ICC agreement values were classified on a six-point scale. Measurements were additionally evaluated as reported by Bland and Altman²⁵ based on d (mean difference), SE of d (standard error of mean differences), 95% CI for d (95% confidence interval [CI] for mean differences), SD_{diff} (standard deviation of differences), and 95% limits of agreement as $d \pm 2SD_{Diff}$.

RESULTS

Descriptive Analysis

Based on both measurement techniques used in the present study, a mean graft volume of $2.768 \pm 0.799 \text{ cm}^3$

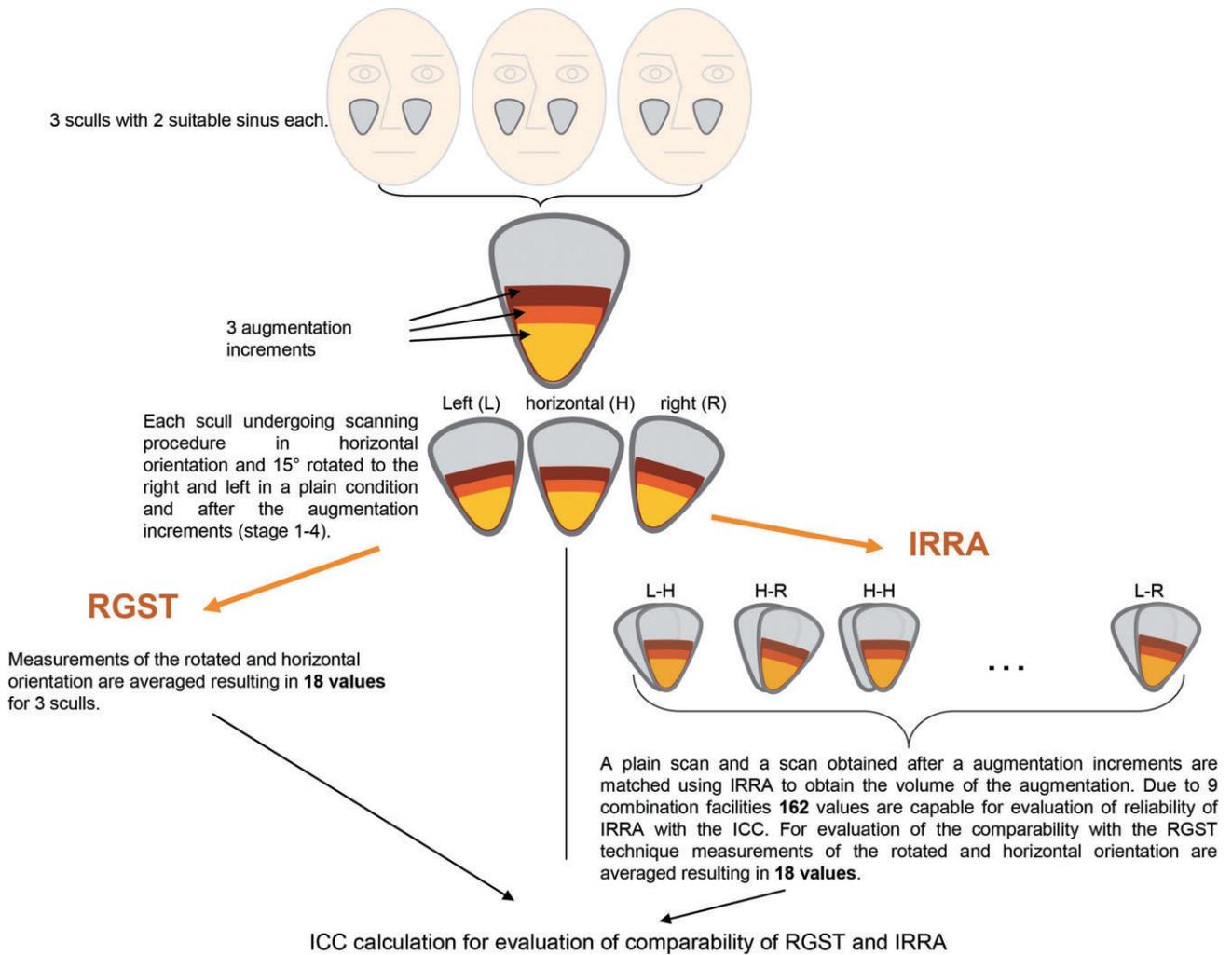


Figure 6 Details of data acquisition and choice of data for statistical evaluation.

(1.810–4.373 cm³) was measured after the first augmentation increment, compared with 4.492 ± 1.035 cm³ (3.105–6.298 cm³) after the second and 5.585 ± 1.090 cm³ (4.002–7.006 cm³) after the third augmentation increment. The RGST reference technique returned mean graft volumes of 2.777 ± 0.905 cm³ (1.852–4.373 cm³) after the first, 4.552 ± 1.151 cm³ (3.183–6.298 cm³) after the second, and 5.656 ± 1.202 cm³ (4.098–7.006 cm³) after the third augmentation increment. Based on all consecutive augmentation increments, the mean graft volume measured with the RGST technique was 4.328 ± 1.595 cm³ (1.852–7.006 cm³). By comparison, the IRRA study technique returned mean graft volumes of 2.767 ± 0.796 cm³ (1.810–4.354 cm³) after the first, 4.486 ± 1.033 cm³ (3.105–6.251 cm³) after the second, and 5.578 ± 1.089 cm³ (4.002–6.970 cm³) after the third grafting increment performed on differ-

ent positions of each skull. Based on all consecutive augmentation increments, the mean graft volume measured with the IRRA technique was 4.277 ± 1.516 cm³ (1.810–6.970 cm³). The mean durations of volumetric processing were 8.5 minutes (7–11) with RGST versus 2.4 minutes (2.3–5.8) with IRRA.

Reliability of IRRA

For the nine different combinations of IRRA measurement, the ICC results are in almost perfect agreement (ICC = 0.999; 95% CI: 0.998–1). Considering the three different baseline situations (horizontal, 15° rotated to right and left), all ICC values exceeded 0.9. Bland–Altman analysis showed that the mean differences between the different IRRA measurements ranged from –0.023 to +0.014, with limits of agreement ranging from –0.199 to +0.182 (Table 2).

TABLE 1 All Values Measured (Expressed in Cubic Centimeters)

Skull	Vol.	Side	RGST	IRRA h-h	IRRA h-l	IRRA h-r	IRRA l-h	IRRA l-l	IRRA l-r	IRRA r-h	IRRA r-l	IRRA r-r	IRRA Mean
1	1	LS	2.809	2.810	2.815	2.797	2.769	2.761	2.793	2.772	2.770	2.800	2.787
1	2	LS	3.448	3.434	3.445	3.404	3.4532	3.414	3.398	3.431	3.401	3.433	3.421
1	3	LS	4.098	4.002	4.088	4.078	4.040	4.069	4.067	4.028	4.047	4.010	4.048
2	1	LS	1.852	1.831	1.837	1.810	1.814	1.855	1.815	1.813	1.828	1.825	1.825
2	2	LS	3.183	3.105	3.143	3.137	3.167	3.182	3.177	3.165	3.151	3.136	3.151
2	3	LS	4.423	4.358	4.040	4.392	4.394	4.457	4.395	4.386	4.378	4.389	4.354
3	1	LS	1.979	2.056	2.030	2.077	2.139	2.130	2.139	2.121	2.164	2.224	2.120
3	2	LS	4.938	4.739	4.765	4.812	4.877	4.865	4.879	4.882	4.888	4.887	4.844
3	3	LS	6.302	6.127	6.067	6.085	6.235	6.230	6.252	6.245	6.235	6.257	6.193
1	1	RS	4.373	4.304	4.243	4.301	4.323	4.354	4.325	4.298	4.314	4.331	4.310
1	2	RS	6.298	6.148	6.149	6.173	6.226	6.226	6.206	6.203	6.202	6.251	6.198
1	3	RS	7.006	6.833	6.869	6.909	6.911	6.970	6.940	6.887	6.907	6.968	6.910
2	1	RS	2.662	2.673	2.662	2.608	2.618	2.638	2.656	2.618	2.641	2.659	2.641
2	2	RS	4.351	4.316	4.292	4.289	4.283	4.298	4.298	4.274	4.293	4.320	4.296
2	3	RS	5.451	5.399	5.416	5.420	5.419	5.464	5.410	5.388	5.404	5.395	5.413
3	1	RS	2.989	2.978	2.983	2.958	2.899	2.921	2.889	2.882	2.877	2.868	2.917
3	2	RS	5.092	5.065	5.112	5.122	4.976	4.982	4.981	4.911	4.948	4.939	5.004
3	3	RS	6.654	6.634	6.610	6.603	6.504	6.545	6.531	6.511	6.485	6.508	6.548

LS, left sinus; RS, right sinus; h, horizontal orientation; l, left angle (15°); r, right angle (15°).

IRRA versus RGST

Once the reliability of IRRA had been demonstrated, the detailed measurements obtained from the various scan-

ning angles were averaged to obtain 18 values for direct comparison with the 18 RGST values. The ICC for the two different methods was 0.999 (95% CI: 0.991–1). Bland–Altman analysis for the agreement between IRRA

TABLE 2 Comparison of the Various IRRA Measurements and the Different Measurement Techniques (RGST and IRRA) by Intraclass Correlation Coefficients and Bland–Altman Analysis

	Intraclass Correlation Coefficients		Bland–Altman Analysis							
	ICC (2,1)	95% CI	Comparison	\bar{d}	SE \bar{d}	95% CI for \bar{d}	SD \bar{d}	95% LoA		
Overall ICC	0.9989	0.9980–0.9995								
Baseline h	0.9989	0.9975–0.9995	hh-hl	+0.014	+0.020	−0.028	+0.056	+0.084	−0.154	+0.182
			hh-hr	−0.009	+0.010	−0.030	+0.012	+0.043	−0.095	+0.077
			hl-hr	−0.023	+0.021	−0.067	+0.021	+0.088	−0.199	+0.153
Baseline l	0.9999	0.9996–0.9999	lh-ll	−0.019	+0.006	−0.031	−0.007	+0.025	−0.069	+0.031
			lh-lr	−0.007	+0.004	−0.016	+0.002	+0.019	−0.045	+0.031
			ll-lr	+0.012	+0.006	−0.001	+0.025	+0.026	−0.040	+0.064
Baseline r	0.9998	0.9995–0.9999	rh-rl	−0.007	+0.005	−0.017	+0.003	+0.020	−0.047	+0.033
			rh-rr	−0.021	+0.008	−0.038	−0.004	+0.034	−0.089	+0.047
			rl-rr	−0.015	+0.006	−0.028	−0.002	+0.027	−0.069	+0.039
RGST-IRRA	0.9988	0.9912–0.9997	RGST-IRRA	+0.051	+0.013	+0.023	+0.079	+0.057	−0.063	
Mean			Mean						+0.165	

ICC, intraclass correlation coefficient; CI, confidence interval; \bar{d} , mean difference; SE \bar{d} , standard error of mean difference; SD \bar{d} , standard deviation of mean difference; LoA, limits of agreement; h, horizontal orientation; l, left angle (15°); r, right angle (15°).

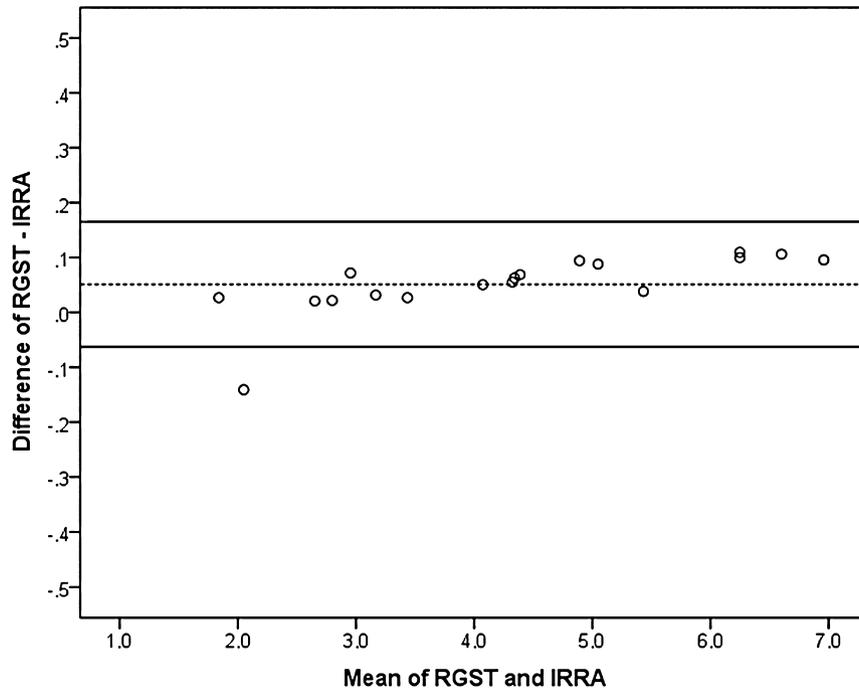


Figure 7 RGST and IRRA measurements as they appear on the Bland–Altman plot, including the 95% limits of agreement.

and RGST yielded a mean difference of 0.051, with limits of agreement ranging from -0.063 to $+0.165$ (see Table 2). The Bland–Altman plot with 95% limits of agreement is shown in Figure 7.

DISCUSSION

Procedures of sinus floor elevation are commonly employed to optimize bone volume for implant placement in atrophic posterior maxillae. Tepper and colleagues²⁶ postulated that the amount and packing density of the grafting material used will have a significant effect on peri-implant stress levels. A three-dimensional finite-element analysis demonstrated that intrabony stress could be reduced by up to 40% in models with adequate osseous support, resulting in better long-term success of implants placed in grafted sinuses.²⁷ Therefore a validated and quick method of collecting volumetric information about maxillary sinus grafts will allow for monitoring their dimensional stability over time and is critical for predictable long-term success. Any technique offering these benefits, such as the IRRA technique, would be a welcome addition to commonly used histologic, histomorphometric, micro-morphometric, or clinical criteria of assessing grafting materials.^{28–35}

The IRRA technique herein reported is based on CT data sets for better comparability, as most techniques of

volumetric measurement have also relied on three-dimensional data sets obtained from CT scans.^{1,14–18,36}

Thanks to the new algorithm introduced in the present study, a measurement technique is obtained that will yield volumetric data irrespective of radiodensity. The RGST technique is not a realistic option for application in vivo, because the density of bone substitutes and/or autogenous bone grafts used for sinus floor elevation is almost identical to the density of the surrounding antral bone. Based on our specific study design, however, selection of an impression material offering suitable properties in terms of HU ($+3071$ HU) enabled us to use the RGST technique as a reference method.²⁰

Various studies have indicated that reliable volumetric results can be obtained with the RGST technique. Gronenschild and colleagues³⁷ found that the volumes measured by RGST or manual perimeter tracing for defined cortical structures in the brain were almost perfectly in agreement, with ICC values ranging from 0.96 to 0.99. Krohn and colleagues³⁸ quantified hollow-sphere phantoms with a diameter of 5 to 20 mL and observed a mean inaccuracy of $3.5 \pm 3.8\%$. Frericks and colleagues³⁹ compared removed livers to preoperative volumetry based on region growing, which revealed a strong statistical association with a Pearson correlation coefficient of $r = 0.98$ ($p < .001$).

In the present study, the mean volumes of the simulated sinus grafts ranged from 1.810 to 7.006 cm³. Very similar ranges of 1.71 to 6.15 cm³¹⁸ or 2.81 to 6.29 cm³³¹ have been reported following real-life sinus elevation procedures *in vivo*. Mean graft volumes ranging from 1.665 ± 0.657 cm³ to 5.057 ± 1.619 cm³ were determined in a CT-based study after clinical procedures of sinus floor elevation aiming for vertical bone gains of 10 to 18 mm.⁴⁰

The high ICCs obtained for the IRRA and the RGST techniques in our study indicate a strong correlation between both approaches. Inter-method reliability is a function of the variation in measurements of the same target obtained with both methods. The Bland–Altman plot confirms that both approaches are interchangeable, as the scattered points are clustered very close to the zero line. The 95% confidence limit for inter-method variation ranged from –0.06 to +0.17 cm³ in the present study, which is clinically acceptable for quantitative evaluation of sinus floor elevations, given a mean volume of 4.28 cm³ across all measurements. Problems of inter-rater reliability can be ruled out, as the dedicated software used did not allow for interactive corrections, thereby making it impossible to interfere with the process of taking the measurements. However, as the patients' heads will not always exactly remain in the same position, the approach taken aimed to take into account repeated readings of the same target when these are complicated by different tilt angles.

As to the intra-method reliability coefficients in this study, all ICCs indicate almost perfect agreement. The mean differences of Bland–Altman analysis comparing the IRRA measurements taken from different angles varied from –0.023 to +0.014, the 95% limits of agreement being –0.154 to +0.182 and –0.199 to +0.153, respectively. These results are clinically acceptable for quantitative evaluation of graft volumes in the wake of sinus floor elevations. No systematic bias (0 not included in the 95% CI) was present in both tests. Most volumetric studies have not indicated specific time requirements. Kirmeier and colleagues¹⁹ reported a fairly high time requirement of 17 to 22 minutes (19.34 ± 3.21) per measurement for manual perimeter tracing. Measurements using the IRRA technique, by contrast, only take 2.8 minutes on average. Combined with its ease of use, the IRRA technique is thus more efficient and user-friendly.

Within the limitations of this experimental phantom study, we were able to introduce a new semi-automated technique for subtractive measurement of graft volumes. This IRRA approach does not require time-consuming manual perimeter tracing of every slice, and it eliminates the need for resorting to the established technique of RGST, which is not an option in assessing grafting procedures *in vivo*. Our investigation leaves little doubt that this IRRA makes for a reliable, valid, reproducible, and time-saving technique of measuring graft volumes. Although its relevance to daily clinical practice may be minor, evaluation of the positional and dimensional stability of grafts following both internal and external procedures of sinus floor elevation is crucial for future research and development purposes. Further studies are needed to evaluate the applicability of the software in determining volume changes following grafting *in vivo*.

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