A New Method to Evaluate Volumetric Changes in Sinus Augmentation Procedure

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ABSTRACT

Background: In sinus augmentation procedure, the assessment of volume changes of grafted materials is important both in the clinical practice and in dental research to evaluate the features of filling materials.

Purpose: In this study, we assessed the repeatability of a new method proposed to evaluate volumetric changes following sinus lift augmentation procedure.

Materials and Methods: In 10 patients, maxillary sinus augmentation procedure with simultaneous implant placement was performed. Maxillary cone beam computer tomographies were taken 1 week after surgery (T1) and 6 months after surgery (T2). At each evaluation the gap inside the implant between the fixture and the bottom of the screw was used as reference point (Rp), and a standardized volume of interest (VOI) centered on the Rp was selected. Masks were chosen to select the graft and bone tissue within the VOI; the volume at T1, T2, and the difference of volume between T1 and T2 were computed. Expert and non-expert operators performed the analysis. Method errors were computed.

Results: The error of the method was 1% for both intra-operator and inter-operator measurements. Tissue contraction at T2 was 19 ± 4% of the total initial volume.

Conclusions: The standardization of the method allows to obtain repeatable measurements.

KEY WORDS: autogenous bone graft, CBCT imaging, computer-assisted, cone beam CT, maxillary reconstruction, maxillary sinus floor elevation, sinus augmentation, x-ray imaging, xenograft

INTRODUCTION

Following tooth extraction, severe alveolar bone atrophy occurs and may compromise the implant placement and prosthetic rehabilitation.[1–3] In maxillary molar region, the sinus lift augmentation procedure performed with several types of grafting materials (autograft, allograft, alloplastic materials, xenograft, or a combination of these) was introduced to recreate the needed bone volume.[4–6]

Autogenous bone, alloplast, and xenograft materials present different remodeling rates and may be characterized by a different volume contraction when grafted in the maxillary sinus.[7]

The success of the sinus lift augmentation procedure may be evaluated considering: (1) the quality of the newly formed bone that allows to a high vital bone/implant contact area; and (2) the three-dimensional stability of the newly formed bone that leads the clinician to predict the needed volume of the graft and maintains the implant bone covered at long-term follow-ups.

Several techniques were proposed in experimental studies to analyze the sinus cavity, to simulate/predict volume graft needed for the sinus augmentation, and to evaluate the volume change of the graft material. Panoramic radiographs were proposed to quantify vertical alterations of the grafted materials; however, no volumetric investigations can be obtained from analysis

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of two-dimensional data and magnification or distortion of images may occur.[8–10] Experimental studies[11–15] analyzed data from three-dimensional computer tomography (CT) and cone beam CT (CBCT): briefly, in each selected slide, sinus floor and the grafted material were manually plotted by an expert operator and the total volume was calculated. This method presents noteworthy bias: (1) freehand drawing of the area of interest on each slide is a lengthy and imprecise procedure, especially because the sinus anatomy is extremely variable; (2) even if great care is taken, clear distinction between grafted area and native bone is not always possible, in particular few months following surgical procedure; and (3) air bubbles were included in the overall calculation.[12]

The presence of a reference point (Rp) and the determination of a standardized area where is performed the evaluation, together with the use of a software for image analysis may help to bypass these biases.

The current study aimed to evaluate the repeatability of a new method proposed to measure volumetric changes following sinus lift augmentation procedure.

MATERIALS AND METHODS

Patients

This study is a prospective clinical trial. Ten patients with unilateral maxillary posterior edentulism, less than 5 mm of residual alveolar crest height, and in need of a sinus lift augmentation procedure for implant placement were included in this study. All patients were more than 18 years old, did not present metabolic disorders, or any systemic counterindication to sinus lift augmentation procedure. The following inclusion criteria were also fixed: tooth extraction in the experimental area from a minimum of 6 months, absence of inflammatory lesions in the experimental area (sinusitis, gingivitis), and signed informed consent. This study was conducted at the Department of Surgical, Reconstructive and Diagnostic Sciences University of Milan, (Fondazione IRCCS Ospedale Maggiore Policlinico, Mangiagalli e Regina Elena, Milan, Italy) following the Declaration of Helsinki for human right and was approved by the Ethical Committee of the Foundation IRCCS Ospedale Maggiore Policlinico, Mangiagalli e Regina Elena, Milan, Italy. All patients signed an informed consent before to be enrolled in the study.

Surgical Procedure

All sites were grafted with a standard mixture of autogenous bone chips (30%) (particle size 0.1–1.0 mm) and deproteinized bovine bone (70%) (Bio-Oss®, Granules 0.25–1.00 mm, Geistlich and Sons, Wolhusen, Switzerland) utilizing the lateral window technique.[4]

Briefly, following exposition of the lateral maxillary wall, a 15 × 10 mm window to the maxillary sinus was created. The Schneiderian membrane was delicately elevated and grafted material was positioned filling the coronal area of the sinus cavity. Implant bed was prepared in the center of the edentulous area following the standard protocol for Astra Tech implants and one small diameter implant was placed (3 × 11 mm) (OsseoSpeed™ 3.0 S, Astra Tech Implant System, DENTSPLY Implants, DENTSPLY IH, Casalecchio di Reno [BO], Italy) in each augmented sinus. A bioresorbable membrane was positioned to cover the created window and to protect the graft (Bio-Gide membrane®, Geistlich and Sons). The mucoperiosteal flap was repositioned and sutured.

Radiography

Maxillary CBCTs (3D Accuitomo 170 XYZ Slice View Tomograph, J. Morita Mfg. Corp., Kyoto, Japan) were performed for all patients at two time points: (1) 1 week after surgery (T1) to verify the absence of early adverse events; and (2) 6 months after surgery (T2) to plan next implant/prosthetic rehabilitation. The same parameters were applied for every scan. The patient's position was regulated with three rays representing the three dimensions of the space, and the CBCT analysis was performed with these settings: 80 KV, 7 mA, 12″ scan time, VOXEL 125 μm, FOV Ø 60 mm × H 60 mm.

All data were elaborated using Mimics (Materialise®, Materialise HQ, Leuven, Belgium). The volume of the grafted material at T1 (V1), the volume of the grafted material at T2 (V2), and the total volume change by subtracting V2 from V1 (ΔV) were calculated.

The software was set on standard parameters of density: air density at −1,000 Hounsfield units (HU) and water at 0 HU.[16–18]

On the CBCT images of each patient, the gap inside the implant between the fixture and the bottom of the screw was taken as an Rp (Figure 1a). In order to obtain a standardized volume of interest (VOI) where the

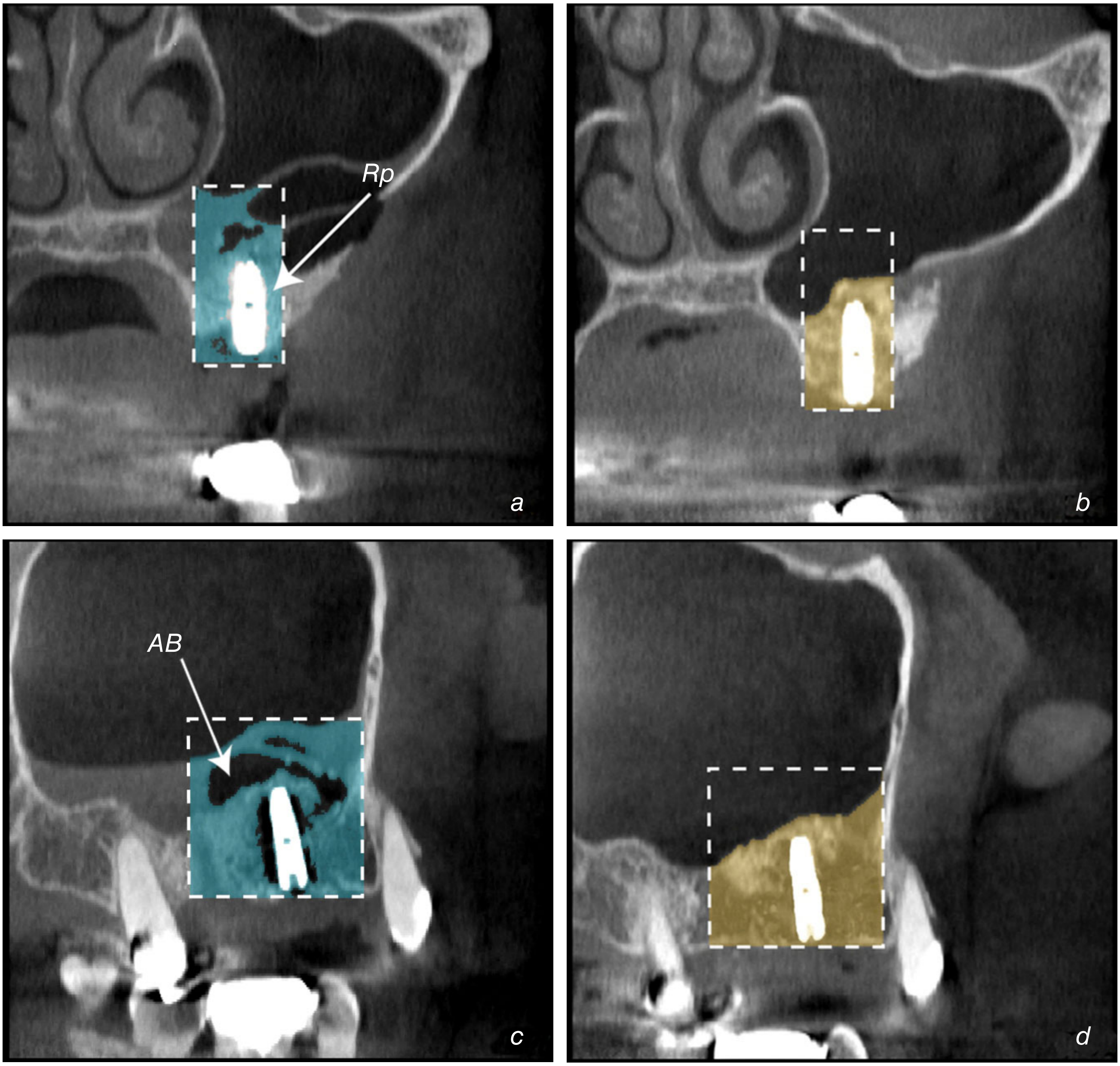

Figure 1 Coronal (A, B) and Sagittal (C, D) sections of the sinus at T1 (A, C) (Cyan mask) and following 6 months (B, D) (Orange mask). The reference point (Rp) was used to center the volume of interest (VOI, dotted line). The Cyan mask (A, C) and the Orange mask (B, D) were calculated. Air bubbles (AB) within the grafted material were excluded from the computation.

examinations are to be performed, an area of 2 cm (sagittal plane) × 2 cm (axial plane) × 1 cm (frontal plane) was defined in the program by the operator and centered on the Rp. The base of the volume was vertically translated and adjusted to the coronal surface of the implant, then the software automatically selected and cropped the VOI.

To isolate the grafted/bone area within the VOI, the operators chose preset masks to individuate different structures basing on specific radiodensity of tissues.[12]

For the analysis of data at T1 (Figure 1, A and C) the Cyan mask (148–1,988 HU) was selected to identify the native bone, the grafted material, and the wound fluid.

Because the remodeling of the graft and the tissue maturation change the tissue density, a different operative sequence was chosen for T2 evaluations (Figure 1, B and D):

- Selection of Green mask: 148 to 2,996 HU (to include cortical and medullary bone)

- Selection of Yellow mask: −700 to 225 HU (soft tissue)
- Orange mask achievement: 226 to 2,996 HU (resulting from the subtraction of the Yellow mask from the Green mask to exclude the Schneiderian membrane, because the wound fluid had disappeared).

In both volume evaluations, the implant volume was not included due to its extremely high density value.

After the operators set the Cyan mask (at V1) and the Orange mask (at V2), the software automatically calculated the corresponding volume.

To assess method error two series of measurements were performed on T1 and T2 graft volumes by one single expert operator and were repeated by a second non-expert operator.

Preliminary Evaluations

Preliminary evaluations were performed to assess the accuracy of the CBCTs analyzed using Mimics. Volumetric measurements of the implant (as standard object) were made using the CBCT system. The mean measurements of the implant volume calculated on all the CBCT images analyzed using Mimics were compared with the known volume given by the manufacturer (*t*-test).

Method Error

Two operators (expert and non-expert) performed all measurements twice and in the interval of 2 weeks.

For both time point evaluations the intra-observer and inter-observer repeatability were computed by paired measurements to identify both random and systematic errors. Random errors were assessed by computing Dahlberg statistics that is, from the differences between the two assessments as follows:

$$Error = \sqrt{\frac{\Sigma(\text{first measurement} - \text{second measurement})^2 /}{2 \times \text{number of couples of repeated measurement}}}$$

t-Test was used to calculate systematic differences either between the first and second within-observer series or between observers. The final error percentage of the method was calculated as the percentage ratio between the variance of the method error (squared Dahlberg's error) and the population variance of the volume measurement (squared standard deviation [SD]).

Statistics

For each value (V1, V2, and ΔV) the mean, SD, and coefficient of variability were computed.

RESULTS

Study Population

A total of 10 patients (5 males and 5 females) were treated. The average patient's age was 58 years (47–66 years). All subjects were non-smokers and presented good health conditions.

Most of the treated sites were completely edentulous in the posterior experimental area and presented missing teeth #15 to #18 or #25 to #28. Only one site had missing teeth #24 to #26 (#27 was still present).

In all sites the residual alveolar crest was 3 mm on average (2–5 mm).

Following 6 months of sinus augmentation, all patients were rehabilitated; the small diameter implant was removed for histological analysis (data not published) and a maximum of three implants were placed.

Data Analysis

Results of the Preliminary Accuracy Test. No significant differences were found comparing the data on the implant volume obtained using Mimics on the CBCTs and the data from the manufacturer (*t*-test, $p > .05$).

Results of the Repeatability Test. No systematic differences were found on values computed either between the first and second within-observer series or between observers (*t*-test, $p > .05$) (Dahlberg's error, 4.8 for intra-observer, 4.55 for inter-observer).

The random error of the method resulted 1% for both the intra-operator and inter-operator measurements.

The mean volume of the grafted material at T1 resulted in 2604.01 ± 531.93 mm^3 (V1) and at T2 resulted in 2104.64 ± 433.17 mm^3 (V2). The mean tissue contraction resulted in 499.37 ± 150.77 mm^3 (ΔV), and corresponded to the 19.17% of the initial total volume (Table 1).

DISCUSSION

In the current study a new method to evaluate the volume tissue changes occurring in the augmented site within the sinus cavity was proposed. Before to design this method, it was necessary to assess the accuracy of the CBCTs analyzed using Mimics. For this purpose, we

TABLE 1 Volumetric Data for Patient: Mean Values of Augmented Tissue at T1 (following 1 Week) and at T2 (following 6 Months), Volume Changes (ΔV), and Percentage of Change on Total Initial Value (ΔV%)

	T1 (mm^3)	T2 (mm^3)	ΔV mm^3	ΔV%
Patient 1	3265.27	2628.74	636.53	19
Patient 2	3045.12	2652.93	392.19	13
Patient 3	2286.40	1750.51	535.90	23
Patient 4	2369.47	1950.29	419.18	18
Patient 5	3159.16	2431.02	728.14	23
Patient 6	2354.21	2013.93	340.28	14
Patient 7	3268.27	2597.66	670.61	21
Patient 8	2036.15	1609.72	426.43	21
Patient 9	2420.77	1853.09	567.69	23
Patient 10	1835.29	1558.58	276.72	15
Mean	2604.01	2104.64	499.37	19
Standard deviation	531.93	433.17	150.77	4
Coefficient of variability	20%	21%	21%	21%

measured the volume of the implant as an object with a standard density, easy to define in the CBCTs and stable at the different healing time points. We compared values from all the CBCT images (at both time points) analyzed using Mimics and data given from the manufacturer. Because the CBCT system used in the present study resulted an accurate method (t-test $p > .05$) for the volume computation, we designed and attested the repeatability of a method to evaluate the volume changing of the augmented maxillary sinus. Previous studies evaluated volume tissue changes by manually plotting the graft in selected CT scans.[12,13] Even if this segmenting method was demonstrated to be accurate,[19] it may take a lot of time to the operator to carefully select the tissue of interest in each slide. Furthermore few months after augmentation procedure, the filling material is integrated and remodeled making it difficult for a non-expert operator to distinguish the grafted tissue from the host tissue and to plot the same area at the post-surgical and post-healing time points.

The method proposed in the present study results from several trials and adjustments to the original protocol. According to the initial protocol, the use of masks was decided to achieve a more precise selection of the healing tissue, excluding the air bubbles. Initially, these masks were applied on the overall area of the sinus cavity trying to select only the material grafted. However, due to the anatomical variability[20] and the presence of bony structures with similar density that could not accurately be excluded, the CBCT was analyzed and it was decided to determine a standardized volume centered on the implant that was placed in the center of the edentulous area and that represented the most clinically relevant site. Applying the last and proposed previous version of the protocol, it was possible to calculate in a standardized and quick (10 minutes per patient) way, the volume of interest of all examined subjects, independently from the sinus anatomy. The error of method calculated in this study supports this hypothesis that the proposed procedure gives repeatable data when applied both by the same operator in different sessions and by more operators with different level of experience.

The remodeling pattern of the filling material seems to be strictly correlated to the three-dimensional features of the recipient site, including: inlay graft thickness, surface area of the graft in contact with basal bone, volume of the recipient site, and surface area of the graft projecting into the sinus cavity.[15] All these aspects, together with the anatomical variability of the sinus, may explain the high SD reported in studies conduced following the segmented method.[12,13] The exclusion of peripheral parts of the graft by focusing on the area around the implant may explain the lower SD (4%) than in previous studies[12,13] and the low coefficient of variability of the ΔV% (21%) observed in the present study.

Because the implant placement contextually to the sinus augmentation is an accepted procedure with an attested long-term high survival rate,[9,21] the one-step procedure was decided and the inner space between the fixture and the healing screw was used as an Rp for all patients. During the analysis of CBCTs, the attention was focused on the more relevant area for the clinician where the implant is placed, and all the anatomical and clinical variables are limited. Furthermore, for the success of the sinus augmentation procedure, it is important not only to consider the volume and the behavior of the graft, but also to include the residual crestal bone as part of the entire tissue that will be remodeled and will host the implants. The method proposed here includes in the computation not only the grafted material but also the native bone of the alveolar crest, thus considering the actual tissue where the implant is usually inserted.

After tooth extraction, alveolar crest starts a remodeling process that induces important dimensional changes during the first 3 months and go on slightly for years.[3,22] In this study, only sites edentulous from a minimum of 6 months were included to minimize the importance of the residual bone changes on the overall computation.

In the overall computation, the healing fluids were included because during the bone healing the blood clot is initially remodeled into granulation tissue and provisional matrix followed by the woven bone and lamellar bone formation.[23]

In this study, analyses were performed on CBCT images. From collected data the total bone volume change in 6 months following sinus augmentation was 19% (± 4%). These results are consistent with data reported from studies performed both on CBCT and CT scans.[12,13,24]

CBCT is an imaging system recently developed with the purpose to overcome limits of the traditional CT. The CBCT scanners allow to reproduce accurate three-dimensional images of maxilla and mandible[25,26] and deliver a lower dose of radiation than a traditional CT scans.[27] For these reasons this technique may be adapted for evaluation of volume tissue changes.

CONCLUSIONS

The calculation of the augmented sinus volume throughout standardized and automatic masks-based method on CBCT data allowed to obtain repeatable measurements. The proposed computation procedure turned out easy and quick for both an expert and non-expert operator and therefore it can be applied in clinical and research settings.

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