Influence of the Height of the Antrostomy in Sinus Floor Elevation Assessed by Cone Beam Computed Tomography: A Randomized Clinical Trial

Shunsuke Kawakami, DDS[1]/Niklaus P. Lang, DDS, PhD[2]/Mauro Ferri, DDS[3]/
Karol Alí Apaza Alccayhuaman, DDS[4]/Daniele Botticelli, BMBS, PhD[4]

Purpose: *To evaluate the influence of the height of the antrostomy on dimensional variations of the elevated space after sinus floor elevation.* ***Materials and Methods:*** *Twenty-four healthy volunteers planned for sinus floor elevation were included in the study. An antrostomy of either 4 mm (group A) or 8 mm (group B) in height was prepared in the lateral wall of the sinus. Cone beam computed tomography scans (CBCTs) were taken before surgery (T0) and after 1 week (T1) and 9 months (T2). Dimensional variation analyses were performed.* ***Results:*** *The CBCTs of 10 patients per group were evaluated. After 1 week (T1), the sinus floor was found elevated in the middle region by 12.0 ± 2.3 mm in group A, while in group B, the height was 11.8 ± 2.1 mm. After 9 months (T2), the respective heights were 9.9 ± 2.4 mm and 8.9 ± 2.7 mm, with a reduction of –2.1 ± 2.2 mm in group A and –3.0 ± 2.6 mm in group B. The area in a central position was reduced by 25.5% to 34.2%, showing a slightly higher shrinkage in group B compared with group A. However, no statistically significant differences were found between the two groups.* ***Conclusion:*** *In maxillary sinus floor elevations performed by the lateral approach, the size of the antrostomy did not affect the clinical and radiographic outcomes.* Int J Oral Maxillofac Implants 2019;34:223–232. doi: 10.11607/jomi.7112

Keywords: *antrostomy size, biomaterial, cone beam tomography, maxillary sinus, sinus augmentation, sinus dimension, sinus height*

Since the first description of sinus floor elevation procedures,[1,2] various techniques using lateral or transcrestal/transalveolar approaches were proposed.[3,4] Due to the pressure balance within the sinus cavity, the elevated space tends to be lost for a physiologic re-pneumatization of the sinus.[5] To avoid such shrinkage of the augmented volume, biomaterials,[6,7] implants,[8,9] or devices[10–13] have been proposed to fill the elevated sinus space. Moreover, different biomaterials have been used that showed various degrees of resorptive properties.[14,15] Autogenous bone has been vastly applied as a filler material; however, it presented a high degree of resorption.[16,17] Conversely, deproteinized bovine bone mineral (DBBM) exhibited a lower degree of resorption and was able to maintain the augmented volume to a higher degree compared with other resorbable fillers.[6,7,17]

Prior to any intervention of sinus floor elevation, an accurate analysis of the anatomy and possible sinusal pathologies is required.[18] The volumetric changes after sinus floor elevation using different types of filler materials evaluated using computed tomography scans (CTs) or cone beam CTs (CBCTs) were analyzed in a systematic review.[19] Autogenous bone presented a higher degree of resorption (42% to 45%), while bone substitutes exhibited a reduced rate of resorption (18% to 22%). DBBM did not show loss in dimensions after 40 days from sinus floor augmentation in rabbits,[7,17] while a collagenated cortico-cancellous porcine bone resorbed up to 50% in a similar experiment in rabbits; however, it was after 8 weeks of healing.[20] The preservation of the elevated sinus space allowed the new bone being formed from the walls of the sinus to reach the most internal aspect of the elevated space.[7,20–22]

[1]Department of Oral Implantology, Osaka Dental University, Osaka, Japan; ARDEC Academy, Rimini, Italy.
[2]Center for Dental Medicine, University of Zurich, Zurich, Switzerland; Professor Emeritus, University of Bern, Bern, Switzerland.
[3]Rafael Nuñez University Corporation, Bolívar, Colombia.
[4]ARDEC Academy, Rimini, Italy.

Correspondence to: Dr Karol Alí Apaza Alccayhuaman, ARDEC Academy, Viale Pascoli 67 – 47923 Rimini, Italy.
Fax: +39 0541 393444. Email: caroline7_k@hotmail.com

Submitted April 16, 2018; Accepted August 4, 2018.

The resorptive properties of the biomaterial affecting the healing have to be considered as well. A resorbable biomaterial resulted in higher osteoclastic activities during the early phases of healing,[16,20] while DBBM allowed the formation of dense tissue surrounding the particles. This tissue was substituted by new bone over time.[7,23,24]

It was demonstrated that the bone was forming from the parent bone of the sinus walls and from the sinus floor.[7,20–22] This, in turn, meant that the integrity of the sinus bony walls was of fundamental importance for new bone formation. This statement is also corroborated by the results from a clinical study in which 24 sinus floor elevations were performed in 21 patients.[25] The area of the antrostomy was assessed, and biopsy specimens were harvested after 5 months of healing. It was concluded that vital bone formation was inversely proportional to the area of the antrostomy. These data suggest that position and size of the antrostomy may be of significance for the outcome when a lateral access is prepared, as the window will remove a part of the source for new bone formation. Antrostomies of 10 × 8 or 6 × 6 dimensions were compared in a randomized clinical study.[26] At a CBCT analysis, no differences were found in dimensions of the augmented volumes. Nevertheless, higher technical difficulties were reported when small access windows were used.

When the antrostomy is prepared, the position of the intraosseous anastomosis (IA), connecting the posterior superior alveolar artery to the infraorbital artery, should be taken into consideration. The mean distance between the IA and the alveolar crest has been reported to be 19 mm, with a minimum distance of 14 mm.[27] Moreover, the diameter of such an artery may be of a size to require a ligature if included in the antrostomy.[28,29]

Considering the importance of the integrity of the sinus bony walls and the position of the IA, it seems of interest to evaluate possible effects of the height of the antrostomy on the dimensional variations. Hence, the aim of the present study was to evaluate the effect of the antrostomy height on the dimension and on dimensional changes over time of the augmented space after sinus floor elevation using a lateral approach.

The hypothesis was that the height of the antrostomy might influence the dimensional changes of the augmented space over time.

MATERIALS AND METHODS

The protocol was approved by the study Ethical Committee of the Corporación Universitaria Rafael Núñez, Cartagena de Indias, Colombia (protocol #01-2015; May 19, 2015). The study was performed following the Declaration of Helsinki on medical protocols and ethics. The protocol comprised two different studies on sinus floor elevation that evaluated different variables in different groups of patients. The present article reports data from the study on antrostomy dimensions. After having comprehensively explained all procedures and possible complications to the patient, informed consent was subsequently obtained. The present study followed the CONSORT statement for the reporting of randomized controlled trials (http://www.consort-statement.org/).

Study Population

Twenty-four healthy volunteers, who desired to receive fixed oral rehabilitation and were in need of sinus floor elevation, were recruited in the present randomized controlled trial (RCT). All the volunteers received definitive implants free of charge at the end of the study. The patients had to fulfill the following inclusion criteria: *(1)* ≥ 21 years of age; *(2)* presence of an edentulous zone in the posterior segment of the maxilla; *(3)* height of the sinus floor ~4 mm or less; *(4)* desiring a prosthetic restoration using a fixed prosthesis supported by implants; *(5)* good general health; *(6)* no contraindications for oral surgical procedures; and *(7)* not being pregnant. The patients were not admitted to the study if they: *(1)* were affected by a systemic disorder; *(2)* received chemotherapeutic or radiotherapeutic treatment; *(3)* were smokers of > 10 cigarettes/day; *(4)* referred with an acute or chronic sinusitis; *(5)* were treated for bone augmentation in the region of interest.

The recruitment of the patients, the surgeries, and the follow-ups were performed at the Corporación Universitaria Rafael Núñez, Cartagena de Indias (Colombia).

The power calculation was performed using the outcomes from a radiographic evaluation of the changes in the height of augmented sinus floors.[30] A minimum n = 10 was obtained. An author (M.F.) not involved in the surgical procedures performed electronically the randomization (randomization.com). Sealed opaque envelopes containing the assignments of the treatment were prepared and opened at the time of surgery, when the surgeon (D.B.) was informed about the randomly allocated treatment.

Clinical Procedures

Local anesthesia was provided, and crestal and releasing incisions were performed. Full-thickness muco-periosteal flaps were elevated, the lateral sinus wall was exposed, and an antrostomy was randomly prepared either 4 mm (group A) or 8 mm (group B) in height, according to the treatment assignment (Figs 1a and 1b). The access window was prepared,

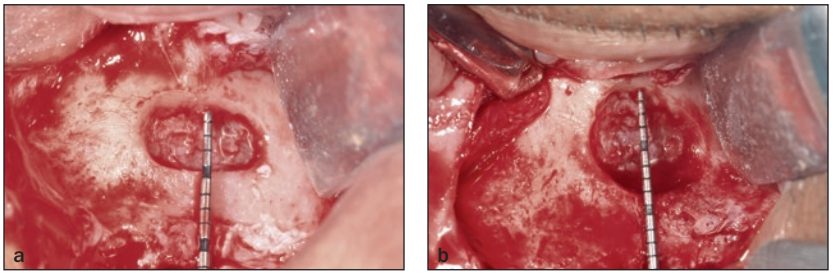

Fig 1 Clinical view. Antrostomy prepared with a height of approximately *(a)* 4 mm or *(b)* 8 mm.

grinding the bone with a diamond insert (SFS 109 029, Komet-Brasseler) mounted on a sonic-air surgical instrument (Sonosurgery TKD). The sinus mucosa was elevated approximately 5 mm above the upper margin of the antrostomy and close to the nasal-palatal sulcus. The height of the antrostomy was adjusted to the standardized protocol, while the length was prepared as needed. The depth of the balcony and the size of the access window were measured using an UNC 15 probe (Hu-Friedy). A collagenated corticocancellous porcine bone (OsteoBiol Gen-Os, 250 to 1,000 µm, Tecnoss) was used to fill the elevated space and softly condensed (Fig 1b). A collagen membrane (OsteoBiol Evolution, 0.3 mm, Tecnoss) was placed to cover the antrostomy. The flaps were secured with single silk sutures. Antibiotics (amoxicillin 875 mg and clavulanic acid 125 mg twice per day for 6 days), nonsteroidal anti-inflammatory drug (ibuprofen 400 mg three times per day for 3 days), and mouthrinses with 0.12% chlorhexidine three times a day for 10 days were prescribed. The patients were also suggested to avoid blowing the nose as well as to open the mouth when sneezing. The sutures were removed after 7 days. The patients were included in a maintenance care system for the full extent of the study. The visits included inspection and cleaning of the wounds after 2 and 4 weeks from surgery and then monthly afterward. The oral hygiene conditions were monitored.

Six months after the surgery, through a small crestal incision, an experimental implant (Sweden & Martina) was placed in a position corresponding to that of a definitive implant. This represented a second step of the present study, and the related results are illustrated elsewhere.

CBCT Imaging Procedures

Three cone beam computed tomography scans (CBCTs) were taken for each patient at three different periods: (T0) before sinus floor elevation aiming to evaluate sinus and bone dimensions, presence of septa, and possible sinus pathologies; (T1) 1 week after the surgery evaluating dimensional changes compared with the T0 and T2 tomography scans; and (T2) 9 months after sinus floor elevation comparing dimensional changes with T0 and T1.

All tomography scans were taken in a specialist radiologic clinic using a 3D Accuitomo 170 Tomograph (J Morita Corporation). A voxel size of 0.125 mm, with a set of the parameters to 8.0 mA, 80 kV, and an exposure time of 12 to 18 seconds were applied. An effective dose irradiation to the patient of 18 to 66 µSv was reported using a 3D Accuitomo 170 Tomograph.[31] The total irradiation for the three CBCTs was 54 to 198 µSv. This dose was lower than that recommended for an annual maximum dose (< 50 mSv) by the Health Physics Society.[32]

CBCT Imaging Analyses

The software i-Dixel 2.0 (J. Morita Corporation) was used to perform measurements. The floor of the nose was chosen as the horizontal reference line both for the coronal (axis X; Fig 2) and lateral views (axis Z; Fig 3). A vertical line crossing the anterior nasal spine and the septum was used as vertical reference axis in the coronal view. In the 1-week tomography, the center of the antrostomy was identified, and the distance from the anterior nasal spine was evaluated. This distance was reported on the graduate scale on the CBCTs of T0 and T2. The section representing the center of the antrostomy was used for measurements in the coronal view, while the section crossing the center of the alveolar bone crest was used for the measurement in the lateral view.

Landmarks Identified in the Coronal View

The landmarks identified in the coronal view were as follows:

- T0 (Fig 2): center of the bony crest (C) and base of the sinus floor (F); base of the infraosseous anastomosis (A)
- T1 (Fig 4): upper margin (UM) and the lower margin (LM) of the antrostomy
- T1 and T2 (Figs 4 and 5): the highest position of the bony tissue/xenograft at the medial, middle, and lateral aspects

Parameters Reported for the Coronal View

The parameters reported for the coronal view were as follows:

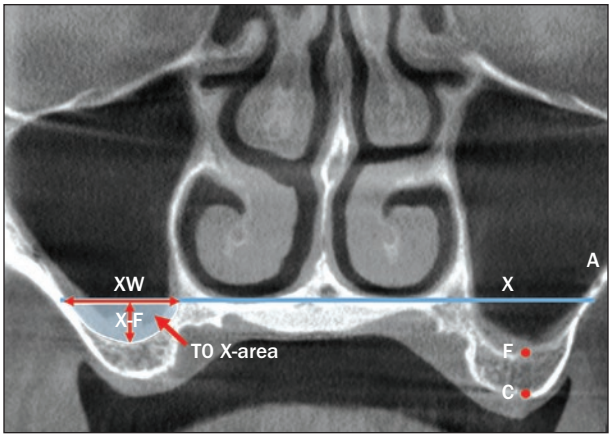

Fig 2 T0: coronal view of a CBCT. X = line drawn following the floor of the nose; C = center of the bony crest; F = base of the sinus floor; A = anastomosis; X-F = nasal floor height; XW (sinus width) = distance evaluated on the line X between the two intersection points with the medial and lateral sinus bone walls; T0 X-area = area delimited by the sinus bone walls and the line X.

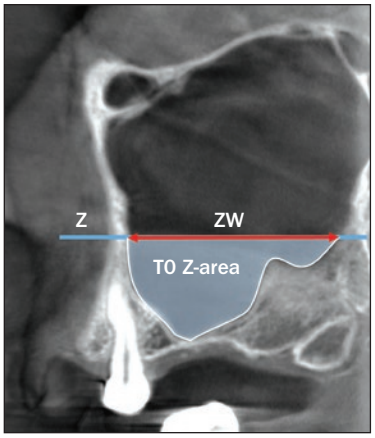

Fig 3 T0: lateral view of a CBCT. Z = line drawn following the floor of the nose; ZW (sinus extension) = distance evaluated on the line Z between the two intersection points with the mesial and distal sinus bone walls; T0 Z area = area delimited by the sinus bone walls and the line Z.

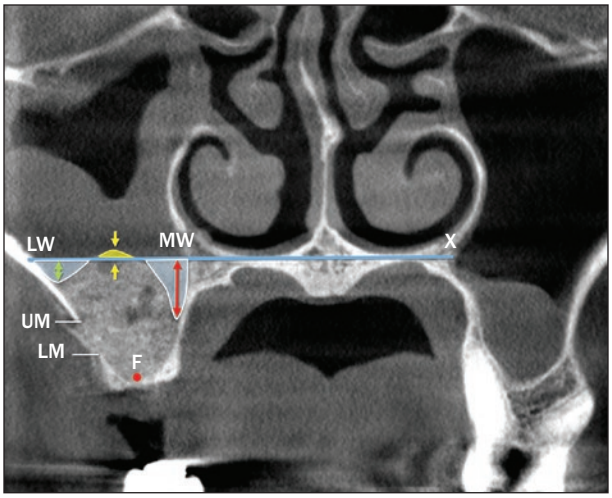

Fig 4 T1: coronal view of a CBCT. X = line drawn following the floor of the nose; F = base of the sinus floor; MW = medial wall of the sinus; LW = lateral wall of the sinus; UM = upper margin of the antrostomy; LM = lower margin of the antrostomy; residual area (bordered in white) = the area below the line X not filled with biomaterial; exceeding area (bordered in yellow) = area above the line X filled with biomaterial/bony tissue. Floor augmentation heights at the medial *(red arrow)*, middle *(yellow arrow)*, and lateral *(green arrow)* aspects.

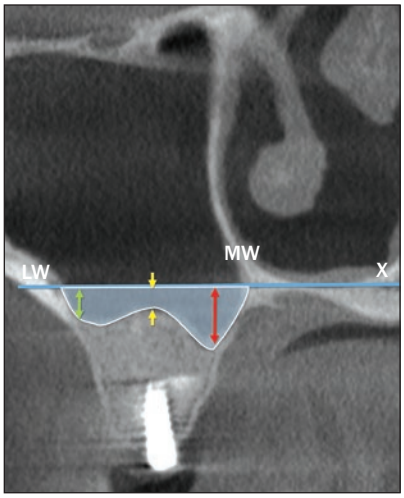

Fig 5 T2: coronal view of a CBCT. X = line drawn following the floor of the nose; MW = medial wall of the sinus; LW = lateral wall of the sinus; residual area (bordered in white) = the area below the line X not filled with biomaterial. Floor augmentation heights at the medial *(red arrow)*, middle *(yellow arrow)*, and lateral *(green arrow)* aspects.

- T0 (Fig 2): mucosa thickness (MT), bone crest height (distance C-F), nasal floor height (distance X-F), anastomosis height (distance A-C, evaluated following the plane of the lateral sinus wall) and its diameter (AD), sinus width (XW; distance between the two intersection points with the medial and lateral sinus bone walls on the axis X), T0 X-area (the area delimited by the sinus bone walls and the axis X)
- T1 (Fig 4): balcony height (distance between LM-F) and window height (distance LM-UM)
- T1 and T2 (Figs 4 and 5): mucosa thickness (MT), floor augmentation heights at the medial, middle, and lateral aspects. The axis X was used as reference at the various periods evaluated. T1 X-area and T2 X-area were obtained subtracting the areas from T0 X-area not filled with biomaterial/bony tissue (residual area) below the axis X and adding the area above the axis X filled with biomaterial/bony tissue (exceeding area; Figs 3 and 5).

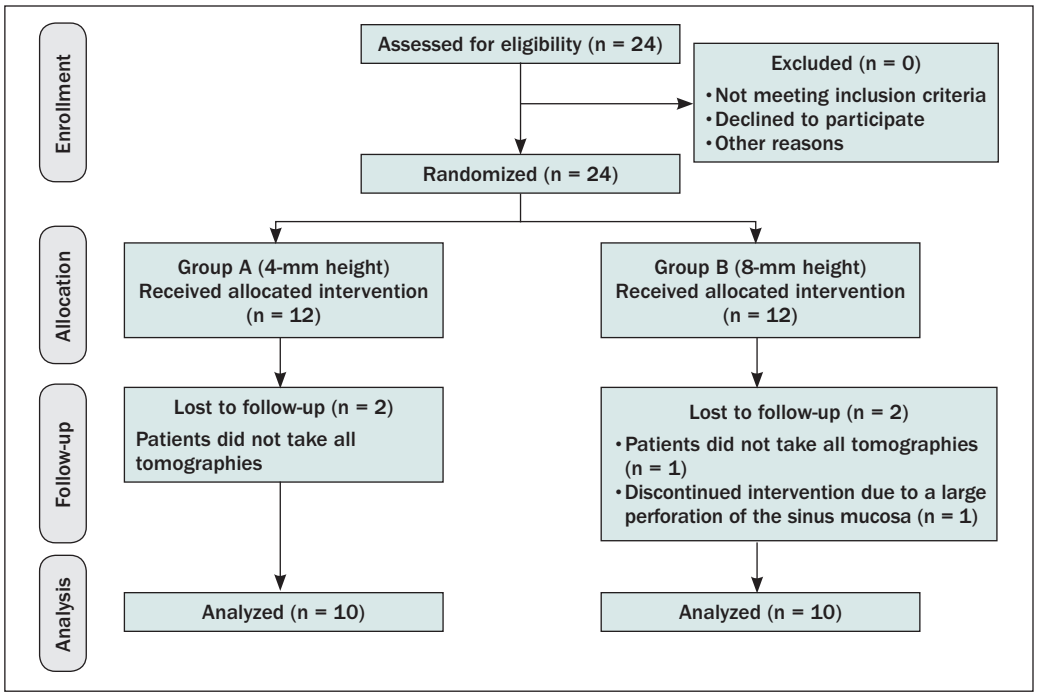

Fig 6 CONSORT 2010 flow diagram.

Parameters Reported for the Lateral View

The parameters reported for the lateral view were as follows:

- T0 (Fig 3): sinus length (distance between the two intersection points with the mesial and distal sinus bone walls on the axis Z; ZW)
- T1 and T2: the largest length of the xenograft/bony tissue (ZE); T1 Z-area and T2 Z-area were obtained subtracting the areas from T0 Z-area not filled with biomaterial/bony tissues located below the axis Z (residual area), and adding the area filled with xenograft/bony tissue above the axis Z (exceeding area)

Data Analysis

The primary outcome measure was the gain in height of the elevated sinus space evaluated in the coronal view. The evaluations were performed in the medial, middle, and lateral aspects. The secondary outcome measure was the area of the elevated zone. All clinical measurements were performed twice by the surgeon (D.B.), and a mean value was used. All radiographic measurements were performed twice by a well-trained researcher (K.A.A.A.), blinded about the aim in the protocols at the time of measurements. Mean values were obtained between the two measurements and used for analysis. Mean values and standard deviations (SD) were calculated for each outcome variable. Differences between groups A and B were analyzed with the IBM SPSS Statistics software (IBM) using the Mann-Whitney test. The level of significance was set at $\alpha = .05$.

RESULTS

The study started in August 2015 and ended in March 2017. Twenty-four patients were included in the study. Four perforations occurred during surgery, two in group A and two in group B. In one patient of group B, the perforation was too large, so the treatment was interrupted and postponed. One perforation of approximately 3 × 4 mm occurred in one patient in group A. The perforation was covered with a collagen membrane. Two small perforations (< 1 mm) were seen, one in each group, and small pieces of collagen membrane were used to protect them. These three patients with small perforations were maintained in the study. Three other patients did not comply with the timetable of the CBCT planning within the limits provided. These three patients and the patient with the treatment interrupted during surgery were excluded from the radiographic analyses. No further dropouts were registered during the follow-up, so the CBCTs of 20 patients were available, 10 for each group (n = 10; Fig 6).

No complications were reported after any surgery or during the following periods of observation. An asterisk was added to the data within the text and tables to indicate that the difference between group A and group B was statistically significant ($P < .05$).

Clinical Measurements

The mean height of the antrostomy was 4.1 ± 0.2* mm and 7.9 ± 0.2* mm for groups A and B, respectively. The mean quantity of biomaterial applied was 0.8 ± 0.2 g and 1.0 ± 0.1 g in groups A and B, respectively (Table 1).

Table 1 Anagraphic and Clinical Data

	Sex	Age (y)	Smokers	Side	Window height (mm)	Window length (mm)	Window area (mm^2)	Balcony (mm)
Group A	4 males; 6 females	57.8 ± 9.6	None	7 right; 3 left	4.1 ± 0.2*	11.8 ± 3.2	48.7 ± 14.7*	4.0 ± 0.8
Group B	4 males; 6 females	55.4 ± 9.8	None	6 right; 4 left	7.9 ± 0.2*	12.5 ± 3.3	98.3 ± 27.1*	3.6 ± 0.5

*$P < .05$.

Table 2 Radiographic Anatomical Data in the Coronal View Taken at Different Periods

	Bone crest height (C-F) at T0	Sinus height (X-F) at T0	Sinus width (XW) at T0	IA height (A-C) at T0	IA diameter at T0	X-area at T0	Balcony height (LM-F) at T1	Window height (LM-UM) at T1
Group A	3.5 ± 1.5	8.5 ± 3.4	14.0 ± 2.8	16.8 ± 3.5	1.1 ± 0.4	82.1 ± 45.4	4.0 ± 0.7	4.3 ± 0.2*
Group B	3.6 ± 1.3	9.3 ± 2.3	14.8 ± 3.4	18.1 ± 3.0	1.2 ± 0.5	94.2 ± 38.9	3.7 ± 0.5	7.9 ± 0.4*

*$P < .05$. Data in millimeters or square millimeters (only the Area X).
IA= intra-osseous anastomosis; T0 = before surgery; T1 = 1 week; T2 = 9 months.

Table 3 Floor Augmentation Heights in the Coronal View Evaluated at Medial, Middle, and Lateral Aspects of Sinus at Various Periods of Observation

	Medial wall			Middle aspect			Lateral wall		
	T1	T2	Δ T1 – T2	T1	T2	Δ T1 – T2	T1	T2	Δ T1 – T2
Group A	6.7 ± 2.2	6.6 ± 1.5	0.0 ± 1.9	12.0 ± 2.3	9.9 ± 2.4	–2.1 ± 2.2	8.6 ± 1.5	7.7 ± 1.7	–0.9 ± 0.9
Group B	6.7 ± 2.0	6.2 ± 2.1	–0.5 ± 1.8	11.8 ± 2.1	8.9 ± 2.7	–3.0 ± 2.6	8.8 ± 2.4	8.5 ± 2.2	–0.3 ± 2.1

T1 = 1 week; T2 = 9 months; Δ = difference. Data in millimeters. $P < .05$.

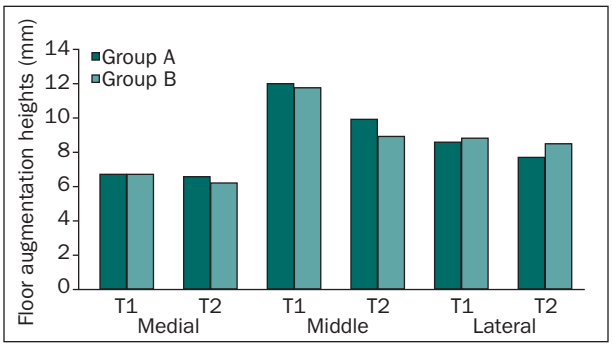

Fig 7 Graph representing the floor augmentation heights in the coronal plane evaluated at the medial, middle, and lateral aspects of the sinus at the various periods of observation (T1 = 1 week; T2 = 9 months). The antrostomy is randomly either high 4 mm (group A) or 8 mm (group B). Data in millimeters.

CBCT Imaging Evaluation

Coronal View. Table 2 reports the anatomical data in the coronal view related to bone crest height (C-F), the sinus height (X-F), and the sinus width (XW) at T0, balcony, and antrostomy heights at T1. Moreover, infraosseous anastomosis position and diameter are also indicated.

At T1, the sinus floor was augmented in the middle aspect by 12.0 ± 2.3 mm in group A and 11.8 ± 2.1 mm in group B (Table 3; Fig 7). At the T2 period (Fig 5), a reduction of –2.1 ± 2.2 mm in group A and of –3.0 ± 2.6 mm in group B was observed resulting in a sinus floor augmentation of 9.9 ± 2.4 mm and 8.9 ± 2.7 mm in the middle aspect, respectively. In the three patients with a small perforation of the sinus mucosa, which was treated with collagen membranes, a mean loss of –0.1 mm was observed in the middle aspect.

At the analyses after 1 week, the sinus was elevated from the floor at the medial and lateral aspects of the sinus by 6.7 ± 2.2 mm and 8.6 ± 1.5 mm in group A and by 6.7 ± 2.0 mm and 8.8 ± 2.4 mm in group B, respectively. After 9 months, the respective measurements were 6.6 ± 1.5 mm and 7.7 ± 1.7 mm at group A and 6.2 ± 2.1 mm and 8.5 ± 2.2 mm in group B.

A reduction of the augmented area of 25.5% ± 18.3% in group A and of 28.1% ± 19.8% in group B was observed (Table 4).

No statistically significant differences for any of the parameters were revealed between the two groups.

Table 5 reports the dimensional variation of the sinus mucosa width among the periods T0, T1, and T2 (Fig 5) for both groups.

A partial/total corticalization of the new sinus floor was visible in nine cases in group A and five cases in group B. The antrostomy was closed in all cases. However, it was found to be partially or totally corticalized in eight cases in group A and six cases in group B.

Table 4 Areas (in mm^2) in the X and Z Planes at Various Periods Evaluated and Shrinkage (in mm^2) and Percentages (%) of Elevated Space Between 1 Week and 9 Months in the Coronal and Lateral Planes

		T0 X-area and T0 Z-area	T1 X-area and T1 Z-area	T2 X-area and T2 Z-area	Δ T1 - T2 (mm^2)	Δ T1 – T2 (%)
Coronal view	Group A	82.1 ± 45.4	103.8 ± 25.5	74.7 ± 19.2	–29.0 ± 20.3	–25.5 ± 18.3
	Group B	94.2 ± 38.9	107.8 ± 15.5	79.3 ± 32.2	–28.5 ± 21.1	–28.1 ± 19.8
Lateral view	Group A	163.9 ± 97.4	171.5 ± 50.0	126.6 ± 49.9	–44.9 ± 34.4	–25.4 ± 20.1
	Group B	163.6 ± 66.9	167.5 ± 36.9	113.0 ± 48.6	–54.5 ± 36.2	–34.2 ± 23.5

P < .05. T0 = before surgery; T1 = 1 week; T2 = 9 months; Δ = difference.

Table 5 Sinus Mucosa Thickness at Various Periods of Evaluation

	T0	T1	T2	Δ T1 - T0	Δ T2 – T1	Δ T2 – T0
Group A	1.7 ± 1.5	3.2 ± 1.5*	2.7 ± 3.5*	1.5 ± 2.4	–0.5 ± 2.9*	1.0 ± 4.2
Group B	1.9 ± 1.9	6.0 ± 3.1*	0.9 ± 0.4*	4.1 ± 3.4	–5.1 ± 3.2*	–1.0 ± 2.0

**P* < .05; none of the differences was statistically significant between group A and group B. T0 = before surgery; T1 = 1 week; T2 = 9 months; Δ = difference. Data in millimeters.

Table 6 Sinus Width and Length of Grafted Zone in Lateral View at 1 Week (T1) and 9 Months (T2) Periods and Reduction of Length Between the Two Periods

	Sinus width ZW at T0	Xenograft length at T1	Xenograft length at T2	Δ T2 – T1
Group A	25.5 ± 5.7	16.7 ± 2.7	15.3 ± 2.5	–1.5 ± 1.1
Group B	26.6 ± 6.2	17.4 ± 3.0	14.7 ± 3.1	–2.7 ± 2.6

Data in millimeters. *P* < .05; none of the differences was statistically significant between group A and group B. T0 = before surgery; T1 = 1 week; T2 = 9 months; Δ = difference.

Lateral View. Table 6 reports the data in the lateral view related to sinus length and the largest length of the xenograft. The horizontal reduction of the hard tissue (bone/xenograft) was 1.5 ± 1.1 mm and 2.7 ± 2.6 mm, for groups A and B, respectively.

At T2, a total reduction of area in percentage was 25.4% ± 20.1% at group A and 34.2% ± 23.5% at group B (Table 4).

DISCUSSION

The present study illustrated the anatomical dimensional changes evaluated by CBCT after sinus floor elevation applying a collagenated cortico-cancellous porcine bone and a lateral access antrostomy with either approximately 4 or 8 mm of height. No major statistically significant differences were seen in changes of the hard tissues between the two groups evaluated.

In the present study, the base of the nose was used as reference plane both in the coronal and lateral views in the CBCT analyses. Lines were drawn that, in the coronal view, were crossing the medial and lateral walls of the sinus (axis X), and in the lateral view were crossing the mesial and distal walls of the sinus (axis Z). These well-defined and stable references over time allowed calculating at T0 the area included between these axes and the sinus bony walls as well as the distance from the axes to the floor of the sinus. At the subsequent periods of evaluation, the dimensional changes were also evaluated, subtracting the areas not occupied by biomaterial/bone tissues below axes X and Z, and adding the areas occupied by biomaterial/hard tissues above the two axes.

The biomaterial applied in the present study was also used in an experiment for sinus augmentation in rabbits.[20] Mainly due to the osteoclastic activity, a resorption up to 50% was observed after 8 weeks of healing. Nevertheless, a loss of biomaterial through the antrostomy was seen. This might have contributed to the shrinkage of volume. In the present clinical study, the amount of biomaterial placed within the elevated space exceeded the dimensions of T0 X-area and T0 Z-area in both groups. After 9 months of healing, a shrinkage of 25% to 34% of the elevated area was found in the two groups with no statistically significant differences. This shrinkage of the elevated space may be attributed to the osteoclastic resorption of the biomaterial used.[14] However, other factors may influence the volumetric reduction of the elevated space due to the pressure balance within the sinus cavity. The soft condensation used to place the biomaterial in the present study may have contributed to the reduction of volume for a consolidation of the graft. Moreover,

the sinus pressure might generate extrusion of biomaterial through the antrostomy.[33] The reduction in dimension observed in the present study was lower at the small compared with the large antrostomy, even though the differences did not reach statistical significance. This difference may be due to a higher displacement of the biomaterial outside the larger antrostomy compared with the smaller antrostomy, as shown in some of the CBCTs analyzed (eg, Fig 4).

The shrinkage in dimensions registered in the present study is in agreement with the data of a systematic review that reported a reduction of 18% to 22% for bone substitutes or composite grafts between 6 months and 2 years.[19]

The height of the elevated region was evaluated after 1 week (T1) at three different sites that were close to the medial sinus wall (medial aspect), in a central location (middle aspect), and close to the lateral wall (lateral aspect). This latter measurement was obviously affected by the presence of the antrostomy. The gain in height in the middle aspect after 1 week (T1) was approximately 12 mm in both groups, again evaluated using axis X as reference line. Including the sinus floor height, the total available height was approximately 16 mm. After 9 months of healing, the augmented height was of 9.9 mm and 8.9 mm in groups A and B, respectively. No statistically significant differences were found either. These results are in agreement with those reported in other clinical studies. In a randomized controlled clinical study,[26] a gain of approximately 8.5 to 8.7 mm was reported after 6 months of healing using a DBBM xenograft. In a retrospective clinical study, no statistically significant differences between antrostomies with vertical height 3 to 5 mm or 6 to 8 mm were found.[34] A gain in height of 8.5 mm at the test group and 9.7 mm in the control group after 1 year from sinus floor elevation was reported.

In another clinical study, the elevated space was filled with beta-tricalcium phosphate with or without platelet-rich plasma.[35] A gain of 11.6 to 13.2 mm was achieved after 6 months of healing. In another clinical study,[36] autogenous bone alone, or an inorganic bovine bone or a mixture of the two biomaterials were used. A gain in height of the sinus floor of 11.0 to 13.2 mm was obtained after 1 to 5 years.

Considering the initial height of the sinus floor, the total available height was approximately 12 to 14 mm in the present study. This height may be considered sufficient for the placement of an implant. The biomaterial used in the present study had a density and a mineral content similar to that of natural human bone (2.43 g/cm^3 and 64.6% for Gen-Os and 2.30 g/cm^3 and 65.0% for human bone), so a high resorption rate may be expected.[37] This has to be taken into consideration when such materials are used. In fact, in the present study, 2 to 3 mm in height was lost during the first 9 months of healing.

At the medial aspect, a height of 6.7 mm was seen in both groups at T1. The mean height of the sinus floor at the level of axis X was 8.5 mm and 9.3 mm in groups A and B, respectively. This, in turn, means that after 1 week of healing, the biomaterial was located approximately 2 mm below axis X and below the nasal-palatal sulcus despite the effort applied to elevate the sinus mucosa up to that level. This may have been due to an imperfect elevation of the sinus mucosa or a deficiency in the placement of the biomaterial in that region. However, a displacement of the biomaterial during the first week of healing may have to be considered as well, owing to the hydrostatic pressure within the sinus cavity. This is supported by the detection of biomaterial outside the antrostomy in some cases, a fact that did not exclude the dislocation toward other directions within the sinus.

The height at which the biomaterial was found close to the lateral wall after 1 week of healing was 8.6 mm in group A and 8.8 mm in group B. Considering balcony and antrostomy heights, the upper margin of the antrostomy was located at approximately 8.3 mm in group A and at 11.6 mm in group B from the sinus floor. This, in turn, means that the biomaterial in group B was located as a mean value a few millimeters below the upper margin of the antrostomy. During surgery, the sinus mucosa was always detached and displaced above the upper margin of the antrostomy. Obviously, the biomaterial was dislocated during the first week of healing, again owing to the sinus pressure and the edema/bleeding of the sinus mucosa/submucosa. After 9 months of healing, the heights at the medial and lateral aspects remained stable (0 to 0.9 mm) in both groups and the antrostomy appeared to be corticalized in most cases (14 out of 20).

The middle aspect of the elevated sinus floor was higher compared with the medial and lateral aspects at T1, thus producing a dome effect of the elevated space. The higher reduction in dimension in the middle aspect compared with the other aspects resulted in a flatter top of the elevated zone. A partial corticalization of the new sinus floor at the top of the elevated zone was seen in most cases in both groups (15 out of 20).

The sinus mucosa had a width of approximately 1.7 to 1.9 mm before surgery. After 1 week following sinus floor elevation, the width increased 2 to 3 times in groups A and B, respectively.

The swelling of the sinus mucosa after sinus floor elevation has been reported in various clinical studies,[33,38] and it has been reported as early as 1 day after surgery.[39]

In the present study, an air-sonic device was used to prepare the antrostomy. This instrument has been shown to reduce the incidence of soft tissue injuries[40,41] and of perforations of the sinus mucosa.[41] In the present study, this tendency was confirmed with four perforations out of 24 sites.

Limitations of the present study that should be considered include the reduced sample size. Moreover, the time frame of 9 months allowed for a tomographic evaluation may not be sufficient for conclusive statements about the healing of the biomaterial used and the influence of the antrostomy dimensions.

CONCLUSIONS

This study has demonstrated that in maxillary sinus floor elevations performed by the lateral approach, the size of the antrostomy did not affect the clinical and radiographic outcomes in terms of obtained sinus floor height.

ACKNOWLEDGMENTS

Tecnoss srl, Giaveno, Italy, provided all biomaterials used for sinus floor elevation. Sweden & Martina SRL, Due Carrare, Padova, Italy, provided funds to Ariminum Odontologica s.r.l., Rimini, Italy, to cover part of the costs for the experiment. The remaining costs were covered by ARDEC Academy, Ariminum Odontologica s.r.l., Rimini, Italy. The scientific support by the Clinical Research Foundation (CRF) for the Promotion of Oral Health, CH- 3855 Brienz, Switzerland, is highly appreciated. Dr Daniele Botticelli declares to be co-owner of Ariminum Odontologica and to be the principal investigator of ARDEC Academy. All the other authors declare no conflict of interest regarding this study.

REFERENCES

1. Boyne PJ, James RA. Grafting of the maxillary sinus floor with autogenous marrow and bone. J Oral Surg 1980;38:613–616.
2. Tatum H Jr. Maxillary and sinus implant reconstructions. Dent Clin North Am 1986;30:207–229.
3. Pjetursson BE, Lang NP. Sinus floor elevation utilizing the transalveolar approach. Periodontol 2000 2014;66:59–71.
4. Lundgren S, Cricchio G, Hallman M, Jungner M, Rasmusson L, Sennerby L. Sinus floor elevation procedures to enable implant placement and integration: Techniques, biological aspects and clinical outcomes. Periodontol 2000 2017;73:103–120.
5. Asai S, Shimizu Y, Ooya K. Maxillary sinus augmentation model in rabbits: Effect of occluded nasal ostium on new bone formation. Clin Oral Implants Res 2002;13:405–409.
6. Xu H, Shimizu Y, Asai S, Ooya K. Grafting of deproteinized bone particles inhibits bone resorption after maxillary sinus floor elevation. Clin Oral Implants Res 2004;15:126–133.
7. Caneva M, Lang NP, Garcia Rangel IJ, et al. Sinus mucosa elevation using Bio-Oss or Gingistat collagen sponge: An experimental study in rabbits. Clin Oral Implants Res 2017;28:e21–e30.
8. Lundgren S, Andersson S, Gualini F, Sennerby L. Bone reformation with sinus membrane elevation: A new surgical technique for maxillary sinus floor augmentation. Clin Implant Dent Relat Res 2004;6:165–173.
9. Cricchio G, Sennerby L, Lundgren S. Sinus bone formation and implant survival after sinus membrane elevation and implant placement: A 1- to 6-year follow-up study. Clin Oral Implants Res 2011;22:1200–1212.
10. Cricchio G, Palma VC, Faria PE, et al. Histological findings following the use of a space-making device for bone reformation and implant integration in the maxillary sinus of primates. Clin Implant Dent Relat Res 2009;11(suppl 1):e14–e22.
11. Cricchio G, Palma VC, Faria PE, et al. Histological outcomes on the development of new space-making devices for maxillary sinus floor augmentation. Clin Implant Dent Relat Res 2011;13:224–230.
12. Johansson LÅ, Isaksson S, Adolfsson E, Lindh C, Sennerby L. Bone regeneration using a hollow hydroxyapatite space-maintaining device for maxillary sinus floor augmentation—a clinical pilot study. Clin Implant Dent Relat Res 2012;14:575–584.
13. Schweikert M, Botticelli D, de Oliveira JA, Scala A, Salata LA, Lang NP. Use of a titanium device in lateral sinus floor elevation: An experimental study in monkeys. Clin Oral Implants Res 2012;23:100–105.
14. Corbella S, Taschieri S, Weinstein R, Del Fabbro M. Histomorphometric outcomes after lateral sinus floor elevation procedure: A systematic review of the literature and meta-analysis. Clin Oral Implants Res 2016;27:1106–1122.
15. Iezzi G, Piattelli A, Giuliani A, et al. Molecular, cellular and pharmaceutical aspects of bone grafting materials and membranes during maxillary sinus-lift procedures. Part 2: detailed characteristics of the materials. Curr Pharm Biotechnol 2017;18:33–44.
16. Scala A, Lang NP, de Carvalho Cardoso L, Pantani F, Schweikert M, Botticelli D. Sequential healing of the elevated sinus floor after applying autologous bone grafting: An experimental study in minipigs. Clin Oral Implants Res 2015;26:419–425.
17. De Santis E, Lang NP, Ferreira S, Rangel Garcia I Jr, Caneva M, Botticelli D. Healing at implants installed concurrently to maxillary sinus floor elevation with Bio-Oss or autologous bone grafts. A histo-morphometric study in rabbits. Clin Oral Implants Res 2017;28:503–511.
18. Iezzi G, Piattelli A, Giuliani A, et al. Molecular, cellular and pharmaceutical aspects of bone grafting materials and membranes during maxillary sinus-lift procedures. Part 1: A general overview. Curr Pharm Biotechnol 2017;18:19–32.
19. Shanbhag S, Shanbhag V, Stavropoulos A. Volume changes of maxillary sinus augmentations over time: A systematic review. Int J Oral Maxillofac Implants 2014;29:881–892.
20. Iida T, Carneiro Martins Neto E, Botticelli D, Apaza Alccayhuaman KA, Lang NP, Xavier SP. Influence of a collagen membrane positioned subjacent the sinus mucosa following the elevation of the maxillary sinus. A histomorphometric study in rabbits. Clin Oral Implants Res 2017;28:1567–1576.
21. Scala A, Botticelli D, Rangel IG Jr, de Oliveira JA, Okamoto R, Lang NP. Early healing after elevation of the maxillary sinus floor applying a lateral access: A histological study in monkeys. Clin Oral Implants Res 2010;21:1320–1326.
22. Scala A, Botticelli D, Faeda RS, Garcia Rangel I Jr, Américo de Oliveira J, Lang NP. Lack of influence of the Schneiderian membrane in forming new bone apical to implants simultaneously installed with sinus floor elevation: An experimental study in monkeys. Clin Oral Implants Res 2012;23:175–181.
23. Botticelli D, Berglundh T, Buser D, Lindhe J. The jumping distance revisited: An experimental study in the dog. Clin Oral Implants Res 2003;14:35–42.
24. Botticelli D, Berglundh T, Buser D, Lindhe J. Appositional bone formation in marginal defects at implants. Clin Oral Implants Res 2003;14:1–9.
25. Avila-Ortiz G, Wang HL, Galindo-Moreno P, Misch CE, Rudek I, Neiva R. Influence of lateral window dimensions on vital bone formation following maxillary sinus augmentation. Int J Oral Maxillofac Implants 2012;27:1230–1238.

26. Baldini N, D'Elia C, Bianco A, Goracci C, de Sanctis M, Ferrari M. Lateral approach for sinus floor elevation: Large versus small bone window - a split-mouth randomized clinical trial. Clin Oral Implants Res 2017;28:974–981.
27. Solar P, Geyerhofer U, Traxler H, Windisch A, Ulm C, Watzek G. Blood supply to the maxillary sinus relevant to sinus floor elevation procedures. Clin Oral Implants Res 1999;10:34–44.
28. Mardinger O, Abba M, Hirshberg A, Schwartz-Arad D. Prevalence, diameter and course of the maxillary intraosseous vascular canal with relation to sinus augmentation procedure: A radiographic study. Int J Oral Maxillofac Surg 2007;36:735–738.
29. Testori T, Rosano G, Taschieri S, Del Fabbro M. Ligation of an unusually large vessel during maxillary sinus floor augmentation. A case report. Eur J Oral Implantol 2010;3:255–258.
30. Zijderveld SA, Schulten EA, Aartman IH, ten Bruggenkate CM. Long-term changes in graft height after maxillary sinus floor elevation with different grafting materials: Radiographic evaluation with a minimum follow-up of 4.5 years. Clin Oral Implants Res 2009;20:691–700.
31. Okano T, Harata Y, Sugihara Y, et al. Absorbed and effective doses from cone beam volumetric imaging for implant planning. Dentomaxillofac Radiol 2009;38:79–85.
32. Health Physics Society. Position statement of the Health Physics Society. Radiation risk in perspective. July, 2010. http://hps.org/documents/risk_ps010-2.pdf. Accessed December 10, 2011.
33. Nosaka Y, Nosaka H, Arai Y. Complications of postoperative swelling of the maxillary sinus membrane after sinus floor augmentation. J Oral Sci Rehabil 2015;1:26–33.
34. Lu W, Xu J, Wang HM, He FM. Influence of lateral windows with decreased vertical height following maxillary sinus floor augmentation: A 1-year clinical and radiographic study. Int J Oral Maxillofac Implants 2018;33:661–670.
35. Kiliç SC, Güngörmüş M. Cone beam computed tomography assessment of maxillary sinus floor augmentation using beta-tricalcium phosphate alone or in combination with platelet-rich plasma: A randomized clinical trial. Int J Oral Maxillofac Implants 2016;31:1367–1375.
36. Mardinger O, Chaushu G, Sigalov S, Herzberg R, Shlomi B, Schwartz-Arad D. Factors affecting changes in sinus graft height between and above the placed implants. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2011;111:e6–e11.
37. Figueiredo M, Henriques J, Martins G, Guerra F, Judas F, Figueiredo H. Physicochemical characterization of biomaterials commonly used in dentistry as bone substitutes—comparison with human bone. J Biomed Mater Res B Appl Biomater 2010;92:409–419.
38. Temmerman A, Van Dessel J, Cortellini S, Jacobs R, Teughels W, Quirynen M. Volumetric changes of grafted volumes and the Schneiderian membrane after transcrestal and lateral sinus floor elevation procedures: A clinical, pilot study. J Clin Periodontol 2017;44:660–671.
39. Makary C, Rebaudi A, Menhall A, Naaman N. Changes in sinus membrane thickness after lateral sinus floor elevation: A radiographic study. Int J Oral Maxillofac Implants 2016;31:331–337.
40. Geminiani A, Papadimitriou DE, Ercoli C. Maxillary sinus augmentation with a sonic handpiece for the osteotomy of the lateral window: A clinical report. J Prosthet Dent 2011;106:279–283.
41. Geminiani A, Weitz DS, Ercoli C, Feng C, Caton JG, Papadimitriou DE. A comparative study of the incidence of Schneiderian membrane perforations during maxillary sinus augmentation with a sonic oscillating handpiece versus a conventional turbine handpiece. Clin Implant Dent Relat Res 2015;17:327–334.