

ORIGINAL ARTICLE

A prospective randomized controlled trial of the two-window technique without membrane versus the solo-window technique with membrane over the osteotomy window for maxillary sinus augmentation

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Abstract

Background: Maturation of the grafted volume after lateral sinus elevation is crucial for the long-term survival of dental implants.

Purpose: To compare endo-sinus histomorphometric bone formation between the solo- and two-window maxillary sinus augmentation techniques with or without membrane coverage for the rehabilitation of multiple missing posterior teeth.

Materials and Methods: Patients with severely atrophic posterior maxillae were randomized to receive lateral sinus floor elevation via the solo-window technique with membrane coverage (Control Group) or the two-window technique without coverage (Test Group). Six months after surgery, bone core specimens harvested from the lateral aspect were histomorphometrically analyzed.

Results: Ten patients in each group underwent 21 maxillary sinus augmentations. Histomorphometric analysis revealed mean newly formed bone values of $26.08 \pm 16.23\%$ and $27.14 \pm 18.11\%$, mean connective tissue values of $59.34 \pm 12.42\%$ and $50.03 \pm 17.13\%$, and mean residual graft material values of $14.6 \pm 14.56\%$ and $22.78 \pm 10.83\%$ in the Test and Control Groups, respectively, with no significant differences.

Conclusions: The two-window technique obtained comparative maturation of the grafted volume even without membrane coverage, and is a viable alternative for the rehabilitation of severely atrophic posterior maxillae with multiple missing posterior teeth.

KEYWORDS

bone regeneration, clinical research, randomized controlled trial, sinus floor elevation

1 | INTRODUCTION

A lack of available bone is a common obstacle to implant installation in the posterior atrophic maxilla. A fundamental prerequisite for implant placement is the presence of bone of adequate quality. To date, lateral-window sinus elevation remains the most reliable and predictable bone augmentation procedure.^{1,2} The technique involves elevation of the sinus membrane from the floor of the maxillary sinus to allow the placement of a bone graft, which requires healing and consolidation periods to develop the requisite biomechanical and biologic features.³

New bone (NB) is believed to sprout inward from the sinus floor and lateral walls in both primates and human.⁴ Peleg and colleagues⁵ confirmed that creating a large lateral window can negatively affect the maturation and early vascularization of a grafted site. It is plausible that preservation of as much of the lateral wall as possible is beneficial for bone remodeling.⁶ The two-window technique is applied to avoid fracturing the maxillary sinus septa, if present.⁷ In cases of multiple missing posterior teeth requiring large-scale bone augmentation, this technique can be an effective treatment option to avoid the excessive removal of lateral bone.⁸ However, the present study applied a bio-resorbable

membrane to cover the osteotomy site during both solo- and two-window maxillary sinus augmentation.⁸

Controversy surrounds the necessity of barrier coverage of the osteotomy site. Tarnow and colleagues⁹ reported that placement of a GORE-TEX (W. L. Gore & Associates, Inc., Newark, DE) membrane over the lateral osteotomy site resulted in a 100% implant survival rate, compared with 93% when no membrane was applied. Similarly, a study by Tawil and Mawla¹⁰ showed that covering the window with a Collagen membrane yielded a higher success rate (93.1%) than no membrane coverage (78.1%). A systematic review¹¹ revealed that membrane placement tends to increase vital bone formation. However, although membrane placement expedites bone formation, some evidence suggests that these surgical procedures may be successful and predictable without membrane barriers.¹² A study by Sohn and colleagues¹³ showed that there were no significant differences in NB formation with or without membrane use. However, few studies have examined the influence of lateral window dimensions with and without membrane coverage on NB formation.

In patients with multiple missing posterior teeth requiring large-scale sinus elevation, the dimensions of the lateral window must be sufficiently large to accommodate the amount of augmentation.¹⁴ In these conditions, the risk of soft tissue displacement of graft material increases, thus preventing bone regeneration in this area. However, the absence of barrier coverage of the osteotomy site may have an adverse effect on implant survival because it reduces the amount of available bone.¹² Use of the two-window technique effectively decreases the dimensions of the lateral window, which may facilitate endo-sinus bone regeneration without the use of barrier membranes. To date, few published reports have compared the quality of bone formation after the preparation of lateral windows of varying sizes with or without membrane coverage for maxillary sinus floor elevation.

The primary aim of this study was to compare the effects on endo-sinus bone formation of the two-window technique without membrane coverage and the solo-window technique with membrane coverage of the osteotomy site for the rehabilitation of multiple missing posterior teeth. The null hypothesis was that there would be no differences between the two techniques in terms of bone volume formation, implant survival rates, and clinical function in a 1-year follow-up period.

2 | MATERIALS AND METHODS

This study was a prospective randomized controlled trial. Patients requiring maxillary sinus augmentation were eligible for enrollment. The inclusion criteria were:

- multiple missing maxillary posterior teeth (two molars and one or two premolars) with a residual bone height <3 mm and buccolingual bone width ≥ 6.5 mm;
- an oro-vestibular distance >12 mm at the level of the center of the lateral window site; and
- an absence of bony septa in the area of the augmented sinus.

Patients were excluded from the study if any of the following exclusion criteria applied:

- severe hemophilia;
- a history of irradiation in the head and neck region <1 year before the start of the study;
- uncontrolled diabetes;
- human immunodeficiency virus infection;
- a smoking habit of >10 cigarettes or cigar equivalents per day;
- local inflammation, including untreated periodontitis; and
- the presence of osseous lesions.

The sample size was calculated for the primary outcome measure (i.e., NB) based on a previous trial¹⁵ that evaluated the effects of lateral window dimensions on maxillary sinus augmentation outcomes: NB% is 3.98% when the lateral window is >90 mm², whereas it is 41.12% when the lateral window is <90 mm². A chi-squared test with a 0.05 two-sided significance level has a power of 80% to detect the difference between the null hypothesis (0.5) and the alternative hypothesis (0.9) when the sample size is 10.

The institutional ethics committee of the Peking University School of Stomatology, Beijing, China, approved this study (reference number: PKUSSIRB-201630090) before patient selection. The study was registered with the Chinese Clinical Trial Register (registration number: ChiCTR-INR-17010493). Patients were fully informed about the procedures and gave informed consent to participate.

2.1 | Study design

Patients who were referred to the Fourth Division of the Peking University School of Stomatology between September 1, 2015 and February 22, 2016 were consecutively selected from those seeking implant rehabilitation. Maxillary sinuses were allocated to either the Control (solo-window technique with membrane coverage) or Test (two-window technique without membrane coverage) Groups. The allocation of patients was randomized using computer-generated permuted block randomization with an allocation ratio of 1:1. Only one investigator, not involved in patient selection or treatment, was aware of the randomization sequence and had access to the randomization list. The randomized codes were enclosed in sequentially numbered, identical, opaque, and sealed envelopes. If both sinuses met the enrollment requirements, the right side was treated using the procedure assigned through randomization and the left side was treated using the other procedure.

2.2 | Clinical procedures

2.2.1 | Preoperative procedures

Following selection, all patients were evaluated and treated for periodontal health until a clinically acceptable oral environment was achieved. Cone-beam computed tomography and panoramic radiography were performed to evaluate the presence of septa, dimensions of the alveolar process, and thickness and status of the sinus membrane.

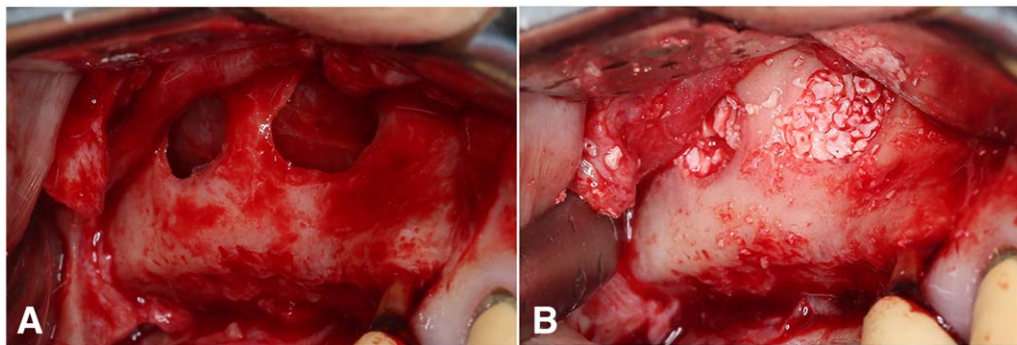


FIGURE 1 Two-window preparation of the lateral wall without membrane coverage. A, Two separate windows were prepared with a bony beam of >5 mm. Note the bony beam located at the first molar site. B, Bone graft material was inserted into the space without the application of a barrier membrane to cover the osteotomy site

2.2.2 | Surgical procedures

All patients received prophylactic antibiotic therapy with 2 g of amoxicillin (500 mg of clarithromycin if allergic to penicillin) 1 hour before treatment. After surgery, amoxicillin (750 mg three times a day), ibuprofen (600 mg three times a day), and chlorhexidine mouthwash (0.2% three times a day) were prescribed for 7 days. All surgeries were undertaken by one surgeon (Q.L.). Surgery was performed under local anesthesia with 4% articaine according to a standardized protocol.¹⁶ Briefly, a crestal incision and vertical releasing incisions were made, followed by full-thickness flap elevation. In the Test Group, two separate lateral windows were prepared with a 5–10-mm bone beam left between the windows (Figure 1). In the Control Group, a solo lateral window was prepared, determined by the amount of augmentation required. The inferior cut was made approximately 2–3 mm from the sinus floor, and the vertical and horizontal lengths were related to the number of missing posterior teeth (Figure 2). All sinuses received a graft consisting of large-particle Bio-Oss (Geistlich Pharma AG, Wolhusen, Switzerland). Sinuses in the Control Group were covered with a resorbable Collagen membrane, whereas sinuses in the Test Group did not receive membrane coverage of the osteotomy window. At the end of the procedure, the soft tissue sections were closed.

2.2.3 | Postoperative management

Patients were instructed to continue with a 0.2% chlorhexidine rinse for 20 seconds and 500 mg of amoxicillin three times per day each. They were advised to consume a soft diet during the first postoperative week, and their healing outcomes were evaluated after 14 days.

2.2.4 | Harvesting of bone biopsy

Six months after surgery, bone biopsy specimens were obtained at a second-stage surgery before implant placement. Bone cores were obtained from the lateral aspect of the former augmentation site, 3 mm above the inferior margin of the lateral access window, and 6 mm deep from the lateral wall (Figure 3). The biopsy core was obtained under external irrigation with sterile saline, and the implant (Thommen Medical AG, Grenchen, Switzerland) was placed according to standard surgical protocols. Healing abutment connection and soft-tissue adjustments were conducted at the same time.

2.3 | Preparation of biopsy samples for histologic analysis

Immediately after harvesting, bone biopsy samples were fixed in 4% paraformaldehyde, demineralized in 15% ethylenediaminetetraacetic acid, and embedded in paraffin. Consecutive horizontal sections (4- μ m

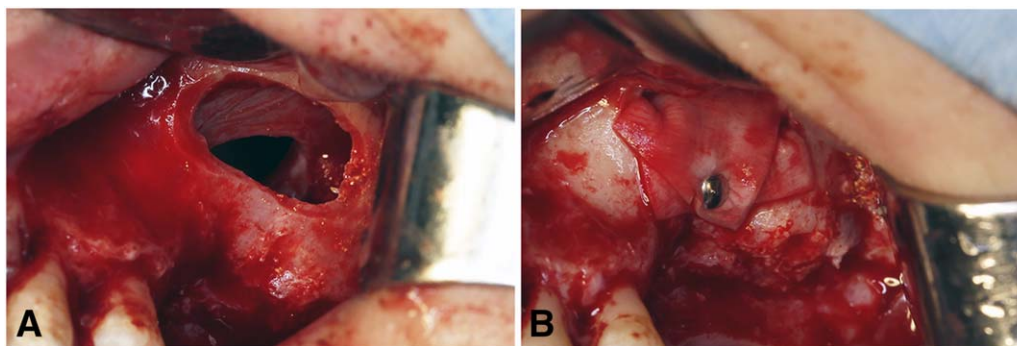


FIGURE 2 Conventional solo-window preparation of the lateral wall with barrier membrane coverage. A, A solo window was prepared with the sinus membrane elevated above the sinus floor. Note that the membrane ruptured during the elevation. B, Bioresorbable membrane was used to cover the osteotomy site created in the lateral wall



FIGURE 3 Bone specimen obtained from the lateral aspect of the augmentation site

thick) were obtained along the central axis of the biopsy core. Four to six sections from the central section of each biopsy specimen were obtained and subjected to hematoxylin and eosin staining.

2.4 | Histomorphometric analysis

The central region of the biopsy, which was situated at the medial aspect of the augmented tissue within the sinus, was analyzed. Histomorphometric analysis was performed to calculate the percentages of NB, connective tissue (CT) and residual graft material (RGM).

The primary and secondary outcome measurements were as follows:

2.4.1 | Primary parameters

Percentages of NB, CT, and RGM: Each section was examined using light microscopy (Leitz Laborlux 12; Leitz, Wetzlar, Germany) at 4× magnification, superimposing a 100-square graticule (1.23 × 1.23 mm; Leica Microsystems GmbH, Wetzlar, Germany) at the ocular level. Analysis of the percentages of NB, CT, and RGM was performed using Image-Pro Plus 6.0 software (Media Cybernetics LP, Silver Spring, MD). The area fraction percentage of each component was determined. Counting was performed three times per bone core and patient.

2.4.2 | Secondary parameters

Soft tissue invagination: Invagination of soft tissue into the sinus was assessed during the second-stage surgery.

Surgical Complications: Surgical complications during maxillary sinus augmentation, in particular hemorrhaging during lateral bone wall osteotomy or perforations of the sinus membrane, were recorded.

All clinical assessments were performed by one previously calibrated examiner (H.DQ) who was not involved in the treatment of the patients.

2.5 | Statistical analysis

The median value and standard deviation of the percentage area of each component was calculated. The *t*-test was used to analyze lateral window dimensions and NB formation between the groups. The chi-

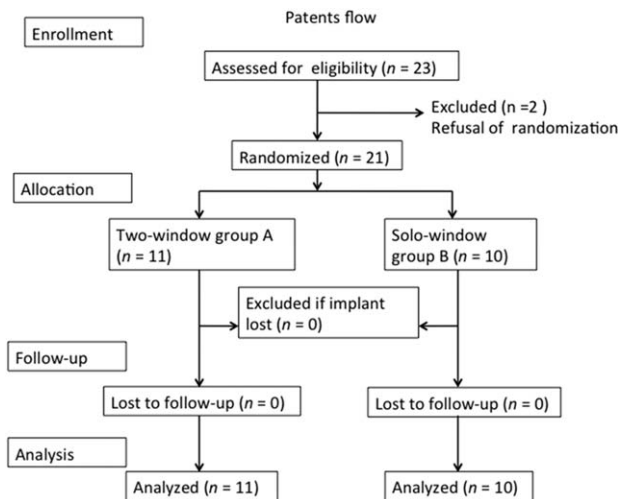


FIGURE 4 Flow diagram. Two screened patients refused randomization and were therefore ineligible for treatment

squared test was used to analyze the enclavation of CT. Statistical significance was set at .05.

The contents were in accordance with the checklist.

3 | RESULTS

A flow diagram showing the phases of the trial is presented in Figure 4.

Twenty-three patients were screened for eligibility, but two patients, who refused randomization, were not enrolled into the trial. Consequently, 20 patients were enrolled and randomized. No patients dropped out during the follow-up period. The 20 patients (nine women and 11 men) had a mean age of 52.3 years (range: 47–64 years), and underwent a total of 21 procedures. The mean residual bone heights in the two groups were 2.98 ± 0.54 mm and 3.06 ± 0.36 mm, with no significant difference. The primary patient characteristics are presented in Table 1. The lateral window area was 80.68 ± 6.17 mm² in the Test Group, with the anterior and posterior bony windows comprising 41.47 ± 6.13 and 39.21 ± 4.24 mm², respectively. The lateral window area in the Control Group, which was 114.31 ± 14.08 mm², was significantly larger than that observed in the Test Group (Table 2).

TABLE 1 Patient and intervention characteristics

	Two-window	Solo-window
Female	4 (40%)	5 (50%)
Mean age at implant insertion (years)	52.8	51.6
Initial residual bone height	2.98 ± 0.54	3.06 ± 0.36
No. of elevated maxillary sinus	11	10
Total number of inserted implants	31	29
Augmented sites with two implants	2	1
Augmented sites with three implants	9	9

TABLE 2 Window dimensions and histomorphometric data values

Elevation technique group	Two-window	Solo-window
Window dimensions (mm ²)	80.68 ± 6.17 (41.47 ± 6.13, 39.21 ± 4.24)	114.31 ± 14.08
NB%	26.08 ± 16.23	27.14 ± 18.11
CT%	59.34 ± 12.42	50.03 ± 17.13
RGM%	14.6 ± 14.56	22.78 ± 10.83

NB, newly formed bone; CT, connective tissue; RGM, residual graft material.

*() indicates the average dimension of anterior and posterior bony windows.

3.1 | Primary outcomes

A total of 21 bone biopsy specimens were obtained and prepared, of which three were too deteriorated to undergo histomorphometric analysis and were thus discarded. Histomorphometric analysis of the remaining 18 specimens revealed that the mean percentages of NB were $26.08 \pm 16.23\%$ and $27.14 \pm 18.11\%$ in the Test and Control Groups, respectively, with no significant difference (Figures 5 and 6). The proportions of each component are shown in Table 2.

3.2 | Secondary outcomes

3.2.1 | Soft tissue invagination

The chi-squared test revealed no statistical significant difference in soft tissue invagination between the Test and Control Groups.

3.2.2 | Surgical complications

Rupture of the sinus membrane occurred in one patient in each group (Table 3). The chi-squared test revealed no significant difference in complications between the two groups ($P = .231$).

4 | DISCUSSION

The present study evaluated the performance of the two-window technique without membrane coverage and the conventional solo-window technique with membrane coverage for the rehabilitation of multiple missing posterior teeth requiring large-scale sinus elevation. The results suggested that both techniques are suitable for the rehabilitation of the posterior maxilla, with no statistically significant differences in NB formation, implant survival rates, bone level changes, or complications.

In the present study, comparable NB formation was observed at the graft site with and without membrane coverage of the osteotomy site, even in patients requiring large-scale sinus floor elevation. To date, controversy surrounds the necessity of membrane coverage of the osteotomy site. Many authors believe that membrane coverage of the lateral osteotomy site is beneficial because it promotes NB growth without soft tissue interference, and thus has a positive effect on implant survival. Tarnow and colleagues⁹ reported a significant increase in the volume of NB obtained with membrane coverage (25.5%) compared with that obtained without membrane coverage (11.9%). In another larger-scale study, NB formation averaged 27.6% and 16.2%, respectively, with and without a barrier membrane.¹⁷ Higher success rates have also been reported with membrane-covered osteotomy sites than with uncovered sites.^{7,9} Conversely, there is some evidence that the application of a barrier membrane does not greatly influence the amount of NB.^{12,18} When considering whether to apply membrane coverage, the dimensions of the lateral osteotomy site should be taken into account. When large-scale maxillary sinus elevation is necessary, the dimensions of the lateral window must be large enough to facilitate the augmentation procedure.¹⁴ In this case, the absence of a barrier membrane increases the risk of graft particle displacement and CT proliferation. The presence of nonosteogenic CT is considered to inhibit NB formation within the graft site, and thus have an adverse effect on implant survival.⁹ The two-window technique may be an effective

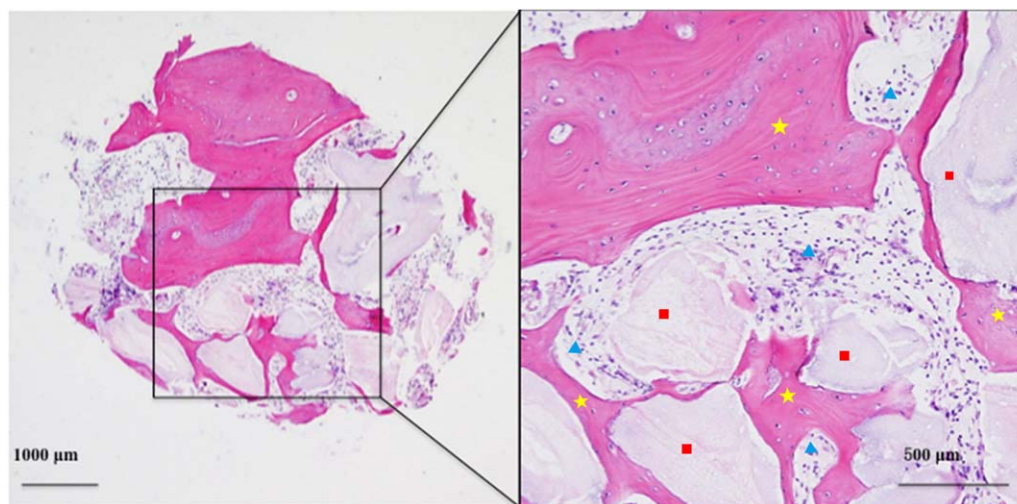


FIGURE 5 Histologic section of a biopsy sample (Test Group). Left: Histologic section of a bone core biopsy obtained from the lateral aspect (hematoxylin and eosin [HE] staining; 4× magnification). Right: Details of the same sample showing vital bone (yellow stars) in intimate contact with remaining allograft particles (red squares) embedded in a nonmineralized tissue matrix (blue triangles; HE staining; 10× magnification)

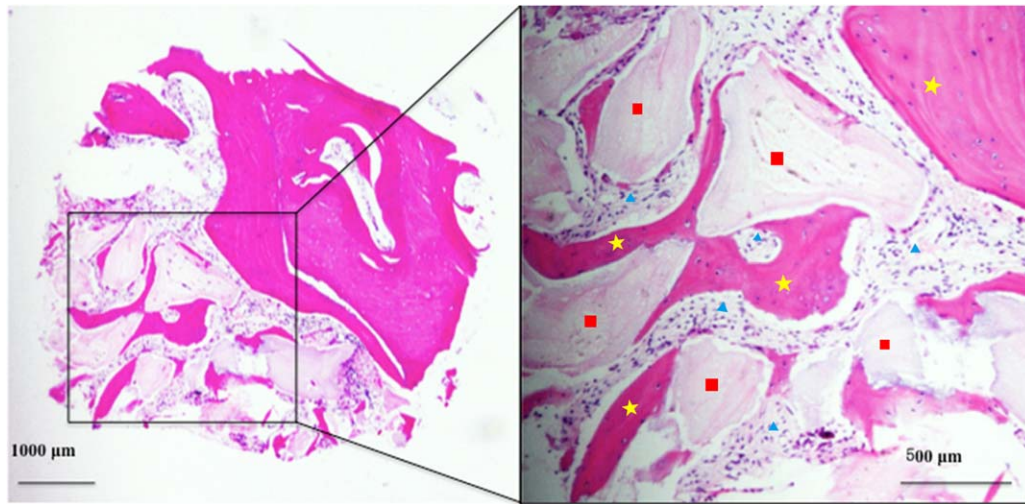


FIGURE 6 Histologic section of a biopsy sample (Control Group). Left: Histologic section providing an overview (hematoxylin and eosin [HE] staining; 4× magnification). Right: Details of the same sample at a higher magnification (HE staining; 10× magnification)

treatment option to avoid excessive lateral bone removal ($80.68 \pm 6.17 \text{ mm}^2$ vs $114.31 \pm 14.08 \text{ mm}^2$ in the Test and Control Groups, respectively) and prevent CT invasion (18.2 vs 44.4% in the Test and Control Groups, respectively).

Endo-sinus bone formation is a complex process wherein elevation of the sinus membrane can induce bone formation directly from the sinus floor.¹⁹ Both human and animal studies have shown that bone formation is initiated inward from the sinus floor and lateral wall.^{20,21} Avila-Ortiz and colleagues¹⁵ showed a remarkable negative correlation between the osteotomy dimensions and NB formation. In a previous study,⁸ the two-window technique effectively induced greater maturation of endo-sinus bone (42.32% NB) than the solo-window technique (26% NB). It can be inferred that the two-window technique, with a residual bony beam >5 mm in length, effectively ensures graft stabilization within the sinus cavity and improves corticalization of the wound surface. However, 42.32% NB remains higher than the 26.08% observed in this study using the same two-window technique. This difference may be attributable to the application of membrane coverage of the lateral osteotomy sites. When considering the application of barrier membranes, their benefits must be carefully weighed against their disadvantages, which include decreased vascular supply to the graft due to exclusion of the buccal flap, the risk of infection, and added

cost. The two-window technique used in this study avoids the aforementioned disadvantages and obtains comparable NB formation even without membrane coverage for large-scale sinus elevation.

The presence of a bone beam between the two windows has additional advantages. Masticatory forces are dissipated from the alveolar process to three enhanced bone pillars in the maxilla: the canine, maxillozygomatic, and pterygomaxillary pillars.²² The maxillozygomatic stress trajectory starts from the apex of the first upper molar and traverses the zygomatic process of the maxilla before reaching the zygoma.²³ The maxillary sinus area exhibits the most stress and deformation. The conventional solo-window preparation is usually located in a first molar-centric area, and much more bone is cut. A residual bone beam between two bony windows preserves the maxillozygomatic pillar as much as possible to avoid the interruption of load transmission. Moreover, the bone beam may allow the fixation of maxillary fractures, Caldwell-Luc surgery, and Le Fort I osteotomy.²⁴ Preservation of lateral bone at this site may also reduce the risk of bleeding.²⁵

The two-window method is slightly technique-sensitive because of the limited surgical field; however, there was no significant difference in the incidence of membrane rupture between the two groups.

One limitation of this study is that the many related variables were not completely controlled, although this was hindered by the inclusion criteria. Also, individual differences in endo-sinus bone formation were not considered. A further study involving the same patients and examining bilateral sinus elevation is needed. Furthermore, the sample size was small, and a longer follow-up period would have been preferable.

In conclusion, the two-window technique obtained comparative maturation and consolidation of the grafted volume even without membrane coverage, and is an effective alternative for the rehabilitation of severely atrophic posterior maxillae with multiple missing posterior teeth.

TABLE 3 Incidence of surgical complications

Complication	Two-window (n = 11)		Solo-window (n = 9)	
	Maxillary sinus (n)	%	Maxillary sinus (n)	%
Intraoperative complications	1	9.1	1	11.1
Rupture of the sinus membrane	1	9.1	1	11.1
Postoperative complications	4	18.2	5	55.6
Infection	0	0.0	1	11.1
Enclavation of connective tissue	2	18.2	4	44.4

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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