

# Randomised Controlled Trial Pre-implant surgery

# Radiographic outcomes of lateral sinus floor elevation with and without bone window repositioning: one-year results of a randomized controlled trial

P. Jia, W. Li, Y. Tang, M. Gao, L. Qiu, Y. Zhu: Radiographic outcomes of lateral sinus floor elevation with and without bone window repositioning: one-year results of a randomized controlled trial. Int. J. Oral Maxillofac. Surg. 2023; 52: 255–263. © 2022 International Association of Oral and Maxillofacial Surgeons. Published by Elsevier Inc. All rights reserved.

Abstract. The objective of this study was to perform a comparative evaluation of the radiographic outcomes of lateral sinus floor elevation with and without bone window repositioning (BLSFE and LSFE, respectively) when applied concomitantly with implant placement. A randomized controlled clinical trial was conducted between February 1, 2016 and May 1, 2017 including 26 individuals with at least one missing tooth. Participants were randomized 1:1 to undergo BLSFE (10 participants, 16 implants) or LSFE (13 participants, 19 implants). Bovine-derived xenograft was used in both groups and the implants were inserted concomitantly. In the BLSFE group, the antrostomy was covered with a repositioned bone window and then with a concentrated growth factors (CGF) membrane. In the LSFE group, the antrostomy was covered with a CGF membrane. Panoramic radiographs were taken before surgery (T0), immediately postoperative (T1), and at 12 months postoperative (6 months after loading) (T2). Marginal bone loss (MBL), apical bone gain, augmented alveolar bone height, and intra-sinus bone augmentation were evaluated on panoramic radiographs at T2. A linear regression analysis with generalized estimating equation models was performed. The implant survival rate was 100% at 1 year after implant surgery. The residual alveolar bone height at T0 was comparable in the BLSFE and LSFE groups (3.58  $\pm$  1.49 mm vs 4.12  $\pm$  1.61, P = 0.32), as was the alveolar bone height at T1 (13.61  $\pm$  1.82 mm vs 12.38  $\pm$  1.82 mm, P = 0.06). At T2 significantly higher alveolar bone height, intra-sinus bone augmentation, and apical bone gain, and lower distal MBL were observed in the BLSFE group when compared to the LSFE group, with adjusting for covariates PY. Jia<sup>a,1</sup>, WJ. Li<sup>b,1</sup>, YM. Tang<sup>a</sup>, M. Gao<sup>a</sup>, LX. Qiu<sup>a</sup>, YB. Zhu<sup>a</sup>

<sup>a</sup>Department of the Fourth Clinical Division, Peking University School and Hospital of Stomatology; National Engineering Research Center of Oral Biomaterials and Digital Medical Devices; Research Center of Engineering and Technology for Digital Dentistry of Ministry of Health; Beijing Key Laboratory of Digital Stomatology, Beijing, PR China; <sup>b</sup>Department of Geriatric Dentistry, Peking University School and Hospital of Stomatology, Beijing, 100081, PR China. Institute of Medical Technology, Peking University Health Science Center, Beijing, 100191, P. R. China.

Keywords: Dental implant; Alveolar ridge augmentation; Sinus floor augmentation; Growth factor; Bone grafting.

Accepted for publication 12 January 2022 Available online 1 July 2022

<sup>&</sup>lt;sup>1</sup> Pingyi Jia and Wenjing Li are the cofirst authors of this article.

(β = 2.44, 95% CI 1.42-3.46, P < 0.0001; β = 2.38, 95% CI 1.35-3.41, P < 0.0001; β = 2.33, 95% CI 1.23-3.42, P < 0.0001; and β = -0.43, 95% CI -0.83 to -0.02, P = 0.038, respectively). No significant difference was observed for mesial MBL or apical bone resorption at T2. Lateral sinus floor elevation with bone window repositioning may result in higher bone augmentation after 1 year than the traditional approach. Further research is needed to elucidate the effect of lateral sinus floor elevation with bone window repositioning.

The implant-supported prosthesis is an important therapeutic option to rehabilitate partially or totally edentulous patients. However, a posterior edentulous maxilla with insufficient vertical height of the residual alveolar crest is a common challenge. Maxillary sinus floor elevation and grafting has been adopted to resolve this clinical problem, either via lateral or transcrestal approach. 1–4

When the residual bone height between the sinus floor and the alveolar crest of the maxilla is less than 5 mm. the lateral sinus floor elevation approach is the first choice.<sup>5-7</sup> During lateral sinus floor elevation, the surgeon needs to graft bone materials through the bone window in the lateral wall of the maxillary sinus. In the classic lateral approach for sinus floor elevation, the bone window is ground out with a round diamond bur.<sup>8,9</sup> For the purposes of gaining sufficient visualization of the surgical area, preventing complications, and facilitating membrane detachment, the surgeon needs to choose both a wide flap and a large bone window during the lateral sinus floor elevation procedure. 10 However, according to a previous animal study, new bone may start to form from the septa of the sinus and the residual bony walls of the maxillary sinus towards the middle of the elevated area. 11 The residual bone wall might be essential to the intra-sinus new bone formation process.<sup>12</sup> Other studies have reported that significantly more bone augmentation in height and width was observed in cases with a smaller bone window when compared to those with a larger bone window. 13,1

In 2006, Palma et al. proposed a bone window replacement technique. <sup>15</sup> The new surgical technique allowed the sinus membrane to be elevated without the help of adjunctive grafting materials and the bone window was replaced after surgery. Histology and histomorphometry examinations showed new bone augmentation. However, compared to

the classic lateral sinus elevation, it remained unclear whether the bone augmentation effect was better with the replaced bone window technique. It was hypothesized that if the bony window of the sinus could be replaced in situ and become revascularized over a short time period, a relatively larger bone window could be used to completely expose the lateral wall of the maxillary sinus and gain more convenient entry to the sinus cavity, and that better bone regeneration in the sinus grafting space would be a potential benefit of the replaced bone window. However, animal experiments have been rare and the results controversial. A histomorphometric study in rabbits compared the effect of repositioning the bony plate over the antrostomy in maxillary augmentation with the classic lateral sinus elevation in which the antrostomy was covered with a collagen membrane. The bone augmentation area and bone density were similar at 8 weeks. <sup>16</sup> Another histomorphometric study in sheep compared the effect of repositioning the bony plate over the antrostomy in maxillary sinus augmentation with the classic lateral sinus elevation, in which the antrostomy was covered with a polylactic membrane. A larger amount of newly formed bone in the close-towindow zone of the grafted area was observed at 4 months.

Nevertheless, the results of animal experiments may be different from the actual clinical situation in humans. Only a few clinical studies using the same technique have been reported. Although these clinical studies showed predictable bone augmentation and implant success in the maxillary sinus, <sup>18,19</sup> it appears that there have been few randomized controlled trials (RCTs) in humans to compare the effect of repositioning the bony plate over the antrostomy in maxillary sinus augmentation with the classic lateral sinus augmentation.

Therefore, the aim of this study was to compare the clinical and

radiographic outcomes of lateral sinus floor elevation with and without bone window repositioning based on an RCT.

### Materials and methods

# Study population

This study was a randomized controlled clinical trial. The study protocol was approved by the institutional ethics committee (PKUSSIRB-201523068). The study was registered with the Chinese Clinical Trial Registry (registration number; ChiCTR-1900025824).

A total of 26 consecutive patients, 14 female and 12 male, with a mean age of 50 years, met the inclusion criteria. All candidates were recruited from patients who visited the Fourth Clinic Department of Peking University Hospital of Stomatology, China for implant treatment, between February 1, 2016 and May 1, 2017. The protocol was explained to the patients and written consent forms were signed by all participants.

The following inclusion criteria were applied: a demand for implant therapy in the maxillary premolar or molar area with a residual bone height of less than 5 mm determined by panoramic radiographs; healthy maxillary sinuses; the possibility of achieving adequate primary stability during sinus floor elevation. The exclusion criteria were as follows: general contraindication for implant surgery; severe haemophilia; poor oral hygiene; smoking; severe bruxism or clenching habits.

The participants were divided randomly into a BLSFE group (test group, lateral sinus floor elevation with bone window repositioning) and an LSFE group (control group, lateral sinus floor elevation) using computer-generated permuted block randomization with an allocation ratio of 1:1. The randomization information was kept in sealed envelopes and the envelopes were opened before surgery.

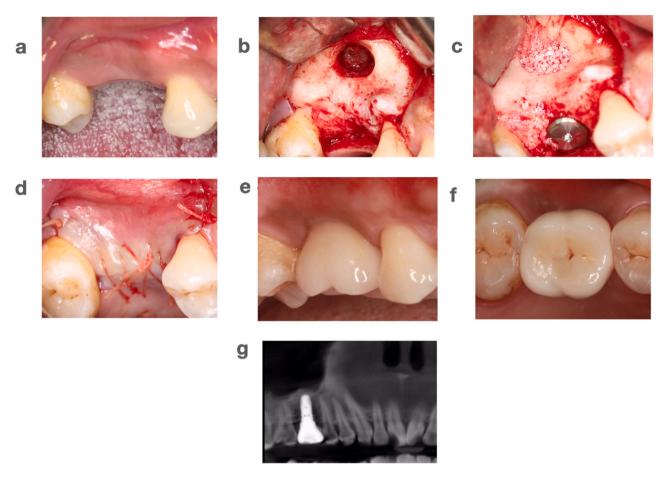


Fig. 1. Treatment procedure in the LSFE group (control group). (a) Preoperative buccal view of the alveolar ridge. (b) A small bone window was made using a round diamond bur and the sinus membrane was then elevated. (c) Bone grafting and implant placement. (d) Wound closure. (e) Buccal view of the final restoration. (f) Occlusal view of the final restoration. (g) Panoramic radiograph taken at 1 year postoperative.

# Surgical and prosthetic procedures

The techniques are illustrated by two posterior maxillary edentulous segments requiring bone augmentation by sinus lift (Figs. 1a and 2a). A midcrestal incision with two vertical releasing incisions was made to raise a full thickness mucoperiosteal flap and expose the anterior sinus lateral wall. In the control group, the planned bone window was ground out using a round diamond bur (Fig. 1b). The inferior margin of the antrostomy was 2 mm above the sinus floor to generate a three-wall compartment. In the test group, after tracing the planned bone window, a piezoelectric device (Piezomed; W&H Dentalwerk Bürmoos GmbH, Bürmoos, Austria) (Fig. 2b) was used to make a bone window, which was later separated entirely from the sinus membrane. The position of the inferior margin of the bone window was equal to the sinus floor. The tip of the piezoelectric saw was tilted to create a tapered osteotomy, to ensure the stability of the bone window when it was repositioned.

In both groups, the sinus membrane was then detached and elevated to create a secluded compartment for the implants. After the elevation was completed, the implant sites were prepared following an undersized drilling protocol, with the aim of obtaining adequate primary stability for implant healing. Deproteinized bovine bone (Bio-Oss; Geistlich Pharma, Wolhusen, Switzerland) was grafted into the mesial, distal, and inside part of the sinus through the access window. Implants were placed (Thommen Medical AG, Grenchen, Switzerland: Element or Contact, diameter 4.0–5.0 mm, length 8–11 mm). Next, bone substitute was grafted through the access window to fully cover the implant inside the sinus (Fig. 1c, Fig. 2c).

In the test group, the bone window was replaced (Fig. 2d) and then covered with a concentrated growth factors

(CGF) membrane (Medifuge MF200; Silfradent srl, Santa Sofia, Italy) (Fig. 2e). In the control group, the antrostomy was directly covered by a CGF membrane. Finally, the mucoperiosteal flap was replaced and closed in both groups (Fig. 1d, Fig. 2f).

Primary stability was evaluated after implant insertion.<sup>20,21</sup> If the insert torque reached 35 N·cm and the implant showed no movement in any direction, a healing abutment was connected with a transmucosal healing protocol. Otherwise, a healing cap was connected with a submerged healing protocol. After a 6-month healing period, 16 single crowns and 13 bridges were delivered on the support of 38 implants. All patients received screw full-ceramic restorations retained (Fig. 1e, f, Fig. 2g).

# Clinical and radiographic assessment

Perforations during sinus membrane elevation were recorded. The implant

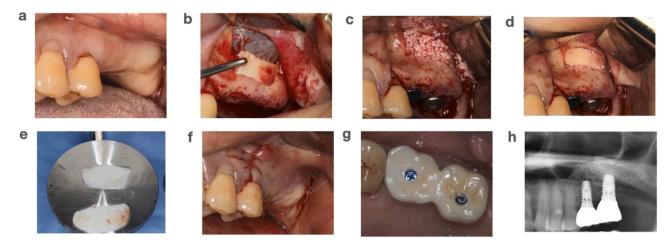


Fig. 2. Treatment procedure in the BLSFE group (test group). (a) Preoperative buccal view of the alveolar ridge. (b) Osteotomy using a piezoelectric saw and removal of the bone window. (c) Bone grafting and implant placement. (d) Bone window repositioning. (e) CGF membrane preparation. (f) Wound closure. (g) Final restoration. (h) Panoramic radiograph taken at 1 year postoperative.

survival rate was calculated at T2 and assessed based on the criteria proposed by Buser et al.: the absence of mobility, the absence of subjective complaints such as pain or paresthesia, the absence of peri-implant infection, and the absence of continuous radiolucency around the implant.<sup>22</sup>

Baseline panoramic radiographs were taken before surgery at T0. Panoramic radiographs were also taken immediately after surgery (T1) and 6 months after loading (T2; 1 year after surgery). Standardized panoramic radiographs were obtained using an X-ray device (Planmeca ProMax Dimax3)

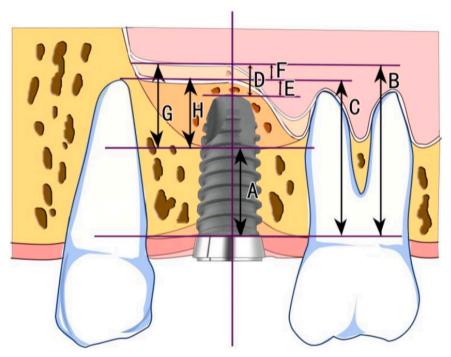


Fig. 3. Depiction of the measurements obtained from the radiographs. (A) Vertical distance between the alveolar crest (implant rough surface and smooth surface junction) and the bottom of the maxillary sinus at T0. (B) Vertical distance between the alveolar crest (implant rough surface and smooth surface junction) and the bottom of the maxillary sinus at T1. (C) Vertical distance between the alveolar crest (implant rough surface and smooth surface junction) and the bottom of the maxillary sinus at (D) Apical bone level at T1. (E) Apical bone level at T2. (F) Apical bone resorption between T1 and T2. (G) The height of the sinus membrane elevation at T1. (H) The augmented bone height in the maxillary sinus at T2.

Ceph; Planmeca, Helsinki, Finland) under the same conditions: an X-ray voltage of 60-62 kV, a current of 8-12 mA, and an exposure time of 16 seconds.<sup>23</sup> Alveolar bone height immediately postoperative was measured on the radiograph taken at T1. Alveolar bone height, apical bone gain, and marginal bone loss (MBL) were measured on the panoramic radiographs at T2. Intra-sinus bone augmentation in height at 1 year after sinus augmentation surgery was calculated as follows: the alveolar bone height at T2 minus the residual bone height at T0. Apical bone resorption at 1 year after sinus augmentation surgery was calculated by subtracting the baseline apical bone gain at T1 from the apical bone gain at T2. MBL was measured in the region between the implant abutment junction and the alveolar bone crest (Fig. 3).

# Statistical analysis

The characteristics of the participants and implants, and the radiographic parameters were compared between the two groups. Variables were presented as the mean ± standard deviation values. The Student t-test was performed for continuous variables and the  $\chi^2$  test for categorical variables. Generalized estimating equation (GEE) models were used to assess the effect for exposure, with adjustment for covariates.<sup>24,25</sup> Only one time-point (T2) was selected for GEE analysis. Considering the situation that there might be more than one implant in one patient, GEE was used to adjust the potential correlation of data. There were five models

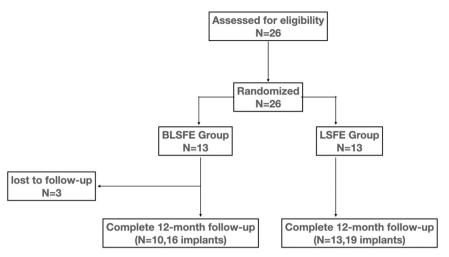


Fig. 4. Flowchart of the study participants. A total of 26 consecutive patients were enrolled and were assigned randomly to the LSFE group (n=13) and BLSFE group (n=13). The 1-year follow-up was completed by 10 participants (76.9%) in the BLSFE group (three participants were lost to follow-up) and 13 participants (100%) in the LSFE group.

used in the GEE: model I, not adjusted for any covariates; model II, adjusted for age and sex; model III, adjusted for residual alveolar bone height at T0; model IV, adjusted for tooth site, implant length, and implant diameter; model V, adjusted for age, sex, residual alveolar bone height at T0, tooth site, implant length, and implant diameter. The results were presented as β (95%) confidence interval (CI)). B Values are the regression coefficients from the analysis, and they represent the mean difference in outcome between the two groups. The statistical analyses were two-tailed and a P-value < 0.05 was considered statistically significant. The statistical power was calculated using PASS version 11.0 (NCSS LLC, Kaysville, UT, USA).

All of the statistical analyses were performed with R (http://www.R-project.org) and EmpowerStats software (www.empowerstats.com, X & Y Solutions, Inc., Boston, MA, USA).

# Results

# Characteristics of participants and implants

A total of 26 consecutive patients were enrolled between February 1, 2016 and May 1, 2017, and were assigned randomly to the LSFE group (n = 13) and BLSFE group (n = 13). The 1-year follow-up was completed by 10 participants (76.9%) in the BLSFE group (three participants were lost to follow-up) and 13 participants (100%) in the

LSFE group (Fig. 4). The participant and implant characteristics are reported in Table 1. No significant difference in age, sex, tooth site (premolar, molar), implant length, or implant diameter was found between the two groups (P > 0.05).

# Implant survival rate and radiographic findings

The residual alveolar bone height at T0  $(3.58 \pm 1.49 \,\mathrm{mm})$  $4.12 \pm 1.61$ , VS P = 0.32) and the alveolar bone height T1  $(13.61 \pm 1.82 \,\mathrm{mm})$  $12.38 \pm 1.82 \,\mathrm{mm}$ , P = 0.06) were comparable in the BLSFE and LSFE groups. The implant survival rate was 100% at T2. Among the outcomes of this study, three indices, T2 alveolar bone height, T2 intra-sinus bone augmentation, and T2 apical bone gain, differed between the two groups (Table 2).

# Generalized estimating equation analysis on the radiographic parameters

Table 3 reports the results of the GEE analysis of the bone augmentation at T2 between the two groups. The analysis showed 2.44 mm greater alveolar bone height in the LSFE with bone window repositioning (BLSFE) group when compared to the LSFE group ( $\beta$  = 2.44, 95% CI 1.42–3.46) in model V, with adjustment for age, sex, residual alveolar bone height at T0, tooth site, implant length, and implant diameter. Similar results were found for

intra-sinus bone augmentation and apical bone gain at T2. Intra-sinus bone augmentation at T2 was 2.38 mm greater in the BLSFE group than that in the LSFE group ( $\beta = 2.38$ , 95% CI 1.35-3.41) and apical bone gain was 2.33 mm greater in the BLSFE group than that in the LSFE group ( $\beta = 2.33$ , 95% CI 1.23-3.42) in model V. Moreover, no significant change was found in the result for alveolar bone height, intra-sinus bone augmentation, and apical bone gain at T2, when adjusting for the covariates or not (models I, II, III, IV, and V). For the outcome variable of distal MBL at T2, no significant difference between the two groups (P > 0.05) was observed in the four models I, II, III, and IV. However, in model V, after adjusting for all covariates, a difference was found between the two groups ( $\beta = -0.43$ , 95% CI -0.83 to -0.02). The results indicated that, independent of these confounders, there was a difference in distal MBL between the LSFE group and BLSFE group: there was less distal bone resorption in the BLSFE group. Regarding the outcomes of mesial MBL and apical bone resorption at T2, no significant differences in bone augmentation were observed with any of the five models.

# **Discussion**

This study, based on an RCT design, comparatively evaluated the 1-year radiographic outcomes of lateral sinus floor elevation with and without bone window repositioning (BLSFE and LSFE, respectively) when applied concomitantly with implant placement. In this study, the implant survival rate was 100% within 1 year, which is consistent with previous studies that have evaluated the survival rates of implants placed following lateral sinus floor elevation without bone window repositioning. 12 In addition, patients obtained a sufficient alveolar bone height (12.02  $\pm$  2.05 mm), and the intra-sinus bone augmentation was stable at 12 months (8.18  $\pm$  2.71 mm).

A previous study reported an average intra-sinus bone gain in height using the lateral approach and bone window repositioning without grafting materials of 11.5 mm at 12 months, <sup>12</sup> which is in line with the results of this study. The main finding of the present study is that the BLSFE group had a better postoperative effect than the LSFE

Table 1. Baseline characteristics of the patients and implants.

Variables	LSFE group	BLSFE group	
Patient-level			
Number	13	10	
Age (years), mean $\pm$ SD	$49.1 \pm 10.2$	$51.1 \pm 10.2$	
Sex, n			
Male	8	4	
Female	5	6	
Implant-level			
Number	19	16	
Tooth site, <i>n</i>			
Premolar	3	3	
Molar	16	13	
Implant length, n			
8 mm	5	6	
9 mm	0	1	
9.5 mm	13	7	
11 mm	1	2	
Implant diameter, n			
4 mm	2	0	
4.2 mm	3	0	
4.5 mm	7	8	
5 mm	7	8	

LSFE, lateral sinus floor elevation; BLSFE, lateral sinus floor elevation with bone window repositioning; SD, standard deviation.

Table 2. Radiographic characteristics of the bone height at T0, T1, and T2.

Variables (mm)	LSFE group $(n = 19)$	BLSFE group $(n = 16)$	
T0 Residual alveolar bone height	4.12 ± 1.61	3.58 ± 1.49	
T1 Alveolar bone height	$12.38 \pm 1.82$	$13.61 \pm 1.82$	
T2 Alveolar bone height	$10.92 \pm 1.51$	$13.32 \pm 1.86*$	
T2 Mesial MBL	$0.39 \pm 0.50$	$0.41 \pm 0.29$	
T2 Distal MBL	$0.75 \pm 0.71$	$0.48 \pm 0.31$	
T2 Intra-sinus bone augmentation	$6.86 \pm 2.40$	$9.74 \pm 2.20*$	
T2 Apical bone gain	$1.74 \pm 1.03$	$3.96 \pm 1.69*$	
T2 Apical bone resorption	$0.76 \pm 0.81$	$0.61 \pm 1.18$	
T2 MBL	$0.57 \pm 0.53$	$0.52 \pm 0.29$	

Data are presented as the mean  $\pm$  standard deviation values. \*P < 0.05. LSFE, lateral sinus floor elevation; BLSFE, lateral sinus floor elevation with bone window repositioning; MBL, marginal bone loss; T0, baseline; T1, immediately after implant surgery; T2, 1 year after surgery.

group, including greater alveolar bone height, intra-sinus bone augmentation, and apical bone gain at T2. In more detail, compared with the LSFE group, the BLSFE group obtained 2.44 mm more alveolar bone height, 2.38 mm more intra-sinus bone augmentation, and 2.33 mm more apical bone gain at the time of the 1-year follow-up. These results were independent of confounding factors such as age, sex, implant characteristics, and baseline residual bone height. The findings verified our hypothesis that the bone augmentation effect would be better with the replaced bone window technique when compared to the classic lateral sinus floor elevation when applied concomitantly with implant placement.

Currently, there appears to be no published RCT in humans that has compared the effects of repositioning the bony plate over the antrostomy in maxillary sinus augmentation using

bone grafts versus the classic lateral sinus floor elevation with bone grafts, covering the antrostomy with CGF membrane or collagen membrane. This RCT study in humans was performed to compare the effects of repositioning the bony plate over the antrostomy in maxillary sinus augmentation versus the classic lateral sinus floor elevation covering the antrostomy with CGF membrane. In another clinical study, the effect of sinus floor elevation using the lateral approach with window repositioning and a xenogeneic bone substitute as a grafting material was evaluated by cone beam computed tomography (CBCT), histological, and histomorphometric analyses.<sup>27</sup> However, the sinus floor elevation was conducted combined with early implant insertion or delayed implant insertion, and intra-sinus bone augmentation was not measured.<sup>27</sup> Importantly, in the current study, alveolar bone height,

intra-sinus bone gain, and apical bone gain in height were higher in the test group than in the control group after 12 months of healing, and this was statistically significant (all P < 0.05).

In a previous study using the replaced bone window technique, the sinus membrane was elevated without the help of adjunctive grafting materials. 15 Studies have indicated that, without grafting materials to support the space, a collapse of the sinus membrane might decrease the intrasinus bone gain over time.<sup>28</sup> Hence, a long implant (implant length > 12 mm) might have to be chosen to support the sinus membrane, compensating for the shrinkage in the elevation height resulting from the collapse of the sinus membrane. 12 In the present study, the bone window was replaced in an approach using bone graft materials. Grafting materials may maintain the space generated during the sinus

Table 3. Results of the multiple regression analysis of bone augmentation at T2 between the LSFE group and BLSFE group; values in millimetres.

Variable	Model I β (95% CI)	Model II β (95% CI)	Model III β (95% CI)	Model IV β (95% CI)	Model V β (95% CI)
LSFE group	Ref.	Ref.	Ref.	Ref.	Ref.
BLSFE group	2.41 (1.16, 3.66)*	2.30 (1.12, 3.49)*	2.41 (1.13, 3.68)*	2.77 (1.66, 3.89)*	2.44 (1.42, 3.46)*
T2 Mesial MBL					
LSFE group	Ref.	Ref.	Ref.	Ref.	Ref.
BLSFE group	0.02 (-0.26, 0.30)	0.04 (-0.22, 0.31)	0.10 (-0.14, 0.34)	0.13 (-0.25, 0.51)	0.21 (-0.21, 0.64)
T2 Distal MBL					
LSFE group	Ref.	Ref.	Ref.	Ref.	Ref.
BLSFE group	- 0.27 (-0.70, 0.17)	- 0.26 (-0.64, 0.13)	- 0.20 (-0.64, 0.24)	- 0.38 (-0.82, 0.06)	- 0.43 (-0.83, -0.02)*
T2 Intra-sinus bone augmentation	3117)	0.12)	0.2.)	0.00)	0.02)
LSFE group	Ref.	Ref.	Ref.	Ref.	Ref.
BLSFE group	2.88 (1.33, 4.44)*	2.92 (1.29, 4.55)*	2.34 (1.06, 3.63)*	2.92 (1.25, 4.59)*	2.38 (1.35, 3.41)*
T2 Apical bone gain	. , ,	, , ,	, , ,	, , ,	, , ,
LSFE group	Ref.	Ref.	Ref.	Ref.	Ref.
BLSFE group	2.22 (1.23, 3.21)*	2.17 (1.26, 3.08)*	2.23 (1.19, 3.27)*	2.45 (1.33, 3.57)*	2.33 (1.23, 3.42)*
T2 Apical bone resorption					
LSFE group	Ref.	Ref.	Ref.	Ref.	Ref.
BLSFE group	-0.15 (-0.96,	-0.17 (-0.98,	-0.05 (-0.91,	-0.60 (-1.32,	-0.58 (-1.33, 0.16)
	0.65)	0.63)	0.80)	0.12)	
T2 MBL	•	•	•	•	
LSFE group	Ref.	Ref.	Ref.	Ref.	Ref.
BLSFE group	- 0.04 (-0.37, 0.29)	- 0.02 (-0.35, 0.31)	0.01 (-0.27, 0.29)	- 0.08 (-0.44, 0.29)	-0.09 (-0.48, 0.31)

T2, 1 year after surgery; LSFE, lateral sinus floor elevation; BLSFE, lateral sinus floor elevation with bone window repositioning; MBL, marginal bone loss; CI, confidence interval.

Outcome: T2 Alveolar bone height, T2 Mesial MBL, T2 Distal MBL, T2 Intra-sinus bone augmentation, T2 Apical bone gain, T2 Apical bone resorption, T2 MBL. Exposure: LSFE group or BLSFE group. \* P < 0.05.

Model I, not adjusted for any covariates. Model II, adjusted for age and sex. Model III, adjusted for residual alveolar bone height at T0. Model IV, adjusted for tooth site, implant length, and implant diameter. Model V, adjusted for age, sex, residual alveolar bone height at T0, tooth site, implant length, and implant diameter.

membrane elevation procedure, so normal length implants were inserted (implant lengths 8–11 mm). Hence, excessive elevation of the sinus membrane is not needed, and a smaller bone window and flap could be applied to reduce the trauma and postoperative responses.

Moderately rough-surface implants with a 1-mm machined collar were inserted in a one-stage approach. In both treatment groups, the implants were placed with the polished collar above the bone crest. At the 12-month followup, the median mesial MBL and distal MBL values were less than 1 mm in both groups. These findings confirm the results of previous studies that have reported minimal to no peri-implant MBL following sinus lift and concomitant implant placement. <sup>29,30</sup>

There were several limitations in this study. The exact mechanism of bone formation inside the sinus has not been completely clarified. It is speculated that the residual bone might provide a basis for new bone formation, since it was proved that reducing the

dimensions of the bone window resulted in a larger amount of bone augmentation.<sup>31</sup> It has been indicated that bone formation may occur from the residual bone towards the sinus floor.<sup>3</sup> An advantage of a replaceable window approach is that the repositioned bone window may better protect the grafted material, preventing leakage of the grafting materials and the ingrowth of connective tissue through the window.<sup>33</sup> Another advantage of the bone window repositioning technique might be that, with a piezoelectric saw of only 0.5 mm in thickness and a very narrow osteotomy line, the replaced bone window could rapidly become revascularized, and bridges of new bone from the edges of the antrostomy may reach the repositioned bone window, ultimately resulting in healing of the bone window with the surrounding lateral sinus wall as a whole. The healed sinus wall might provide osteoblast cells to favour the colonization of the graft, and the replaced bone window might partially bond to the newly formed bone in the sinus.

Another limitation of the present study is that the intra-sinus bone augmentation was measured on two-dimensional panoramic X-rays, and there might have been a distortion due to this technique. A CBCT evaluation method is required for future research. Additional studies with a longer observation period and with a larger sample size are also necessary for further validation. In addition, another limitation of this study is the lack of sample size calculation before the study. However, considering that statistical significance was obtained for some of the outcomes, the power should be sufficient to detect differences for these outcomes.

In conclusion, the findings of this study suggest that the radiographic prognosis for the bone window repositioning technique in combination with grafting material and regular length implants is better than that of the classic lateral sinus floor elevation. Further studies are required to elucidate the effect of lateral sinus floor elevation with bone window repositioning.

# **Funding**

Funding was received from the programme for new clinical techniques and therapies of Peking University School and Hospital of Stomatology (PKUS-SNCT-15A142015).

# Competing interests

None.

# Ethical approval

The study protocol was approved by the institutional ethics committee (PKUSSIRB-201523068).

### Patient consent

Patient consent was obtained.

### References

- Boyne PJ, James RA. Grafting of the maxillary sinus floor with autogenous marrow and bone. *J Oral Surg* 1980; 38:613-6.
- Tatum Jr. H. Maxillary and sinus implant reconstructions. *Dent Clin N Am* 1986; 30:207–29.
- 3. Wood RM, Moore DL. Grafting of the maxillary sinus with intraorally harvested autogenous bone prior to implant placement. *Int J Oral Maxillofac Implants* 1988;3:209–14.
- Mandelaris GA, Rosenfeld AL. A novel approach to the antral sinus bone graft technique: the use of a prototype cutting guide for precise outlining of the lateral wall. A case report. *Int J Periodontics Restor Dent* 2008:28:569–75.
- Engelke W, Capobianco M. Flapless sinus floor augmentation using endoscopy combined with CT scan-designed surgical templates: method and report of 6 consecutive cases. *Int J Oral Maxillofac Implants* 2005;20:891–7.
- Kara MI, Kirmali O, Ay S. Clinical evaluation of lateral and osteotome techniques for sinus floor elevation in the presence of an antral pseudocyst. *Int J Oral Maxillofac Implants* 2012; 27:1205–10.
- 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. *Periodontology* 2000 2017; 73:103–20.
- Kent JN, Block MS. Simultaneous maxillary sinus floor bone grafting and placement of hydroxylapatite-coated implants. *J Oral Maxillofac Surg* 1989; 47:238–42.

- Peleg M, Mazor Z, Chaushu G, Garg AK. Sinus floor augmentation with simultaneous implant placement in the severely atrophic maxilla. *J Periodontol* 1998:69:1397–403.
- Baldini N, D'Elia C, Mirra R, Ferrari M.
  Minimally invasive flap compared to a
  trapezoidal flap in lateral approach
  maxillary sinus elevation procedures:
  four-month post-loading results from a
  split-mouth randomised controlled trial.
  Int J Oral Implantol 2019;12:209–24.
- Scala A, Botticelli D, Faeda RS, Garcia Rangel Jr I, Americo 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;23:175–81.
- 12. Yu H, He D, Qiu L. 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. Clin Implant Dent Relat Res 2017; 19:1099–105.
- 13. Yu H, Qiu L. A prospective randomized controlled trial of two-window versus solo-window technique by lateral sinus floor elevation in atrophic posterior maxilla: results from a 1-year observational phase. Clin Implant Dent Relat Res 2017;19:783–92.
- 14. 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;33:661–70.
- 15. Palma VC, Magro-Filho O, de Oliveria JA, Lundgren S, Salata LA, Sennerby L. Bone reformation and implant integration following maxillary sinus membrane elevation: an experimental study in primates. Clin Implant Dent Relat Res 2006; 8:11–24.
- 16. Omori Y, Ricardo Silva E, Botticelli D, Apaza Alccayhuaman KA, Lang NP, Xavier SP. Reposition of the bone plate over the antrostomy in maxillary sinus augmentation: a histomorphometric study in rabbits. Clin Oral Implants Res 2018;29:821–34.
- Perini A, Ferrante G, Sivolella S, Velez JU, Bengazi F, Botticelli D. Bone plate repositioned over the antrostomy after sinus floor elevation: an experimental study in sheep. Int J Implant Dent 2020:6:11.
- 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;6:165-73.

- 19. Lundgren S, Johansson AS, Cricchio G, Lundgren S. Clinical outcome and factors determining new bone formation in lateral sinus membrane elevation with simultaneous implant placement without grafting material: a cross-sectional, 3–17 year follow-up study. Clin Implant Dent Relat Res 2019;21:827–34.
- Monje A, Ravida A, Wang HL, Helms JA, Brunski JB. Relationship between primary/mechanical and secondary/biological implant stability. *Int J Oral Maxillofac Implants* 2019;34:s7–23.
- 21. Sciasci P, Casalle N, Vaz LG. Evaluation of primary stability in modified implants: analysis by resonance frequency and insertion torque. *Clin Implant Dent Relat Res* 2018;20:274–9.
- 22. Buser D, Weber HP, Lang NP. Tissue integration of non-submerged implants. 1-year results of a prospective study with 100 ITI hollow-cylinder and hollow-screw implants. *Clin Oral Implants Res* 1990;1:33–40.
- 23. Tang Y, Yu H, Wang J, Gao M, Qiu L. Influence of crown-to-implant ratio and different prosthetic designs on the clinical conditions of short implants in posterior regions: a 4-year retrospective clinical and radiographic study. *Clin Implant Dent Relat Res* 2020;22:119–27.
- 24. Lipsitz SR, Fitzmaurice GM, Orav EJ, Laird NM. Performance of generalized estimating equations in practical situations. *Biometrics* 1994;50:270–8.
- Zeger SL, Liang KY. Longitudinal data analysis for discrete and continuous outcomes. *Biometrics* 1986;42:121–30.
- 26. 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; 22:1200–12.
- 27. Tawil G, Barbeck M, Unger R, Tawil P, Witte F. Sinus floor elevation using the lateral approach and window repositioning and a xenogeneic bone substitute as a grafting material: a histologic, histomorphometric, and radiographic analysis. *Int J Oral Maxillofac Implants* 2018;33:1089–96.
- 28. 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;44:660–71.
- 29. Fornell J, Johansson LA, Bolin A, Isaksson S, Sennerby L. Flapless, CBCT-guided osteotome sinus floor elevation with simultaneous implant installation. It radiographic examination and surgical technique. A prospective 1-year follow-up. Clin Oral Implants Res 2012;23:28–34.

- Farina R, Franceschetti G, Travaglini D, Consolo U, Minenna L, Schincaglia GP, Riccardi O, Bandieri A, Maietti E, Trombelli L. Radiographic outcomes of transcrestal and lateral sinus floor elevation: one-year results of a bi-center, parallel-arm randomized trial. Clin Oral Implants Res 2019;30:910–9.
- 31. 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**:1230–8.
- 32. Falah M, Sohn DS, Srouji S. Graftless sinus augmentation with simultaneous dental implant placement: clinical results and biological perspectives. *Int J Oral Maxillofac Surg* 2016;45: 1147–53.
- 33. Testori T, Mandelli F, Valentini P, Wallace S. A novel technique to prevent the loss of graft material through the antrostomy after sinus surgery: technical

note. *Int J Oral Maxillofac Implants* 2014:**29**:e272–4.

Correspondence to: Fourth Division Peking University School and Hospital of Stomatology 41 Middle East 4th Ring Rd Chaoyang District 100025 Beijing China.

E-mail: zhuyibo\_bjmu@hotmail.com