

Osteotome sinus floor elevation with concentrated growth factor and simultaneous implant placement with or without bone grafting: a retrospective study

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Abstract. The aim of this study was to compare the clinical effects of osteotome sinus floor elevation (OSFE) combined with concentrated growth factor (CGF) and simultaneous implant placement with or without bone grafting in the maxillary posterior region, where the residual bone height (RBH) was 4–6 mm. A total of 44 patients who underwent OSFE combined with CGF and the simultaneous placement of 60 implants (group A, 31 implants with bone grafting; group B, 29 implants without bone grafting) were included in this retrospective study. The clinical indicators of implants were observed for 24 months. Sinus floor lift height was 6.02 ± 0.99 mm in group A and 5.81 ± 0.72 mm in group B ($P = 0.360$) after surgery. There was no significant difference in the vertical bone resorption between the two groups at 24 months ($P = 0.097$). Postoperative pain at 14 days (visual analogue scale) was significantly greater in patients with bone grafting when compared to those without bone grafting ($P < 0.001$). There was no significant difference in marginal bone loss (MBL) between the two groups ($P = 0.707$ for MBL during the first 12 months, $P = 0.922$ for MBL during months 12–24). The implant success rate was 100% with or without bone grafting. The technique of OSFE with CGF, either with or without bone grafting, is safe and reliable in patients with RBH 4–6 mm.

Key words: sinus floor augmentation; bone grafting; dental implant; growth factors; Bone regeneration.

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Patients with the loss of molar teeth in the posterior maxilla often have an insufficient quantity and quality of alveolar bone, making dental implant placement challenging. The lateral sinus floor elevation (LSFE) technique was proposed by Tatum¹ in 1986 in order to overcome these anatomical limitations. The surgical procedure achieves exposure of the maxillary sinus cavity through a bony window created in the lateral wall, followed by Schneiderian membrane lifting and bone grafting. This technique is time-consuming and traumatic, but has shown a predictable success rate. In 1994, Summers² introduced the osteotome sinus floor elevation (OSFE) technique. Unlike the LSFE, this technique affords direct access to the sinus via apical elevation of the Schneiderian membrane using osteotomes. The grafting material is then packed into the newly created confined space. Compared with LSFE, OSFE can reduce the surgical time and postoperative discomfort, enhance primary implant stability, and promote osseointegration³.

According to the Sinus Consensus Conference of 1996, the OSFE technique should be limited to cases with a residual bone height (RBH) ranging from 6 mm to 10 mm.³ When the RBH is between 4 mm and 6 mm, the LSFE technique should be applied⁴. However, with improvements in implant design and surgical techniques, the high predictability of implant therapy has encouraged a re-evaluation of this RBH limitation. Favourable outcomes with the use of OSFE have been reported at more compromised sites, even with RBH around 4 mm⁵.

Platelet-rich fibrin (PRF) is a first-generation platelet concentrate. PRF is an autologous grafting material that eliminates any risk of disease transmission. Furthermore, its jelly-like consistency favours stability of the clot and of the grafting material. This natural material seems to accelerate the physiological wound healing and appears to accelerate new bone formation in association with bone grafts⁶.

Concentrated growth factor (CGF) was developed by Sacco in 2006⁷. CGF is produced by centrifuging blood samples with a special centrifuge device (Medifuge, Silfradent, S. Sofia, Italy), similarly to PRF. However, the different centrifugation speed results in the isolation of a much larger and denser fibrin matrix that is richer in growth factors⁷. This new material for application in biological repair has gradually been introduced in oral implant surgery, especially in maxillary sinus augmentation. It is rich in various

concentrated growth factors and fibrin, which can promote tissue repair and regeneration, and it can also promote the formation of new bone in the sinus when used with OSFE⁸.

Nedir et al.^{9–11} reported that OSFE without bone grafting in 17 patients with a mean preoperative RBH of 5.4 ± 2.3 mm, who had a total of 25 implants installed, resulted in an average immediate postoperative height gain of 4.9 ± 1.9 mm. The cumulative survival rate was 100% at 10 years of follow-up. Therefore, according to these studies, OSFE without bone grafting can result in good bone gain.

Research on bone graft substitutes in OSFE combined with CGF is limited and controversial. Therefore, the purpose of this study was to compare the clinical effects of OSFE using CGF with or without bone grafts in patients with an RBH between 4 mm and 6 mm, and to evaluate the predictability of OSFE using CGF without bone grafting when RBH is between 4 mm and 6 mm.

Patients and methods

This was a retrospective study of patients who underwent dental implant placement by OSFE technique using CGF, with or without a bone graft. This study was performed between December 2013 and June 2017 in the Department of Stomatology of Zhangzhou Hospital affiliated to Fujian Medical University. The study design and clinical procedures were approved by the Ethics Committee of the Affiliated Zhangzhou Hospital of Fujian Medical University (No. 20200212).

Inclusion criteria were as follows: age >18 years; maxillary molar missing for more than 6 months; RBH of 4–6 mm in the posterior maxillary tooth area; adequate space for dental implant restoration in the missing tooth area; no untreated periodontal disease; normal blood pressure and blood glucose, or controlled within the normal range.

Exclusion criteria were as follows: patients with severe systemic diseases and intolerance to implant surgery; acute inflammation of the maxillary sinus; patients with severe osteoporosis; severe bruxism.

Preoperative CGF preparation

Venous blood was drawn from the patient's upper arm 10 minutes before surgery and was placed into two to four special test tubes without anticoagulant. Each tube holds approximately 10 ml in volume. The test tubes were not shaken

and were immediately placed into the Medifuge centrifuge (Silfradent). The programme for CGF preparation was set and the tube was centrifuged for 12 minutes. This separated the blood into three layers: an upper layer of serum, a middle layer of fibrin coagulant, namely CGF, and a bottom layer of red blood cells and platelets. The middle CGF layer was obtained and pressed into a membrane using a special tool, which was used for the maxillary sinus lift (**Supplementary Material** Fig. S1). The bottom layer of red blood cells and platelets was mixed with Bio-Oss (Geistlich Pharma).

Surgical technique

The surgery was performed under local anaesthesia. A mid-crestal incision was made, following which the alveolar ridge was exposed. The implant position was determined using a small round bur, and the hole was enlarged step by step using reaming drills of increasing diameter; the preparation depth was 1 mm from the bottom of the maxillary sinus. The sinus membrane was then lifted to the expected height with a maxillary sinus elevator of the same diameter as the final drill. The integrity of the Schneiderian membrane was assessed by Valsalva manoeuvre and manually with a depth gauge¹². For patients treated with graft, two to four pieces of CGF membrane were packed into the space below the elevated Schneiderian membrane and the mixture of red blood cells/platelets and Bio-Oss was then grafted. Straumann Soft Tissue Level implants were then placed and the wound was sutured. In patients treated without graft, two to four pieces of CGF membrane were inserted into the new space without bone graft materials, and Straumann Soft Tissue Level implants were placed at the same time. The wound was then sutured.

Cone beam computed tomography (CBCT) was performed immediately after the operation. The patients were advised to avoid sniffing, sneezing, coughing, swimming, and flying during the 2 weeks after surgery. A local ice compress was used during the 24 hours after surgery to reduce local swelling and pain. Postoperative oral antibiotics were given for 3 days to prevent infection, and the sutures were removed 14 days after surgery. The second stage surgery was performed 6 months after the operation, and the final crown restoration was installed 2 weeks later. The patients were asked to attend regular follow-up examinations every 6 months. Cross-sectional CBCT images obtained at

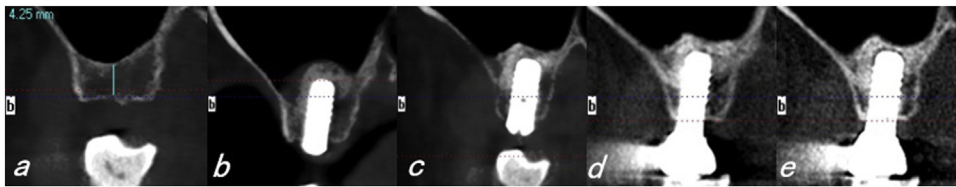


Fig. 1. Group A radiographic measurements. CT scans were obtained before surgery (a), immediately after surgery (b), and at 6 months (c), 12 months (d), and 24 months (e) after surgery.



Fig. 2. Group B radiographic measurements. CT scans were obtained before surgery (a), immediately after surgery (b), and at 6 months (c), 12 months (d), and 24 months (e) after surgery.

the different time periods are shown in Fig. 1 and 2.

Imaging indexes

Four planes perpendicular to the long axis of the implant were identified, as shown in Fig. 3. Plane 'A' passed through the highest point of the sinus floor after the maxillary sinus lifting, plane 'B' was perpendicular to the apex of the implant, plane 'C' passed through the implant at the level of the bottom of the maxillary sinus (the proximal, distal, buccal, and palatal sides were assessed), and plane 'D' passed through the implant at the level of the crest of the alveolar ridge (the proximal, distal, buccal, and palatal sides were assessed). Measurements were obtained for the proximal, distal, buccal, and palatal sides of planes C and D, accurate to 0.01 mm, and the mean value was calculated. All of the data were obtained and recorded by the same researcher.

The following were calculated: (1) residual bone height (RBH): the vertical distance between plane C and plane D was measured immediately before surgery. (2) Crestal bone level (CBL): the vertical distance between planes B and D. The CBL was recorded immediately after surgery (CBL_0) and at 6 months (CBL_6), 12 months (CBL_{12}), and 24 months (CBL_{24}) postoperative. (3) Implant protrusion length (IPL): the vertical distance between planes B and C, which is equal to the difference between CBL_0 and RBH ($IPL = CBL_0 - RBH$). (4) Apical bone height (ABH): the vertical distance between planes A and B. This was measured immediately after surgery and at 6, 12, and

24 months. The mean value of ABH was calculated four times, accurate to 0.01 mm. (5) Sinus floor lifted height (SFLH): the vertical distance between planes A and C, which was equal to the sum of ABH measured at each follow-up and IPL measured immediately after surgery ($SFLH = ABH + IPL$). (6) Vertical bone resorption (VBR): the difference in SFLH between the different follow-up time points. VBR

at 6 months after the operation was recorded as $VBR_6 = SFLH_6 - SFLH_0$, VBR at 6–12 months was recorded as $VBR_{12} = SFLH_{12} - SFLH_6$, and VBR at 12–24 months after the operation was recorded as $VBR_{24} = SFLH_{24} - SFLH_{12}$. (7) Marginal bone loss (MBL): the difference in value of CBL between the different follow-up time points. MBL at 12 months after surgery was recorded as

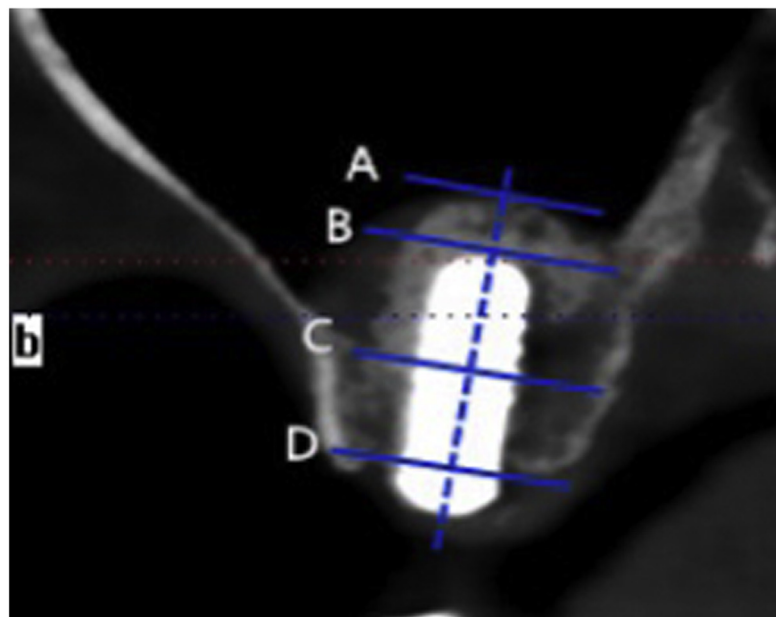


Fig. 3. Imaging measurements. Four planes perpendicular to the long axis of the implant were identified: plane A at the highest point of the sinus floor after maxillary sinus lifting, plane B at the apex of the implant, plane C passing through the implant at the level of the bottom of the maxillary sinus (the proximal, distal, buccal, and palatal sides were assessed), and plane D passing through the implant at the level of the crest of the alveolar ridge (the proximal, distal, buccal, and palatal sides were assessed).

$MBL_{12} = CBL_{12} - CBL_6$. MBL within the 12–24 months after the operation was recorded as $MBL_{24} = CBL_{24} - CBL_{12}$.

Pain was evaluated 14 days after surgery using a 0–10 visual analogue scale (VAS)¹³. A score of 0 indicates no pain from the operation and a score of 10 indicates severe pain from the operation.

The implant success rate was determined according to the criteria proposed by Buser and Mericske-Stern¹⁴: absence of (a) persistent subjective complaints, (b) recurrent peri-implant infection with suppuration, (c) mobility, (d) persistent radiolucency.

Statistical analysis

Microsoft Excel was used to establish the original database; all data were carefully checked and verified. IBM SPSS Statistics version 23.0 (IBM Corp., Armonk, NY, USA) statistical software was used for the statistical analysis of the data. Continuous variables were expressed as the mean \pm standard deviation ($\bar{x} \pm s$); the independent samples *t*-test was used to compare RBH, SFLH, VBR, MBL, and VAS pain score data between groups A and B. Countable variables were expressed as the rate (*n* (%)); the χ^2 test was used to compare the success rates. The test level was set at $\alpha = 0.05$. $P < 0.05$ was considered to indicate a statistically significant difference.

Results

The study included 44 patients who received a total of 60 implants. Group A (with bone grafting) comprised 22 patients, 14 male and eight female, ranging in age from 33 to 71 years (mean 54.82 ± 9.44 years) (**Supplementary Material** Table S1). CGF and Bio-Oss bone material were used after OSFE and 31 implants were placed at the same time. Group B

(without bone grafting) comprised 22 patients, 15 male and seven female, ranging in age from 21 to 73 years (mean 52.23 ± 14.88 years) (**Supplementary Material** Table S1). CGF was applied but no bone grafting was performed, and 29 implants were placed. The general data were compared between the two groups of patients and there were no statistically significant differences ($P > 0.05$). All implants were Straumann Soft Tissue Level implants with a diameter of 4.1 mm or 4.8 mm and a length of 8 mm or 10 mm.

The implant success rate in the two groups was 100% during the observation period. No biological or mechanical complications occurred during the follow-up period, such as peri-implantitis or infection.

One case of maxillary sinus membrane perforation was observed in each group. The patients with maxillary sinus membrane perforation achieved normal function with the implant restoration within 24 months after the operation, and there was no obvious discomfort.

Radiographic assessment

The results of the radiographic assessment are reported in **Table 1**. The mean RBH of the alveolar crest before surgery was 5.01 ± 0.64 mm in group A and 5.23 ± 0.49 mm in group B ($P = 0.134$). Immediately after surgery, the mean SFLH was 6.02 ± 0.99 mm in group A and 5.81 ± 0.72 mm in group B ($P = 0.360$) (**Fig. 4**). There was no statistically significant difference in RBH or SFLH between the two groups.

The VBR in group B was higher than that in group A at 6 months ($P < 0.001$) and at 12 months ($P = 0.022$), while the VBR at 24 months was the same in both groups ($P = 0.097$) (**Fig. 5**).

There was no statistically significant difference in MBL between the two groups at 12 months ($P = 0.707$) or at 24 months ($P = 0.922$) (**Fig. 6**).

Postoperative pain

The mean VAS score for pain was significantly higher in group A (4.05 ± 1.53) when compared to group B (1.77 ± 1.19) ($P < 0.001$) (**Fig. 7**).

Discussion

This study found a 100% implant success rate and satisfactory bone gain in both groups during the observation period, indicating that the technique of OSFE with CGF, either with or without bone grafting, is able to provide successful results in patients with a severely atrophic maxilla (RBH 4–6 mm). Some scholars have reported that the implant failure rate with OSFE is higher when the RBH is < 4 mm¹⁵. Rosen et al.¹⁶ performed a study in which 174 implants were placed after OSFE and observed for an average period of 22.2 months, and reported a success rate of 96% when RBH was ≥ 5 mm. The present study also demonstrated a high implant success rate. Therefore, the RBH is not the only factor that determines the feasibility of maxillary sinus floor augmentation.

New bone formation within the sinus was also observed after OSFE without any grafting materials. Some scholars consider that the space and blood clot are the two key factors for new bone formation¹⁷. Scala et al.¹⁸ performed lateral sinus floor lifting without bone graft in eight monkeys and placed the implants at the same time. They stated that the sinus membrane lifting provided space, blood clots filled the space, and new bone was gradually generated. In the present study, CGF was placed in all patients and it provided a spatial support at the floor of the maxillary sinus and maintained space for new bone formation; these results are similar to those of the researchers above.

When RBH is severely deficient, the initial stability of the implant is poor. Bone grafting can increase the initial sta-

Table 1. Residual bone height, sinus floor lifted height, vertical bone resorption, and marginal bone loss in group A and group B (mean \pm standard deviation values).

Group	Before Surgery	After Surgery	6 months after Surgery		12 months after Surgery		24 months after Surgery	
	RBH (mm)	SFLH (mm)	VBR6 (mm)	VBR12 (mm)	MBL12 (mm)	VBR24 (mm)	MBL24 (mm)	
Group A	5.01 ± 0.64	6.02 ± 0.99	0.93 ± 0.21	0.11 ± 0.03	0.97 ± 0.18	0.11 ± 0.02	0.11 ± 0.02	
Group B	5.23 ± 0.49	5.81 ± 0.72	1.26 ± 0.10	0.12 ± 0.02	0.99 ± 0.17	0.11 ± 0.02	0.10 ± 0.02	
T value	-1.519	0.922	-7.471	-2.354	-0.377	-1.687	0.099	
P	0.134	0.360	0.000	0.022	0.707	0.097	0.922	

RBH, residual bone height before surgery; SFLH, sinus floor lifted height; VBR₆, vertical bone resorption during the first 6 months; VBR₁₂, vertical bone resorption during 6–12 months; VBR₂₄, vertical bone resorption during 12–24 months; MBL₁₂, marginal bone loss during the first 12 months; MBL₂₄, marginal bone loss during 12–24 months

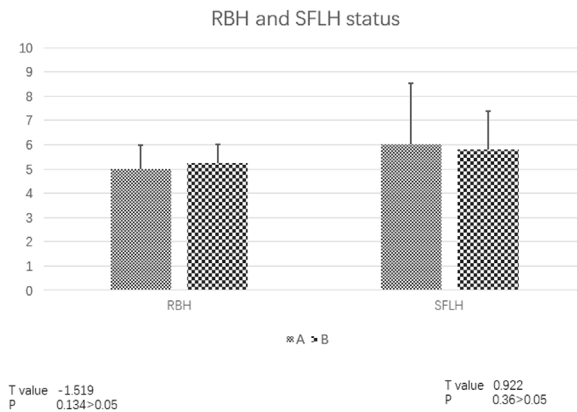


Fig. 4. Mean residual bone height (RBH, mm) and sinus floor lifted height (SFLH, mm), and comparisons between the two groups.

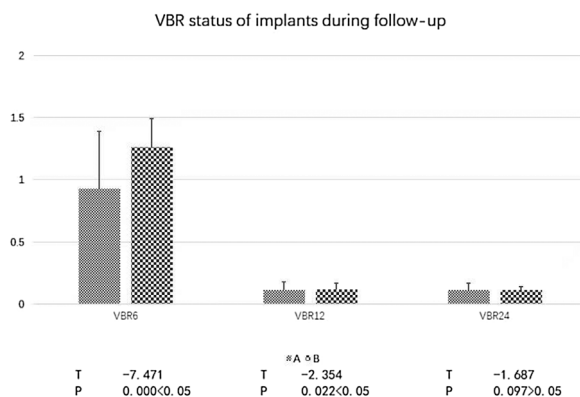


Fig. 5. Mean vertical bone resorption (VBR, mm) around the implants during follow-up (up to 6 months (VBR₆), 6–12 months (VBR₁₂), and 12–24 months (VBR₂₄)), and comparisons between the two groups.

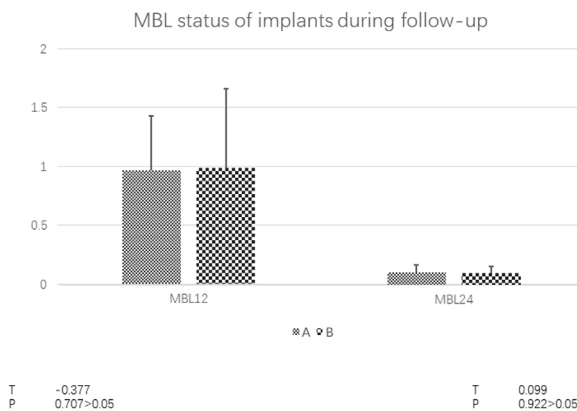


Fig. 6. Mean marginal bone loss (MBL, mm) around the implants during follow-up (up to 12 months (MBL₁₂) and 12–24 months (MBL₂₄)), and comparisons between the two groups.

bility of the implant, but it can also increase the postoperative complications such as pain and/or swelling and/or infection. CGF is a new technology in the field of regenerative medicine²⁰. Kim et al.²¹

used the OSFE technique with CGF alone. The results of their study indicated that CGF can be applied alone in OSFE, and good sinus bone augmentation can be obtained. In the current study, OSFE with

CGF, either with or without bone grafting, resulted in good bone gain in the sinus, which is similar to the results of Kim et al.

Kim et al.²² reported the results of 32 implants placed using the OSFE technique in patients with an average RBH of 7.35 mm. Chen et al.²³ reported 25 implants placed using the OSFE technique with CGF. The results of both of these studies showed that VBR mainly occurred at 6 months after the operation, followed by stable bone remodelling and significantly reduced VBR. In the present study, the majority of the VBR occurred at 6 months postoperatively in both groups, and the VBR changes tended to stabilize at 6 months after the operation, which is consistent with the results of the studies by Kim et al.²¹ and Chen et al.²³.

In 1986, Albrektsson and Zarb²⁴ showed that MBL mainly occurs during the first year. It was suggested that MBL of <0.2 mm per year after 1 year of functional implant loading could be considered as success. In the present study, there was no significant difference in MBL between the group with bone graft and the group without bone graft during the 24 months of follow-up; MBL mainly occurred during the first 12 months postoperatively, which is similar to the reports presented by many scholars²⁵.

With OSFE, the most common intraoperative complication is maxillary sinus membrane perforation, with an incidence of 3.8%²⁷. Some scholars have shown that CGF can repair the perforated maxillary sinus membrane²⁸. In the present study, the sinus membrane perforation rate was 3.3% (2/60) for both groups. Although bone grafting was performed in group A, the CGF was placed to separate the bone graft material from the perforated maxillary sinus membrane. There was no postoperative infection in any of the patients. With the use of CGF, regardless of whether a bone graft was used, there was no significant relationship between maxillary sinus membrane perforation and the success rate of the implant.

According to the VAS score for the subjective evaluation of pain by the patients after surgery, the patients treated with bone graft had a greater postoperative pain response, while those treated without a bone graft using CGF alone had a smaller postoperative pain response. Therefore, in clinical practice, OSFE without bone grafting is recommended if conditions allow.

This study focused on the performance of the OSFE technique with CGF in patients with a RBH of 4–6 mm. Despite

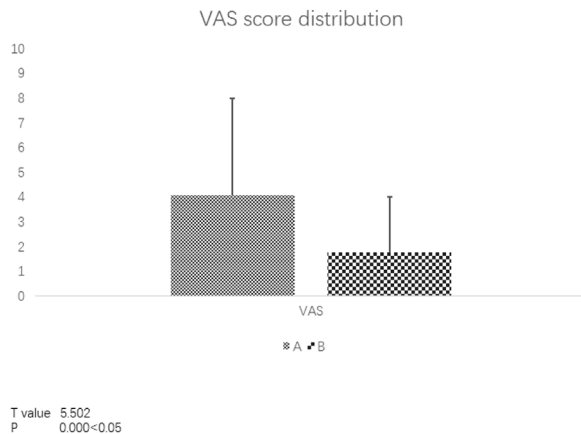


Fig. 7. Mean visual analogue scale (VAS) pain scores at 14 days after surgery, and comparison between the two groups.

the strict anatomical inclusion criteria and the skill demanded for the operation, the results indicated that this protocol could allow simultaneous sinus floor elevation and implant installation in the atrophic posterior maxilla with RBH 4–6 mm. Nevertheless, the study duration was only 24 months, a relatively short period of time, so studies with a larger sample size and longer term follow-up are needed to validate this protocol. Moreover, it would be interesting to investigate the performance of CGF as the only grafting material in sinus augmentation for patients with a RBH of <4 mm in future studies.

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Competing interests

The authors declare that they have no competing interests.

Ethical approval

Approval was obtained from the Medical Ethics Committee of Zhangzhou Hospital (No. 20200212).

Patient consent

Not required.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version,

at doi:<https://doi.org/10.1016/j.ijom.2021.10.010>.

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