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Immediately or delayed sinus augmentation after pseudocyst removal: A randomized trial

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Abstract

Purpose: To compare clinical and histological outcomes of sinus augmentation performed immediately or 3 months after pseudocyst removal through a prospective randomized controlled study.

Materials and Methods: In total, 33 sinus augmentation procedures were performed in 31 patients. Augmentation was performed either immediately after pseudocyst removal (one-stage intervention) or after 3 months (two-stage intervention). Six months postoperatively, bone specimens were harvested, and histomorphometric analysis was performed as primary outcome. Data were recorded and evaluated for implant survival rates, marginal bone resorption, complication rate, and patient-centered outcomes (visual analogue scale [VAS]).

Results: There were no baseline differences between groups or dropouts. Twelve biopsies obtained for histomorphometric analysis showed that delayed sinus augmentation, when compared to immediate led to a 1.1% increased mineralized bone ratio (95% confidence interval [CI]: −15.9 to 13.7). Graft leakage and acute sinusitis occurred in one patient in the one-stage group, none in the two-stage group. No pseudocyst recurrence was observed until the end of 1-year follow-up. Median VAS scores for overall acceptance were significantly increase of 1.4 (95% CI: 0.3–2.56) in immediate group. The degree of post-operative discomfort was not significantly different, although an increase of VAS (0.52, 95% CI: −0.32 to 1.37) was observed in delay group.

Conclusions: Both procedures of sinus augmentation immediately and 3 months after pseudocyst removal could obtain comparable histological outcomes and had low complication rates. Patients who underwent the one-stage procedure had a short treatment course and high satisfaction rates, but this procedure is technically challenging to perform.

This clinical trial was not registered prior to participant recruitment and randomization. The clinical trial registration number is ChiCTR2200063121. The hyperlink is as follows: https://www.chictr.org.cn/showproj.html?proj=172755.

KEYWORDS
antral pseudocyst, bone regeneration, graft, maxillary sinus, sinus elevation, sinus floor augmentation

Summary Box

What is known
- The pathologic status of the maxillary sinus can affect the outcome of grafting and occurrence of complications. Surgical interventions for removing a pseudocyst and then performing sinus augmentation are controversial.
- Only case reports and case series are available on this topic.

What this study adds
- This is the first prospective randomized study to compare two modified minimally invasive surgical interventions that allow removal of the pseudocyst before sinus augmentation.

1 | INTRODUCTION

Maxillary sinus augmentation via the lateral window approach is routinely performed and is a safe procedure when extensive deficient posterior alveolar bone height is to be rehabilitated to allow for placement of implants.[1] The physiological and pathologic status of the maxillary sinus greatly affects the outcome of grafting and occurrence of intraoperative and postoperative complications.[2]

Of the pathologies of the maxillary sinus, antral pseudocysts are most frequent, with a prevalence from 1.4% to 21%.[3] Pseudocyst mainly differs from mucocele in appearance as a faintly dome-shaped radiopaque lesion; a pseudocyst does not destroy adjacent bone and occurs because of local retention of inflammatory exudates surrounded by loose connective tissue.[3,4] Although the management of lateral sinus floor elevation (LSE) in the presence of a pseudocyst remains controversial, the decision for the type of surgery depends on the goal of preventing intraoperative and postoperative complications and potential graft failure.[3,5]

The Caldwell-Luc or endoscopic surgery has been considered as the golden standard to completely remove a pseudocyst,[6] but is difficult in a routine setting, as patients require a long healing time, is associated greater surgical trauma, and needs sophisticated instruments and assistance from an otorhinolaryngologist. Timmenga and colleagues[7] found that LSE has positive consequences in patients without signs of pre-existing maxillary sinusitis. From a routine dentistry perspective, removal of a pseudocyst from the lateral maxillary sinus wall is preferred by both dental surgeons and patients.

The antral pseudocyst is generally asymptomatic and may vary in size.[8] In patients with small-sized antral pseudocyst, LSE can be performed without removing or treating the pseudocyst.[9] However, in patients with large pseudocysts, the residual space of the sinus is reduced and probably will obstruct the ostium, which may result in sinusitis or retention cyst.[6] Some studies suggest aspiration of mucus before sinus membrane elevation; however, almost 30% of the maxillary sinus cysts increased in size after a follow-up of 38 to 102 months.[10] If the connective tissue surrounding the pseudocyst is not managed, patients may have a high risk of recurrence.[10]

Pignataro and colleagues[11] observed that better preoperative conditions are associated with a lower risk of postoperative complications. Kara and colleagues suggested that pseudocyst should be aspirated or removed prior to sinus augmentation.[12] Lin[5] and Yu[13] proposed two-stage and one-stage surgeries to remove the pseudocyst before LSE, and these are the two most routinely performed dental procedures.

Thus far, only case reports and case series are available on this topic. No prospective studies have documented to compared one- and two-stage procedure to remove pseudocyst prior to LSE.

The purpose of the present prospective randomized controlled study was to compare the clinical and histological outcomes of patients who had undergone LSE when performed immediately after pseudocyst removal versus those who had undergone LSE after 3 months of pseudocyst removal.

2 | MATERIALS AND METHODS

This was a prospective randomized comparative study which complies with the consort guidelines. The institutional ethics committee of the Peking University School of Stomatology approved this study (reference number: PKUSSIRB-202168134). The clinical trial registration number is ChiCTR2200063121. The hyperlink is as follows: https://www.chictr.org.cn/showproj.aspx?proj=172755.

Patients who were referred to implant rehabilitation for LSE and management of pseudocyst were included if they fulfilled the following criteria: Residual alveolar ridge height less than 5 mm under the maxillary sinus; a faint, dome-shaped radiopaque pseudocyst in the sinus (Figure 1); and provided voluntary informed consent. Patients were excluded if they had any systemic or local disease that would compromise the prognosis, smoking of >10 cigarettes or cigar equivalents per day. Patients who did not return to the hospital for at least 1 year were excluded from the final analysis. All patients had undergone one-stage or two-stage surgery between February 2016 and February 2021 at 4th division, Peking University School of Stomatology were screened.

The sample size was calculated for the primary outcome based on the previous studies that assessed histological outcome after LSE with and without pseudocyst.[13,14] They reported the percentage of mineralized bone (MB) was 24.9% ± 18.1% and 42.32% ± 13.07%, respectively. A chi-squared test with a 0.05 two-sided significance level has a power of 80% to detect the difference when the sample size is 15.

FIGURE 1 Radiographs showing a faint dome-shaped radiopaque pseudocyst in the maxillary sinus. (A) Coronal plane. (B) Sagittal plane.
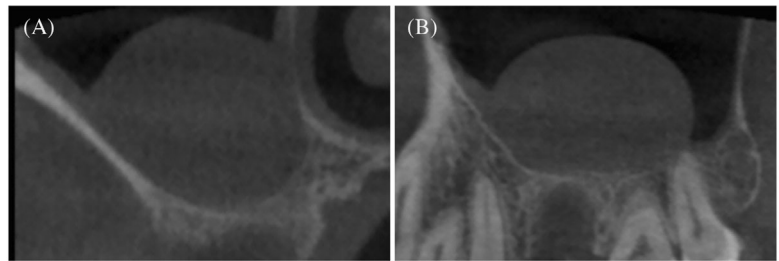
FIGURE 2 Bone augmentation procedure in immediate (A–F) and delayed group (G–L). (A) Elevation of the mucoperiosteal flap to expose the buccal wall of the maxillary sinus. (B) After creating a small round bony window, the mucous fluid aspirated by opening the sinus membrane with a fine needle. (C) Loose connective tissue surrounding the pseudocyst removed with tissue pliers. (D) The Schneiderian membrane observed after a large bony window was created. (E) Concentrated growth factor in place covering the elevated perforated membrane. (F) The collagen membrane covering the osteotomy site and stabilized with bone tacks. (G) A rectangular bony access created for pseudocyst removal. (H) The sinus membrane perforated intentionally. (I) Enucleation of the pseudocyst by gentle traction using micro tissue pliers. (J) After irrigation with saline solution, a rectangular bony wall placed to cover the bony access. (K) Healing of the lateral osteotomy wall 3 months after pseudocyst removal. (L) A standard bony access prepared to perform sinus augmentation.
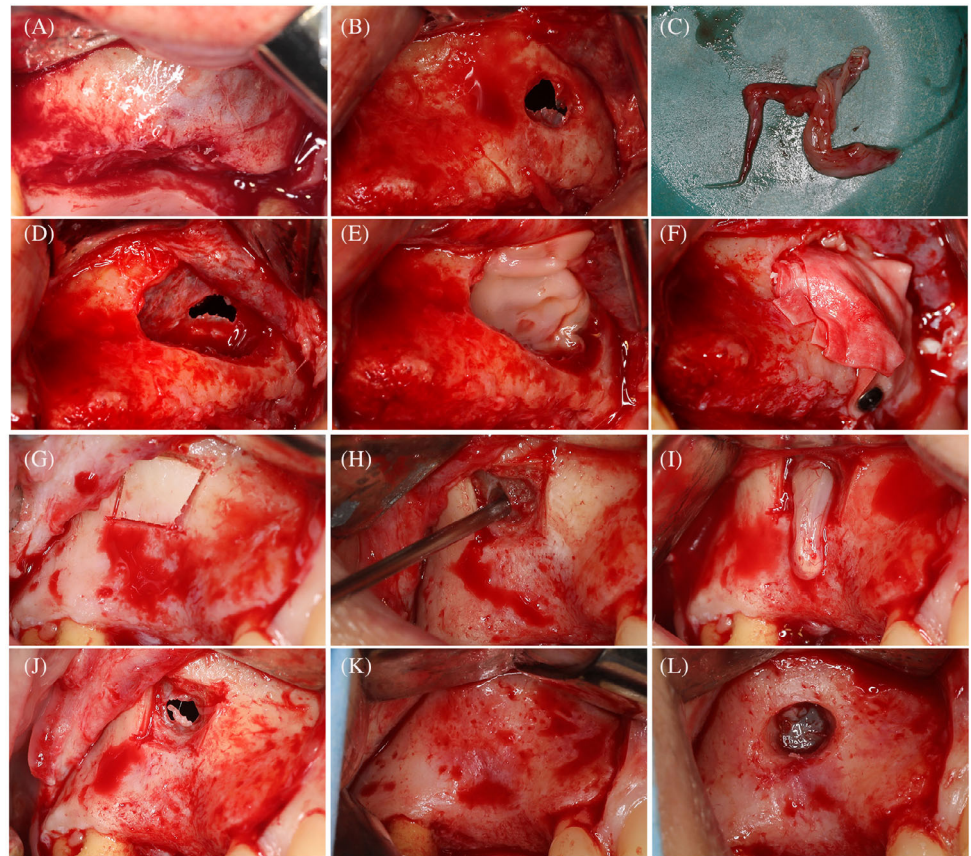
Provided the patients met the inclusion criteria, the implant site was randomly allocated to either one-stage surgery group (immediate Group) or two-stage surgery group (delayed Group), using computer-generated permuted block randomization with an allocation ratio of 1:1. Treatment allocation was assigned by means of closed non-transparent envelopes from the randomized list and were opened after bone exposure during surgery. The process of randomization involved the researcher (Huajie Yu).

2.1 | Operative procedure

Cone beam computed tomography (CT) was performed to determine dimensions of residual alveolar ridge and the presence and status of the pseudocyst before the surgery.

All patients received prophylactic antibiotic therapy with 2 g of amoxicillin (500 mg of clarithromycin in case of penicillin allergy) 1 h before treatment. After a routine flap elevation, the lateral maxillary bony wall was exposed.

In immediate Group, surgical procedure was performed, as described in a previous study.[13] In brief, following lateral maxillary wall exposure (Figure 2A), a smaller lateral bony window was first formed. The sinus membrane was intentionally perforated and aspiration of the fluid was performed (Figure 2B). Lesion was removed through the small bony access (Figure 2C). After irrigation with saline solution, a larger circle bony window was prepared. Sinus membrane could be gently elevated without increasing membrane perforation (Figure 2D) and then covered with absorbable collagen membrane (Figure 2E).

In delayed Group, a rectangular bony window was created using an ultrasonic instrument (Figure 2G). The sinus membrane was

perforated using a fine syringe, and mucous fluid was aspirated (Figure 2H). The pseudocyst was aspirated with a metal aspirator and then removed with micro tissue pliers (Figure 2I). After irrigation with saline solution, the prepared rectangular bony wall was relocated to cover the bony window (Figure 2J). After 3 months of healing, an incision was made according to the previous incision mark, following which full-thickness flap elevation was performed (Figure 2K). A regular round lateral window was created according to the extent of augmentation (Figure 2L). LSE and grafting were performed according to the standard surgical protocol.

In all sinus augmentation procedures, one-layer collagen membrane was used to cover the elevated membrane and another absorbable collagen membrane to cover the osteotomy window (Figure 2F). The flap was closed tension free.

2.2 | Harvesting of bone biopsy and implant placement

Six months after the surgery, bone specimens were harvested using a trephine bur (outer diameter, 2 mm) from the central aspect of the previous lateral bony window. Bone biopsy samples were fixed in 4% paraformaldehyde, demineralized in 15% ethylenediaminetetraacetic acid, and then embedded by paraffin. Consecutive horizontal sections were obtained along the central axis of the biopsy core. Central sections of each specimen were obtained and used for hematoxylin and eosin staining. Histomorphometric analysis was performed to calculate MB, bone substitute materials (BS), and nonmineralized tissue (NMT) components.

Implants (Thommen Medical AG, Grenchen, Switzerland) were placed simultaneously during bone augmentation or into augmented sites according to primary stability. Final restoration was completed after 3 months.

Standardized panoramic radiographs were taken immediately and 12 months after implant placement. Cone beam CT was recorded at the 1-year follow-up.

2.3 | Primary outcomes

The percentage of newly formed bone was determined using histomorphometric analyses. The percentages of MB, BS, and NMT were determined using Image-Pro Plus 6.0 software (Media Cybernetics LP, Silver Spring, MD). Each bone core was counted three times for each patient.

2.4 | Secondary outcomes

2.4.1 | Implant survival rates

Implant survival was assessed using the following criteria: absence of implant mobility, absence of pain or recurrent peri-implant infection, absence of continuous radiolucency around the implant and progressive marginal bone loss.

2.4.2 | Peri-implant marginal bone resorption

The average mesial and distal distance between the most coronal visible point of bone-implant contact and implant shoulder level was considered as the bone level. Resorption value was the difference in bone level measured immediately and at the 1-year follow-up after implant placement.

2.4.3 | Surgical complications

Termination of surgery due to membrane tear during sinus augmentation, bone graft leakage, post-operative infection, and cyst recurrence were included.

2.4.4 | Patient-centered outcomes

Degree of satisfaction with surgery, as judged by patients using a 10-cm visual analogue scale (VAS) at 2 weeks after sinus bone augmentation and/or implant placement.

For the VAS score, patients were administered the following questions:

1. How would you rate your overall acceptance with the whole intervention process?
2. How would you rate your postoperative discomfort?

2.5 | Statistical analysis

Continuous and discrete variables were described using mean (standard deviation) and frequency, respectively. T-test was used to analyze MB formation, bone resorption, and VAS scores between groups. Differences in implant survival and complication rates were compared between the two groups using Fisher's exact chi-square tests. All statistical comparisons were performed at a significance level of 0.05.

3 | RESULTS

A total of 31 patients were initially screened in the study. Of these, two patients in test group and three patients in control group who were unable to attend the recall visit within at least 1 year were excluded. In one patient in immediate Group, no pseudocyst mucous fluid was obtained during aspiration. The patient was managed after 2 months and was excluded from the study. In total, 25 patients with 26 maxillary sinuses were included in the analysis (Figure 3). The demographic characteristics of patients are shown in Table 1.

FIGURE 3 Study flowchart.
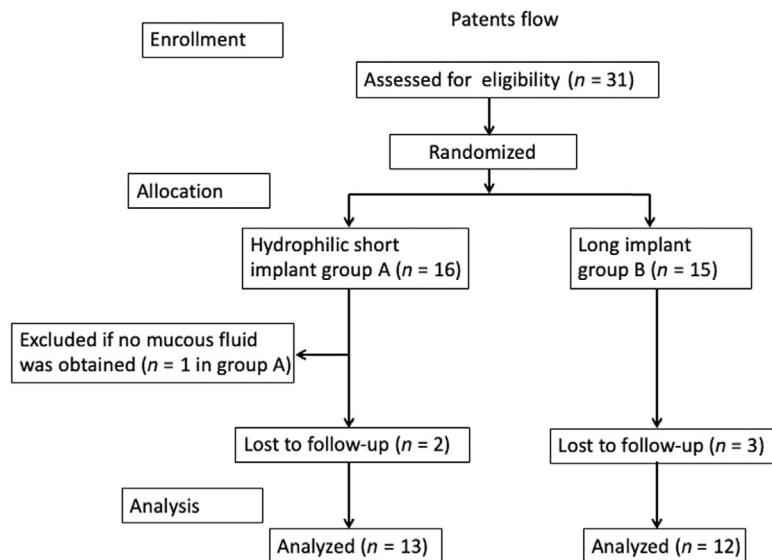
TABLE 1 Patient and intervention characteristics.

	One-stage surgery	Two-stage surgery
Female/Male	10/3	7/5
Mean age at implant insertion (years)	49.5 ± 10.23	46.6 ± 11.53
Number of elevated maxillary sinus	14	12
Number of sinus bone augmentation with simultaneous implant placement	5	4
Total number of inserted implants	23	18

3.1 | Primary outcomes

Of the 25 patients, implants were placed in 17 augmented sinuses that allowed biopsy core harvesting. Of these, four in immediate Group and 1 in delayed Group deteriorated and were excluded from the analysis. For histomorphometric analysis, biopsies were performed in seven patients from immediate Group and five from delayed Group. The analysis revealed that the mean MB was 22.6% ± 12.7% and 23.7% ± 9.0% in one- and two-stage groups, with no significant difference ($p = 0.87$) (Figure 4). Other data are presented in Table 2.

3.2 | Secondary outcomes

All 21 implants osseointegrated uneventfully and were restored. No implant loss was observed in either group.

Graft leakage due to rupture of the sinus membrane occurred in one patient in immediate Group, whereas no such observation was reported in delayed Group. No pseudocyst recurrence was observed until the end of the 1-year follow-up.

The median VAS scores for overall satisfaction were significantly different in Groups A and B (5.2 ± 0.3 vs. 6.7 ± 0.4, $p = 0.015$), respectively. No significant difference in the degree of postoperative discomfort was observed between the two groups (7.9 ± 0.3 vs. 8.4 ± 0.4 in Groups A and B, respectively, $p = 0.21$).

4 | DISCUSSION

In the present study, both timings for performing LSE were found to be suitable for rehabilitating posterior teeth in anatomical and pathological conditions such as antral pseudocyst. Based on positive patient-centered outcomes, reduced treatment trauma and time, and relatively lower complication rate, one-stage intervention using "two-bony-window" technique seemed a promising alternative for the management of a pseudocyst.

Thus far, the management of maxillary sinus pseudocyst in patients requiring sinus floor elevation is controversial. According to the results of present study and literature reports, the presence of a pseudocyst should not be considered as an absolute contraindication to sinus floor augmentation. If the pseudocyst occupies large space in the sinus, further management of the pseudocyst will be required to avoid a potential risk of relapse, in which case the intra-sinus physiological environment of the sinus ostium may be compromised because of sinus elevation.[12] Lin and colleagues presented a modified two-stage technique that could be successfully applied in clinical practice.[5] Yu and colleagues reported a case series of LSB with simultaneous removal of pseudocyst.[13] In their study, histomorphometric analysis revealed a mean percentage of 24.9% of MB.[13]

Based on the management philosophy of above-mentioned studies, both techniques in the present study involved intentional perforation of the sinus membrane, followed by removal of the cyst. In the two-stage surgery, a second intervention was required to augment the endo-sinus sites. A modified rectangular bony window was
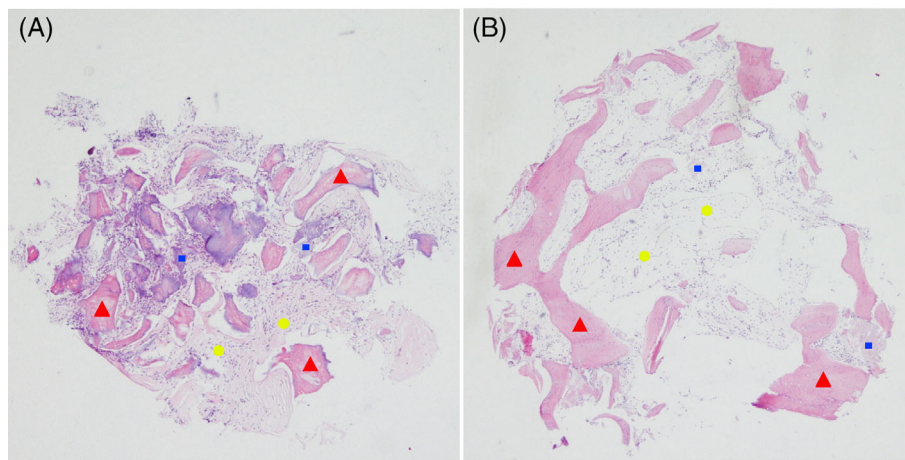
FIGURE 4 Histological section of a bone specimen. Newly formed bone (red triangles) surrounding the grafted materials (yellow stars) and nonmineralized matrix (blue squares) (H&E 4*). (A) Representative section from the one-stage group. (B) Representative section from the two-stage group.

TABLE 2 Radiographic and histomorphometric data values.

	One-stage surgery	Two-stage surgery	p value
MB%	22.6 ± 12.7	23.7 ± 9.0	0.87
BS%	37.2 ± 4.4	41.3 ± 6.6	0.22
NMT%	40.3 ± 10.0	35.1 ± 5.2	0.31

Abbreviations: BS, bone substitute materials; MB, mineralized bone; NMT, nonmineralized tissue.

created and rehabilitated by relocating the prepared bony wall. During the LSE in the second operation, the bony wall was always intact, which effectively prevents connective tissue invagination from affecting endo-sinus bone regeneration. Histologically, maturation of the endo-sinus bone (22.56% and 23.67%) after 6 months healing in the present study was comparable to that reported to previous studies, ranging from 15.7% to 42.3%.[14,15] The ratio of new bone formation is an important evaluation index for sinus bone augmentation that is related to osseointegration and long-term survival rate of the implants.[16]

The two-stage intervention is relatively safe for maxillary sinus augmentation after the sinus membrane has healed and prevents membrane tear-related leakage of bone grafts. However, this procedure required a postoperative healing period of at least 3 months. Although the treatment time is shorter than Caldwell-Luc or endonasal endoscopic surgery reported in the literature,[6] patients still require a secondary surgical intervention. The total treatment time and trauma can affect patients' cooperation and compliance.

The one-stage intervention involves performing sinus floor elevation immediately after removal of the pseudocyst. To reduce the risk of further sinus membrane tear after removal of the cyst, the "two-bony-window" technique was applied to augment the sinus. The initial small bony window was prepared for removing the cyst without further sinus membrane tear. A concentric larger window was then created to facilitate easier access to repair the perforated membrane and complete sinus augmentation. Because conventional sinus floor elevation is associated with a membrane perforation rate of 30%,[17] simultaneous sinus augmentation is feasible, and its effect is predictable.

Considering positive patient-centered outcomes and reduced treatment trauma and time with the one-stage treatment approach compared with the two-stage therapy, the "two-bony-window" technique is a promising alternative for the management of a pseudocyst.

Intra and postoperative complications such as infection were relatively less frequent in both groups. The prevalence of sinusitis after conventional sinus augmentation is reported approximately in 3% to 20% patients,[18,19] which is comparable to prevalence in the present study. Until the end of the follow-up, no recurrence of pseudocyst was reported. Compared to the two-stage intervention, the one-stage surgery is associated with the risk of leakage of bone grafts and termination of bone graft due to membrane tear; however, the difference between two groups was not statically significant. In the one-stage group, the postoperative radiograph of one patient showed bone graft particles, but no obvious clinical symptoms were observed in the patient, and this finding did not affect the following treatment. This technique is relatively sensitive and requires more clinical experience to implement.

Although pseudocyst removal and sinus augmentation were conducted in one operation in test group, no significant difference was noted in the post-operative discomfort between groups. "Two-bony-window" technique is essentially similar to the repair technique for membrane tear during sinus augmentation, which would not lead to further trauma and discomfort. On the other hand, patient overall acceptance with one-stage solutions is significantly higher than the control group, due to less surgery times and treatment time. In the test group, a mean treatment time needed to finish the whole procedure, is 3 months less than the control group on average. The results revealed that the major worries of patients were the issues of fear and anxiety relating to potential pain and complication after surgery. For the aforementioned reasons, the use of "two-bony-window" technique can contribute to patients' treatment options.

This study has some limitations. First, a relatively small number of subjects were included, and the follow-up was relatively short. Second, histological evaluation of all samples could not be performed in all cases. Further clinical longitudinal prospective studies are necessary to confirm the long-term success of both surgical procedures.

5 | CONCLUSIONS

The present study is the first randomized controlled study to compared clinical outcomes of maxillary sinus floor elevation performed immediately and 3 months after pseudocyst removal.

1. Both procedures could obtain comparable histological outcomes and had low complication rates.

2. One-stage procedure had a short treatment course and patients who underwent this procedure had increased satisfaction and acceptance.

3. "Two-bony-window" technique is an effective alternative for sinus augmentation immediately after pseudocyst removal.

AUTHOR CONTRIBUTIONS

Huajie Yu: Data analysis, Drafting article. **Yiman Tang**: Data collection. **Danqing H**e: Data analysis, Statistics, Critical revision. **Lixin Qiu**: Concept, Approval of article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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