Since 1949, China has experienced three “baby booms”: (1) 1949 to 1958, (2) 1962 to 1965, and (3) 1981 to 1990. The first two groups of baby boomers are reaching retirement age and making increasing use of medical and dental practices; this trend will continue in the coming years. According to the Seventh National Population Census, the number of people aged 60 and older in China is 260 million. According to the Fourth National Oral Health Survey, in the group aged 35 to 74 years, the proportion of people who have missing teeth without restoration increases gradually with age from 18.6% to 47.7%. Furthermore, the incidence of periodontal disease in adults is > 90%. Loss of alveolar height due to periodontal disease and tooth extraction combined with the possibility of secondary sinus pneumatization that occurs in the posterior maxilla often does not allow for the placement of dental implants. Various techniques have been proposed to facilitate implant placement in the atrophic posterior maxilla, including lateral approach sinus floor augmentation, osteotome sinus floor augmentation, and short implants.

The maxillary sinus floor augmentation (MSFA) procedure using a lateral window approach was initially developed by Tatum in the 1970s, was first published by Boyne and James in 1980, and was considered a highly predictable therapeutic modality by 1996. A recent meta-analysis recommended MSFA as an effective and well-documented technique, with a 5-year survival rate of 88.6% to 100%. Surgical procedures for maxillary sinus surgery have been widely documented; however, consistent data regarding the effect of various factors on long-term clinical outcomes are still lacking.

Purpose: To identify the impact of residual bone height on 5-year implant survival and prosthetic complication rates in patients who underwent maxillary sinus grafting. Materials and Methods: A total of 87 consecutive patients were treated with 104 lateral approach maxillary sinus floor augmentation procedures with 100% deproteinized bovine bone and received 169 implants. The analysis considered patient age, sex, time of implant placement, and residual bone height. Results: The mean follow-up was 68.2 months (0 to 103 months). The mean residual bone height was 1.8 mm in the study group and 4.1 mm in the control group. The 5-year implant survival and prosthetic complication rates were, respectively, 97.4% and 8.0% in the study group and 100% and 12.5% in the control group. Residual bone height, sex, age, and time of implant placement were not significant factors for the 5-year implant survival or prosthetic complication rate. The lateral bone wall was significantly thinner in the study group. The grafted bone height reduction was significantly different at 6 months and 2 years postoperatively in both groups, but there was no difference in the change in grafted bone height reduction over time between the two groups. Conclusion: A residual bone height < 3 mm did not impact the survival rates of implants placed in grafted maxillary sinuses or the prosthetic complication rate after 5 years of functional loading.

Keywords: atrophic maxilla, longitudinal studies, residual bone height, sinus floor augmentation, survival

14th Division of Peking University School and Hospital of Stomatology, National Center of Stomatology, National Clinical Research Center for Oral Diseases & National Engineering Laboratory for Digital and Material Technology of Stomatology, Beijing, PR China.

Correspondence to: Dr Lixin Qiu, 4th Division, Peking University School and Hospital of Stomatology, No. 22, Zhongguancun South Avenue, Haidian District, Beijing, 100081, PR China. Email: qiulixin@pkuss.bjmu.edu.cn

Submitted May 11, 2021; accepted June 5, 2022.

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quality and complications might influence the long-term survival of implants placed in grafted maxillae. However, these factors lack strong evidence and expert consensus since this surgical protocol has evolved over the last two decades regarding grafting materials and implant characteristics. Also, long-term clinical outcomes appear to vary across countries, ethnic groups, and economic levels. In addition, there is heterogeneity between different studies, and findings cannot be arbitrarily applied.

Some studies have shown that the implant survival rate tends to decrease when the RBH decreases. Other studies did not find a significant effect of RBH on the implant survival rate. However, the number of included studies was not large, and most of the studies reported a great variety of study designs, implant types, timings of implant placement, prosthesis designs, grafting materials used, and quality of local alveolar bone. The aim of this retrospective clinical investigation was to determine the effect of RBH on the 5-year implant survival and prosthetic complication rates for implants placed in grafted maxillary sinuses.

**MATERIALS AND METHODS**

**Patients**
The Institutional Review Board of Peking University School and Hospital of Stomatology approved the research project (PKUSSHIRB-2016113115).

In this retrospective single-unit study, the charts of consecutive patients undergoing lateral approach sinus augmentation from February 2012 to December 2015 were reviewed, and data were collected via specific forms. The observation period continued to December 2020, resulting in a minimum follow-up period of 60 months after implant insertion. Patients were followed up by clinical visits, telephone, or both. The study was conducted in accordance with the Helsinki Declaration.

The inclusion criteria were (1) primary maxillary sinus surgery, (2) an RBH of < 6.5 mm, and (3) use of the INICELL (Thommen Medical) implant system. The exclusion criteria were (1) an American Society of Anesthesiologists (ASA) score ≥ III; (2) systemic disease (rheumatoid arthritis, immunosuppressive chemotherapy, uncontrolled diabetes mellitus, or other autoimmune diseases); (3) a history of radiotherapy in the head and neck region; (4) pregnancy; (5) a history of sinus surgery; and (6) metabolic or degenerative diseases of the bone (e.g., osteoporosis, diabetes mellitus, hyperparathyroidism) and long-term medication with corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs).

Patients were divided into two groups according to the preoperative RBH on CBCT: the control group (RBH ≥ 3 mm) and the study group (RBH < 3 mm; Fig 1).

**Treatment**
All patients received prophylactic antibiotic therapy 1 hour before treatment. Under local anesthesia with 4% articaine, a crestal incision with vertical releasing incisions was performed. A full-thickness flap was elevated and reflected laterally to expose the lateral wall of the sinus. Then, a bone window was outlined with a round diamond bur or piezoelectric device. The bone in the center of the window was removed, and the sinus membrane was exposed. Specially designed hand instruments were used to elevate the sinus membrane carefully. Bio-Oss (Geistlich Pharma), the only grafting material used in the study, was packed layer by layer. The lateral bone window was covered with a resorbable collagen membrane (Bio-Gide, Geistlich Pharma). If the residual ridge condition allowed primary stability of the implants, the implants were inserted during the same surgical session as the sinus augmentation (simultaneous procedure). Otherwise, the implants were placed in a subsequent surgical phase after a healing period of 6 to 8 months (delayed procedure; Fig 1). The same commercially pure titanium implants were placed according to the manufacturer’s protocol (INICELL, Thommen Medical). Postoperatively, the patient was advised to refrain from sneezing and nose blowing. After surgery, antibiotics, painkillers, and chlorhexidine mouthwash...
were prescribed. None of the patients routinely used nasal drops.

In the simultaneous procedure, implant abutment connection and prosthetic loading of implants were performed after 6 months; in the delayed procedure, the consolidation time for the grafts was 8 months, and implant loading was then performed after 3 months.

Radiography
Preoperative evaluations included CBCT and panoramic radiographs. Patients underwent CBCT on Planmeca ProMax 3D and were positioned parallel to the office floor with a Frankfort-Horizontal plane. The settings were 90 kV and 10/12 mA, and the exposure volume was 90 mm in diameter and 90 mm in height. The sagittal, coronal, and axial images were reformatted using a software program (Planmeca Romexis 3.7.0. R). The slice thickness of the multiplanar reconstruction images was 0.2 mm. The measurements were approximated to the nearest 0.01 mm with a caliper.

According to typical clinical practice, patients were followed up for 1 month, 12 months, and annually thereafter, and radiographic films were taken if necessary. Reviewers recorded the sinus contour,28 initial bone height, lateral sinus wall thickness, intrasosseous vessel diameter, and grafted bone height (GBH). Planmeca software was used to automatically correct the magnification on radiographic films. All measurements were made twice at two different times.

Variables
The grafted bone healing period refers to the time between sinus floor augmentation and implant insertion. The implant healing period refers to the time between implant insertion and prosthetic loading, including definitive and provisional prosthetics.

The follow-up period is the time interval between prosthesis insertion (both definitive and provisional) and the last follow-up visit.

The primary outcomes were as follows:

1. Implant survival rate: According to the modified Albrektsson criteria,29 implant survival is defined as the absence of implant loosening or shedding. The implant survival time is the time elapsed from implant placement to implant loss for any reason. Loss of patients at follow-up is defined as a missing value. The survival rate of the implant was calculated at the implant level.

2. Incidence of prosthetic complications: Prosthetic complications included food impaction, porcelain fracture, dislodged cemented crowns, loosened screw-retained crowns, and fractured restorative components. The prosthetic-complication time is defined as the time from prosthetic placement until any of the aforementioned complications occurred. Loss of patients at follow-up is defined as a missing value. The prosthetic complication rate was calculated at the patient level.

3. GBH change over time: GBH was defined as the vertical distance measured between the lowest and highest levels of the grafted area. GBH was evaluated immediately, 6 months, and 2 years after sinus floor augmentation.

Statistical Analysis
Unordered categorical data, including sex, age, tooth site, number of missing teeth, distribution of maxillary sinus contours, distribution of simultaneous implants or delayed implants, and membrane perforation rate, were compared between groups by the chi-square test. Vessel diameter and lateral bone thickness were compared by the t test. A mixed model was established with GBH as the dependent variable, GBH at baseline as a fixed covariate, groups and time and interaction between groups and time as the fixed factors, and patient as a random factor. The GBH differences between the groups and within the groups at different time points were tested using pairwise comparisons. The Bonferroni method was used for multiple comparisons. The implant survival rate and the prosthetic complication rate are described using the Kaplan-Meier curve and were compared between groups using the log-rank test. The significance level was set at \( P \leq .05 \) for the statistical tests. All statistical analyses were performed using SPSS 24.0 (IBM, SPSS).

The STROBE guidelines were adhered to in the preparation of this article.

RESULTS

Patients and Radiographic Features
Eighty-seven patients who met the inclusion criteria were recruited. Seventeen patients received bilateral sinus floor augmentation. Among them, there were 8 patients in the study group and 4 patients in the control group. The other 5 patients who had bilateral sinus surgery had both of their sinuses included, one in the study group and one in the control group. Seventy patients received unilateral sinus floor augmentation (31 patients in the study group and 39 patients in the control group). A total of 104 maxillary sinuses were eligible for inclusion: 52 sinuses in the study group and 52 sinuses in the control group.

The preoperative RBH was 1.8 \( \pm 0.6 \) (0.5 to 2.8) mm in the study group and 4.1 \( \pm 1.0 \) (3 to 6.5) mm in the control group, with a significant difference \( (P = .001) \). The baseline information of both groups is shown in Table 1. There were no significant differences in sex, age, tooth site, sinus contour, or vessel diameter in the lateral bone between
the two groups. The percentage of patients with multiple tooth loss was significantly higher in the study group than in the control group. There was a significant difference in the thickness of the bone at the open window between the two groups.

**Surgical Complications**

Three patients (5.8%) in the study group and two (3.8%) in the control group had sinus membrane perforation, and the difference was not statistically significant ($P = .65$). After proper treatment, the maxillary sinus floor augmentation and implant placement were successful. The above five patients had good long-term results at follow-up, with no implant loss. None of the patients in this study had severe bleeding complications or sinusitis. Postoperative swelling in almost all patients followed a routine pattern, reaching its maximum 48 hours postsurgery and gradually subsiding over approximately 1 week.

**Grafted Bone Healing Period**

The grafted bone healing period for the delayed procedure was $5.4 \pm 1.5$ months (5, 4 to 10) in the study group and $4.5 \pm 0.9$ months (4, 3 to 6) in the control group, with a significant difference found by one-way t test ($P = .008$). The implant healing period was $5.5 \pm 1.1$ (6, 4 to 7) months in the study group and $5.9 \pm 1.0$ (6, 4 to 8) months in the control group in patients with simultaneous implants. One-way t test revealed no significant difference ($P = .31$). Among delayed implantation patients, the implant healing period was $5.4 \pm 1.7$ (6, 1 to 9) months in the study group and $5.2 \pm 2.1$ (5, 2 to 9) months in the control group. There was no significant difference between groups ($P = .59$).

**Fig 2** Comparison of the grafted bone healing period and implant healing period between the two groups. (a) The grafted bone healing period of the two-stage procedure was $5.4 \pm 1.5$ months (5, 4 to 10) in the study group and $4.5 \pm 0.9$ months (4, 3 to 6) in the control group, with a significant difference found by one-way t test ($P = .008$). (b) The implant healing period was $5.5 \pm 1.1$ (6, 4 to 7) months in the study group and $5.9 \pm 1.0$ (6, 4 to 8) months in the control group in patients with simultaneous implants. One-way t test revealed no significant difference ($P = .31$). (c) Among delayed implantation patients, the implant healing period was $5.4 \pm 1.7$ (6, 1 to 9) months in the study group and $5.2 \pm 2.1$ (5, 2 to 9) months in the control group. There was no significant difference between groups ($P = .59$).
Placement was 84.6% (44/52) in the study group and 44.2% (23/52) in the control group, with a significant difference ($P < .001$; Fig 1).

**Implant Healing Period**

The present study only included and counted the implants located within the grafted area of the maxillary sinus. A total of 169 implants were inserted, with a diameter of 4.0 to 6.0 mm and a length of 8.0 to 14.0 mm. A total of 99 implants were placed in the study group and 70 implants in the control group. The implant healing period was 5.5 ± 1.1 (6, 4 to 7) months in the study group and 5.9 ± 1.0 (6, 4 to 8) months in the control group in patients with simultaneous procedures. The one-way $t$ test revealed no significant difference ($P = .31$; Fig 2b). Within the delayed procedure, the implant healing period was 5.4 ± 1.7 (6, 1 to 9) months in the study group and 5.2 ± 2.1 (5, 2 to 9) months in the control group. There was no significant difference between the groups ($P = .59$; Fig 2c).

**Change in GBH**

The height of the grafted bone immediately, 6 months, and 2 years postoperation was significantly different between the study and control groups ($P < .01$). There was also a significant difference in GBH at the three different time points within the study and control groups ($P < .05$). The joint variable of time*group did not differ, indicating that there was no difference in the trend in the GBH reduction over time between the two groups ($P = .63$).

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<td>10.5 ± 2.2</td>
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<tr>
<td><strong>Control group</strong></td>
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<td>9.6 ± 2.1</td>
<td>8.9 ± 1.7</td>
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*Table 2 Changes in GBH Over Time*

Table 2 shows the changes in GBH over time in the study and control groups. The heights of the grafted bone immediately, at 6 months, and at 2 years were significantly different between the study and control groups ($P < .01$). There was also a significant difference in GBH among the three different time points within the study and control groups ($P < .05$). The joint variable of time*group did not differ, indicating that there was no difference in the trend in the GBH reduction over time between the two groups ($P = .63$).

**Implant Survival Rate**

At the time of data collection, the prostheses had been functional for 68.2 ± 22.5 (71, 0 to 103) months, and the loss to follow-up percentage was 11.5%. The 5-year implant survival rate was 97.4% in the study group and 100% in the control group. Statistical results showed no association between the 5-year implant survival rate and patient-related factors or implant characteristics, such as RBH, sex, age, and time of implant placement (Fig 3a). Only one implant failure occurred in the study group, and no implant loss occurred in the control group. The failed implant in the study group was a single implant placed in the grafted maxilla of the patient’s left first molar (RBH of 1.8 mm). The implant failed because two adjacent teeth next to the implant (maxillary left first and second premolar) experienced severe periodontal disease and became extremely loose, causing high stress force and occlusal overload to the implant. The implant was fractured and eventually removed by the clinician after 62 months of prosthetic functioning.
The 5-year prosthetic complication rate was 8.0% in the study group and 12.5% in the control group. Prosthetic complications continued to occur over time. RBH, sex, age, and time of implant placement were not significant factors affecting the 5-year prosthetic complication rate (Fig 3b). Prosthetic complications in the study group included two cases of porcelain fracture, three cases of food impaction, five cases of a dislodged crown, one case of implant fracture, and one case of restorative component fracture. There were four cases of porcelain fracture, eight cases of food impaction, and two cases of a dislodged crown in the control group.

The preoperative, postoperative, and follow-up CBCT images of a typical case in the study and control groups are shown in Fig 4, respectively.

**DISCUSSION**

This is a long-term retrospective, single-institution, large-sample clinical study using the same implant system and the same deproteinized bovine bone grafting material. The 5-year implant survival rate was 97.4% in the study group and 100% in the control group. RBH, sex, age, and time of implant placement were not
significant factors affecting implant survival. Some previous studies did not find a significant effect of RBH on the implant survival rate. Mardinger et al followed 55 patients and found that the 3-year implant success rate was 92% and 98.7% for patients with RBH ≤ 4 mm and > 4 mm, respectively, with a borderline statistically significant difference. Geur et al followed 303 implants and found that the 3-year implant survival rates were 91.7%, 94.1%, and 100% for RBHs of < 4 mm, 4 to 8 mm, and > 8 mm, respectively, without significant differences. Hurzeler et al reported a 5-year implant survival rate of 95.2% in patients with RBH < 4 mm, and RBH had no effect on implant success. However, Chao et al conducted a meta-analysis including 12 studies and showed a significant trend indicating that the implant survival rates increased with RBH. The implant survival rate tended to increase as the initial bone height rose from approximately 1 to 5 mm and stabilized at a high rate when the initial bone height was ≥ 5 mm. The effect of RBH on implant survival rate is currently inconclusive because the literature presents a great variety in study designs, implant systems, timing of implant placement, grafting materials used, and follow-up time.

The present study used the same implant system with a microrough surface, screw-type, cylindrical/conical, machined collar with a height of 1 to 1.5 mm, and hydrophobic/superhydrophilic surface state. The development of new implant surfaces and implant-abutment connections might contribute to the high survival rate of implants placed in the grafted maxillary sinus in the present study. Sandblasted, large-grit, acid-etched, surface-treated implants have a higher survival rate than machine-surfaced implants in grafted maxillary sinuses. Researchers have shown that the microrough sandblasted and the thermal acid-etched surface of implants can promote intrinsic implant stability. In addition, conical implants with a large implant neck diameter can compress the alveolar bone and improve the initial implant stability, which has been reported to be the main reason for implant loss in many studies. Another modification of this implant system is the superhydrophilic surface, which may increase the implant survival rate, as another study found that implants with a superhydrophilic surface had a higher bone-to-implant contact and achieved better implant stability in the early healing phase. All the surgeries were performed by one surgeon (L.Q.) with 30 years of experience, which is a critical factor for obtaining a high implant survival rate.

In the study group, one implant loosened due to poor osseointegration as an early failure but was not counted as an implant failure in this study. This patient with an RBH of 1 mm received MSFA with simultaneous cyst removal, and 6 months later, three implants were inserted. Two months later, when detaching the healing abutments, one implant loosened due to poor osseointegration, so the surgeon removed the implant and placed a new, wider implant that subsequently functioned well. Beck et al found that after a healing period of 6 months after sinus floor augmentation, the most apical part of the augmentation area appeared to contribute only minimally to the treatment outcome since new bone formation at this distance was relatively low. A pretreatment bone height of 4 to 5 mm was recommended for simultaneous implant placement. Whenever the clinician has hesitations, a delayed procedure would be beneficial, as delayed placement improves implant stability and could eventually lead to identification of more desirable implant positions and angulations.

The present study used Bio-Oss as the only grafting material, resulting in clinically stable long-term outcomes, consistent with other studies. Mordenfeld et al followed 20 patients who had maxillary sinus floor augmented with a mixture of 80% deproteinized bovine bone (DBB) and 20% autogenous bone over 10 years and found a statistically significant reduction in GBH between 3 months and 2 years but no further significant reduction up to 10 years postoperation. Zhang et al found a 22% reduction in grafted bone volume at 6 months postoperatively and correlated it with factors such as a wide sinus and multiple missing teeth. Lu et al found a 7.6% reduction in GBH and a 15.3% reduction in grafted bone volume 2 years after surgery. In this study, GBH decreased significantly at 6 months and 2 years in the two groups. However, this decreasing trend was not significantly different between the study and control groups.

The lateral bone thickness in the study group was significantly smaller than that in the control group, which suggests that the lower the RBH was, the thinner the lateral bone wall was. Therefore, the sinus membrane may be more prone to tearing during lateral window preparation in patients with severely resorbed bone. In addition, it is recommended to prepare two small bone windows instead of a large window to avoid an insufficient blood supply from the sinus bone to the grafting materials in severely resorbed bone.

CONCLUSIONS

RBH was not associated with membrane perforation rate, implant survival rate, prosthetic complication rate, or change in grafted bone reduction after 5 years of functional loading in grafted maxillary sinuses.
ACKNOWLEDGMENTS

The authors declare that they have no conflicts of interest with the contents of this article.

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