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Radiological Changes Associated with New Bone Formation Following Osteotome Sinus Floor Elevation (OSFE): A Retrospective Study of 40 Patients with 18-Month Follow-Up

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
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Background: Osteotome sinus floor elevation (OSFE) is used to increase the bone volume at the site of the maxillary sinus through the transalveolar approach, and may require support with bone grafting. The aim of this retrospective study was to evaluate the radiological changes associated with new bone formation following OSFE during an 18-month follow-up period.

Material/Methods: Forty patients (including 51 implants) underwent OSFE with final dental reconstruction with a single crown, six months after surgery. Of the 51 dental implants, 24 were implanted with bone grafts, and 27 were implanted without bone grafts. All patients were reviewed using preoperative cone beam computed tomography (CBCT) and panoramic radiographs in postoperative follow-up immediately after OSFE, at six-month follow-up, at 12-month follow-up, and at 18-month follow-up. The degree of new bone formation following OSFE was measured by endo-sinus bone gain (ESBG) in the digital radiographs, and the related factors were analyzed.

Results: At 18-month follow-up, the mean ESBG was 2.55±2.24 mm (range, 0.1–8.6 mm). Partial correlation analysis showed that there was no significant correlation between residual bone height (RBH) and ESBG (partial correlation coefficient –0.143) (P=0.328). There were significant positive correlations between the implant protrusion length (IPL) and ESBG (partial correlation coefficient 0.560) (P=0.000), and whether to perform bone grafts and ESBG (partial correlation coefficient 0.596) (P=0.000).

Conclusions: Following OSFE combined with a short implant, the IPL and the performance of bone grafts were significantly associated with new bone formation.

MeSH Keywords: **Dental Implants • Sinus Floor Augmentation • Technology, Radiologic**

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Background

Reconstruction of the atrophic posterior maxilla is challenging because of limited maxillary residual bone height (RBH) and low bone density [1,2]. In 1986, Tatum proposed a lateral approach to sinus floor elevation [3]. A transalveolar approach to maxillary sinus floor elevation, using a set of tapered osteotomes with increasing diameters, referred to as 'osteotome sinus floor elevation' (OSFE) was introduced by Summers in 1994 [2]. Both approaches can serve as solutions to the reconstruction of the atrophic maxilla. In the initially described sinus augmentation procedures, the lateral window approach, or the transalveolar procedure, different bone-grafting materials are required to maintain bone space and induce bone regeneration [1–3]. In the past few decades, several modifications to the originally described sinus augmentation procedures have been made [4–6]. Lundgren et al. have shown that sinus lift without bone grafting can also induce bone formation in the maxillary sinus and can result in a favorable success rate, and this method is considered to be a less invasive and less traumatic procedure, which is less costly [7].

Currently, with the development of the implant materials, implant design, and surgical technique, the sinus elevation techniques are becoming increasingly simplified and are now used more widely [8–10]. Even in cases with an extremely atrophic posterior maxilla with a residual bone height (RBH) of ≤4 mm, the five-year success rate of implants has been reported to be as high as 94.1% in the no bone graft group and 90% in the bone graft group [6,11].

There have been some previously published radiologic studies that have reported the findings following sinus elevation, including the evaluation of volume changes of the grafts, the differences between the bone graft group and the no bone graft group in new bone formation, and the osteotome versus the lateral approach [12–14]. In 2013, Altintas et al. reported the assessment of new bone formation after sinus augmentation with a lateral window approach and compared a bone grafted group and non-bone grafted group [15]. In this study, both groups showed new bone formation around the implants, and new bone density in the non-bone grafted group was significantly greater compared with the grafted group [15]. Lai et al. compared osteotome sinus elevation with and without grafting and concluded that there were no significant differences between the two groups in implant survival rate, with the cumulative survival rates for the two groups being 97.38% and 92.13%, respectively [16]. In the same study, there was the finding that endo-sinus bone gain (ESBG) was significantly correlated with implant protrusion length following OSFE in non-bone graft group, and was not significantly correlated with RBH [16]. However, in this previous study, the conclusions were based on analysis of part of the data from the study and included only 30 implants [16]. Few previous studies have focused on the correlation between new bone formation following OSFE and the possible factors that affect this outcome, including the effects of bone grafts, the original RBH, and dental implant design.

Cone beam computed tomography (CBCT) had many advantages when used in the diagnosis of sinusitis, the integrity and thickness of the sinus membrane, the measurement of the size and boundaries of tumors, as well as anatomical structures including septa and blood vessels [17,18]. Panoramic radiographs have been used more often in routine clinical examination because of the lower cost and lower levels of radiation exposure when compared with CBCT. For these reasons, in the present study, CBCT was used in the initial preoperative assessment of the study participant, while panoramic radiographs were used for postoperative follow-up.

The aim of this retrospective study was to assess the radiological changes associated with new bone formation following OSFE during an 18-month follow-up period and to evaluate the correlations between RBH, IPL, the use of bone grafting and ESBG.

Material and Methods

Study population

A retrospective study of patients who underwent osteotome sinus floor elevation (OSFE) at the hospital of Stomatology, Wuhan University, China between from 2012 to 2016 was undertaken. The same surgeon performed all surgical procedures. The study design and clinical procedures were performed in accordance with Helsinki Declaration. The study was approved by Medical Ethics Committee, the School and Hospital of Stomatology, Wuhan University, China. The design of the study was registered on Chinese Clinical Trial Registry (ChiCTR) (Registration Number: ChiCTR-RRC-17013283). To remove potential bias from the use of different implant devices, a single dental implant, the Bicon implants (Bicon, LLC, Boston, MA, USA) was used in all patients who were enrolled in the study. All patients signed an informed consent at the beginning of dental implant treatment.

The patient inclusion criteria for this study were: osteotome sinus floor elevation (OSFE) and simultaneous insertion of the Bicon implant; the availability of at least an initial preoperative cone beam computed tomography (CBCT); panoramic radiographs performed immediately following surgery, and at six-month follow-up, 12-month follow-up, and at 18-month follow-up; available and detailed medical records, including medical and dental history, surgical records, details on the use and type of bone grafts; the use of prosthetic reconstruction using single-implant, single crown restorations.

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Table 1. Implant length and diameter.

	Implant diameter	
	4.5 mm	5 mm
Number of implants	20	31
Implant length, n		
6 mm	17	28
8 mm	3	3

The patient exclusion criteria for this study were: a diagnosis of metabolic bone disease, uncontrolled diabetes, periodontal disease, pregnancy, any systemic disease that prevented surgery, including heart disease, hypertension or coagulopathy, maxillary sinusitis, and sinus elevation performed using a lateral approach. Forty patients, with 51 implants, met the inclusion criteria of the study. The research was designed and conducted in compliance with the current Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement (*www.strobe-statement.org*).

Radiological techniques

Before surgery, each patient included in the study had undergone an initial preoperative CBCT. Panoramic radiographs were calibrated using a small steel ball with a diameter of 5 mm. If the panoramic radiographs showed that the bone height under the maxillary sinus floor was not sufficient for directly implant placement and maxillary sinus floor elevation was needed, then the CBCT was supplemented to identify the vertical bone height under the sinus floor accurately and to identify any septa in the maxillary sinus. The treatment protocols for OSFE and simultaneous insertion of the implants were finally determined by the findings from the preoperative CBCT imaging.

Surgical study design

The surgical procedures were performed under local anesthesia according to the surgical guidelines provided by Bicon implant system (Bicon, LLC, Boston, USA) and included 51 Bicon implants in 40 patients. The distribution of the implants, with respect to length and diameter, is summarized in Table 1. Short implants combined with OSFE were used in patients with an atrophic maxilla. All implants were placed in sites using a submerged technique and with a two-stage surgical procedure with an undisturbed healing time of six months. After six months of healing, prosthetic treatment for each was undertaken for each patient according to the implant manufacturer's guidelines.

Surgical procedures

For all 40 patients, pre-operative patient preparation included rinsing of the mouth with a 0.1% solution of chlorhexidine for 2 min. Local anesthesia was administered in the buccal and palatal regions of the surgical site. Following a mid-maxillary crest incision with or without a releasing incision, a full-thickness mucoperiosteal flap was raised. A round-shaped bur was initially used to mark the implant position. Then, minimal pilot drilling (Ø2.2 mm) was performed to a depth approximately 1 mm away from the sinus floor boundary according to the extent indicated from a review of the pre-operative CBCT scan. The elevation of the maxillary sinus was achieved using the Ø2.2 mm osteotome by light malleting to achieve the initial sinus elevation and was developed with osteotomies of gradually increasing diameters until the final depth was achieved. All implants were placed in sites using a submerged technique and using a two-stage procedure. A panoramic radiograph was immediately taken after surgery in all the cases.

Postoperative treatment

Postsurgical care following the implant placement with the osteotome technique was same as that following standard implant placement. Rinsing of the mouth with a 0.12% solution of chlorhexidine for 60 seconds, five times a day, for 14 days was prescribed. Anti-inflammatory drugs and the antibiotics, cefradine, and metronidazole were prescribed following surgery.

Prosthetic procedures, including implants

Following a healing period of six months, for each patient, a panoramic radiograph was taken to examine whether there was continued radiolucency around the implant body. Then the second stage surgery was undertaken. Four weeks after the second stage surgery, dental impressions were made. Two weeks later, prosthetic abutments were inserted, and the final restorations were performed. The implants were used to support single crowns.

Analysis of the radiographic findings

For each implant, five radiographs were analyzed: the initial CBCT radiograph before surgery (T0); the immediate postoperative panoramic radiograph (T1); the six-month postoperative panoramic radiograph (T2); the 12-month postoperative panoramic radiograph (T3); and the 18-month postoperative panoramic radiograph (T4).

The digital radiographic data were analyzed using the DICOM Image Web Viewer version 6.1.0.0 (EBM Technologies, Inc.). The radiographic parameters were analyzed by a single radiology assistant, who was unaware of the patient's treatment details.

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Measurement of the radiographic parameters and analysis of the data were performed again after 24 hours. The intra-examiner agreement was compared and shown to be good, and the intraclass correlation coefficient (ICC) was 0.957 (P=0.000). All measurements were expressed in millimeters.

Key radiographic parameters were recorded. The residual bone height (RBH) was the distance from the floor of the maxillary sinus to the alveolar bone crest, which was always positive, and was only assessed before surgery using CBCT (T0). The implant length (IL) was measured, and the magnification of the panoramic radiograph was corrected by measuring the length of the implant and comparing the actual length of the implant. The implant protrusion length (IPL) in the sinus elevation procedure was the length of the implant extending into the maxillary sinus and was usually positive, measured immediately after surgery (T1) at the mesial (IPLm) and distal (IPLd) implant sides; the IPLm, IPLd, IPL (the mean of IPLm and IPLd), respectively were recorded. The peri-implant endo-sinus bone level (PEBL) was the distance between the apical implant level and peri-implant endo-sinus bone level which were recorded as mesial (PEBLm), distal (PEBLd) and mean of mesial and distal (PEBL). If the PEBL was above the apical implant level, then the value was recorded as positive; when the PEBL was below the apical implant level, the value was recorded as negative. The ESBG was the sum of the IPL and the PEBL. The PEBL and the ESBG were measured immediately after the surgery (T1), and at each follow-up visit at six months postoperatively (T2), at 12 months postoperatively (T3), and at 18 months postoperatively (T4).

Statistical analysis

Statistical analysis of data was performed using SPSS software version 19.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics included the mean and standard deviations (SD) to assess the RBH, IPL, and ESBG. The Student's t-test was used to compare the ESBG after OSFE with and without bone graft. A paired-sample t-test analyzed the ESBG at different time points. The correlation coefficient and the partial correlation coefficient were used to assess the correlation between RBH/IPL/whether to graft and ESBG. P-values <0.05 were considered to be statistically significant.

Results

Patient characteristics

A retrospective review of patient clinical records from our center, between 2012 and 2016, identified a total of 72 patients (with 89 Bicon implants) who underwent osteotome sinus floor elevation (OSFE) and who had final reconstruction with single-implant crowns at the Hospital of Stomatology, Wuhan University, performed by the same surgeon. There were 40 patients (with 51 Bicon implants), who met the inclusion criteria of the study, including 21 men and 19 women, mean age 50.6±12.93 years (range, 22–70 years). The patient selection process and study design are shown in Figure 1. Of the 51 dental implants, 24 were implanted with bone grafts (Geistlich Bio-Oss® Ltd., Manchester, UK), and the remaining 27 were implanted without bone grafts.

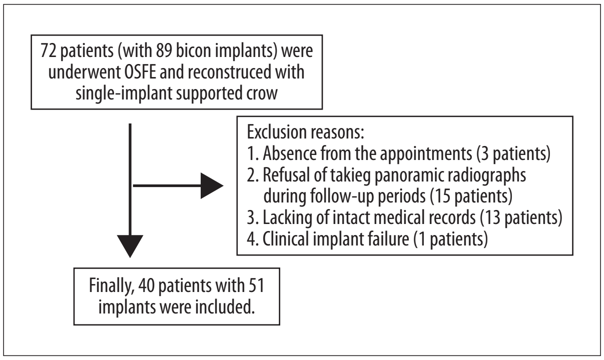

Figure 1. Flow diagram of the patient selection process.

Radiographic analysis based on the residual bone height (RBH)

The average height of the original bone was 5.37±1.28 mm (range, 2.3–7.9 mm). The findings of the radiographic analysis, based on residual bone height (RBH) are shown in Table 2. Partial correlation analysis determined whether to perform bone grafting and the implant protrusion length (IPL) showed that there was no significant correlation between the endo-sinus bone gain (ESBG) and RBH, with a partial correlation coefficient of –0.143 (P=0.328).

Radiographic analysis based on the follow-up time after OSFE

For each implant, five radiographs were analyzed: the initial CBCT radiograph before surgery (T0); the immediate postoperative panoramic radiograph (T1); the six-month postoperative panoramic radiograph (T2); the 12-month postoperative panoramic radiograph (T3); and the 18-month postoperative panoramic radiograph (T4). At T1 the average ESBG was 2.84±2.67 mm, at T2 the average ESBG was 2.70±2.38 mm, at T3 the average ESBG was 2.68±2.33 mm, at T4 the average ESBG was 2.55±2.24 mm. Figure 2 shows the radiographic follow-up of the Group 1 (graft group) and Group 2 (non-graft group) before and immediately after surgery, and at six months, 12 months, and 18 months after surgery.

The changes of ESBG at different follow-up times in the graft group and non-graft group are shown in Figure 3. In the graft

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Table 2. Radiographic analyses based on RBH at 18 months post-surgery.

	Residual bone height (RBH) (mm)		
	2–4	4–6	6–8
Number of implants	7	26	18
Mean (mm)	3.04±0.65	5.18±0.57	6.54±0.68
Endo-sinus bone gain (ESBG) (mm)	5.84±2.10	1.83±1.74	2.31±1.86
Number of using graft	7	8	9
Implant protrusion length (IPL) (mm)	3.31±1.11	1.28±0.86	1.15±0.77

Between RBH and ESBG, the correlation coefficient was –0.524 (P=0.000), and partial correlation coefficient was –0.143 (P=0.328).

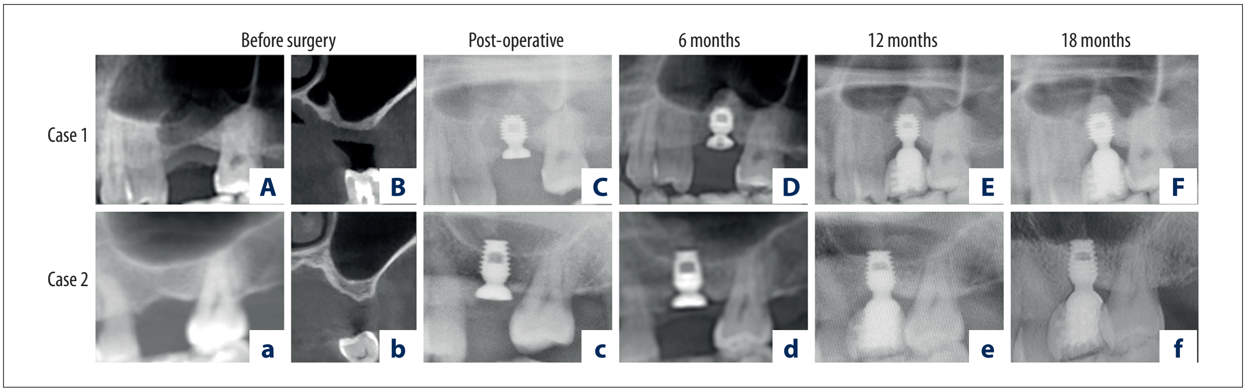

Figure 2. Panoramic radiographs and cone beam computed tomography (CBCT) images of Case 1 from the graft group and Case 2 from the non-graft group at follow-up. (**A**) Panoramic radiographs of Case 1 (graft group) before surgery. (**B**) Cone beam computed tomography (CBCT) of Case 1 (graft group) before surgery. (**C–F**) Panoramic radiographs of Case 1 (graft group) immediately, six months, 12 months, and 18 months after surgery. (**a**) Panoramic radiograph of Case 2 (non-graft group) before surgery. (**b**) CBCT of Case 2 (non-graft group) before surgery. (**c–f**) Panoramic radiographs of Case 2 (non-graft group) immediately, six months, 12 months, and 18 months after surgery.

group, at T1 the average ESBG was 4.63±2.35 mm, at T2 the average ESBG was 4.28±2.37 mm, at T3 the average ESBG was 4.09±2.38 mm, and at T4 the average ESBG was 3.96 ± 2.38 mm. The ESBG in bone graft group between baseline (T1) and different follow-up time points (T2, T3, T4) were statistically different. (P=0.016, P=0.002, and P=0.000, respectively). The average ESBG in non-bone graft group was 1.24 ± 1.80 mm (T1), 1.36±1.37 mm (T2), 1.33±1.22 mm (T3), and 1.29±1.07 mm (T4). There was no statistically significant difference in ESBG between baseline (T1) and the follow-up time points (T2, T3, T4) in non-bone graft group (P=0.445, P=0.944, and P=0.843, respectively).

Radiographic analysis based on the IPL

The IPL in the sinus elevation procedure ranged from –0.1–5.35 mm, with a mean of 1.51±1.12 mm. The radiographic analysis, based on IPL findings, are shown in Table 3. After controlling for the two factors of bone grafting and RBH, partial correlation analysis showed a moderately significant

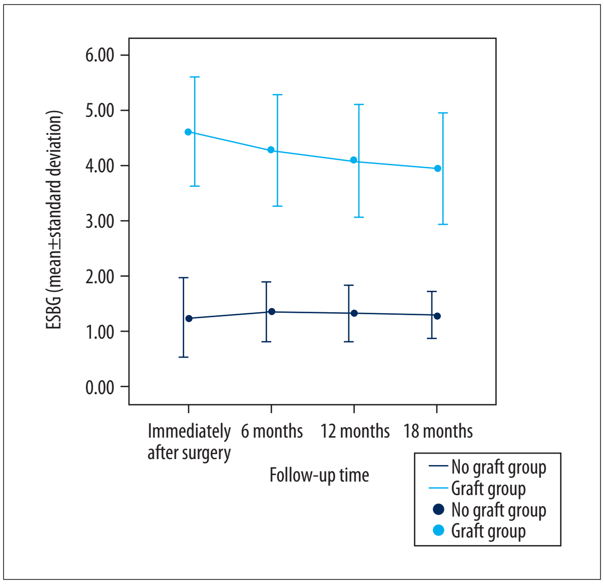

Figure 3. Changes of endo-sinus bone gain (ESBG) in the graft group and the non-graft group during follow-up.

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Table 3. Radiographic analyses according to IPL at 18 months post-surgery.

	Implant protrusion length in sinus elevation procedure (IPL) (mm)		
	0–2	2–4	4–6
Number of implants	36	13	2
Mean (mm)	0.97±0.63	2.53±0.50	4.73±0.88
Endo-sinus bone gain (ESBG) (mm)	1.75±1.69	4.09±2.14	6.80±2.55
Residual bone height (RBH) (mm)	5.74±0.96	4.75±1.43	2.65±0.49
Number of using graft	14	8	2

Between IPL and ESBG, the correlation coefficient was 0.665 (P=0.000), and partial correlation coefficient was 0.560 (P=0.000).

Table 4. Radiographic analyses based on graft or no graft at 18 months after surgery.

	Graft	No graft
Number of implants	24	27
Endo-sinus bone gain (ESBG)	3.96±2.38 mm	1.29±1.07 mm
Residual bone height (RBH) (mm)	5.00±1.51 mm	5.70±0.94 mm
Implant protrusion length(IPL) (mm)	1.80±1.37 mm	1.26±0.77 mm

Between whether to use graft and ESBG, the correlation coefficient was 0.602 (P=0.000), and partial correlation coefficient was 0.596(P=0.000).

correlation between the ESBG and IPL, with a partial correlation coefficient of 0.560 (P=0.000).

Radiographic analysis based on bone grafting and non-bone grafting

The mean ESBG at 18 months after surgery in bone graft group and non-bone graft group are shown in Table 4. Controlling for the RBH and IPL, partial correlation analysis showed a moderately significant correlation between the ESBG and the use of bone grafts, with a partial correlation coefficient of 0.596 (P=0.000).

Discussion

The purpose of this radiological research study was to investigate new bone formation in the maxillary sinus following osteotome sinus floor elevation (OSFE) surgery and to determine the possible influencing factors. The study evaluated original residual bone height (RBH), implant protrusion length (IPL) in the sinus elevation procedure and whether to use bone grafts. The follow-up time from OSFE was 18 months, and the outcome indicator was endo-sinus bone gain (ESBG). For each implant, five radiographs were analyzed: the initial cone beam computed tomography (CBCT) radiograph before surgery (T0); the immediate postoperative panoramic radiograph (T1); the six-month postoperative panoramic radiograph (T2); the 12-month postoperative panoramic radiograph (T3); and the 18-month postoperative panoramic radiograph (T4). The findings of this study were that the mean ESBG decreased from 2.84±2.67mm (T1) to 2.55±2.24mm (T4) after 18-month follow-up. Correlation analysis showed that bone grafting and IPL were moderately correlated with ESBG. Partial correlation analysis showed no significant correlation between RBH and ESBG.

According to the recommendations of the Report of the Sinus Consensus Conference of 1996, the RBH was considered to be the key indicator to determine which kind of maxillary sinus elevation technique to be used [1]. With the successful application of short dental implants minimal requirements for RBH during OSFE have changed [13,19,20]. In the present study, OSFE was performed in patients with an RBH that ranged from 2.3 mm to 7.9 mm. According to a two-year comparative radiographic study by Kim et al., the mean gain in alveolar height was inversely related to RBH [21]. Si et al. reported the opposite finding in a three-year randomized controlled clinical trial, which showed that the ESBG was not significantly correlated with RBH [22]. However, in the present study, there was a moderately significant negative correlation between ESBG and RBH, but when controlling for two other influencing factors, whether to graft and implant protrusion length (IPL), partial correlation analysis showed no significant correlation between ESBG and RBH. Therefore, RBH appears to be a key factor in obtaining initial stability and is critical in selecting which method to develop. These findings also indicate that RBH might have influenced how much ESBG was required, but did not directly affect the amount of ESBG.

Previously published studies have shown that IPL in sinus elevation in the non-bone graft patient group was positively correlated with ESBG [16,22]. These previous findings support

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those of the present study, but in this study, correlation analysis showed that ESBG was moderately significantly correlated with IPL regardless of whether additional factors were controlled. In the present study, IPL was the most significant factor that influenced the final ESBG. However, the mean IPL was 1.54±1.14 mm in the present study, which was less than that previously published. The reason for this finding might have been that short implants were used in the present study, with a mean length of 6.24±0.65 mm. When RBH and bone gain was enough to maintain the primary stability and long-term stability, the lower the IPL, which resulted in less invasive surgery and reduced discomfort for the patient during surgery.

In this study, the radiographic analysis showed that there was a statistically significant difference between the bone graft group and non-bone graft group in ESBG at 18 months postoperatively. The ESBG in the bone graft group was significantly reduced by the 18-month follow-up period, which was consistent with previously published studies [6,21,22]. Partial correlation analysis showed a significant positive correlation between ESBG and the bone graft group after controlling for RBH and IPL, which indicated that the use of the bone graft might promote effective osteogenesis. With the application of short dental implants, it was not necessary to include a high degree of height elevation when performing sinus floor elevation. The implant that protrudes into the maxillary sinus can support the maxillary sinus mucosa and maintain some osteogenic space. The bone graft performs the same role as IPL in osteogenesis. Also, tension could be buffered by the bone graft to prevent maxillary sinus mucosal perforation. Considering the risk of sinus membrane perforation, infection, and inadequate amounts of bone around the implant, grafting the proper amount of bone was safer and contributed to more new bone formation following OSFE.

This study had several advantages that included the use of uniform surgical standards, with the exclusion of patients who did not conform to the study design and requirements. Most of the patients eliminated from the study included those who did not undergo a timely review of panoramic radiographs or who did not attend required follow-up visits. The data collected from the clinical settings, including whether to implant, and which implant systems to use, the radiological indicators, and all influencing factors that could be assessed were all considered; The influencing factors were analyzed using both correlation analysis and partial correlation analysis. Pre-operative cone beam computed tomography (CBCT) was used to provide an accurate baseline image and provided high-quality data with a lower radiation dose compared with standard CT.

This study included several limitations. This retrospective study was performed at a single center that relied upon the quality of clinical and radiological records and images. The inclusion of patients, the choice of surgical methods, IPL, and other factors, were challenging to use blind, which might have resulted in study bias. The follow-up time of 18 months was relatively short, and future studies should include long-term follow-up. Also, the follow-up radiographs were panoramic radiographs in the retrospective study and although all the panoramic radiographs were made using the same machine, with the patient in the same position, and the imaging was calibrated to reduce bias, future prospective studies should be undertaken using peri-apical radiographs with parallel technique for the assessment of two-dimensional (2D) radiological outcomes or using CBCT for assessing three-dimensional (3D) radiological results.

Conclusions

The findings of this retrospective radiological study showed that implant protrusion length (IPL) and the application of simultaneous bone grafts were moderately significantly correlated with new bone formation in the maxillary sinus following osteotome sinus floor elevation (OSFE). Short dental implants combined with OSFE might be a good solution for reconstruction of the atrophic posterior maxilla, and appropriate use of bone grafts might result in an improved clinical outcome.

Conflict of interest

None.

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