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Six-year extension results of a randomized trial comparing transcrestal and lateral sinus floor elevation at sites with 3–6 mm of residual bone

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Abstract

Objectives: To comparatively evaluate the 6-year outcomes of transcrestal and lateral sinus floor elevation (tSFE and lSFE, respectively).

Methods: The 54 patients representing the *per-protocol* population of a randomized trial comparing implant placement with simultaneous tSFE versus lSFE at sites with a residual bone height of 3–6 mm were invited to participate in the 6-year follow-up visit. Study assessments included: peri-implant marginal bone level at the mesial (mMBL) and distal (dMBL) aspects of the implant, proportion of the entire implant surface in direct contact with the radiopaque area (totCON%), probing depth, bleeding on probing, suppuration on probing, and modified plaque index. Also, the conditions of the peri-implant tissues at 6-year visit were diagnosed according to the case definitions of peri-implant health, mucositis, and peri-implantitis from the 2017 World Workshop.

Results: Forty-three patients (21 treated with tSFE and 22 treated with lSFE) participated in the 6-year visit. Implant survival was 100%. At 6 years, totCON% was 96% (IR: 88%–100%) in tSFE group and 100% (IR: 98%–100%) in lSFE group ($p = .036$). No significant intergroup difference in patient distribution according to the diagnosis of peri-implant health/disease was observed. Median dMBL was 0.3 mm in tSFE group and 0 mm in lSFE group ($p = .024$).

Conclusions: At 6 years following placement concomitantly with tSFE and lSFE, implants showed similar conditions of peri-implant health. Peri-implant bone support was high in both groups and was slightly but significantly lower in tSFE group.

KEYWORDS
bone regeneration, dental implants, maxillary sinus, mucositis, peri-implantitis, surgical procedures

Clinical trial registration: ClinicalTrials.gov ID: NCT02415946.

1 | INTRODUCTION

Transcrestal and lateral sinus floor elevation (tSFE and lSFE, respectively) are validated options to restore the ridge dimensions for implant placement at atrophic, edentulous maxillary posterior sites (Al-Moraissi et al., 2019; Listl & Faggion Jr., 2010; Lundgren et al., 2017). Knowledge of the technical factors that are relevant for reducing the invasiveness has significantly expanded over the years (Farina, Franzini, Trombelli, & Simonelli, 2023, Valentini & Artzi, 2023), thus reinforcing the applicability of both interventions. Several randomized or quasi-randomized trials have been conducted comparing tSFE and lSFE for chair time (Bacevic et al., 2021; Farina et al., 2018), morbidity (Al-Almaie et al., 2017; Bacevic et al., 2021; Bensaha, 2011; Cannizzaro et al., 2009; Farina et al., 2018; Temmerman et al., 2017;Yu et al., 2017; Zhou et al., 2021), radiographic outcomes (Al-Almaie et al., 2017; Bacevic et al., 2021; Bensaha, 2011; Cannizzaro et al., 2009; Farina et al., 2019; Temmerman et al., 2017; Yu et al., 2017; Zhou et al., 2021), surgery-related costs and specific aspects of oral health-related quality of life (Farina, Simonelli, Franceschetti, Travaglini, et al., 2022). Follow-up data from comparative randomized studies, however, remains limited to a few trials with a follow-up of 2 (Yu et al., 2017; Zhou et al., 2021), 3 (Al-Almaie et al., 2017; Farina, Simonelli, Franceschetti, Minenna, et al., 2022) or 5 years (Cannizzaro et al., 2013), the majority of which refers to different surgical conditions between treatments (Al-Almaie et al., 2017; Cannizzaro et al., 2013; Yu et al., 2017).

To the best of our knowledge, the present study is the first presenting the 6-year outcomes (in terms of peri-implant bone stability, as well as the conditions of the peri-implant marginal tissues) of a randomized trial comparing tSFE and lSFE.

2 | MATERIALS AND METHODS

2.1 | Experimental design and study population

Details regarding the study methodology have been reported in previous articles (Farina et al., 2018, 2019; Farina, Franzini, Minenna, et al., 2023; Farina, Simonelli, Franceschetti, Minenna, et al., 2022; Farina, Simonelli, Franceschetti, Travaglini, et al., 2022). Briefly, patients contributing one edentulous maxillary posterior site with a residual bone height of 3–6 mm were randomly assigned to receive tSFE or lSFE.

tSFE was performed according to the *Smart Lift* technique (Trombelli et al., 2008; Trombelli, Minenna, Franceschetti, Minenna, & Farina, 2010; Trombelli, Minenna, Franceschetti, Minenna, Itro, & Farina, 2010). After placing a plug of collagen matrix (Mucograft Seal®; Geistlich Pharma AG, Wolhusen, Switzerland), the trephined bone core was pushed cranially with a calibrated osteotome (*Smart Lift Elevator*) to fracture the sinus floor. If no perforation was detected, a predetermined amount (see Farina et al., 2018 for details) of bovine-derived xenograft (Bio-Oss® spongiosa granules, particle size 0.25–1.0 mm; Geistlich Pharma AG) was pushed through the implant site/s with the *Smart Lift Elevator*.

In lSFE group, rotating and/or manual instruments were used to obtain lateral access to the maxillary sinus. Immediately after the elevation of the sinus membrane with manual instruments, a bovine-derived xenograft (Bio-Oss® spongiosa granules, particle size 0.25–1.0 mm or 1–2 mm; Geistlich Pharma AG) was placed. Implant bed preparation was performed according to the sequence of burs recommended by the implant manufacturer (Thommen Medical AG), and the lateral access was covered with a resorbable collagen membrane (Bio-Gide®; Geistlich Pharma AG).

For both tSFE and lSFE, the clinical procedures that were followed in the case of membrane perforation have been described previously (Farina et al., 2018).

Implants (SPI Inicell Element©; Thommen Medical AG) were inserted immediately after the completion of the grafting procedure with the 1.0-mm polished collar above the bone crest and were loaded between week +24 and week +32 (6-month visit). At the 1-year visit, patients received personalized indications regarding their supportive periodontal care (SPC) program based on their PerioRisk level (Trombelli et al., 2009), and were left free to perform SPC at the center where they underwent surgery or other dental settings. In the period January 2021 – June 2022, the 54 patients representing the *per-protocol* population of the trial completing the 1-year study period (Farina et al., 2019) were invited to participate in a follow-up visit (which was identified as the "6-year follow-up visit").

The experimental protocol was approved by the Local Ethical Committees of Ferrara (protocol number: 140386) and Modena-Reggio Emilia, Italy (protocol number: 144/14), and the project was registered in www.clinicaltrials.gov (study ID: NCT02415946). Each patient provided a written informed consent prior to inclusion in the study. The present report adheres to the guidelines for reporting parallel-group randomized trials (CONSORT; http://www.consort-statement.org/) and confirms that recognized standards (Declaration of Helsinki; European Medicines Agency Guidelines for Good Clinical Practice) have been followed.

2.2 | Outcome measures

The clinical and radiographic assessments at the 6-year follow-up visit, as well as the methods for the calibration of radiographic measurements reproduced those of the 3-year follow-up visit (Farina, Simonelli, Franceschetti, Travaglini, et al., 2022). Assessments were performed by a single, blinded, and calibrated examiner (M.S.) and included: peri-implant marginal bone level at the mesial (mMBL) and distal (dMBL) aspects of the implant (Figure 1a); proportion of the entire implant surface in direct contact with the radiopaque area (totCON%), derived as the ratio (%) between the length (mm) of the implant surface in direct contact with the peri-implant radiopaque area (native bone + newly formed tissue) and the extent of implant surface (Farina, Simonelli, Franceschetti, Travaglini, et al., 2022; Franceschetti et al., 2020)

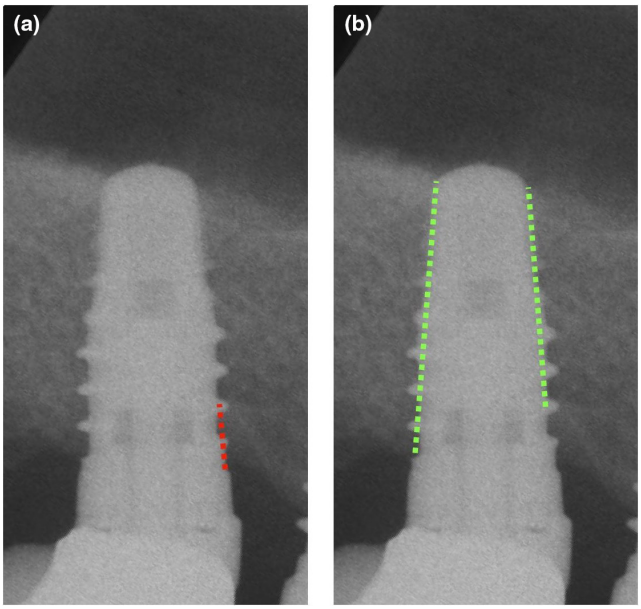

FIGURE 1 (a). Assessment of the linear distance (in mm) between the apical margin of the implant shoulder and the most coronal bone-to-implant contact at the mesial and distal implant aspects on periapical radiographs taken at the 6-year follow-up visit. To account for radiographic distortion, measurements were adjusted for a coefficient derived from the ratio: true length of the implant/ radiographic implant length, to obtain peri-implant marginal bone level at the mesial and distal aspect (mMBL and dMBL, respectively). (b). Assessment of the length (in mm) of the implant surface in direct contact with the peri-implant radiopaque area (native bone + newly formed tissue) on periapical radiographs taken at the 6-year follow-up visit. The measurement was expressed as a percentage proportion of the entire implant surface (totCON%).

(Figure 1b); probing depth (PD, 6 sites/implant); bleeding on probing (BoP, 6 sites/implant); suppuration on probing (SoP, 6 sites/implant); plaque score, evaluated as the presence/absence of visible plaque deposits after application of a plaque disclosing agent (PII; 4 sites/implant). Based on data on interproximal bone loss, PD, BoP, and SoP, the conditions of the peri-implant tissues at 6-year visit were classified according to Berglundh et al. (2018) as peri-implant health (i.e., no increase >0.5 mm in mMBL and/or dMBL compared with 1-year periapical radiograph; no increase in PD compared with 1-year visit; and no BoP+and/or SoP+ sites); peri-implant mucositis (i.e., no increase >0.5 mm in mMBL and/or dMBL compared with 1-year radiograph; at least 1 BoP + and/or SoP + site); or peri-implantitis (i.e., increase >0.5 mm in mMBL and/or dMBL compared with 1-year radiograph; increased PD compared with 1-year visit; at least 1 BoP + and/or SoP + site).

2.3 | Statistical analysis

The patient was regarded as the statistical unit. For patients receiving two implants concomitantly with sinus floor elevation, only the implant, which had been previously selected for the 1-year follow-up study (Farina et al., 2019) was considered for the present analysis. In one patient in ISFE group, the 6-year periapical radiograph could not be analyzed due to technical issues related to file storage, thus preventing radiographic measurements and formulation of peri-implant diagnosis.

For each patient, the algebraic sum of mMBL and dMBL was calculated and expressed as a percentage ratio of the implant surface (i.e., radiographic implant length × 2 + implant diameter), thus obtaining the percentage of marginal implant surface not in contact with the radiopaque area. Negative mMBL and/or dMBL values were considered 0 for this specific calculation. The percentage of apical implant surface not in contact with the radiopaque area was calculated according to the following formula: 100% – totCON% – percentage of marginal implant surface not in contact with the radiopaque area.

Descriptive and inferential statistics were performed on the fraction of the PP study population attending the 6-year follow-up visit. Since all numerical variables showed a non-normal and non-symmetric distribution, they were expressed as median and interquartile range (IR).

totCON% at 6 years was compared either within each group (i.e., with 1- and 3-year data) or between groups. Changes in mMBL and dMBL between 1 and 6 years were calculated (with a negative value of MBL change indicating a coronal displacement of the peri-implant bone crest) and compared between groups. Within-group comparisons were performed by the Friedman-Wilcoxon signed rank test and Wilcoxon test, while treatment groups were compared using the χ^2 test or Fisher's exact test for categorical variables and the Mann–Whitney *U* test for numerical and ordinal variables. The level of statistical significance was fixed at 0.05.

3 | RESULTS

3.1 | Study population

Forty-three patients (21 treated with tSFE and 22 treated with ISFE) accepted to participate in the 6-year visit (Figure 2), which was performed after a mean of 5.8 and 5.7 years from surgery in tSFE and ISFE groups, respectively. All tSFE and ISFE patients presenting at the 6-year visit had also participated in the previous study visits (i.e., postsurgery, 1 year, and 3 years), and did not show significant intergroup differences for presurgery patient- and site-related characteristics (Table 1). In each treatment group, 2 nonsmokers started smoking and 2 former smokers restarted smoking between the 1- and 6-year follow-up visits. In tSFE group, 1 patient underwent chemotherapy (year 2020) and 1 patient underwent radiotherapy (year 2021) for breast cancer. At the 6-year visit, all implants were present, contributing to masticatory function. No prosthetic complications were self-reported by the patients or diagnosed in the period between 3 and 6 years postsurgery. All patients and implants were considered for the analysis of primary and secondary outcome measures. The mean interval between consecutive SPC visits was

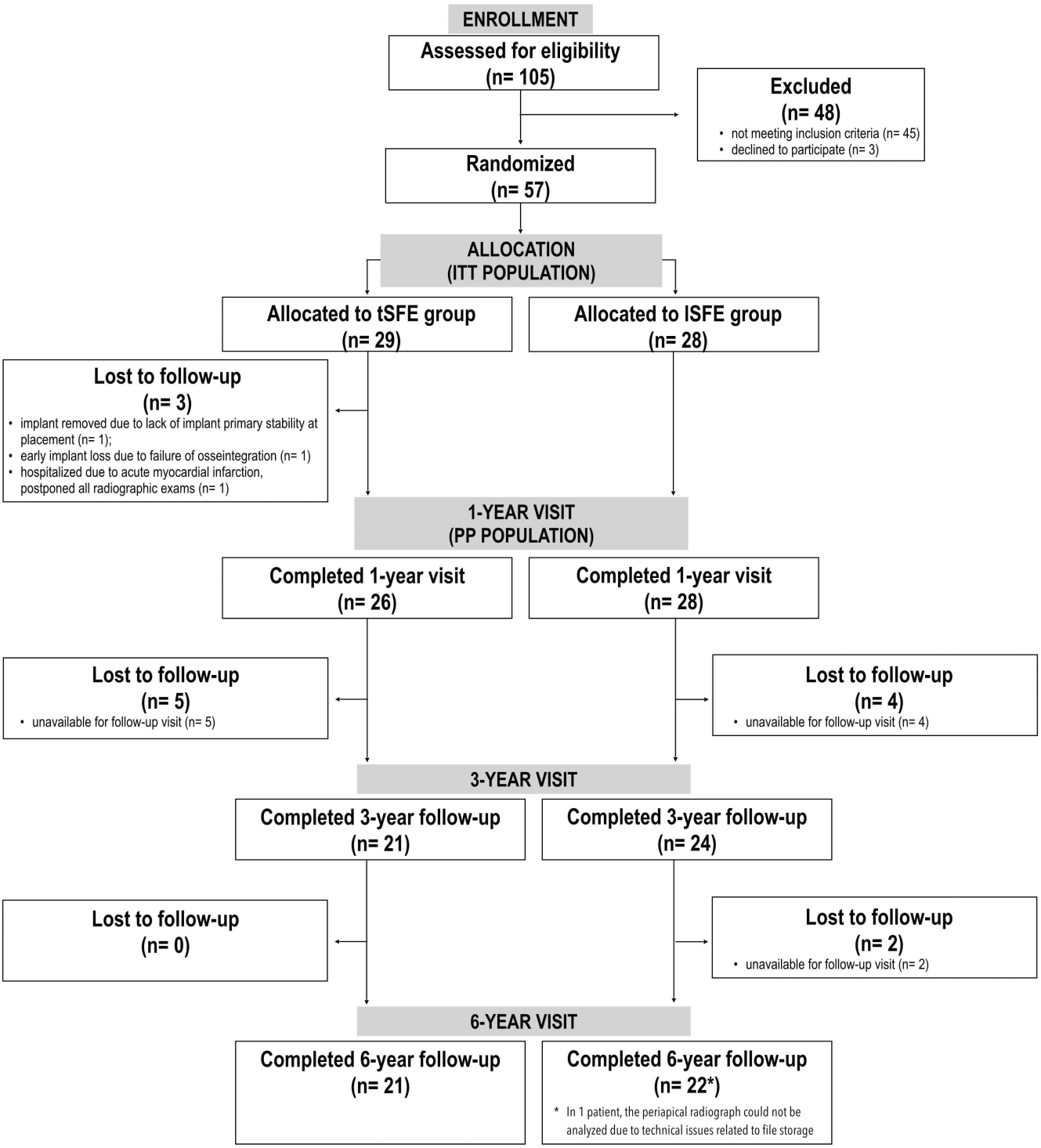

FIGURE 2 Flow chart of patient inclusion and follow-up.

6 months (IR: 4–6) and 6 months (IR: 3.3–6) in tSFE and ISFE groups, respectively ($p = .897$).

3.2 | totCON%

totCON% values for tSFE and ISFE groups at 1, 3, and 6 years are illustrated for each patient, as well as median values in Figure 3a,b. In tSFE group, median totCON% values significantly decreased from 1 to 6 years ($p = .013$), but none of the comparisons between consecutive intervals (i.e., 1 year vs. 3 years and 3 years vs. 6 years) reached statistical significance (Figure 3a). No significant variation in totCON% was observed in ISFE group ($p = .134$) (Figure 3b).

At 6 years, totCON% was 96% (88% – 100%) in tSFE group and 100% (98% – 100%) in ISFE group, the difference between groups being statistically significant ($p = .036$). Among cases with

totCON% <100%, totCON% ranged between 68% and 99% in tSFE group ($n=15$) and between 75% and 99% in ISFE group ($n=8$) (Figure 4). In these cases, the vast majority of implants showed a certain amount (ranging from 1% to 12% in tSFE group and from 1% to 8% in ISFE group) of exposure of the marginal portion of the implant, while the exposure of the apical portion of the implant (ranging from 1% to 28% in tSFE group and 20%–25% in ISFE group) was observed in a limited number of patients of both treatment arms (Figure 4).

3.3 | Conditions of the peri-implant marginal tissues

The frequency and percentage of peri-implant health, peri-implant mucositis, and peri-implantitis cases was 7 (33.3%), 8 (38.1%), and 6 (28.6%), respectively, in tSFE group, and 7 (33.3%), 13 (61.9%), and 1 (4.7%), respectively, in ISFE group ($p=.078$). Among peri-implant mucositis cases, the number of patients with 1, 2, 3, 4, 5, or 6 BoP-positive sites was 3 (37.5%), 1 (12.5%), 3 (37.5%), 1 (12.5%), 0, and

TABLE 1 Patient and implant characteristics of the patients attending the 6-year follow-up visit).

	tSFE group ($n=21$)	ISFE group ($n=22$)	p Value
Age (years)	58.0 (55.0–65.0)	59.0 (55.5–63.8)	.881
Gender (n males/females)	12/9	8/14	.227
Smoking (n never smoked/former smokers/current smokers)	7/10/4	12/6/4	.349
RBH (mm)	4.5 (4.0–5.4)	4.0 (3.9–4.9)	.280
n implants placed concomitantly with sinus lift: 1/2	18/3	17/5	.698
Implant length (mm)	9.5 (9.5–11.0)	9.5 (9.5–11.0)	.562
Implant diameter (mm)	4.0 (4.0–4.0)	4.0 (4.0–4.0)	.603

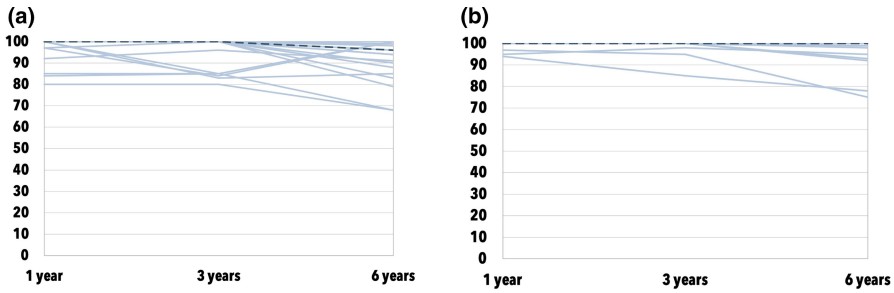

FIGURE 3 totCON% values as recorded for each patient (continuous lines) or expressed as median values (dotted lines) at 1, 3, and 6 years in tSFE (Figure 2a) and ISFE (Figure 2b) group.

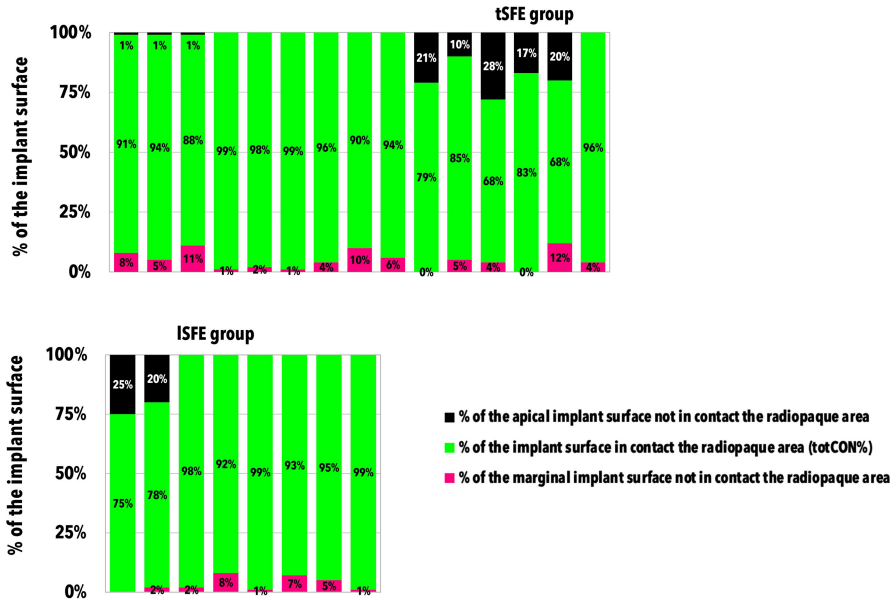

FIGURE 4 Exposure of the implant surface to either the maxillary sinus or oral cavity in tSFE and ISFE cases with 6-year totCON% <100%.

0, respectively, in tSFE group, and 4 (30.8%), 4 (30.8%), 2 (15.4%), 0, 3 (23.0%), and 0, respectively, in lSFE group. The distribution of peri-implant mucositis patients according to the number of sites with BoP was not significantly different between groups (p = 0.312). No SoP-positive sites were detected in both groups. mPBL was −0.4 mm (IR: −1.0, 0.2 mm; min-max: −1.2 – 1.8) in tSFE group and −0.5 mm (IR: −1.1, 0; min-max: −1.2 – 0.9) in lSFE group (p = 0.401). dPBL was 0.3 mm (IR: 0, 1.1; min-max: −1.2 – 1.7) in tSFE group and 0 mm (IR: −0.8, 0.4; min-max: −1.2 – 1.5) in lSFE group (p = 0.024). mPBL and dPBL values determined a median exposure of the marginal portion of the implant surface of 2% and 0% in tSFE and lSFE groups, respectively. Peri-implant PD was ≤4 mm in tSFE group, except for one mesiobuccal site where PD was 6 mm. In lSFE, 5 sites at 4 implants had a PD of 5 mm ($n = 4$) or 6 mm ($n = 1$), while the remaining sites had a PD≤4 mm. No significant difference in median PD ($p = .308$) was observed between groups.

3.4 | Plaque index

The median prevalence of implant surfaces with visible plaque deposits was 0% (IR: 0, 50; min-max: 0–75) in tSFE group and 25% (IR: 0, 25; min-max: 0–100) in lSFE group, with no significant intergroup difference ($p = .928$).

4 | DISCUSSION

The results of the present study showed that high implant survival rates and levels of peri-implant bone support (as expressed through totCON%, the median of which amounted to 96% for tSFE and 100% for lSFE) can be obtained at 6 years following tSFE and lSFE. Our findings are consistent with those of other RCTs comparing tSFE and lSFE and using a parameter similar to totCON% to assess endo-sinus bone–implant contact rate at 2 years following surgery (Zhou et al., 2021) or evaluating the 5-year implant survival rate (Cannizzaro et al., 2013). At 6 years, a significant difference in median totCON% was observed between groups. This difference can be attributed to the slight but significant decrease in totCON% from 1 to 6 years in tSFE group.

A limited number of cases in tSFE and lSFE groups (8 and 2, respectively) manifested a partial exposure of the implant apex at 6 years. When considering the results of the present analysis in relation to those from the 3-year follow-up (Farina, Simonelli, Franceschetti, Travaglini, et al., 2022) as well as another 2-year RCT comparing tSFE and lSFE (Zhou et al., 2021), it appears that beyond the initial remodeling occurring between postsurgery and 1-year after surgery (Zhou et al., 2021), a progressive dimensional reduction of the endo-sinus bone-to-implant contact rate can be observed, being still not evidently manifest and significant at 2–3 years (Farina, Simonelli, Franceschetti, Travaglini, et al., 2022; Zhou et al., 2021) but more evident at 6 years as outlined in the present analysis. Based on the fact that (i) in the present study, implants with 6-year totCON% = 100% were generally characterized by a higher height of the radiopaque area over the implant apex at 1 year when compared to implants with 6-year totCON% <100% (data not shown), and (ii) a percentage reduction to 72.6% of 6-month height has been observed at 36 months for sites undergoing tSFE in combination with a DBBM graft (Franceschetti et al., 2020), it could be reasonable to hypothesize that overfilling the endosinusal area (thus resulting in an excess of radiopaque area beyond the implant apex at 6–12 months) may contribute preventing implant exposure to the sinus cavity at 6 years due to the remodeling of the grafted area. This hypothesis, however, goes beyond the purpose of the present study, remains based on subgroups with limited numerosity, and should therefore considered with caution.

In the present material, a significantly different pattern of marginal bone loss was observed between implants placed with tSFE (showing a median bone loss of 0.3 mm at the distal aspect) and lSFE (showing peri-implant bone stability at the level of the implant shoulder mesially and distally). The magnitude of marginal bone loss observed in tSFE group is highly consistent with that reported at 5 years after placement around either implants of the same manufacturer placed entirely in native bone (0.42 mm, Kahramanoğlu et al., 2020) or different types of implants placed concomitantly with tSFE (0.41 mm, Cannizzaro et al., 2013). Differently, median mMBL and dMBL values observed in our lSFE group at 6 years are not consistent with the average 5-year MBL value (0.72 mm) reported by Cannizzaro et al. (2013) for implants placed concomitantly with lSFE. Also, differences in marginal bone loss as observed in our study between tSFE and lSFE groups could not be explained by differences in patient demographic characteristics (Table 1) or differences in patient/implant exposure to factors with a documented influence on peri-implant MBL such as diabetes (Ayele et al., 2023; Lv et al., 2022), smoking status (Ayele et al., 2023; Uribarri et al., 2017), intensity/regularity of SPC (Atieh et al., 2021; Carra et al., 2023), and amount of supragingival plaque deposits (Mameno et al., 2020). It must be considered, however, that MBL assessments of the present study were based on nonstandardized radiographs, and the magnitude of marginal bone loss observed in the majority of the present tSFE and lSFE cases fell within the radiographic measurement error of 0.5 mm.

A similar patient distribution according to peri-implant diagnosis was observed in the two groups. Peri-implant mucositis was the most prevalent condition, and mucositis cases did not show intergroup differences in terms of BoP prevalence. Differently from the 3-year follow-up study where peri-implant mucositis was the only disease condition to be detected and was observed with a high prevalence in both treatment groups (Farina, Simonelli, Franceschetti, Travaglini, et al., 2022), some peri-implantitis cases occurred at 6 years. This was observed despite the fact that patients followed an SPC regimen based on sessions of professional plaque removal with a recall frequency tailored on the patient risk profile. This finding indirectly supports the role of peri-implant inflammation as a precursor of peri-implantitis and points out the difficulty in finding effective strategies (to implement a regular SPC regimen) for a predictable, complete resolution of peri-implant mucositis (Jepsen

et al., 2015). The 6-year prevalence of peri-implantitis cases was higher compared with other reports with a similar length of follow-up for tSFE (Soardi et al., 2013) and ISFE (Krennmair et al., 2019; Lin et al., 2011). Comparison between studies, however, is limited by the fact that the reference trials used more relaxed bone loss thresholds (e.g., >2 mm, Krennmair et al., 2019) or did not report the criteria (Lin et al., 2011; Soardi et al., 2013) to define a peri-implantitis case. In our study, stringent criteria (a change>0.5 mm in MBL, in particular) were used to define peri-implantitis as recommended in the 2017 World Workshop for case definitions in the presence of data from previous examinations (Berglundh et al., 2018). Consistently with our considerations, the application of the bone loss threshold (≥3 mm) that has been recommended by the 2017 World Workshop for peri-implantitis case definition in the absence of data from previous examinations (Berglundh et al., 2018) would have led to no peri-implantitis cases in the present cohort.

The present material must be considered in the light of some methodological and technical limitations. The use of a parallel-arm study design rather than a split-mouth design did not allow for controlling the effect of the individual healing response to the investigated treatments. Despite the recruitment phase being effective in creating two treatment groups that were balanced for several patient- and site-related factors with a documented effect on tSFE and ISFE outcomes, other factors the effect of which was substantiated later than the clinical phase of our study (e.g., shape and dimensions of the maxillary sinus; Avila et al., 2010, Zheng et al., 2016, Lombardi et al., 2017, Stacchi et al., 2018, 2022) could not be considered when allocating patients to experimental treatments. The nature of the radiopaque area in contact with the implant surface was not evaluated through histological/histomorphometric assessments. Also, the percentage of exposed implant surface in the apical region was mathematically derived (and not directly measured) due to the limited possibility to perform accurate linear measurements in the apical region of the implant on periapical radiographs. In this respect, the apical region of the radiographs could occasionally show some distortion (e.g., due to a low palate vault), thus making it preferrable to derive the exposed apical portion of the implant rather than directly measuring it. Also, computed tomography scans at 1 year after surgery showed that some ISFE cases showed a substantial height of the graft beyond the implant apex (Farina et al., 2019), thus making it impossible to capture and monitor overtime the entire grafted area with a periapical radiograph. For this reason, no assessments of the grafted area beyond the implant apex could be included in the present follow-up study.

In conclusion, the results of the present study showed that similar conditions of peri-implant health can be observed at 6 years following implant placement concomitantly with tSFE and ISFE. Peri-implant bone support was high in both groups and was slightly but significantly lower for tSFE group (96%) compared with ISFE group (100%). When considered in relation to data recorded at earlier observation intervals (Farina et al., 2019; Farina, Simonelli, Franceschetti, Minenna, et al., 2022), these results suggest that the minor modifications in peri-implant bone support occurring on average in tSFE group do not compromise implant survival rate and peri-implant health conditions at 6 years following surgery, thus similarly supporting tSFE and ISFE as equally valid options for the implant-supported rehabilitation of the atrophic posterior maxilla. This consideration, however, should also be considered in the light of previous companion papers from the same clinical trial (Farina et al., 2018, 2019; Farina, Franzini, Minenna, et al., 2023; Farina, Simonelli, Franceschetti, Minenna, et al., 2022; Farina, Simonelli, Franceschetti, Travaglini, et al., 2022), the results of which favored tSFE for several aspects such as chair time, incidence of postoperative signs and symptoms, discomfort, dose of anesthesia, and amount of xenograft (see Farina, Franzini, Trombelli, & Simonelli, 2023 for review).

AUTHOR CONTRIBUTIONS

R.F. and L.T. designed the study and finalized the manuscript for submission. R.F., O.R., G.P.S., and L.T. performed the investigated treatments. R.F., A.S., and L.T. drafted the manuscript. M.S. performed all measurements and prepared the study dataset, and R.F. performed the data analysis.

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CONFLICT OF INTERESTS STATEMENT

The authors have no conflicts of interest to declare in relation to the present study.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

The experimental protocol was approved by the Local Ethical Committees of Ferrara (protocol number: 140386) and Modena-Reggio Emilia, Italy (protocol number: 144/14).

PATIENT CONSENT

Each patient provided a written informed consent before participation.

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REFERENCES

Al-Almaie, S., Kavarodi, A. M., Alorf, A., & Alzahrani, S. (2017). A Split-mouth design comparison for lateral and Crestal sinus lift techniques with dental implants placements: Short communication. *The Open Dentistry Journal*, *30*(11), 603–608. https://doi.org/10.2174/1874210601711010603

Al-Moraissi, E. A., Altairi, N. H., Abotaleb, B., Al-Iryani, G., Halboub, E., & Alakhali, M. S. (2019). What is the Most effective rehabilitation method for posterior Maxillas with 4 to 8 mm of residual alveolar bone height below the maxillary sinus with implant-supported prostheses? A frequentist network meta-analysis. *Journal of Oral and Maxillofacial Surgery*, *77*(1), 70.e1–70.e33. https://doi.org/10.1016/j.joms.2018.08.009

Atieh, M. A., AlAli, F., & Alsabeeha, N. H. M. (2021). Outcome of supportive peri-implant therapy on the rates of peri-implant diseases and marginal bone loss: A systematic review and meta-analysis. *Quintessence International*, *52*(2), 122–131. https://doi.org/10.3290/j.qi.a45428

Avila, G., Wang, H. L., Galindo-Moreno, P., Misch, C. E., Bagramian, R. A., Rudek, I., Benavides, E., Moreno-Riestra, I., Braun, T., & Neiva, R. (2010). The influence of the bucco-palatal distance on sinus augmentation outcomes. *Journal of Periodontology*, *81*(7), 1041–1050. https://doi.org/10.1902/jop.2010.090686

Ayele, S., Sharo, N., & Chrcanovic, B. R. (2023). Marginal bone loss around dental implants: Comparison between diabetic and non-diabetic patients-a retrospective clinical study. *Clinical Oral Investigations*. https://doi.org/10.1007/s00784-023-04872-z [Online ahead of print].

Bacevic, M., Compeyron, Y., Lecloux, G., Rompen, E., & Lambert, F. (2021). Intraoperative and postoperative outcomes of sinus floor elevation using the lateral window technique versus the hydrodynamic transalveolar approach: A preliminary randomized controlled trial. *Clinical Oral Investigations*, *25*(9), 5391–5401. https://doi.org/10.1007/s00784-021-03847-2

Bensaha, T. (2011). Evaluation of the capability of a new water lift system to reduce the risk of Schneiderian membrane perforation during sinus elevation. *International Journal of Oral and Maxillofacial Surgery*, *40*(8), 815–820. https://doi.org/10.1016/j.ijom.2011.04.005

Berglundh, T., Armitage, G., Araujo, M. G., Avila-Ortiz, G., Blanco, J., Camargo, P. M., Chen, S., Cochran, D., Derks, J., Figuero, E., Hämmerle, C. H. F., Heitz-Mayfield, L. J. A., Huynh-Ba, G., Iacono, V., Koo, K. T., Lambert, F., McCauley, L., Quirynen, M., Renvert, S., … Zitzmann, N. (2018). Peri-implant diseases and conditions: Consensus report of workgroup 4 of the 2017 world workshop on the classification of periodontal and Peri-implant diseases and conditions. *Journal of Periodontology*, *89*(Suppl 1), S313–S318. https://doi.org/10.1002/JPER.17-0739

Cannizzaro, G., Felice, P., Leone, M., Viola, P., & Esposito, M. (2009). Early loading of implants in the atrophic posterior maxilla: Lateral sinus lift with autogenous bone and bio-Oss versus crestal mini sinus lift and 8-mm hydroxyapatite-coated implants. A randomised controlled clinical trial. *European journal of. Oral Implantology*, *2*(1), 25–38.

Cannizzaro, G., Felice, P., Minciarelli, A. F., Leone, M., Viola, P., & Esposito, M. (2013). Early implant loading in the atrophic posterior maxilla: 1-stage lateral versus crestal sinus lift and 8 mm hydroxyapatite-coated implants. A 5-year randomized controlled trial. *European journal of. Oral Implantology*, *6*(1), 13–25.

Carra, M. C., Blanc-Sylvestre, N., Courtet, A., & Bouchard, P. (2023). Primordial and primary prevention of peri-implant diseases: A systematic review and meta-analysis. *Journal of Clinical Periodontology*. https://doi.org/10.1111/jcpe.13790 [Online ahead of print].

Farina, R., Franceschetti, G., Travaglini, D., Consolo, U., Minenna, L., Schincaglia, G. P., Riccardi, O., Bandieri, A., Maietti, E., & Trombelli, L. (2018). Morbidity following transcrestal and lateral sinus floor elevation: A randomized trial. *Journal of Clinical Periodontology*, *45*(9), 1128–1139. https://doi.org/10.1111/jcpe.12985

Farina, R., Franceschetti, G., Travaglini, D., Consolo, U., Minenna, L., Schincaglia, G. P., Riccardi, O., Bandieri, A., Maietti, E., & Trombelli, L. (2019). Radiographic outcomes of transcrestal and lateral sinus floor elevation: One-year results of a bi-center, parallel-arm randomized trial. *Clinical Oral Implants Research*, *30*(9), 910–919. https://doi.org/10.1111/clr.13497

Farina, R., Franzini, C., Minenna, L., Trombelli, L., & Simonelli, A. (2023). Effectiveness, morbidity and costs of transcrestal and lateral sinus floor elevation at sites with different residual bone height. A re-analysis of data from a parallel-arm randomized trial. *The International Journal of Oral & Maxillofacial Implants* [In press].

Farina, R., Franzini, C., Trombelli, L., & Simonelli, A. (2023). Minimal invasiveness in the transcrestal elevation of the maxillary sinus floor: A systematic review. *Periodontology 2000*, *91*(1), 145–166. https://doi.org/10.1111/prd.12464

Farina, R., Simonelli, A., Franceschetti, G., Minenna, L., Schincaglia, G. P., Riccardi, O., & Trombelli, L. (2022). Peri-implant tissue conditions following transcrestal and lateral sinus floor elevation: 3-year results of a bi-center, randomized trial. *Clinical Oral Investigations*, *26*(5), 3975–3986. https://doi.org/10.1007/s00784-021-04364-y

Farina, R., Simonelli, A., Franceschetti, G., Travaglini, D., Consolo, U., Minenna, L., Schincaglia, G. P., Riccardi, O., Bandieri, A., & Trombelli, L. (2022). Implant-supported rehabilitation following transcrestal and lateral sinus floor elevation: Analysis of costs and quality of life from a bicenter, parallel-arm randomized trial. *Minerva Dental and Oral Sciences*, *71*(1), 16–24. https://doi.org/10.23736/S2724-6329.21.04539-3

Franceschetti, G., Farina, R., Minenna, L., Riccardi, O., Stacchi, C., Di Raimondo, R., Maietti, E., & Trombelli, L. (2020). The impact of graft remodeling on peri-implant bone support at implants placed concomitantly with transcrestal sinus floor elevation: A multicenter, retrospective case series. *Clinical Oral Implants Research*, *31*(2), 105–120. https://doi.org/10.1111/clr.13541

Jepsen, S., Berglundh, T., Genco, R., Aass, A. M., Demirel, K., Derks, J., Figuero, E., Giovannoli, J. L., Goldstein, M., Lambert, F., Ortiz-Vigon, A., Polyzois, I., Salvi, G. E., Schwarz, F., Serino, G., Tomasi, C., & Zitzmann, N. U. (2015). Primary prevention of peri-implantitis: Managing peri-implant mucositis. *Journal of Clinical Periodontology*, *42*(Suppl 16), S152–S157. https://doi.org/10.1111/jcpe.12369

Kahramanoğlu, E., Aslan, Y. U., Özkan, Y., & Özkan, Y. (2020). The clinical and radiologic outcomes of early loaded implants after 5 years of service. *International Journal of Oral and Maxillofacial Implants*, *35*(6), 1248–1256. https://doi.org/10.11607/jomi.7630

Krennmair, S., Hunger, S., Forstner, T., Malek, M., Krennmair, G., & Stimmelmayr, M. (2019). Implant health and factors affecting peri-implant marginal bone alteration for implants placed in staged maxillary sinus augmentation: A 5-year prospective study. *Clinical Implant Dentistry and Related Research*, *21*(1), 32–41. https://doi.org/10.1111/cid.12684

Lin, I. C., Gonzalez, A. M., Chang, H. J., Kao, S. Y., & Chen, T. W. (2011). A 5-year follow-up of 80 implants in 44 patients placed immediately after the lateral trap-door window procedure to accomplish maxillary sinus elevation without bone grafting. *International Journal of Oral and Maxillofacial Implants*, *26*(5), 1079–1086.

Listl, S., & Faggion, C. M., Jr. (2010). An economic evaluation of different sinus lift techniques. *Journal of Clinical Periodontology*, *37*(8), 777–787. https://doi.org/10.1111/j.1600-051X.2010.01577.x

Lombardi, T., Stacchi, C., Berton, F., Traini, T., Torelli, L., & Di Lenarda, R. (2017). Influence of maxillary sinus width on new bone formation after Transcrestal sinus floor elevation: A proof-of-concept prospective cohort study. *Implant Dentistry*, *26*(2), 209–216. https://doi.org/10.1097/ID.0000000000000554

Lundgren, S., Cricchio, G., Hallman, M., Jungner, M., Rasmusson, L., & Sennerby, L. (2017). Sinus floor elevation procedures to enable implant placement and integration: Techniques, biological aspects and clinical outcomes. *Periodontology 2000*, *73*(1), 103–120. https://doi.org/10.1111/prd.12165

Lv, X., Zou, L., Zhang, X., Zhang, X., Lai, H., & Shi, J. (2022). Effects of diabetes/hyperglycemia on peri-implant biomarkers and clinical and radiographic outcomes in patients with dental implant restorations: A systematic review and meta-analysis. *Clinical Oral Implants Research*, *33*(12), 1183–1198. https://doi.org/10.1111/clr.14010

Mameno, T., Wada, M., Otsuki, M., Okuno, I., Ozeki, K., Tahara, A., & Ikebe, K. (2020). Risk indicators for marginal bone resorption around implants in function for at least 4 years: A retrospective longitudinal study. *Journal of Periodontology*, *91*(1), 37–45. https://doi.org/10.1002/JPER.18-0756

Soardi, E., Cosci, F., Checchi, V., Pellegrino, G., Bozzoli, P., & Felice, P. (2013). Radiographic analysis of a transalveolar sinus-lift technique: A multipractice retrospective study with a mean follow-up of 5 years. *Journal of Periodontology*, *84*(8), 1039–1047. https://doi.org/10.1902/jop.2011.100684

Stacchi, C., Lombardi, T., Ottonelli, R., Berton, F., Perinetti, G., & Traini, T. (2018). New bone formation after transcrestal sinus floor elevation was influenced by sinus cavity dimensions: A prospective histologic and histomorphometric study. *Clinical Oral Implants Research*, *29*(5), 465–479. https://doi.org/10.1111/clr.13144

Stacchi, C., Rapani, A., Lombardi, T., Bernardello, F., Nicolin, V., & Berton, F. (2022). Does new bone formation vary in different sites within the same maxillary sinus after lateral augmentation? A prospective histomorphometric study. *Clinical Oral Implants Research*, *33*(3), 322–332. https://doi.org/10.1111/clr.13891

Temmerman, A., Van Dessel, J., Cortellini, S., Jacobs, R., Teughels, W., & Quirynen, M. (2017). Volumetric changes of grafted volumes and the Schneiderian membrane after transcrestal and lateral sinus floor elevation procedures: A clinical, pilot study. *Journal of Clinical Periodontology*, *44*(6), 660–671. https://doi.org/10.1111/jcpe.12728

Trombelli, L., Farina, R., Ferrari, S., Pasetti, P., & Calura, G. (2009). Comparison between two methods for periodontal risk assessment. *Minerva Stomatologica*, *58*(6), 277–287.

Trombelli, L., Minenna, P., Franceschetti, G., Farina, R., & Minenna, L. (2008). SMART-LIFT: una nuova procedura minimamente invasiva per la elevazione del pavimento del seno mascellare. *Dental Cadmos*, *76*, 71–83.

Trombelli, L., Minenna, P., Franceschetti, G., Minenna, L., & Farina, R. (2010). Transcrestal sinus floor elevation with a minimally invasive technique. *Journal of Periodontology*, *81*(1), 158–166. https://doi.org/10.1902/jop.2009.090275

Trombelli, L., Minenna, P., Franceschetti, G., Minenna, L., Itro, A., & Farina, R. (2010). Minimally invasive technique for transcrestal sinus floor elevation: A case report. *Quintessence International*, *41*(5), 363–369.

Uribarri, A., Bilbao, E., Marichalar-Mendia, X., Martínez-Conde, R., Aguirre, J. M., & Verdugo, F. (2017). Bone remodeling around implants placed in augmented sinuses in patients with and without history of periodontitis. *Clinical Implant Dentistry and Related Research*, *19*(2), 268–279. https://doi.org/10.1111/cid.12450

Valentini, P., & Artzi, Z. (2023). Sinus augmentation procedure via the lateral window technique-reducing invasiveness and preventing complications: A narrative review. *Periodontology 2000*, *91*(1), 167–181. https://doi.org/10.1111/prd.12443

Yu, H., Wang, X., & Qiu, L. (2017). Outcomes of 6.5-mm hydrophilic implants and long implants placed with lateral sinus floor elevation in the atrophic posterior maxilla: A prospective, randomized controlled clinical comparison. *Clinical Implant Dentistry and Related Research*, *19*(1), 111–122. https://doi.org/10.1111/cid.12439

Zheng, X., Teng, M., Zhou, F., Ye, J., Li, G., & Mo, A. (2016). Influence of maxillary sinus width on Transcrestal sinus augmentation outcomes: Radiographic evaluation based on cone beam CT. *Clinical Implant Dentistry and Related Research*, *18*(2), 292–300. https://doi.org/10.1111/cid.12298

Zhou, Y., Shi, Y., Si, M., Wu, M., & Xie, Z. (2021). The comparative evaluation of transcrestal and lateral sinus floor elevation in sites with residual bone height ≤6 mm: A two-year prospective randomized study. *Clinical Oral Implants Research*, *32*(2), 180–191. https://doi.org/10.1111/clr.13688

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