Received: 23 December 2022 | Revised: 3 May 2023 | Accepted: 27 May 2023

DOI: 10.1111/cid.13236

ORIGINAL ARTICLE

WILEY

Sinus floor augmentation using crestal approach in conjunction with hydroxyapatite/cross-linked collagen sponge: A pilot study

Luigi Canullo DDS, PhD[1] | Massimo Del Fabbro MSc, PhD[2,3] | Federica Colantonio DDS[4] | Roberta Iacono[5] | Carlo Raffone[4] | Andrea Pedetta Mdt[4] | Shahnawaz Khijmatgar MDS[2] | Lior Shapira[6]

[1]Department of Surgical Sciences, University of Genova, Genoa, Italy

[2]Department of Biomedical, Surgical, and Dental Sciences, University of Milan, Milan, Italy

[3]Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy

[4]Private Practice, Rome, Italy

[5]Department of Oral and Maxillofacial Science, Sapienza University of Rome, Rome, Italy

[6]Department of Periodontology, Hebrew University and Hadassah Medical Center, Jerusalem, Israel

Correspondence
Luigi Canullo, Largo R. Benzi 10, 16132 Genoa, Italy.
Email: luigicanullo@yahoo.com

Abstract

Background: Different biomaterials were suggested for sinus floor augmentation (SFA). Recently, new materials were launched showing true bone formation without remnants.

Purpose: The aim of this prospective study was to evaluate an hydroxyapatite-based, sugar cross-linked collagen sponge (OSSIX™ Bone) in transcrestal SFA (t-SFA).

Materials and methods: Twenty-four patients with edentulous posterior maxilla and residual bone height (RBH) >4 mm underwent t-SFA with OSSIX™ Bone as grafting material and simultaneous implant placement. The implant Stability Quotient (ISQ) was measured by resonance frequency analysis (RFA) directly after implant insertion and at 6 months. Differences in bone height (BH) and volume were determined in CBCT and x-rays at baseline versus 1 year of follow-up. Graft volume was evaluated by tridimensional reconstructions. Linear regression analysis was used to evaluate the effect of bucco-palatal sinus dimension, RBH, and length of the implant protruding (PIL) into the sinus, on the graft height (GH) changes up to 1 year, and on the graft volume at 1 year. Autocorrelation between time lag and augmented bone volume was evaluated through time series analysis correlograms. Health-related quality-of-life outcomes were captured.

Results: Twenty-two patients completed the study. The mean RBH measured at baseline was 5.81 ± 2.2 mm. The mean graft volume was 1085.8 ± 733.4 mm^3. The mean GH, measured in the immediate post-operative period, at 6 and 12 months respectively, was 7.24 mm ±1.94; 6.57 mm ± 2.30; 5.46 mm ± 2.04. The mean ISQ measured after the implant placement was 62.19 ± 8.09, and 6 months later was 76.91 ± 4.50. There was a significant correlation between buccolingual dimension and graft volume at 1 year. Neither buccolingual volume nor RBH had a significant effect on GH change, while the PIL showed a significant positive correlation ($P = 0.02$ and $P = 0.03$ at 6 and 12 months, respectively). The correlograms indicated no significant correlation, meaning that there is no tendency for graft volume to increase or decrease over time, therefore suggesting graft stability, at least up to one year of follow-up. 86% of patients had no chewing interference.

Conclusion: Within the limitations of the study, OSSIX™ Bone could be considered a valid material for SFA due to its manageability and its positive results in promoting new bone formation with long-term stability. T-SFA is confirmed as a less invasive and less painful method.

KEYWORDS
bone grafting, bone regeneration, implant, sinus augmentation, sinus lift procedure

What is known

Transcrestal sinus floor augmentation (t-SFA) with simultaneous implant placement is a predictable and safe surgical approach to rehabilitate posterior edentulous regions of the maxilla when residual bone height (RBH) is >4 mm.

What this study adds

Hydroxyapatite-based, sugar cross-linked collagen sponge can be considered as a valid alternative graft material for sinus floor augmentation (SFA).Based on the positive patient-reported outcome measures and the low number of painkillers taken following surgery, this study further confirms the minimal invasiveness of t-SFA.The use of endosinusal elevators helps improve the prognosis, minimizing the risk of stretching/tearing on the mucosa.

1 | INTRODUCTION

Several materials have been described in the literature for the regeneration of bone defects.[1,2] Biologically speaking, bone regeneration is the result of the interaction between the graft material and the host. In fact, bone defect healing is influenced by the physical properties of the biomaterial[3] and defect morphology[4] together with the individual's regenerative pattern.[5]

Sinus floor augmentation (SFA) is a well-documented surgical procedure that allows implant-prosthetic rehabilitation in cases of edentulous atrophic posterior maxilla with insufficient residual bone height (RBH) for implant placement. The lateral approach SFA is usually used to measure the potentiality and the capability of graft material to regenerate.[6,7] In this study, a transcrestal SFA (t-SFA) was performed. T-SFA was chosen in order to reduce the invasiveness of the surgery,[8] in particular, in terms of intra- and postoperative morbidity.[9] Moreover, this approach involves the simultaneous insertion of the dental implant and avoids second surgery. Studies have shown the validity of this technique and its superiority over lateral sinus floor elevation on sites with a RBH of 4–8 mm.[10–13]

Animal-derived bone matrices have been demonstrated to be helpful in bone regeneration and volume maintenance in post-extractive sites.[14] Evaluation of deproteinized bovine bone mineral (DBBM) and β-tricalcium phosphate (β-TCP) combined with t-SFA found significant graft remodeling at 6 months in the β-TCP group and 5 membrane perforations out of 38 surgeries performed.[15]

OSSIX™ Bone (Dentsply Sirona, Charlotte, NC, USA), is a new, resorbable, osteoconductive graft material forming a sponge-like matrix of 80% synthetic microparticulate hydroxyapatite (HA) alloplast graft with 20% sugar cross-linked porcine type 1 collagen to support the formation of new bone. The collagen molecules are highly cross-linked with sugar, which gives long-term stability to the structure.[16] In addition, as OSSIX™ Bone is an ossifying collagen sponge, there is no product particle migration and it cannot be dispersed in the sinus, even in the case of large tears in the mucosa.[17]

The aim of the present study is to evaluate the outcomes achieved using OSSIX™ Bone in t-SFA over a 12-month healing period.

2 | MATERIALS AND METHODS

2.1 | Study design and ethics statements

The study is designed as an investigator-initiated prospective study to further evaluate the clinical performance of grafting material (Figure 1) in the SFA. The present study was carried out following the principles embodied in the Helsinki Declaration, in its latter form.[18] On April 17, 2020, the Ethics Committee Lazio 1 authorized the clinical study protocol on a human model registered under the number: 432-17/4/2020. Each participant signed an informed consent statement, and all their data were anonymized.

This protocol study was conducted in a private dental clinic in Rome (Italy) and one surgeon (LC) performed all the surgical procedures.

2.2 | Sample size

In order to achieve a power of 80% and a level of significance (alpha) of 5% (two-sided), to detect a mean difference (change in the graft height [GH] at follow-up as compared to baseline) of 1.0 mm between

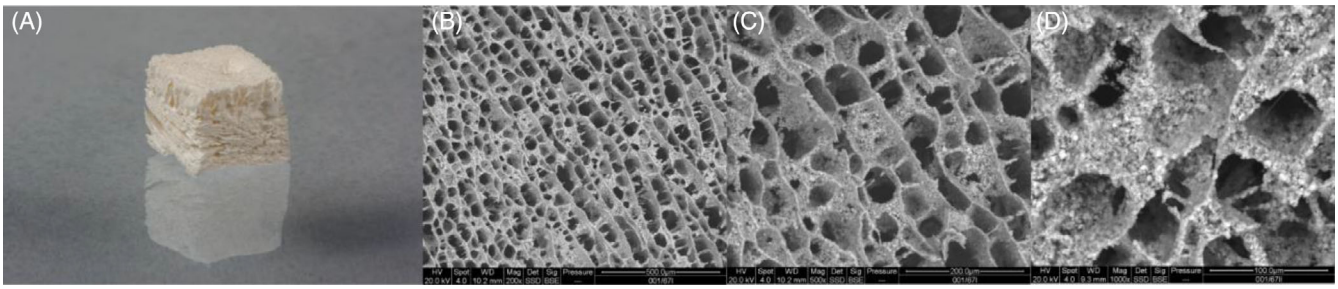

FIGURE 1 (A) OSSIX™ Bone Sponge-like, porous, space-maintaining block. OSSIX™ Bone appears in the SEM images as an organized honeycomb-like spongeous structure where small hydroxyapatite particles are randomly dispersed within and on the solid collagen wall structure of the product. (B) ×200; (C) ×500; (D) ×1000.

pairs, assuming that the standard deviation of the differences is 1.5 mm, the study would require a sample size of 21 paired observations. Taking into account a possible drop-out rate of 15%, it was planned to recruit 24 participants.[19]

2.3 | Patient selection

Participants were recruited from patients requiring an implant-supported restoration in the posterior maxilla and a maxillary sinus floor elevation between May 2020 and January 2021, according to the following inclusion and exclusion criteria:

2.3.1 | Inclusion criteria

- Residual alveolar bone height (RBH) of edentulous maxilla below the floor of the maxillary sinus of ≥4 mm.
- Males and females between 30 and 80 years old.
- Patients with healthy periodontal conditions (treated periodontitis, PI < 25%, BoP < 25%).
- Patients that are willing to sign an informed consent and participate in a clinical study.
- Generally fit and healthy and able to undergo oral surgical procedures under local anesthesia.
- Extraction of teeth at the surgical site at least 12 weeks prior to sinus floor elevation.

2.3.2 | Exclusion criteria

- Patients who smoke over 5 cigarettes/day.
- Pregnant or lactating women (confirmed by verbal inquiry).
- Chronic systemic pathologies (eg, diabetes) and malignant tumors of the head and neck area.
- History of local radiation therapy.
- Patients taking bisphosphonates or any drugs interfering with the healing process (cortisone intake).
- Any sites where an implant has already failed.
- Untreated periodontitis.
- Dental sites with acute infections.
- Chronic inflammatory diseases of the oral cavity (eg, Bullous Lichen Planus, Pemphigus Vulgaris, etc).
- Patients with known collagen hypersensitivity and/or with sensitivity to porcine-derived materials.

2.4 | Surgical protocol

After administration of local anesthesia, with articaine 4% with adrenaline 1:100 000, the patients were instructed to rinse with 0.2% chlorhexidine solution for 5 min. A full-thickness gingival flap was elevated in the alveolar ridge area to the mucogingival junction and a fully guided crestal osteotomy was conducted.

Guided surgery was chosen for site preparation as the precise drill calibration and optimum drill length should reduce the risk of membrane damage.[20,21] The initial drilling was performed above the sinus floor using a pilot drill (2–3 mm, depending on preoperative CBCT guidance) following a customized surgical drill guide. Access to the sinus mucosa was created using a M.I.S.E. EVO kit (Sweden & Martina, Due Carrare, Padua, Italy). The elevators were used to gradually lift the Schneiderian membrane. In addition, 5 × 5 × 10 mm increments of OSSIX™ Bone graft were placed in the created space, moisten with the patient's blood, and condensed by the osteotomes to further elevate the Schneiderian membrane. The integrity of the membrane was maintained and confirmed using a dental microscope to allow the pressure to elevate the membrane and prevent displacement of the grafting material into the sinus. Following site preparation, CSR implants, (5 mm diameter, 10–13 mm length; Sweden & Martina SpA, Due Carrare, Padua, Italy) were placed immediately in the same surgical site (Figure 2) using a device able to determine the torque insertion curve and insertion torque value (peak of the curve, ITV) of the implant (SA-310 W&H Elcomed implant units, W&H, Burmoos, Austria). Primary implant stability following installation was confirmed using an Osstell® Mentor device (Osstell, AB, Göteborg, Sweden). To adapt flaps for primary intention, sutures 6.0 (Polynil, Sweden & Martina SpA, Due Carrare, Padua, Italy) were used. After the surgery, a post-

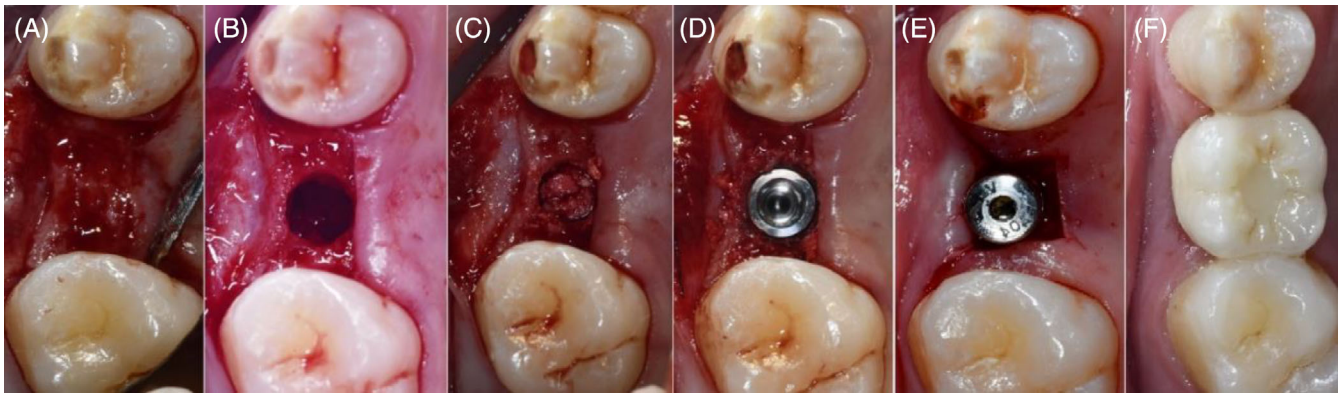

FIGURE 2 Surgical sequence. (A) Crestal bone after flap elevation. (B) Elevation of the Schneiderian membrane with transcrestal access. (C) Bone graft insertion. (D) Implant placement. (E) Second surgical stage to expose the implant and inserting the healing abutment. (F) Crown positioning.

operative periapical x-ray was performed to assess post-operative placement.

2.5 | Post-surgical instructions

The patients received systemic antibiotic therapy (amoxycillin–clavulanic acid 875 mg/125 mg) in tablet formulations, three times daily for 4 days. All patients were instructed to take analgetic/anti-inflammatory drugs only if needed.

The suture removal visit was scheduled 10–14 days after surgery and in this circumstance, condition-specific health-related quality of life (HRQL) and a VAS questionnaire based on a questionnaire from Shugars and colleagues were used.[22]

2.6 | Clinical and radiographic measures

Resonance frequency analysis (RFA) values were performed using the Osstell® Mentor device at implant placement and loading (6 months) to determine the implant stability quotient (ISQ). The ISQ was derived from the mean of two measurements: one bucco-palatally from the buccal side and one mesiodistally from the mesial side.

The formation of new bone was measured by changes in bone height and volume, assessed by CBCT and x-ray before surgery and after 12 months (Figures 3 and 4). Tridimensional reconstructions of the sinus grafts were made using 3D software at https://www.slicer.org/[23] (3D Slicer, Harvard University, NIH) and a standard triangulation language file (.stl) was created for each patient (Figure 5). Moreover, linear measurements of the graft were recorded for GH. Graft volume was evaluated using computer-aided design (CAD) software (Exocad, Gmbh, Darmstadt, Germany).

Bone density was assessed from preoperative (pristine bone) and 1-year (graft only) CBCT in Hounsfield units (HU) using RealGUIDE 5.0 software (3Diemme, Cantù, Italy). The following values of the Hounsfield scale correspond to different densities: D4 >350 HU; D3 350–850 HU; D2 850–1250 HU; D1 >1250 HU.

Data were recorded and sent for statistical analysis.

2.7 | Statistical methods

Descriptive statistics are provided through mean, median, and standard deviation (SD) for continuous variables. For non-continuous categorical variables, frequencies and percentages were calculated. The normality of variables distribution was evaluated by Shapiro–Wilk test. The softwares used for the statistical analysis were GraphPad Prism 5 for Windows (Version 5.03, GraphPad Software Inc.), and Stata 17 (StataCorp LLC, Texas, USA).

Linear regression analysis was used to evaluate the effect of bucco-palatal sinus dimension, residual ridge height, and length of the implant protruding into the sinus (PIL), on the GH changes up to 1 year, and on the graft volume at 1 year. Time series statistics were applied to evaluate the autocorrelation between the time lag and augmented bone volume through time series analysis correlograms, in order to determine if there was a significant trend toward resorption. A correlogram (a graph of autocorrelations) with pointwise confidence intervals based on Bartlett's formula for MA(q) processes is a commonly used tool to check randomness in a data set. If random, autocorrelations should be near zero for any and all time-lag separations. If non-random, then one or more of the autocorrelations will be significantly non-zero.

3 | RESULTS

Results are summarized in Table 1. Twenty-four healthy adult patients (12 male and 12 female, with a mean age of 55.2 ± 11.2) were enrolled in the present study. Each patient received one implant. One patient dropped out, due to circumstances unrelated to the study, and the data was not included in the analysis. One implant failed after

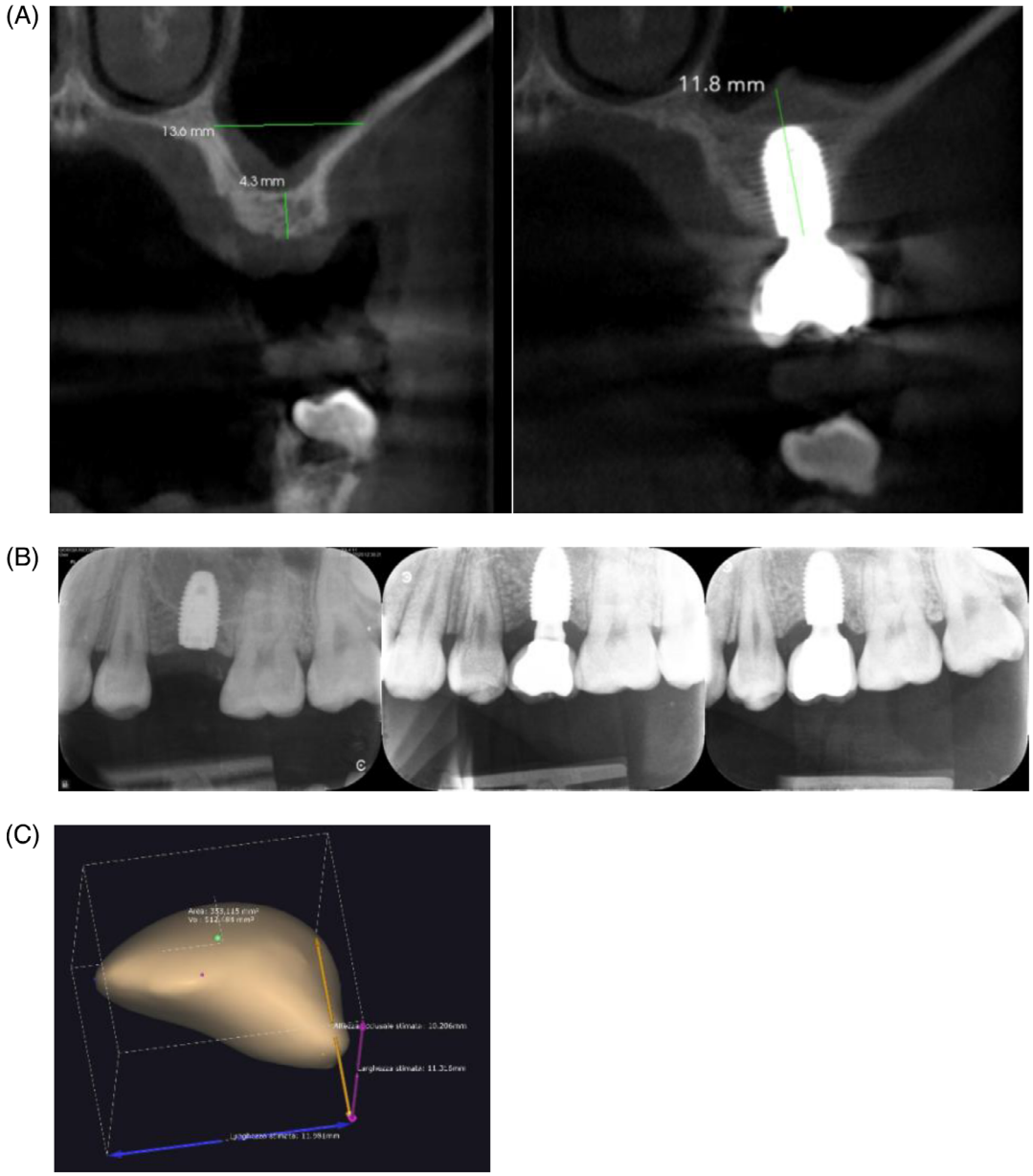

FIGURE 3 (A) Two illustrative CBCT cross-sectional slices taken from the same patient representing pre-op and 12 months post-op clinical condition, underling the bone support gained with t-SFE. (B) X-rays immediately after surgery, 6 month post-op and 1-year follow-up. (C) 3D reconstruction and measurement of the augmentation volume.

6 months of follow-up. The reason for the failure could not be determined. The implant success rate in the study was 22 out of 23 implants (95.45%). All statistical analysis was performed on 22 implants/patients.

One intraoperative complication occurred, in a patient with a sinus diameter (SD) of 13.3 mm. A perforation occurred during the detachment of the Schneiderian membrane (prior to OSSIX™ Bone insertion) and nasal bleeding for 1 day was observed. However, the tearing had not affected the clinical success of the surgery. No post-surgical complications, such as infections or graft migration, were recorded.

Concerning the radiological analysis, the mean RBH measured at baseline was 5.95 mm ± 2.24 (range 4.0–9.3 mm). The mean graft volume measured comparing the preoperative versus 1-year follow-up CBCT was 1085.8 ± 733.4 mm^3 (range: 148.95–2704.55 mm^3). GH (total bone height − RBH) was measured in three different observation periods on periapical x-ray: immediately after surgery, at 6 and 12 months, the mean ± SD were respectively 7.24 ± 1.94; 6.57 ± 2.30; 5,46 ± 2.04 (range T0: 2.97–11,17 mm; range T6: 2.00–11.17 mm; range T12: 1.67–9.67 mm) (Table 2). Implants were inserted with mean ITV 26.92 ± 18.86 N cm (range: 5–70 N cm). The mean ISQ measured immediately after the implant placement was 62.19 ± 8.09 (range: 43.5–77). A statistically significant increase was registered after 6 months, before prosthetic placement (ISQ mean value ± SD: 76.91 ± 4.50) (range 64.5–82).

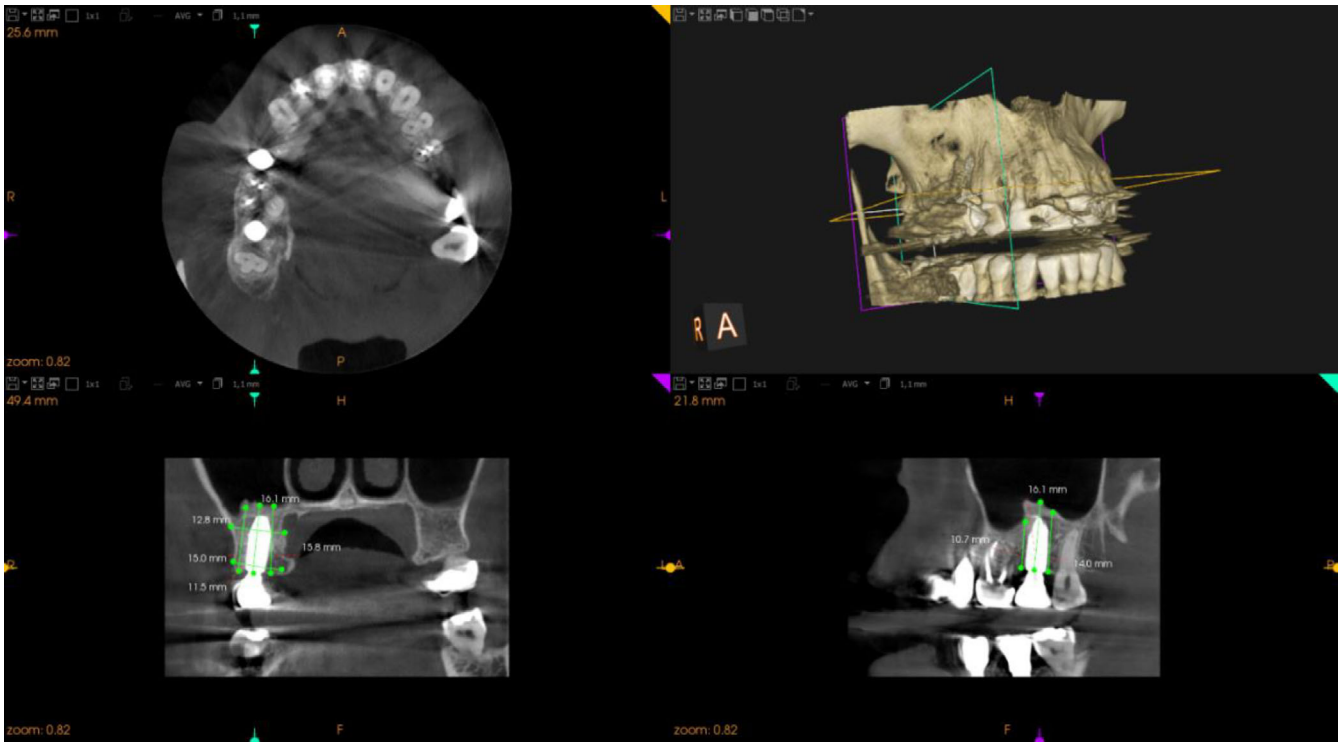

FIGURE 4 Linear measurements with 3shape software at 1 year follow up CBCT. Bone height was determined calculating the average of three different measurements. The buccolingual diameter was measured at a distance of 10 mm from the margin of the bone crest.

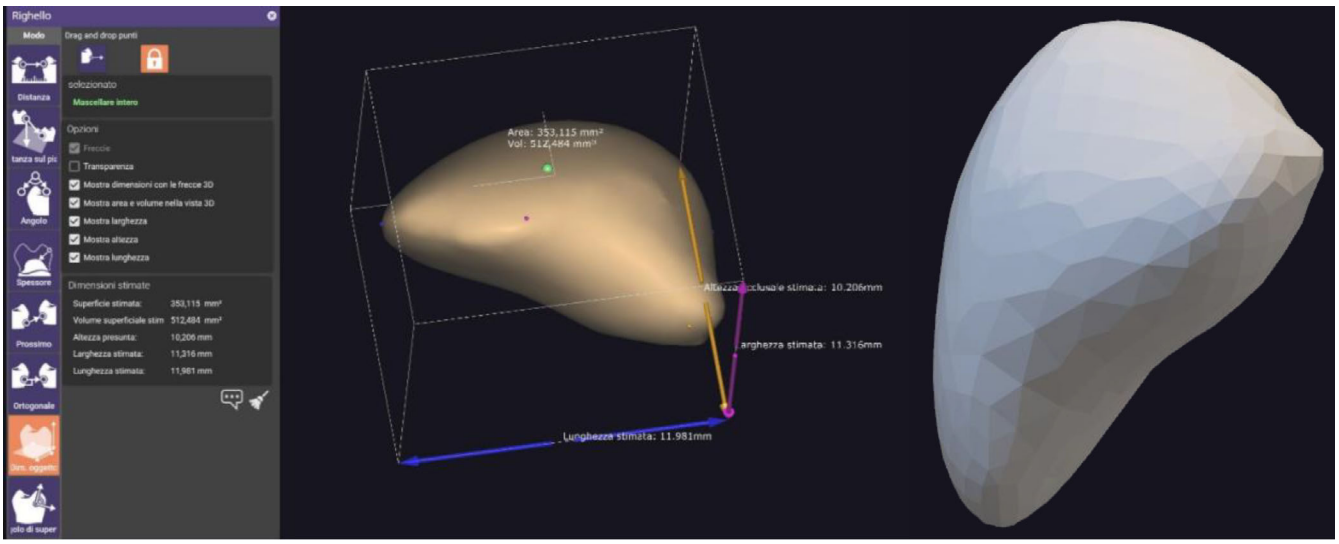

FIGURE 5 3D reconstruction of the bone graft at 1 year follow up.

The mean bone type density at baseline (pristine bone) was 468.52 ± 239.57 HU (range: 122–900 HU). The mean bone density of the graft material after 12 months was 543.39 ± 219.94 HU (range: 27–938 HU).

There was a significant correlation between bucco-palatal dimension of the sinus and graft volume at 1-year follow-up (Figure 6). Neither bucco-palatal dimension nor RBH, had a significant effect on change in GH, while PIL into the sinus showed a significant positive correlation ($p = 0.02$ and $p = 0.03$ at 6 and 12 months, respectively) (Figure 7). The correlograms indicated no significant correlation, which means that there is no tendency for graft volume to increase or decrease over time, therefore suggesting stability of the graft, at least up to 1-year follow-up (Figure 8).

The analysis of the answers given to the HRQL survey (Figure 9), revealed that 86% of patients had no chewing interference and 100% were able to work. Ninety-five percent of patients never experienced

bleeding or bruising. Regarding post-surgical pain management, 66% of patients took only one ibuprofen tablet (within 24 h following the surgery) and only 34% took two tablets in the days following surgery. No patients felt the need to take additional analgesic tablets.

4 | DISCUSSION

In the present study, we showed the efficacy of OSSIX™ Bone as graft material during t-SFA. In addition, we demonstrated a correlation between total bone height (TBH), RBH, GH and bucco-palatal diameter of the maxillary sinus at 10 mm from the bone crest at 0, 6, and 12 months.

In fact, a statistically significant positive linear correlation between TBH and RBH was present. In contrast, when GH and RBH were analyzed, a non-statistically significant negative linear correlation was outlined. These findings are related to the surgical technique and the use of a standardized amount of bone graft during the surgeries. In addition, when bucco-palatal diameter and GH or TBH were considered, a non-statistically significant relation was observed. These results contrast with the latest research on this topic which analyzes the relationship between GH and sinus width, and reports a negative correlation between these parameters.[24] The results of the present study may be related to the use of sinus mucosa elevators to detach the periosteum and the Schneiderian membrane. This minimized the risk of mucosal stretching/tearing, as may occur in complex scenarios such as a large sinus or thin mucosa.

Several studies of the influence of different types of elevators on t-SFA have indeed shown the important role of elevator design.[25] Furthermore, when the influence of PIL and GH was analyzed, it showed a linear correlation, suggesting the ability of the protruding part of the implant to assist in graft stabilization. Greater PIL directly influences the initial graft volume, with less resorption at 12 months suggesting that better bone support was achieved with higher PIL. Nonetheless, higher

TABLE 1 Study design and results.

Patients (*n*)	**24**
Gender (male/female)	12/12
Age (years old)	55.2 ± 11.2
Smokers (%)	12.5%
RBH (mm)	5.81 ± 2.20
Bucco-palatal diameter (mm)	12.73 ± 2.75
Graft height (mm)	7.24 ± 1.94
Total bone height at 12 months (mm)	11.38 ± 2.50
Bone density of the residual bone at baseline (HU)	468.52 ± 23957
Bone density of the graft at 12 months (HU)	54339 ± 219.94

TABLE 2 Parameters of linear regressions

	Graft height 6-month			**Graft height 12-month**			**Graft volume 12-month**		
	Slope	**R^2**	***p*-value**	**Slope**	**R^2**	***p*-value**	**Slope**	**R^2**	***p*-value**
Pre-op RBH	−0.44 ± 0.21	0.19	0.05*	−0.28 ± 0.19	0.10	0.16	−118.2 ± 67.68	0.13	0.10
Bucco-palatal diam	−0.20 ± 0.18	0.06	0.30	0.11 ± 0.16	0.024	0.49	147.8 ± 49.38	0.31	0.007
Protruding implant length	0.70 ± 0.29	0.24	0.02*	0.60 ± 0.26	0.21	0.03*	37.63 ± 103.9	0.007	0.72

Note: Slope represents how much the y value changes when the *x* value changes by 1 unit and describes both the direction and the stepness of the line. The coefficient of determination, R^2, is the proportion of the variation in the dependent variable that is predictable from the independent variable, ranges from 0 to 1. The *p*-value is widely used in statistical hypothesis testing, if the *p*-value is less than 0.05 that is taken to mean that the observed data is sufficiently inconsistent with the null hypothesis for the null hypothesis to be rejected. The *p*-value helps to understand if the difference between the observed and the hypothesized result is due to the randomness introduced by the sampling, or if this difference is statistically significant.
*Significantly different.

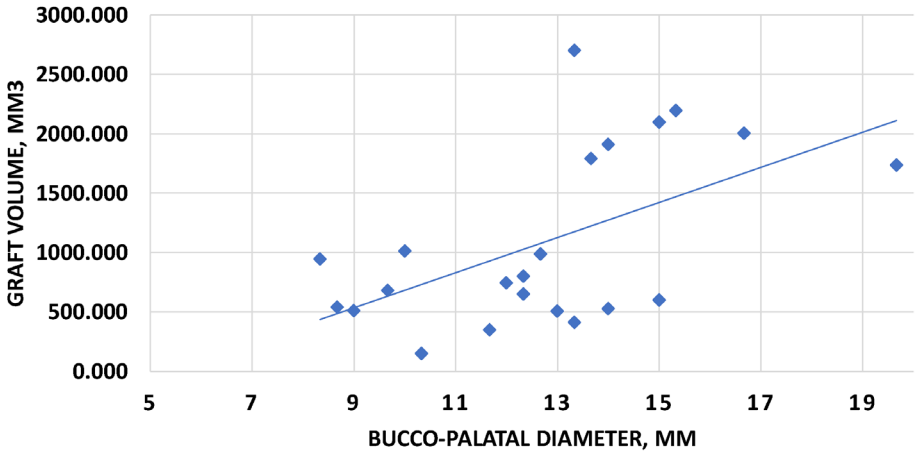

FIGURE 6 Linear relation buccopalatal diameter and graft volume. *X*-axis is the preoperative bucco-palatal diameter in mm. The *Y*-axis is the graft volume 12 months post in mm^3. The line indicates that there is significant relation between BPD and graft volume that could be related to the use of mucosa elevators.

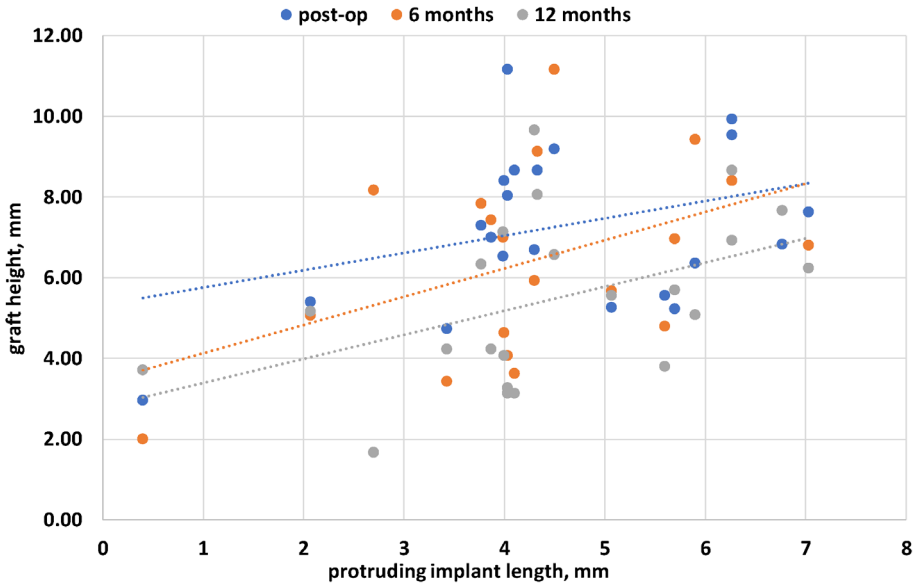

FIGURE 7 Linear relation graft height (GH) and protruding implant length in the sinus (PIL). *X*-axis is the protruding implant length into the sinus in mm. The *Y*-axis is the graft height after surgery (blue), 6 months follow-up (orange) and 1 year follow-up (gray) in mm. The tree lines indicate that there is a significant relation between PIL and GH.

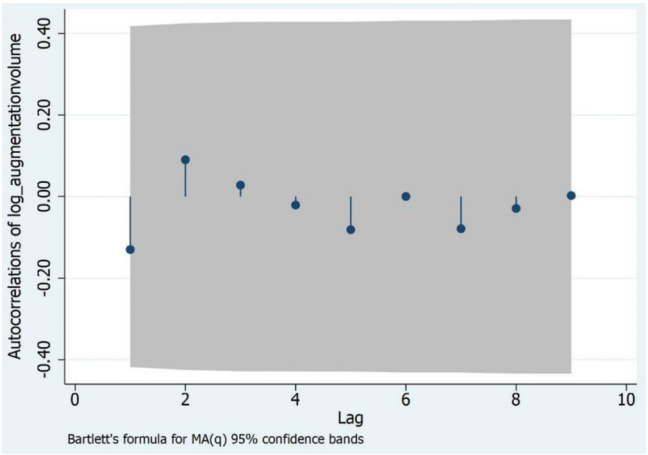

FIGURE 8 Time series analysis correlograms illustrating serial correlation (autocorrelation) in data that changes over time. The gray shaded area is 95% confidence interval band. The dots represent the autocorrelation between the time lag and the autocorrelation of augmented bone volume. *X*-axis is the time lag over a period of 12 months. The *Y*-axis gives the values between +1 and −1. The values close to +1 indicate clustering while values close to −1 indicate dispersion. This set of data likely has no significant correlation which indicates that as the time passes there is no significant gain in volume. If the data was significant, there would be a pattern in autocorrelation (ie, consistent upward or downward pattern as you travel across the *X*-axis).

PIL can increase the risk of perforations and the optimal protrusion length needs to be evaluated clinically. Long-term follow-up and histological examinations need to be performed to investigate the bone quality and stability of the apical part of the graft in association with PIL and to assess the relationship between PIL and grafting procedures.

According to the literature, HA has the best volume stability over time when compared with DPBM, DBBM or β-TCP. In fact, the shrinkage rate of HA has been reported at 20%. DPBM has 40%, DBBM 25% and β-TCP at least 50%. The resorption rate of OSSIX bone in the present study was 19.7%, of the initial volume, which is lower than the rate of most of the materials reported in the literature.[21] Although shrinkage might include some discrepancy due to the inaccuracy of the traditional periapical x-ray method. Resorption occurred mainly in the last 6 months of the follow-up together with bone maturation and remodeling, underlying the optimal biomechanical stability of the graft in the first phase of the healing. The use of a sponge-like graft may counteract the intra-sinus pressure produced during respiration that affects the quantity and quality of newly formed bone.[26] The lack of increase or decrease in graft volume over time to 1-year follow-up suggested stability of the graft, at least up to 1-year follow-up.

Only one case of membrane perforation was reported (4.5%) which is lower than reported in recent studies (perforation of the Schneiderian membrane during osteotomy is the most common complication, with an incidence rate of around 20%–25%).[27] The low rate of postoperative complications might also be related to the sponge-like consistency of the graft. In fact, this might help to reduce intraoperative over-compression of the Schneiderian membrane. In addition, a dental operative microscope was used to directly check the action of the sinus elevator on the Schneiderian membrane with better feedback from the surgeon especially when the RBH was <5 mm. Moreover, the use of the elevator plays an important role in increasing the safety of the procedure by reducing the pressure on the membrane and thus decreasing the complication rate.

At the same time, it can be speculated that the combination of spongy material and intra-sinus elevators may suggest a crestal approach also in the case of wide sinuses, with a large bucco-palatal diameter. According to Lombardi and colleagues,[24] sinus cavities with an internal diameter wider than 13 mm should be treated with a lateral approach. In fact, the complication rate in wide sinuses is relatively higher than in cases with narrow sinuses[28]: 2.8% early implant

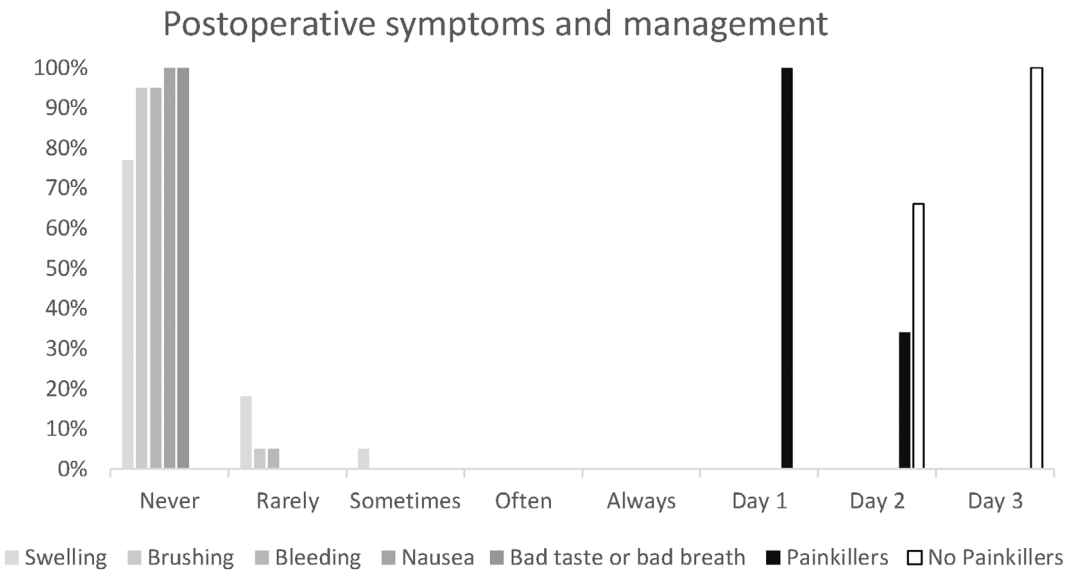

FIGURE 9 HRQL survey and painkillers assumption.

failure, 7.2% membrane perforation, 0.9% acute sinusitis, 0.7% implant displacement into the sinus cavity, 0.2% oro-antral fistula, all of which significantly associated with the presence of large sinus cavities. In contrast to lateral SFA, post-operative symptoms (eg, swelling, bleeding) are lower in frequency and intensity in crestal SFA approaches. The minimal discomfort, pain and other associated symptoms experienced by the patients in the present study were demonstrated by the low intake of painkillers, which seems to be lower than that associated with lateral SFA.[29]

In the present study, 10 of 22 wide sinuses were treated, and only in one case, with a SD of 13.3 mm did a perforation occur, with no further clinical complications. As OSSIX™ Bone is an ossifying collagen sponge with no product particle migration,[17] its use was likely particularly helpful to prevent graft material dispersion in the sinus cavity of this patient. It could be also speculated that spongy materials may facilitate the membrane perforation.

The ISQ value and bone hardness (bone type density) were found to significantly increase over time. While this may be due to de novo bone formation, confirmatory clinical studies with histological analysis are necessary. Although no histological analysis was carried out in this study and the number of patients was limited, the results showed that OSSIX™ Bone could be considered to be a clinically useful material for use in t-SFA.

The minimal discomfort, pain and other associated symptoms experienced by the patients in the present study were demonstrated by the low intake of painkillers, which seems to be lower than that associated with lateral SFA.[28]

5 | CONCLUSIONS

Within the limitations of the present study, t-SFA is confirmed to be a less invasive method, less painful and with milder postoperative symptoms than lateral SFA. In addition, only one perforation was reported, in which there was no migration of the study material.

In conclusion OSSIX™ Bone, in combination with endosinusal elevators, could be considered as a suitable material for t-SFA due to its good outcomes in promoting the formation of new bone.

AUTHOR CONTRIBUTIONS

Luigi Canullo: Conception, design, data collection, drafting and critical revision of the article. **Massimo Del Fabbro:** Statistics and critical revision of the article. **Federica Colantonio**: Data collection and drafting of the article. **Roberta Iacono:** Data interpretation and drafting of the article. **Carlo Raffone:** Data analysis and drafting of the article. **Andrea Pedetta**: Critical revision of the article. **Shahnawaz Khijmatgar:** Statistics. **Lior Shapira**: drafting and critical revision of the article. All authors have read and agreed to the published version of the manuscript.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

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

ORCID

Luigi Canullo https://orcid.org/0000-0001-9875-2929
Massimo Del Fabbro https://orcid.org/0000-0001-7144-0984

REFERENCES

1. Clementini M, Morlupi A, Canullo L, Agrestini C, Barlattani A. Success rate of dental implants inserted in horizontal and vertical guided bone regenerated areas: a systematic review. *Int J Oral Maxillofac Surg*. 2012;41:847-852. doi:10.1016/j.ijom.2012.03.016

2. Thoma DS, Zeltner M, Hüsler J, Hämmerle CH, Jung RE. EAO supplement working group 4 – EAO CC 2015 short implants versus sinus lifting with longer implants to restore the posterior maxilla: a systematic review. *Clin Oral Implants Res*. 2015;26:154-169. doi:10.1111/clr.12615
3. García-Gareta E, Coathup MJ, Blunn GW. Osteoinduction of bone grafting materials for bone repair and regeneration. *Bone*. 2015;81:112-121. doi:10.1016/j.bone.2015.07.007
4. Sculean A, Nikolidakis D, Schwarz F. Regeneration of periodontal tissues: combinations of barrier membranes and grafting materials – biological foundation and preclinical evidence: a systematic review. *J Clin Periodontol*. 2008;35(8 Suppl):106-116. doi:10.1111/j.1600-051X.2008.01263.x
5. Götz W, Reichert C, Canullo L, Jäger A, Heinemann F. Coupling of osteogenesis and angiogenesis in bone substitute healing – a brief overview. *Ann Anat*. 2012;194(2):171-173. doi:10.1016/j.aanat.2011.10.002
6. Testori T, Weinstein T, Taschieri S, Wallace SS. Risk factors in lateral window sinus elevation surgery. *Periodontol 2000*. 2019;81(1):91-123. doi:10.1111/prd.12286
7. Lundgren S, Johansson AS, Cricchio G, Lundgren S. Clinical outcome and factors determining new bone formation in lateral sinus membrane elevation with simultaneous implant placement without grafting material: a cross-sectional, 3–17 year follow-up study. *Clin Implant Dent Relat Res*. 2019;21(5):827-834. doi:10.1111/cid.12758
8. Farina R, Franzini C, Trombelli L, Simonelli A. Minimal invasiveness in the transcrestal elevation of the maxillary sinus floor: a systematic review. *Periodontol 2000*. 2022;91:145-166. doi:10.1111/prd.12464
9. Farina R, Franceschetti G, Travaglini D, et al. Morbidity following transcrestal and lateral sinus floor elevation: a randomized trial. *J Clin Periodontol*. 2018;45(9):1128-1139. doi:10.1111/jcpe.12985
10. Del Fabbro M, Corbella S, Weinstein T, Ceresoli V, Taschieri S. Implant survival rates after osteotome-mediated maxillary sinus augmentation: a systematic review. *Clin Implant Dent Relat Res*. 2012;14-(Suppl 1):e159-e168. doi:10.1111/j.1708-8208.2011.00399.x
11. Aludden H, Mordenfeld A, Hallman M, Christensen AE, Starch-Jensen T. Osteotome-mediated sinus floor elevation with or without a grafting material: a systematic review and meta-analysis of long-term studies (≥5-years). *Implant Dent*. 2018;27(4):488-497. doi:10.1097/ID.0000000000000798
12. Tetsch J, Tetsch P, Lysek DA. Long-term results after lateral and osteotome technique sinus floor elevation: a retrospective analysis of 2190 implants over a time period of 15 years. *Clin Oral Implants Res*. 2010;21(5):497-503. doi:10.1111/j.1600-0501.2008.01661.x
13. Al-Moraissi EA, Altairi NH, Abotaleb B, Al-Iryani G, Halboub E, Alakhali MS. 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. *J Oral Maxillofac Surg*. 2019;77(1):70.e1-70.e33. doi:10.1016/j.joms.2018.08.009
14. Silva LD, de Lima VN, Faverani LP, de Mendonça MR, Okamoto R, Pellizzer EP. Maxillary sinus lift surgery—with or without graft material? A systematic review. *Int J Oral Maxillofac Surg*. 2016;45(12):1570-1576. doi:10.1016/j.ijom.2016.09.023
15. Trombelli L, Franceschetti G, Stacchi C, et al. Minimally invasive transcrestal sinus floor elevation with deproteinized bovine bone or β-tricalcium phosphate: a multicenter, double-blind, randomized, controlled clinical trial. *J Clin Periodontol*. 2014;41(3):311-319. doi:10.1111/jcpe.12210
16. Tal H, Kozlovsky A, Artzi Z, Nemcovsky CE, Moses O. Long-term biodegradation of cross-linked and non-cross-linked collagen barriers in human guided bone regeneration. *Clin Oral Implants Res*. 2008;19(3):295-302. doi:10.1111/j.1600-0501.2007.01424.x
17. Neiva R. Evolution of biomaterials in implant dentistry leads to enhanced tissue quality. *Compend Contin Educ Dent*. 2022;43(7):454-455.
18. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA*. 2013;310(20):2191-2194. doi:10.1001/jama.2013.281053
19. Dhand, NK, Khatkar MS. (2014). Statulator: an online statistical calculator. Sample size calculator for comparing two paired means. Accessed February 15, 2023. http://statulator.com/SampleSize/ss2PM.html
20. Pistilli R, Canullo L, Pesce P, Pistilli V, Caponio C, Sbricoli L. Guided implant surgery and sinus lift in severely resorbed maxillae: a retrospective clinical study with up to 10 years of follow-up. *J Dent*. 2022;121:104137. doi:10.1016/j.jdent.2022.104137
21. Bouwman WF, Bravenboer N, Ten Bruggenkate CM, Eijsackers FA, Stringa N, Schulten EAJM. Tissue level changes after maxillary sinus floor elevation with three types of calcium phosphate ceramics: a radiological study with a 5-year follow-up. *Materials (Basel)*. 2021;14(6):1471. doi:10.3390/ma14061471
22. Shugars DA, Benson K, White RP Jr, Simpson KN, Bader JD. Developing a measure of patient perceptions of short-term outcomes of third molar surgery. *J Oral Maxillofac Surg*. 1996;54(12):1402-1408. doi:10.1016/s0278-2391(96)90253-0
23. Fedorov A, Beichel R, Kalpathy-Cramer J, et al. 3D slicer as an image computing platform for the quantitative imaging network. *Magn Reson Imaging*. 2012;30(9):1323-1341. doi:10.1016/j.mri.2012.05.001
24. Lombardi T, Stacchi C, Berton F, Traini T, Torelli L, Di Lenarda R. Influence of maxillary sinus width on new bone formation after Transcrestal sinus floor elevation: a proof-of-concept prospective cohort study. *Implant Dent*. 2017;26(2):209-216. doi:10.1097/ID.0000000000000554
25. Li Y, Hu P, Han Y, et al. Ex vivo comparative study on three sinus lift tools for transcrestal detaching maxillary sinus mucosa. *Bioengineered*. 2017;8(4):359-366. doi:10.1080/21655979.2016.1228497
26. Asai S, Shimizu Y, Ooya K. Maxillary sinus augmentation model in rabbits: effect of occluded nasal ostium on new bone formation. *Clin Oral Implants Res*. 2002;13(4):405-409. doi:10.1034/j.1600-0501.2002.130409.x
27. Molina A, Sanz-Sánchez I, Sanz-Martín I, Ortiz-Vigón A, Sanz M. Complications in sinus lifting procedures: classification and management. *Periodontol 2000*. 2022;88(1):103-115. doi:10.1111/prd.12414
28. Stacchi C, Bernardello F, Spinato S, et al. Intraoperative complications and early implant failure after transcrestal sinus floor elevation with residual bone height ≤5 mm: a retrospective multicenter study. *Clin Oral Implants Res*. 2022;33(8):783-791. doi:10.1111/clr.13959
29. Rengo C, Fiorino A, Cucchi A, et al. Patient-reported outcomes and complication rates after lateral maxillary sinus floor elevation: a prospective study. *Clin Oral Investig*. 2021;25(7):4431-4444. doi:10.1007/s00784-020-03755-x

How to cite this article: Canullo L, Del Fabbro M, Colantonio F, et al. Sinus floor augmentation using crestal approach in conjunction with hydroxyapatite/cross-linked collagen sponge: A pilot study. *Clin Implant Dent Relat Res*. 2023;25(5):974-983. doi:10.1111/cid.13236