One-year post-loading prospective case series

Volumetric changes in sinuses augmented with a crestal approach

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The aim of the present prospective study was to evaluate the implant survival rate, complications and three-dimensional radiologic outcomes of maxillary sinus floor augmentation via a minimally invasive crestal approach and simultaneous implant placement.

Introduction

Implant placement in the posterior maxilla remains a challenge due to risks such as resorption of the alveolar bone, poor bone quality, or pneumatization of the maxillary sinus. According to recent prospective studies and a Cochrane systematic review, if the residual alveolar bone height is between 3 and 6 mm, sinus floor elevation can be accomplished with a one-stage crestal approach [1–5].

The most common technique to elevate the sinus floor by inserting a bone graft using a crestal approach employs osteotomes, as suggested by *Tatum* and *Summers* [6,7]. The major advantage of this closed surgical technique is lower morbidity compared to a conventional lateral approach. However, a main concern with this technique is the limited amount of bone augmentation. Moreover, a wide range of complications can occur [8], of which the most frequent intraoperative one is perforation of the Schneider membrane because of the limited visibility during surgery. Another possible complication is benign paroxysmal positional vertigo (BPPV) experienced after a sinus elevation with osteotomes [9]. To overcome these drawbacks, new options for minimally invasive transcrestal sinus surgery with minimal patient discomfort have been proposed to improve the safety and reliability of the procedure – using an inflated balloon catheter and hydraulic or negative pressure.

Elevation of the Schneiderian membrane using a crestal approach and hydraulic pressure was first described by *Chen* et al. in 2005 [10]. A sinus lift using hydraulic pressure included detachment of the Schneiderian membrane through injection of a liquid, filling the sub-Schneiderian space with a bone graft material, and simultaneous implant placement. This technique achieves a highly predictable clinical outcome and extremely low morbidity and shorter interventions in situations with insufficient residual alveolar bone [3,4].

Various systems are available for elevating the sinus membrane up to 7 mm using hydraulic pressure. Animal and human studies suggest that the CAS Kit (Osstem Implant, Seoul, South Korea) is a valid treatment concept for minimally invasive crestal sinus elevation surgery, although further studies are needed to confirm these results [4,11].

The aim of the present prospective study was to evaluate the implant survival rates, complications and three-dimensional radiologic outcomes of maxillary sinus floor augmentation using a minimally invasive crestal approach with simultaneous implant placement. This trial followed the provisions of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.

Materials and methods

This study was designed as a proof-of-concept case series as part of a larger prospective observational trial. Consecutive patients requiring implant treatment in the posterior maxilla with a minimally invasive crestal sinus procedure were recruited and treated at a private clinic in Rome, Italy, between September 2014 and December 2016 [11]. The surgical procedures were performed by an expert clinician (MT) with experience in implant placement and sinus augmentation.

The study was conducted according to the principles embodied in the Helsinki Declaration of 1975 for biomedical research involving human subjects, as revised in 2013. All patients were

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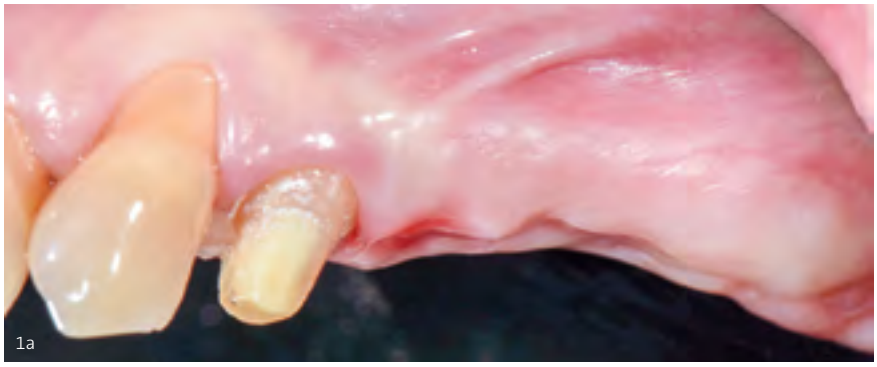

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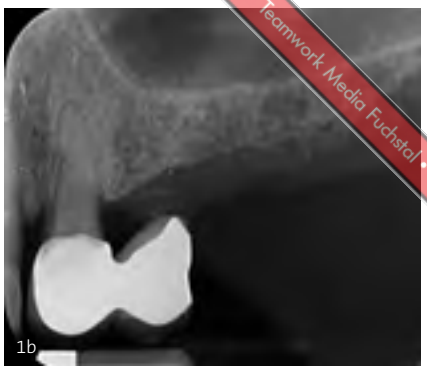


1b

1a and b I Preoperative clinical (a) and radiographic (b) examination.

informed about the nature of the study and gave their written consent for surgical and prosthetic procedures and for the use of clinical and radiologic data. The radiological protocol used in this study had already been approved by the Scientific Technical and Ethical Committee of the University of Sassari (2069/CE) [1,2].

Patients aged 18 years or older able to sign an informed consent and requiring a minimally invasive sinus floor augmentation ahead of implant-supported restoration treatment, with a residual bone height of ≥ 2 mm at the prospective implant site, was enrolled in the present study. Patients were excluded if they presented with general contraindications to implant surgery, such as irradiation in the head and neck area during the year before implantation; uncontrolled diabetes; pregnancy or lactation; substance abuse; psychiatric therapy or unrealistic expectations; previous or ongoing treatment with oral or intravenous bisphosphonates or immunocompromised patients. Also excluded were heavy smokers (≥ 11 cigarettes/day), post-extractive sites, or poor oral hygiene or motivation (untreated periodontitis measured as bleeding on probing and/or plaque index ≥ 25 %).

Before the surgery, cone-beam computed tomography (CBCT) scans were taken (field of view 80 × 150 mm; voxel size 0.3 µm; 4.5 seconds; 90 kV; 6.3–10 mA; 579.7–920.9 mGy cm²) (Figs. 1a and b). Intranasal spray therapy (thiamphenicol glycinate acetylcysteinate 810 mg/4 ml) was administered twice a day, starting the day before surgery. One hour prior to surgery, a single dose of antibiotics (2 g of amoxicillin and clavulanic acid, or 600 mg of clindamycin if allergic to penicillin) was administered prophylactically. A 0.2 % chlorhexidine digluconate mouth rinse was administered for two minutes prior to surgery. Local anesthesia using articaine with adrenaline 1 : 100,000 was administered.

Surgical and prosthetic protocols

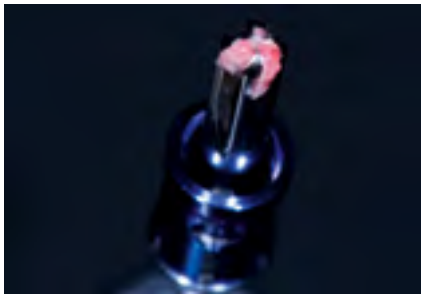
The implant site was prepared using the CAS drills (CAS Kit; Osstem Implant) according to a previously published customization of the drilling protocol suggested by the manufacturer [4]. The hydraulic membrane lifter was inserted into the drilled hole and 2 to 3 ml of saline solution was gently injected into the sinus to elevate the sinus membrane. Afterward, the bone carrier and a bone condenser were used to fill the sinus with 0.5 to 1 ml of synthetic hydroxyapatite enriched with magnesium (450- to 600-µm granules; Sintlife, Finceramica, Faenza, Italy). After the sinus lift was completed, the diameter of the drill was increased with the last stopper still connected, matching the final diameter of the planned implant and the bone quality (Fig. 2).

Finally, a self-tapping tapered TSIII implant (Osstem Implant) was placed at the bone level (Figs. 3 to 6). The wound was sutured with a 4-0 polyglactin 910 suture (Vicryl V271; Ethicon, West Somerville, NJ, USA). Antibiotic coverage was continued for seven days (1 g of amoxicillin and clavulanic acid or 300 mg of clindamycin twice a day) after surgery. A 0.2 % chlorhexidine digluconate mouth rinse was administered for one minute twice a day for two weeks, and a soft diet was recommended for one month. Ibuprofen 400 mg or paracetamol 1 g was to be taken in the event of pain. Immediately after the procedure and at the follow-up one year after loading, control CBCT scans were taken (field of view 60 × 80 mm; voxel size 0.3 µm; 2.3 seconds; 90 kV; 5–8 mA; 192.4–307.8 mGy cm²) .

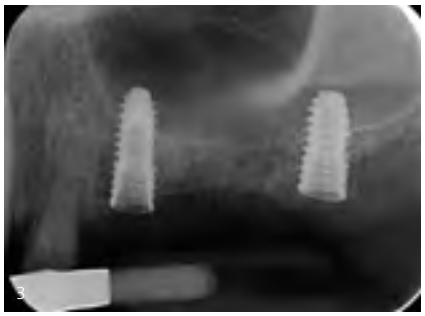
Six months after implant placement, a second-stage surgical procedure was performed, making sure to preserve the keratinized tissue around the dental implant. A healing abutment was placed; no provisional restoration was provided. A definitive digital impression was taken using the 3M True Definition Scanner (3M Italia; Pioltello, Milan, Italy). Four to six weeks after the second-stage surgery, a CAD/CAM screw-retained zirconia restoration was delivered. The occlusion was adjusted to avoid premature contacts. Periapical radiographs and clinical photographs were taken. Follow-up visits were scheduled every three months after implant placement.

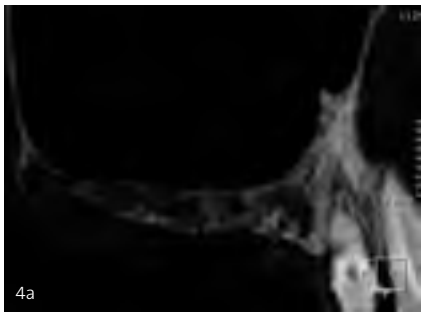
Outcome metrics included:

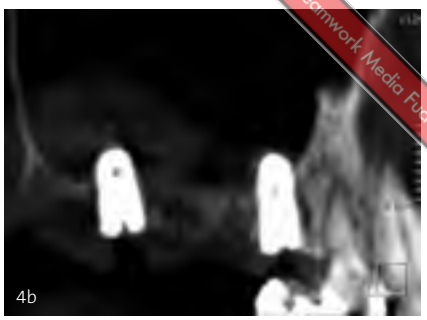
- Implant survival rate: An implant was considered a failure if it presented any mobility, implant fracture or an infection that mandated implant removal.
- A restoration was considered failed if it needed to be replaced by an alternative restoration.

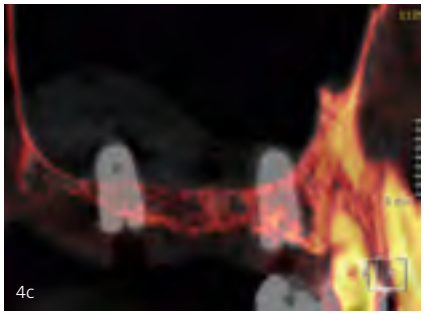


2 I Detail of bone chip formation between cutting blades of the CAS drill.

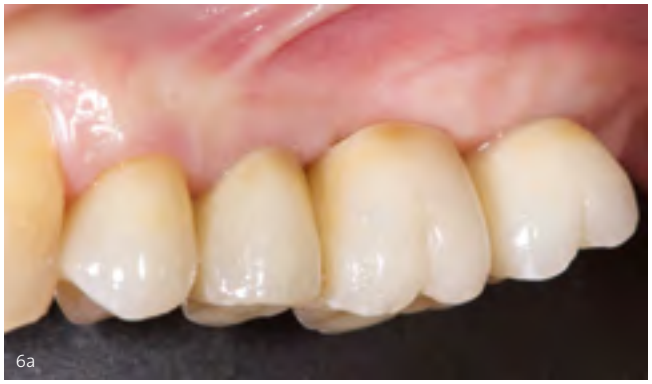


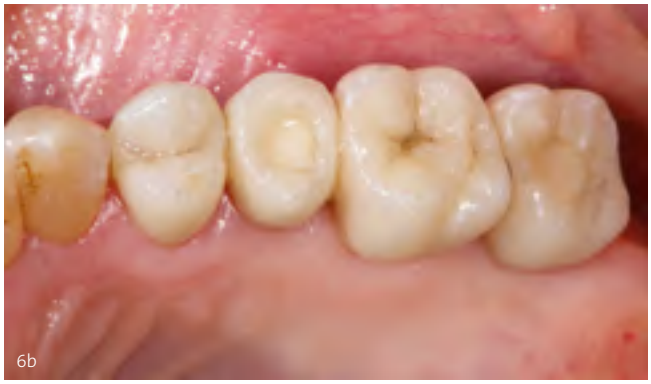






3 I Periapical radiograph taken during implant placement.
4a to c I CBCT scans taken before (a) and after (b) implant placement and superimposition (c).
5 I Periapical radiograph taken during the definitive implant impression.
6a to c I Postoperative clinical (a, b) and radiographic (c) examination.





- Presence of biological (pain, swelling, suppuration, etc.) or mechanical (screw loosening or fracture of the framework and/or the veneering material, etc) complications.
- Marginal bone-level changes as assessed by intraoral digital periapical radiographs made (Digora Optime; Soredex, Tuusula, Finland) using the paralleling technique and commercially available film holders at implant placement (baseline), implant loading, and one year after loading. The averaged mesial and distal distances from the most coronal margin of the implant and the first bone-to-implant contact was measured to the nearest 0.01 mm and taken as the marginal bone level. The difference in levels between time points was taken as marginal bone loss (MBL).
- Volumetric measurements of sinus grafts were performed on the CBCT scan using the Fusion adjunctive module of the OnDemand 3D software (Cybermed, Yuseong-gu, Daejeon, South Korea). The CBCT scans were taken before implant placement, immediately after, and at the one-year follow-up, following the ALARA (as low as reasonably achievable) principle. The SMAR (Soredex Metal Artifact Reduction) technology was also used to minimize scatter from metal artefacts. A clinician (EX) not previously involved in the study assessed all radiographic measurements.
- Patients' self-reported post-surgical pain and swelling were assessed three days after surgery on an ordinal scale (0 = no pain/swelling; 1 = mild pain/swelling; 2 = moderate pain/swelling; 3 = severe pain/swelling).
- The implant stability quotient (ISQ) was recorded by the surgeon using resonance frequency analysis (Osstell Mentor; Osstell, Goteborg, Sweden). Buccopalatal and mesiodistal measurements were taken and averaged, with the result being displayed by the device in ISQ units, ranging from 1 to 100. The values were recorded at the time of implant placement (baseline) and at the six-month follow-up (second-stage surgery).

All data were analyzed according to a preestablished plan. Descriptive analysis was performed for mean ± standard deviation (SD), median, and 95 per cent confidence interval (CI) using Number (version 5.2) for Mac OS High Sierra 10.X. Comparisons between follow-ups were made by a paired student t-test using SPSS (Version 22.0; IBM Corporation, Armonk, NY, USA) for Mac OS High Sierra 10.X. All statistical comparisons were conducted at a 0.05 level of significance. The statistical unit was one patient.

Results

In total, ten patients (five women, five men) with a mean age of 52.2 ± 7.1 years (range: 42–69) received 17 self-tapping tapered TSIII implants (Osstem Implant) and simultaneous sinus floor elevation using a crestal approach (CAS Kit; Osstem) and hydraulic pressure. No drop-outs had occurred at the follow-up one year after loading and no deviation from the original protocol. The mean follow-up time was 19.3 ± 3.6 months after implant loading (range: 12–25 months). All implants were inserted at torques between 35 and 45 Ncm. Patient and implant characteristics are reported in Table 1.

No implants and no prostheses failed during the follow-up period. No membrane tear and no other intraoperative or postoperative adverse events were observed. The mean marginal bone loss at the follow-up one year after loading was 0.22 ± 0.19 mm (95 % CI, 0.06–0.38; p = 0.000). Bone volume at implant placement was 0.81 ± 0.12 ml (95 % CI, 0.75–0.87). At the one-year follow-up examination, a slight bone contraction of 8.1 % was observed (0.74 ± 0.15 ml; 95 % CI, 0.73–0.87; difference, 0.7 ± 0.04 ml; 95 % CI, 0.04–0.08; p = 0.000). The mean pain value was 0.49 ± 0.65 (range 0–3); mean swelling value was 0.31 ± 0.44 (range 0–2). At implant placement, the mean ISQ value was 67.1 ± 4.6 (95 % CI, 64.8–69.2) and increased during the follow-up period, reaching a mean value of 72.3 ± 2.7 (95 % CI, 71.7–74.3). The difference was statistically significant (5.2 ± 3.0; 95 % CI, 3.6–6.4; p = 0.000). All data are reported in Tables 2 and 3.

Patient and implant characteristics	
Premolar region	1 (5.9 %)
First-molar region	13 (76.5 %)
Second-molar region	3 (17.6 %)
4.5 × 8.5-mm implants	2 (11.75 %)
4.5 × 10-mm implants	5 (29.5 %)
4.5 × 11.5-mm implants	2 (11.75 %)
6 × 10-mm implants	2 (11.75 %)
5 × 10-mm implants	4 (23.5 %)
5 × 11.5-mm implants	2 (11.75 %)
D2 bone quality	1 (10.0 %)
D3 bone quality	7 (70.0 %)
D4 bone quality	2 (20.0 %)
Light smokers	4 (40.0 %)

Table 1: Patient and implant characteristics.

Mean outcome metrics one year after loading	
Marginal bone loss	0.22 ± 0.19 mm
Pain	0.49 ± 0.65 (range 0–3)
Swelling	0.31 ± 0.44 (range 0–2)

Table 2: Mean outcome metrics (one year after loading).

Discussion

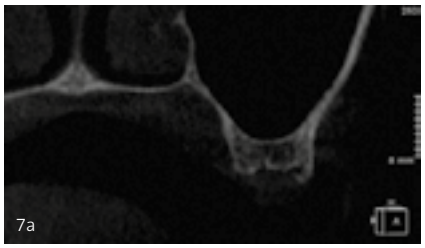
This study aimed to evaluate the clinical and radiologic data, one year after loading, of a minimally invasive crestal approach to sinus membrane elevation with special designed drills in combination with hydraulic pressure. Because this research had been designed as a prospective cohort study, its primary limitation is the lack of a control group.

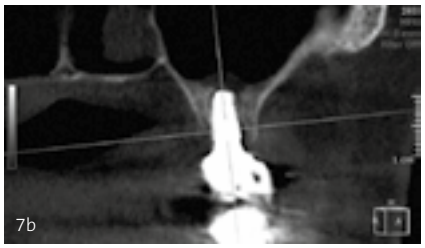
Nevertheless, the results of the present study were in agreement with a previously published report using the same drills system (CAS Kit; Osstem) [4]. During the entire follow-up period, no implant and prosthesis failed and no membrane tear was experienced. Therefore, the major clinical consideration of this study was that sinus membrane elevation can be safely performed in combination with implant placement using special designed drills and hydraulic pressure. Although this approach was used with a residual bone height of 2 mm, the data should be interpreted with caution due to the small sample size.

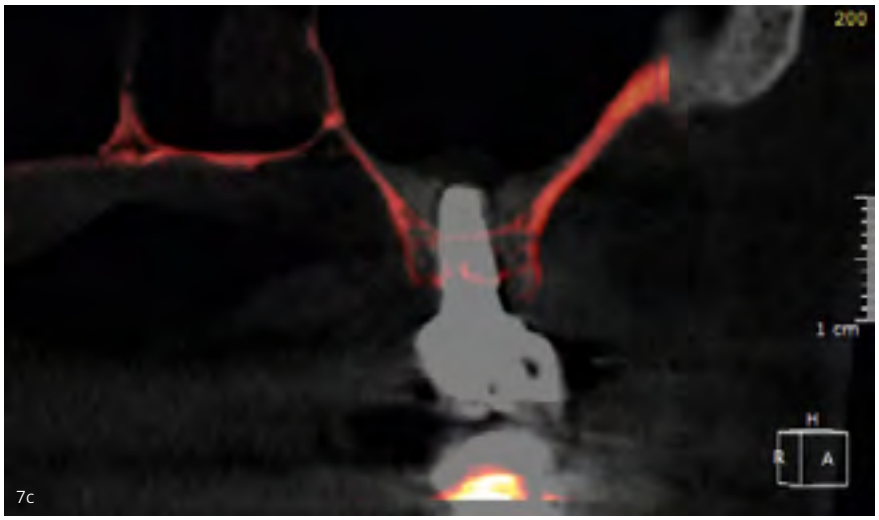
A major concern is the ability to ensure high primary implant stability in a severely atrophied ridge. In the present study, most patients presented with a bone density of class 3 and 4 according to the classification proposed by *Misch* [13]. In all these cases, the implant sites were underprepared by the manufacturer's suggestions. The drilling protocol allowed for implant stability at between 35 and 45 Ncm, with a mean ISQ value at placement of 67.1.

Mean outcome metrics at baseline and at the follow-up one year after loading				
Outcome	Implant placement	One year after loading	Difference	P value
Volumetric changes (CC)	0.81 ± 0.12	0.74 ± 0.15	0.7 ± 0.04	0.000
ISQ value	67.1 ± 4.6	72.3 ± 2.7	5.2 ± 3.0	0.000

Table 3: Mean outcome metrics at baseline and at the follow-up one year after loading.







7a to c I CBCT scans taken before implant placement (a) and one year after loading (b) and superimposition (c).

A three-dimensional comparison was performed. The data showed that a slight bone contraction of 8.1 per cent was observed at the follow-up one year after loading (Figa. 7a to c). These results are slightly better than the data reported in a previous report using the same radiographic method [1,2]. A possible explanation could be that in the present study, the sinus was filled with magnesium-substituted hydroxyapatite nanocrystals placed mechanically using the bone carrier and the bone condenser, limiting the possibility that resorbable air or saline bubble might be introduced into the sinus.

The technology used to measure bone volume contraction allows a superimposition of volume data using voxel information. This technology, known as "mutual information", calculates the statistical dependence between two volumes and the intensity and correlation values of entropy, and compares the difference in the entropy of the sum of individual images and the joint entropy of combined images to merge the data. Superimpositions of the postoperative and -year follow-up (DICOM data) were made automatically by drawing a volume of interest (VOI) overlay over an area involving unchanged anatomical landmarks (for example teeth, basal skull, implants) and manually checked for a complete match, ensuring the highest accuracy for the superimposition. Then the volumes of grafted material were calculated segment by segment in the sinus cavity using the segmentation tool (On-Demand 3D; Cybermed). This tool provides volumetric information based on the opacity of the grafted material. The segmented area included implants and graft material. However, the implants could be clearly distinguished from the grafted materials by their density and structure and were excluded from the measurements.

According to a Cochrane review [15], the use of bone substitute in combination with sinus floor elevation is questionable if more than 3 mm of bone height is present. Nevertheless, there is no consensus about the amount of bone gain to be expected using a crestal approach. A recent animal study showed that CAS Kit (Osstem) was superior to the osteotome sinus-floor elevation with added bone, for a bone gain of 7 mm in height, with a lower incidence of membrane perforation (one out of twelve cases, compared with seven out of twelve cases) [16].

Proper implant position has a significant impact in the functional and aesthetic results. Computer-assisted template-based implant placement has become increasingly popular over the last decade. With the introduction of advanced 3D imaging, it became possible to preoperatively combine anatomical information about the underlying hard and soft tissues with the ideal prosthetic parameters [17–19]. In the present study, implants were placed using a computer-guided, template-assisted approach. Nevertheless, the surgical template still had to be removed during implant site development and membrane sinus elevation. With the introduction of the OneCas Kit (Osstem), the implant site can now be prepared through the surgical template without removing it. This improves the accuracy of the final implant position, making the surgical procedure easier and faster.

Conclusions

A crestal approach to sinus floor elevation using dedicated drills with simultaneous implant placement is a viable treatment option for the minimally invasive treatment of the posterior atrophic maxilla. Further studies are needed to confirm these results.

Conflict-of-interest statement: *Dr Marco Tallarico* and *Dr Yong-Jin Kim* are global speakers for Osstem Implant. However, the data belongs to the authors, and the company did not interfere with the conduct of the trial or the publication of its results in any way.

The references are available at www.teamwork-media.de/literatur

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