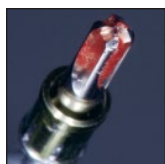




Maxillary Sinus Membrane Elevation Using a Special Drilling System and Hydraulic Pressure: A 2-Year Prospective Cohort Study



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The purpose of this study was to evaluate clinical and radiologic outcomes using a newly developed device for maxillary sinus membrane elevation. Patients with a residual bone height of at least 3 mm were enrolled. Crestal sinus lift elevation and sinus graft were performed using the crestal approach sinus (CAS) kit. Graft was avoided if the residual bone crest was ≤ 2 mm less than the length of the planned implant. Outcome measures were implant and prosthesis failure, any biologic or technical complications, and marginal bone loss (MBL). A total of 35 consecutive patients underwent 49 crestal elevations of the sinus membrane. All the implants were followed for at least 2 years after placement (mean follow-up 37.3 months; range 24 to 54 months). No implants or prostheses failed during follow-up, and no membrane tears or other intraoperative or postoperative adverse events were observed. At the 2-year follow-up, mean MBL was 0.33 ± 0.24 mm (95% confidence interval: 0.08 to 0.30 mm). A total of 32 implants were placed after filling the sinus with anorganic bovine bone, while 17 implants were placed without grafting the sinus. Post-hoc analysis was performed using the sinus grafting remodeling index (SGRI) to evaluate radiographically the tissue remodeling patterns. The SGRI was statistically significantly higher when the sinus was grafted ($P = .000$). The CAS kit may provide a new option for minimally invasive crestal sinus surgery. Long-term randomized controlled trials with larger sample size are needed to confirm these preliminary results.

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Implant placement has become a widespread dental procedure to restore partially and completely edentulous patients.^{1,2} However, the success rate of osseointegrated implants in the maxilla, especially in the posterior region, seems to be significantly lower when compared to the implant success rate in the mandible.¹ This is partially due to the poor quality and quantity of bone in the maxilla, as well as the pneumatization of the maxillary sinus after tooth extraction.

Sinus lift procedures using a lateral approach overcome this drawback, increasing bone volume in the sinus cavity.³ However, this surgical procedure requires execution of a large mucoperiosteal flap, leading to significant postoperative morbidity.^{4,5} Furthermore, sinus membrane perforations, nosebleed, infection, rhinosinusitis, and high postoperative pain, swelling, and hematoma have to be considered as possible complications.^{6,7}

Crestal sinus lift approach was first described by Tatum⁸ and modified by Summers.⁹ Subsequently, various modifications to the original technique have been reported to improve the reliability and safety of the membrane elevation.^{10,11} The major concern with the crestal sinus lift approach is that the elevation of the sinus membrane is performed without direct optical control. Moreover,

a limited amount of bone gain is expected using these techniques. Recently, crestal lift techniques using hydraulic pressure have been proposed with the aim to provide high predictability in clinical outcomes, together with extremely low morbidity, higher bone gain, and shortened surgery time.^{12–15}

Maxillary sinus augmentation is based on the principle of guided bone regeneration using the sinus membrane as a natural barrier. Although a high success rate and bone gain have been obtained using this surgical technique, evidence is still lacking regarding whether to graft or not graft the maxillary sinus.¹⁶ However, there is some evidence that without grafting it is possible to achieve histologic bone formation.¹⁷

The aim of the present prospective study was to evaluate clinical and radiologic outcomes using a newly developed device for maxillary sinus membrane elevation by crestal sinus lift approach with a special drilling system and hydraulic pressure (CAS-Kit, OSSTEM). This trial followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement (<https://www.strobe-statement.org>).

Materials and Methods

This preliminary investigation was designed as a prospective cohort study aimed to evaluate clinical and radiologic outcomes using a newly developed device for maxillary sinus membrane elevation. Patients were recruited and treated at a private practice (Parabiago, Milan) by a single

operator (F.G.), between March 2012 and September 2014. The investigation was conducted according to the principles embodied in the Helsinki Declaration of 1975 for biomedical research involving human subjects, as revised in 2008. All patients were informed about the nature of the study and gave written consent for surgical and prosthetic procedures and for the use of clinical and radiologic data.

The inclusion criteria were as follows: patient aged 18 years or older, able to sign an informed consent; patient required an implant-supported restoration of the atrophic posterior maxilla and presented a residual bone height of at least 3 mm (maximum 8 mm) and width of 6 mm distal to the canine measured on cone beam computed tomography scan, and smoking ≤ 10 cigarettes/day. Exclusion criteria were as follows: general contraindications to implant surgery, teeth extracted < 3 months before implant placement, subjected to irradiation in the head and neck area < 1 year before implantation, uncontrolled diabetes, pregnant or nursing, substance abuse, heavy smoker, psychiatric therapy or unrealistic expectations, immunosuppressed or immunocompromised, treated or under treatment with oral and intravenous aminobisphosphonates, lack of opposite occluding dentition/prosthesis in the area intended for implant placement, severe bruxism or clenching, acute infection or severe inflammation (ie, sinusitis) in the area intended for bone augmentation and implant placement, untreated periodontitis, poor oral hygiene and motivation (full-mouth bleeding on probing and

full-mouth plaque index $> 25\%$), and patients participating in other studies, if the present protocol cannot be properly followed as a result.

The day of surgery, a single dose of antibiotics (2 g amoxicillin and clavulanic acid, or 600 mg clindamycin if allergic to penicillin) was administered prophylactically 1 hour prior to surgery. Chlorhexidine 0.2% mouthrinse was administered for 1 minute prior to surgery. Local anesthesia using articaine with adrenaline 1:100,000 was administered. A midcrestal incision was made, and a full-thickness mucoperiosteal flap was elevated. The implant recipient site was prepared according to the drilling protocol suggested by the manufacturer (CAS-Kit, OSSTEM).

This drilling protocol was carefully followed by a twist drill connected with a stopper at 2 mm shorter than the available bone height (distance between the bone crest and the most inferior point of the sinus floor, measured on the long axis of the planned implant). The diameter of the drill was increased to 2.8 mm with the stopper still connected, maintaining a drilling speed of 800 rpm as recommended. Before the final preparation, the drilling protocol was customized so that the 2.8-mm drill was immediately connected with a stopper as the available bone height and the maxillary sinus floor was prepared (Figs 1 to 5). The depth gauge (OSSTEM) with the last-used stopper was inserted to check the sinus floor preparation and the resilience of the maxillary sinus membrane. If the sinus floor was intact, the 2.8-mm drill was used with a stopper 1 mm longer until complete erosion of

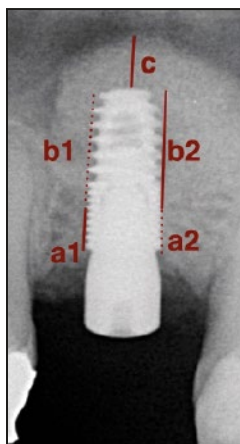


Fig 1 (left) Radiographic measurements. a1 = residual bone height (mm), medial; a2 = residual bone height (mm), distal; b1 = implant in sinus (mm), medial; b2 = implant in sinus (mm), distal; c = distance between the apex of the implant and the upper bone graft.

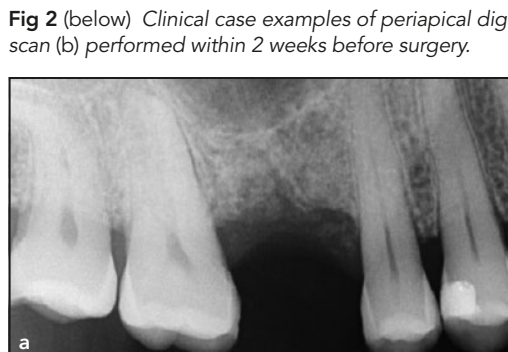


Fig 2 (below) Clinical case examples of periapical digital radiograph (a) and cone beam computed tomography scan (b) performed within 2 weeks before surgery.



Fig 3 Drilling protocol to prepare the maxillary sinus floor.

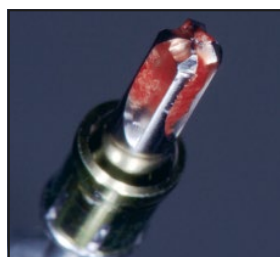


Fig 4 Detail of bone chip formation between cutting blades of the CAS drill.

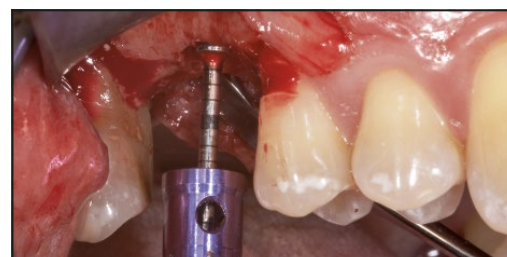
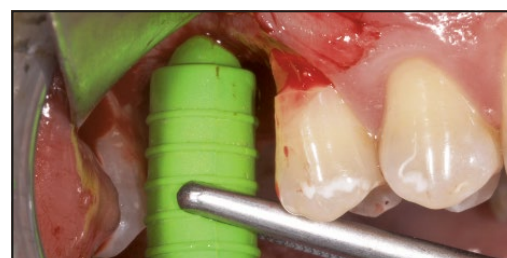


Fig 5 The depth gauge with the last-used stopper was inserted to check the sinus floor preparation and the resilience of the maxillary sinus membrane.

the sinus floor was achieved. At this point, the hydraulic lifter was inserted into the drilled hole and 2 to 3 mL of saline solution was gently injected into the sinus to elevate the maxillary sinus membrane. The saline solution was retracted back into the syringe and slight physiologic bleeding was noted in the retracted saline solution. The hydraulic pressure pump of the CAS-Kit (OSSTEM) device was used to test the sinus membrane for perforation; water transition through the nose indicated a membrane perforation (Fig 6). Afterward, if the difference between the residual bone height and the length of the planned implant was > 2 mm, the bone carrier and the bone condenser were used to fill the hole with 0.5 to 1 mL of anorganic bovine bone material (Bio-Oss, granule sizes 0.25 to

Fig 6 The hydraulic lifter was inserted into the drilled hole, and 2 to 3 mL of saline solution was gently injected into the sinus to elevate the maxillary sinus membrane; this device was even used to test the sinus membrane for perforation.



1 mm, Geistlich). In case of multiple implants, the bone spreader drill (OSSTEM) was used to spread the material to the lateral part, maintained at 30 rpm. Otherwise, if the difference between the residual bone height and the length of the planned implant was < 2 mm the bone graft was avoided. The length and diameter of dental implants was selected based on the bone structure, maxillary sinus pathology, and type of prosthesis planned.

After the sinus lift procedure was completed, the diameter of the drill was increased with the last stopper still connected, according to the diameter of the planned implant, maintaining a drilling speed of 800 rpm as recommended. Finally, a self-tapping implant (OSSTEM) was placed in the prepared site up to the bone level at a speed of 25 rpm with the motor set at 45 Ncm torque. The cover screw was connected and the wound was sutured with a 4-0



Fig 7 (left) The bone carrier and the bone condenser were used to fill the hole with 0.5 to 1 mL of anorganic bovine bone material (Bio-Oss granule sizes 0.25 to 1 mm, Geistlich) when planned.

Fig 8 (right) A self-tapping implant (OSSTEM) was placed into the prepared site.

polyglactin 910 suture (Vicryl V271, Ethicon) (Figs 7 and 8).

Antibiotic was continued for 7 days (1 g amoxicillin and clavulanic acid or 300 mg clindamycin twice a day) after surgery. Chlorhexidine 0.2% mouthrinse was administered for 1 minute twice a day for 2 weeks, and a soft diet was recommended for 1 month. Ibuprofen 400 mg or paracetamol 1 g was administered in case of pain. Sutures were removed after 1 week, at which time oral hygiene instructions were strengthened. At 6 months after implant placement, a second-stage surgery using a split-thickness incision preserving and providing keratinized tissue around dental implants was performed. A healing abutment was placed, and no provisional was delivered. The implant was manually tested for stability, tightening the abutment with a 20-Ncm torque by the blind assessor (C.G.). A preliminary impression with a pickup impression coping was taken using a polyether material (Impregum TM, 3M ESPE). At 1 month after second-stage surgery, metal-ceramic crowns or fixed partial prostheses cemented on titanium abutment were delivered. The occlusion was adjusted to avoid any premature contacts. Periapical radiographs and clinical photographs were taken. Follow-up visits

were scheduled every 3 months after implant placement.

Outcome measures were implant and prosthetic survival rates, complications, marginal bone levels, and sinus graft remodeling.

Implant failure was defined as implant mobility or any infection dictating implant removal, or implant fracture or any other mechanical complication rendering the implant useless. The stability of each individual implant was measured manually by tightening the abutment screw at delivery of definitive crowns or by assessing the stability of the implant-supported crown using the handle of two metallic instruments at the 6-month follow-up in function. A prosthesis was considered a failure if it needed to be replaced by a new prosthesis. Any biologic (pain, swelling, mobility, and suppuration) or technical complication (abutment or veneering material fracture, screw loosening or fracture) was recorded during follow-up by the operators who performed all the surgical and prosthetic procedures.

Mesial and distal bone level changes were measured as the distance from the mesial and distal margin of the implant neck (inserted slightly below the buccal bone level) to the most coronal point where the bone appeared to be in contact

with the implant. For each implant, mean mesial and distal measurements were averaged, and then the measurements were averaged at patient level. Measurements were evaluated on periapical digital radiographs taken with the paralleling technique using a film holder (Rinn XCP, Dentsply), at implant placement (baseline), and then yearly. Differences between follow-ups were taken as marginal bone loss. All readable radiographs were displayed in an image analysis program (ImageJ version 1.38, National Institutes of Health) and calibrated for every single image using the known distance of two consecutive implant threads. In the case of an unreadable radiograph, the radiograph was made again. All radiographic measurements were assessed by a blinded clinician not previously involved in the study (G.T.).

The same blinded clinician evaluated radiographically the tissue remodeling patterns using the sinus grafting remodeling index (SGRI) proposed by Brägger et al¹⁸ as follows: 0 = no bone/graft visible, 1 = cloudy appearance of new bone/graft, 2 = clearly visible new bone/graft and disappearing structures of original sinus floor, 3 = new bone/graft with new cortical plate and the former boundary of the sinus floor

disappearing. Evaluations were done on periapical digital radiographs taken with the paralleling technique using a film holder (Rinn XCP, Dentsply) at implant placement and then yearly up to 2 years after implant placement (Fig 9).

Statistical Analysis

Data were collected in spreadsheets (Excel, Microsoft). All data analysis was carried out according to a pre-established analysis plan by a biostatistician with expertise in dentistry (M.T.). Descriptive analysis was performed using mean \pm SD, median, and 95% confidence interval (CI) (SPSS for Mac OS X version 22.0, IBM). Differences in means were compared by nonparametric Mann-Whitney *U* test. The patient was the statistical unit of the analyses. Dichotomous and continuous outcomes were compared using chi-square test and one-way analysis of variance, respectively. All statistical comparisons were conducted at the .05 level of significance.

Results

A total of 35 consecutive patients (18 women, 17 men) with a mean age at implant insertion of 55.7 years (range: 36 to 74 years) and severe atrophy of the posterior maxilla underwent 49 crestal elevations of the sinus membrane, insertion of bone graft when planned, and implant placement at the planned site. All the patients were followed for at least 2 years after implant place-

Table 1 Patient and Implant Characteristics

	Graft	No graft	Total	P
Mean age at implant insertion (y)	56.5	54.2	55.7	NA
Women	10	8	18	.088
Men	14	3	17	
Smokers	3	2	5	.656
Implants placed in the premolar molar area	10	7	17	.755
Implants placed in the first molar area	19	9	28	
Implants placed in the second molar area	3	1	4	
< 10-mm-long implants	13	11	24	.108
\geq 10-mm-long implants	19	6	25	
< 5-mm implant diameter	5	0	5	.085
\geq 5-mm implant diameter	27	17	44	
Patients that received 1 implant	16	5	21	.234
Patients that received 2 or more implants	8	6	14	
Mean residual alveolar ridge height (mm)	5.27 (1.36)	5.85 (1.77)	5.45 (1.33)	.205
Mean follow-up (mo)	36.4	39.3	37.3	.447

ment. The mean follow-up was 37.3 months (range: 24 to 54 months). Of the patients, 5 were light smokers (\leq 10 cigarettes/day). The mean residual alveolar ridge height was 5.45 ± 1.33 mm (range: 2.87 to 8.87 mm; 95% CI: 5.08 to 5.97 mm). A total of 32 implants were placed after the sinus was filled with 0.5 to 1 mL of anorganic bovine bone material (Bio-Oss, Geistlich), while 17 procedures were performed without grafting the sinus. There was no apparent imbalance between patients who received or did not receive graft biomaterial. The main patient and implant characteristics are reported in Table 1.

At the last follow-up examination, no implants or prostheses had failed. No membrane tears or other intraoperative or postoperative adverse events were observed.



Fig 9 Periapical digital radiographs were taken with the paralleling technique using a film holder (Rinn XCP, Dentsply) at implant placement and after implant loading.

Mean marginal bone loss experienced during the 2-year follow-up was 0.33 ± 0.24 mm (95% CI: 0.08 to 0.30 mm). Post hoc analysis showed no differences between grafted and nongrafted procedures ($P = .205$). Radiographic data are reported in Tables 2 and 3. At the 2-year follow-up examination, 28 out of 32 implants placed with bone graft materials scored a SGRI

Table 2 Mean (\pm SD) Marginal Bone Levels (mm)

	Final restoration	1 y	2 y
Graft (n = 24)	0.11 \pm 0.17	0.31 \pm 0.20	0.40 \pm 0.26
No graft (n = 11)	0.24 \pm 0.17	0.52 \pm 0.26	0.65 \pm 0.28
Total (n = 35)	0.14 \pm 0.18	0.37 \pm 0.24	0.47 \pm 0.29

Table 3 Mean (\pm SD) Marginal Bone Loss (mm)

	Baseline – 1 y	1 y – 2 y	Baseline – 2 y
Graft (n = 24)	0.22 \pm 0.19	0.10 \pm 0.11	0.30 \pm 0.25
No graft (n = 11)	0.28 \pm 0.18	0.11 \pm 0.08	0.41 \pm 0.22
Total (n = 35)	0.24 \pm 0.19	0.10 \pm 0.10	0.33 \pm 0.24
P	.352	.600	.205

Table 4 Mean (\pm SD) SGRI Index (Implant Level)¹⁸

	Baseline – 1 y	1 y – 2 y	Baseline – 2 y
Graft (n = 32)	1.59 \pm 0.61	2.25 \pm 0.51	2.86 \pm 0.34
No graft (n = 17)	0.76 \pm 0.83	1.35 \pm 0.49	2.12 \pm 0.70
Total (n = 49)	1.31 \pm 0.80	1.94 \pm 0.66	2.61 \pm 0.61
P	.001	.000	.000

of 3 (87.5%) according to Brägger et al,¹⁸ while the remaining 4 implants scored a SGRI of 2 (12.5%). The overall mean SGRI was 2.86 ± 0.34 mm. For the implants that did not receive graft, the overall mean SGRI was 2.12 ± 0.70 mm. Three implants scored a SGRI of 1 (17.6%), most of the implants scored a SGRI of 2 (n = 9; 52.9%), and 5 implants scored a SGRI of 3 (29.4%). The overall mean SGRI was 2.1 ± 0.7 . At each follow-up, the SGRI was statistically significantly higher when the sinus was grafted ($P = .000$; Table 4).

Discussion

The purpose of this study was to evaluate the clinical and radiologic outcomes of a newly developed device for maxillary sinus membrane

elevation by a crestal approach with special drilling system and hydraulic pressure, and to present data on this procedure performed with or without graft material to augment the maxillary sinus.

The main limitation of the present investigation was the small sample size that may have hidden some differences. Another limitation was the lack of standardization of the implant length/diameter used in the study, which may have increased heterogeneity between the implants. Nevertheless, 35 consecutive participants underwent 49 crestal elevations of the sinus membrane, which may allow pilot data and create sample size estimations for larger, randomized studies.

The present study is one of the first reporting data from maxillary sinus membrane elevation via a

crestal approach performed using special drilling system and hydraulic pressure. This makes evaluation of how the present results would fit with other comparable studies difficult.

In the present study, the decision of whether to graft the sinus was correlated to the presurgical residual bone crest and confirmed after implant site preparation. Implants with apices protruding 2 to 3 mm into the maxillary sinus following elevation of the sinus membrane without graft may have resulted in spontaneous bone generation.¹⁹ The predictability of such bone formation without grafting material may be questioned.¹⁶ In the present study, graft material (Bio-Oss, Geistlich) was applied where the residual bone height was < 6 mm (mean residual alveolar ridge height was 5.45 ± 1.33 mm; range: 2.87 to 8.87 mm; 95% CI: 5.08 to 5.97 mm).

No membrane tears (membrane integrity could be only assumed from the clinical point of view when using a closed approach) or other intraoperative adverse events were recorded; other studies in the literature have reported low rates of intraoperative complications using a specific crestal sinus lifting device.^{15,20} Soardi et al²⁰ reported a 1% overall failure rate on 323 crestal sinus lifts, with only the sinus membrane perforations.

When osteotomes were used instead of a specific crestal sinus lift device in the past, more adverse events occurred, as Pjetursson³ reported in a study in which membrane perforations diagnosed by the Valsalva maneuver were detected in 10.8% of the treated sites.

According to the clinical experience of the present authors, when perforation was detected no grafting material had been used.

In the procedures where no graft was used, 5 of 17 crestal elevations (29.4%) scored a SGRI of 3, 9 (52.9%) scored 2, and the remaining 3 (17.6%) scored 1. The overall mean SGRI was 2.9 in the grafted sinus lift vs 2.1 in the nongrafted procedures, with no statistically significant differences. This could mean that implants placed with grafting material surpassed the sinus demarcation more than implants placed with no graft.

Similar results were presented by Pjetursson,³ where the same SGRI was used. In the implants with grafting material, the crestal sinus elevations with a score of 3 ranged from 19.4% to 45.5% (range over six ratings) while the implants without grafting material ranged from 2% to 21.6%. On the other hand, a score of 0 was assigned to a range from 21.6% to 66.3% in the nongrafted implants and from 7.8% to 30.7% in the implants where the grafting material was used.

The variability of the scores among the different raters indicate that the reliability of the SGRI system must be questioned; even the long-term clinical significance of these data should be analyzed with a larger sample. According to the present data, the CAS-Kit device seems to be predictable and safe. The main advantages of this approach are the low morbidity compared with a classical later approach and the easy handling that requires a short learning curve.

Conclusions

The CAS-Kit is a valid treatment concept for minimally invasive crestal sinus surgery. Mean SGRI was statistically significantly higher when the sinus was grafted. Long-term randomized controlled trials with larger sample size and longer follow-up are needed to confirm these preliminary results.

Acknowledgments

The authors reported no conflicts of interest related to this study.

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