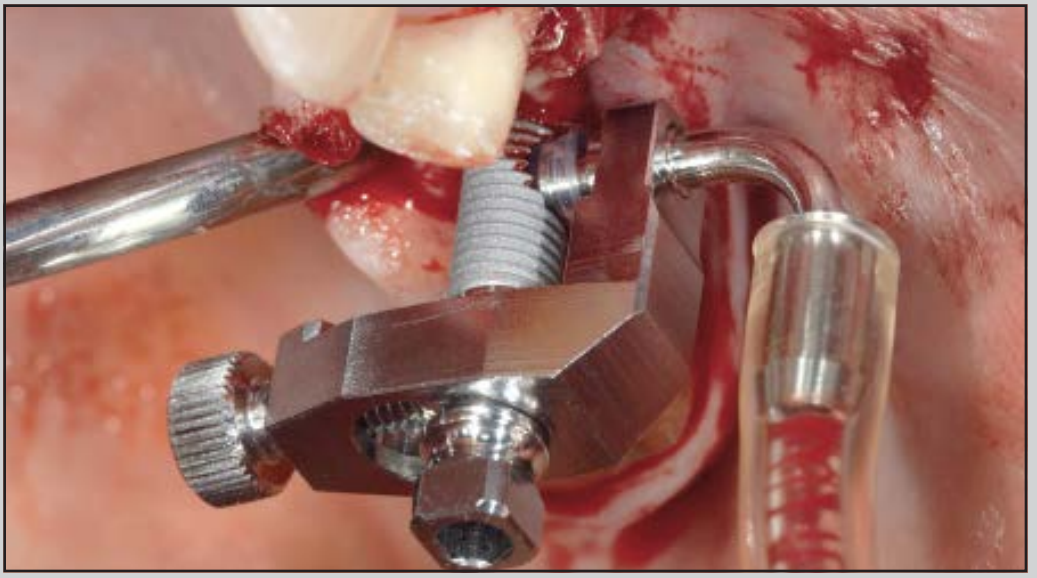
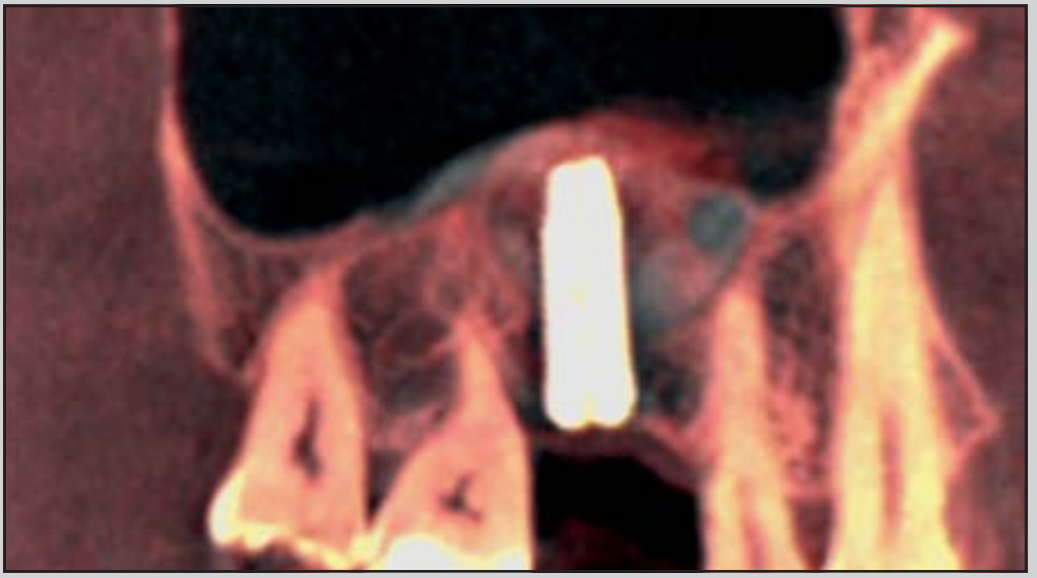
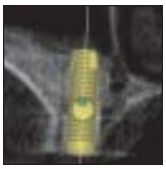




Minimally Invasive Sinus Augmentation Procedure Using a Dedicated Hydraulic Sinus Lift Implant Device: A Prospective Case Series Study on Clinical, Radiologic, and Patient-Centered Outcomes



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The aim of this study was to evaluate clinical and radiologic outcomes of a novel device that allows simultaneous hydraulic sinus membrane elevation, bone grafting, and implant placement. A sample of 18 consecutive participants with severe atrophy of the posterior maxilla underwent transcrestal elevation of the sinus membrane and implant placement. At the 6-month follow-up, the following parameters were assessed: implant success, any complications, marginal bone loss (MBL), three-dimensional (3D) graft measurements, implant stability quotient (ISQ), and graft density. No implants failed during follow-up (10.8 ± 2.8 months; range: 7–14 months). No membrane tears or other adverse events were observed. Mean residual alveolar ridge height was 4.78 ± 0.88 mm. Six months after the procedure, the mean MBL was 0.18 mm. The mean sinus membrane elevation was 12.78 ± 2.18 mm (range: 10.7–14.23). Along the basic 3D reference planes, the dimensions of grafted bone measured around implants were as follows: axial area = 239.7 ± 57.68 mm^2; sagittal area = 257.0 ± 60.83 mm^2; coronal area = 143.3 ± 29.46 mm^2. The mean volume of the graft was 2.38 ± 0.26 mL at baseline and 2.05 ± 0.24 mL 6 months after graft maturation (difference: 0.33 ± 0.29 mL, P = .0090). Graft density (in Hounsfield units [HU]), improved during healing from 322.0 ± 100.42 HU to 1,062.0 ± 293.7 HU; difference 740.0 ± 295.35 HU (P = .0001). The mean ISQ value was 65.5 at implant placement, and it increased to 74.1 at the 6-month examination (P = .0014). Of 18 patients, 12 experienced no pain (66.6%) and 10 experienced no swelling (55.5%). No severe pain or swelling was reported in any of the cases. The mean number of analgesic tablets consumed was 0.78 ± 0.67. Mean surgical time was 24.0 ± 4.07 minutes. The iRaise Sinus Lift System may provide a new option for minimally invasive transcrestal sinus surgery with minimal patient discomfort. A physiologic contraction of 13.9% of its original volume was experienced during healing. Long-term clinical studies are needed to confirm these preliminary results.
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Different approaches have been reported to augment the maxillary sinus cavity of the severely atrophied posterior maxilla, with simultaneous or delayed implant placement.[1–3] Pjetursson et al reported that implant placement in combination with a lateral window sinus lift is a predictable treatment option, showing high implant survival rates and low incidences of complications.[4] However, maxillary sinus floor elevation using a lateral approach implies execution of a large mucosal periosteal flap that inevitably affects postoperative recovery and the additional expense of the augmentation procedure.[5] Sinus membrane perforations, nose bleeding, postoperative pain, swelling, hematoma, and possible sinus infection could be considered as major risks.[6]

The elevation of the maxillary sinus floor through the alveolar crest (transalveolar) was first described by Tatum[7] and modified by Summers,[8] who introduced the osteotome sinus floor elevation approach. Fracture of the sinus floor can be performed by means of osteotomes[7–10] or burs, with[11,12] or without[7] stop drills. Various modifications to the original technique have been reported to improve the reliability and safety of the membrane elevation, including inflation of a balloon catheter[13] and hydraulic[14] or negative pressure.[15]

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Need for bone grafting of the maxillary sinus to house implant	General contraindications to implant surgery
Refusal to undergo a conventional lateral sinus augmentation procedure	Subjected to irradiation in the head and neck area < 1 one year before implantation
Residual alveolar crest of at least 3 mm in height and 5 mm in width distal to the canine as measured on CBCT scan	Uncontrolled diabetes
	Pregnant or nursing
	Substance abuse
	Heavy smoker (≥ 11 cigarettes/day)
	Psychiatric therapy or unrealistic expectations
	Immunosuppressed or immunocompromised
	Treated or under treatment with oral or intravenous aminobisphosphonates
	Lack of opposite occluding dentition/prosthesis in the area intended for implant placement
	Severe bruxism or clenching
	Healed sites (at least 3 months after teeth extraction)
	Untreated periodontitis
	Poor oral hygiene and motivation (full mouth bleeding on probing and full mouth plaque index > 25%)
	Patients participating in other studies, if this prevents the present protocol from being properly followed

According to a recent Cochrane systematic review, if the residual alveolar bone height is 3 to 6 mm, a transcrestal approach to lift the sinus lining and place 8-mm implants may lead to fewer complications than a lateral window approach and placement of implants at least 10 mm long.[2] Nevertheless, the success and survival rates of dental implants decrease with reduced residual bone height.[16–18]

In 2014, Better et al[19] published a preliminary report on a closed sinus floor elevation procedure accomplished using a dedicated dental implant. The aim of the present prospective study was to evaluate clinical and radiologic outcomes of a novel self-tapping endosseous implant system (iRaise, Maxillent) dedicated to sinus augmentation via a minimally invasive transcrestal approach and simultaneous implant placement, and to assess the oral health–related quality of life (OHQoL) of treated patients. This trial followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.[20]

Materials and methods

This study was a proof-of-concept of a larger prospective observational trial. Consecutive patients requiring a minimally invasive implant treatment of the atrophic posterior maxilla were recruited and treated at the surgical, microsurgical, and medical science department of the University of Sassari, Italy, between September 2014 and December 2014. Hopeless teeth were atraumatically extracted at least 3 months before implant placement. Surgical procedures were performed by two clinicians (M.T. and S.M.M.) with extensive experience in implant placement and sinus augmentation procedures who were properly trained in the use of the iRaise Sinus Lift System (Maxillent) before starting the study. The investigation 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 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 study protocol was approved by the Scientific Technical and Ethical Committee of the University of Sassari (2069/CE).

Any patient aged 18 years or older, able to sign an informed consent, and requiring an implant-supported restoration of the atrophic posterior maxilla was enrolled for the present study. Inclusion and exclusion criteria are reported in Table 1. Light smokers were included and patients were catego-

rized as no smoker or light smoker (≤ 10 cigarettes/day). Cone beam computed tomography (CBCT) scans were performed for each patient within 2 weeks before surgery (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 cm^2), immediately after the procedure, and at the 6-month follow-up (field of view 60 × 80 mm; voxel size 0.3 µm; 2.3 seconds; 90 kV; 5–8 mA; 192.4–307.8 mGy cm^2) as part of the regular treatment protocol. CBCT parameters were set as low as reasonably achievable.

Intranasal spray therapy (thiamphenicol glycinate acetylcysteinate 810 mg/4 mL) and cortisone (betamethasone 1 mg) were administered twice a day starting the day before surgery.

The day of surgery, a single dose of antibiotic (2 g amoxicillin and clavulanic acid, or clindamycin 600 mg 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 adrenalin 1:100,000 was administered. A midline 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 and reported in a previously published paper.[19] The length of the implant (ranging from 13 to 16 mm) had been selected in advance based on the residual bone height, measured using the preoperative CBCT scans, from the bone crest to the floor of the sinus along the implant-planned axis. According to the manufacturer's instructions, implants 13 mm in length were used for bone height of up to 4 mm, 14.5-mm-long implants for bone height of up to 6 mm, and 16-mm-long implants for bone heights of up to 8 mm. The iRaise Sinus Lift implant (Maxillent) was inserted into the osteotomy channel for the entire working length. The single-use tube connector was screwed to the implant tubing port. The connector does not touch the implant except for the silicone ring (medical silicone intended for implantation) (Fig 1). Then 2 to 3 mL of saline solution was gently injected into the sinus through the 1.5-mm-diameter internal L-shaped channel isolated from the prosthetic connection and the oral cavity.[19] The saline solution was retracted back into the syringe and slight physiologic bleeding was noted in the retracted saline solution (Fig 1). Afterward, a syringe filled with a flowable bone graft material (MBCP Gel, Biomatlante) was connected to the same port. MBCP Gel is a 100% synthetic injectable bone substitute composed of 60% biphasic calcium phosphate and 40% hydroxyapatite suspended in a soluble polymer. The spaces between the granules created by the polymer offer total macroporosity with a permeability > 80%. Two syringes of 1 mL each (2 mL total volume) of bone graft material with a granulometry ranging from 80 to 200 µm was slowly injected through the implant channel into the sinus after being mixed with 0.1 mL of 0.9% sterile saline solution. After the grafting procedure was completed, the hydraulic system was disconnected by the implant inserted for its entire length into the osteotomy channel and the grafted sinus cavity and left to heal according to a submerged protocol. Additional implants were placed in the treated area after the iRaise surgical sequence was completed.

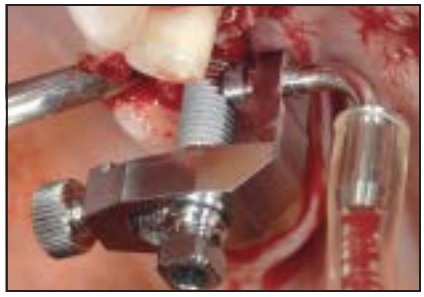


Fig 1 *The iRaise Sinus Lift implant inserted into the osteotomy channel. Physiologic slight bleeding can be noted in the retracted saline solution.*

Intranasal spray therapy (thiamphenicol glycinate acetylcysteinate 810 mg/4 mL) and cortisone (betamethasone 1 mg) were continued for 10 days after surgery. 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. Six months after implant placement the healing abutments were connected.

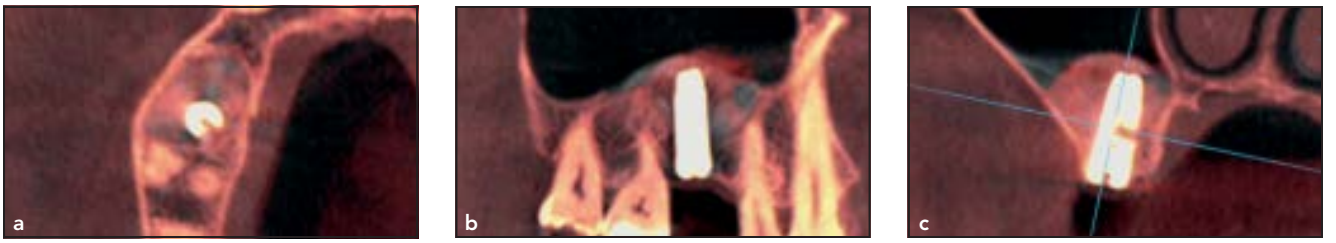


Fig 2 *Grafted bone area measurements. Postoperative volumetric data* (gray) *were subtracted to the original scenario* (red) *using the Fusion adjunctive module of OnDemand 3D software version 1.0.9.3223 (Cybermed). Magnification of the axial* (a), *sagittal* (b), *and coronal* (c) *views.*

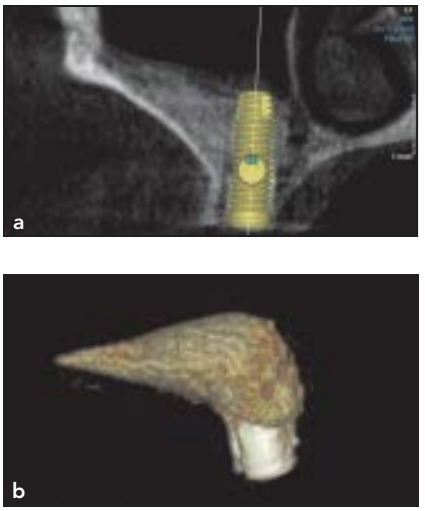
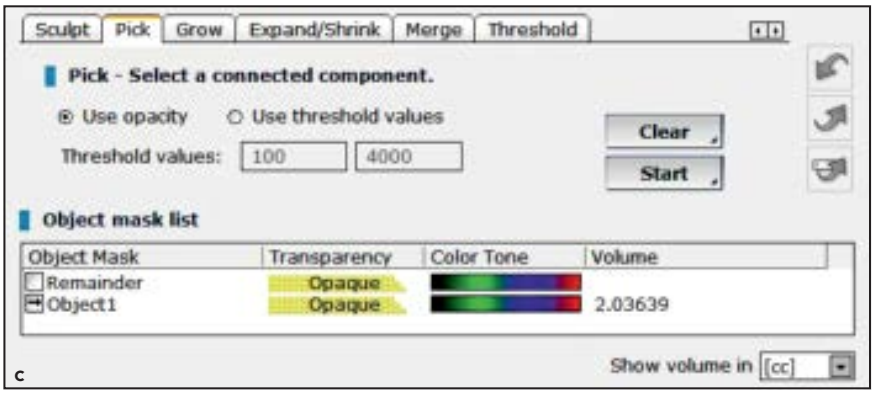


Fig 3 *Sequence of the grafted material volume calculation using opacity after CBCT scan subtraction.*



The definitive prosthesis was delivered directly on the implants 8 to 9 months after implant placement. Occlusion was carefully checked. Recall appointments for oral hygiene maintenance and oral hygiene instructions were set for every 4 months after loading. Hygiene and dental occlusion were evaluated at each visit.

The Digital Imaging and Communication in Medicine (DICOM) data were exported into OnDemand 3D software version 1.0.9.3223 (Cybermed) to perform all measurements. Two superimpositions of the DICOM data were performed: pre- and immediately postsurgery, and immediately post- and 6 months after surgery. The DICOM data were matched based on unchanged anatomical areas (eg, teeth, basal skull, implants) and manually checked for a complete match using the Fusion adjunctive module (Cybermed). Postoperative volumetric data were subtracted to the original scenario, and 6-month volumetric data were subtracted to the immediate postsurgery data.

Outcome measures

The outcome measures of this study were as follows:

- Implant success: *(1)* absence of recurring peri-implant infection with suppuration; *(2)* absence of persistent subjective complaints such as pain, foreign body sensation, and/or dysesthesia, *(3)* absence of a continuous radiolucency around the implant, and *(4)* absence of any detectable implant mobility.

- Any biologic (pain, swelling, or suppuration) and/or mechanical (screw loosening or fracture of the framework and/or the veneering material) complications.
- Marginal bone level changes: assessed by intraoral digital periapical radiographs taken with the parallelling technique by means of a customized holder at implant placement (baseline) and at 6-months follow-up. All readable radiographs were displayed in an image analysis program (DfW 2.8 for Windows, Soredex) and evaluated by an independent radiologist. The software was calibrated using the known distance of two adjacent threads. The distance from the most coronal margin of the implant collar and the top of the bone crest was taken as marginal bone level. Mesial and distal values were averaged for each implant at the time of implant placement and then at 6 months follow-up. The difference between time points was taken as marginal bone loss (MBL).
- Increased bone height (iBH): calculated as the distance between the bone crest and the most superior radiopaque sign of the graft material, measured along the implant long axis. Bone gain was determined by the difference between the iBH and the preoperative residual alveolar bone height (aBH), calculated as the distance between the bone crest and the floor of the sinus, measured along the long axis on the ideal implant position.
- Bone grafted area: calculated by manually drafting the perimeters of the augmented bone area on each of the 3D reference planes (axial, coronal, sagittal) using the fused set of DICOM data. All measurements were taken before surgery, immediately after surgery, and 6 months later, and compared (Fig 2).
- Volumetric measurements of sinus grafts: performed with OnDemand 3D software (Cybermed) using the previously generated set of DICOM data. The volumes of the grafted material were calculated using automatic tools, based on its opacity (Fig 3). The implants could be distinguished clearly from original bone by density and structure and were excluded from the grafted bone measurements. All the two- and three-dimensional radiographic measurements were assessed by the same experienced radiologist, who was not previously involved in the study.
- Graft density: measured on the CBCT scans and converted to Hounsfield unit (HU) using automatic tools in the same software (Fig 4). According to Cassetta et al,[21] the HU was equal to gray density values multiplied by a conversion ratio of 0.7. Measurements were made immediately after surgery and 6 months later.
- Implant stability quotient (ISQ): recorded by the surgeon using resonance frequency analysis. The measurements were performed at implant placement (baseline) and at the 6-month follow-up. An Osstell Mentor device was used in accordance with a previously published report.[22,23]
- Patient self-reported postsurgical pain, on an ordinal scale (0 = no pain; 1 = mild pain; 2 = moderate pain; 3 = severe pain): assessed 3 days after surgery at the postoperative checkup by a blinded assessor.
- Patient self-reported post-surgical swelling, on an ordinal scale (0 = no swelling; 1 = mild swelling; 2 = moderate swelling; 3 = severe swelling): assessed 3 days after surgery at postoperative checkup by the blinded assessor.
- Consumption of painkillers: number of tablets used (out of 12 tablets provided [Ibuprofen 400 mg, or paracetamol 1g for those allergic to NSAIDs]): recorded 3 days after surgery at the postoperative checkup by the blinded assessor.
- Surgical time (in minutes): calculated from the induction of local anesthesia to the placement of the last suture.

Statistical analysis

All data analysis was carried out according to a preestablished analysis plan by a biostatistician with

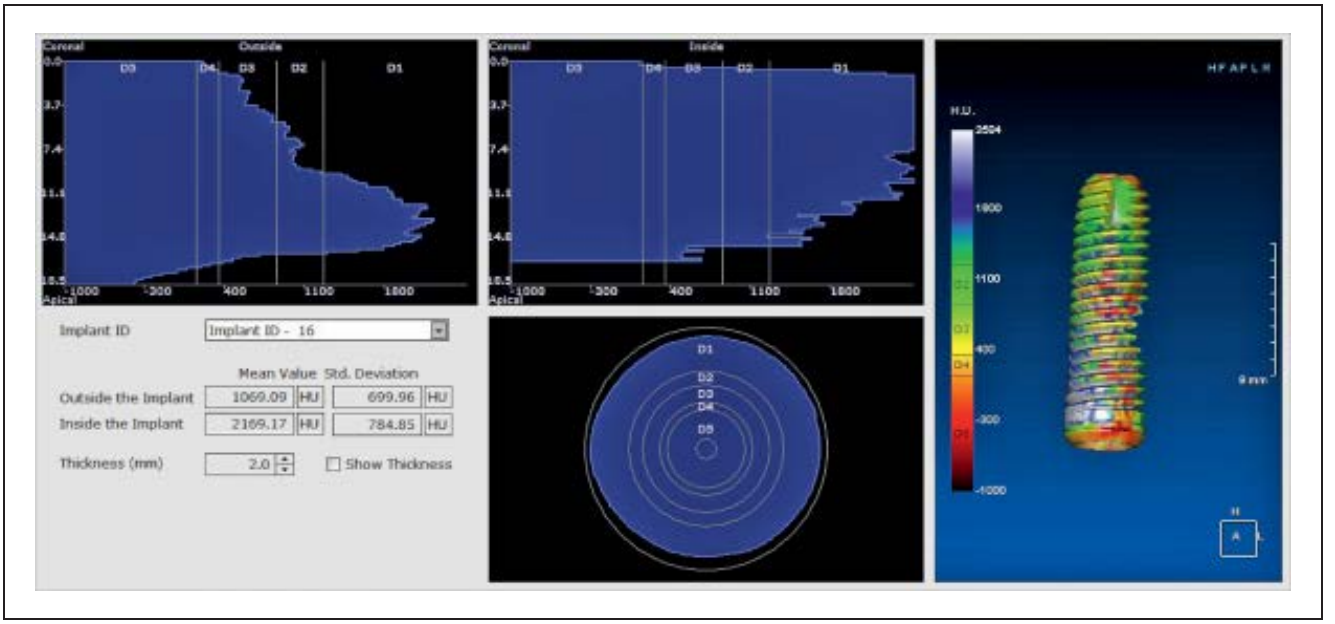


Fig 4 *Graft density measurement.*

Table 2 Primary patient and implant characteristics	
Women (n [%])	10 (55.5)
Age at insertion (y)	52.7 (range: 33–63)
Smokers (n [%])	0 (0.0)
Implants placed (iRaise, Maxillent) (n [%])	18 (62.1)
Patients who received two implants (n [%])	7 (38.9)
Patients who received three implants (n [%])	2 (11.1)
13-mm-long implants (iRaise)	0 (0.0)
14.5-mm-long implants (iRaise)	16 (88.9)
16-mm-long implants (iRaise)	2 (11.1)
4.2-mm implant diameter (iRaise)	14 (77.8)
5.0-mm implant diameter (iRaise)	4 (22.2)
Implants in first molar position	16 (88.9)
Implants in second molar position	2 (11.1)

expertise in dentistry. Descriptive analysis was performed using the mean ± standard deviation (SD), median, and 95% confidence interval (CI) (SPSS for Mac OS X version 22.0, IBM). Differences in means between groups were compared by Mann-Whitney *U* test. Comparisons between each time point and the baseline measurements were made by paired *t* test. All statistical comparisons were conducted at the .05 level of significance. The patients were used as the statistical unit.

Results

The main patient and implant characteristics are reported in Table 2. A total of 18 consecutive participants (10 women, 8 men) with a mean age of 52.7 years (range: 33–63 years) and severe atrophy of the posterior maxilla underwent transcrestal elevation of the sinus membrane, insertion of bone graft, and implant placement at the planned site (Fig 5). The mean follow-up was 10.8 ± 2.8 months (range: 7–14 months). The mean residual alveolar ridge height was 4.78 ± 0.88 mm (range: 3.6–6.4 mm; 95% CI: 3.12–5.28 mm). A total of 29 implants were placed (18 iRaise implant systems and 11 adjunctive iSure implants, Maxillent). At the 6-month follow-up examination, no implants had failed. No membrane tears or other intraoperative or postoperative adverse events were observed.

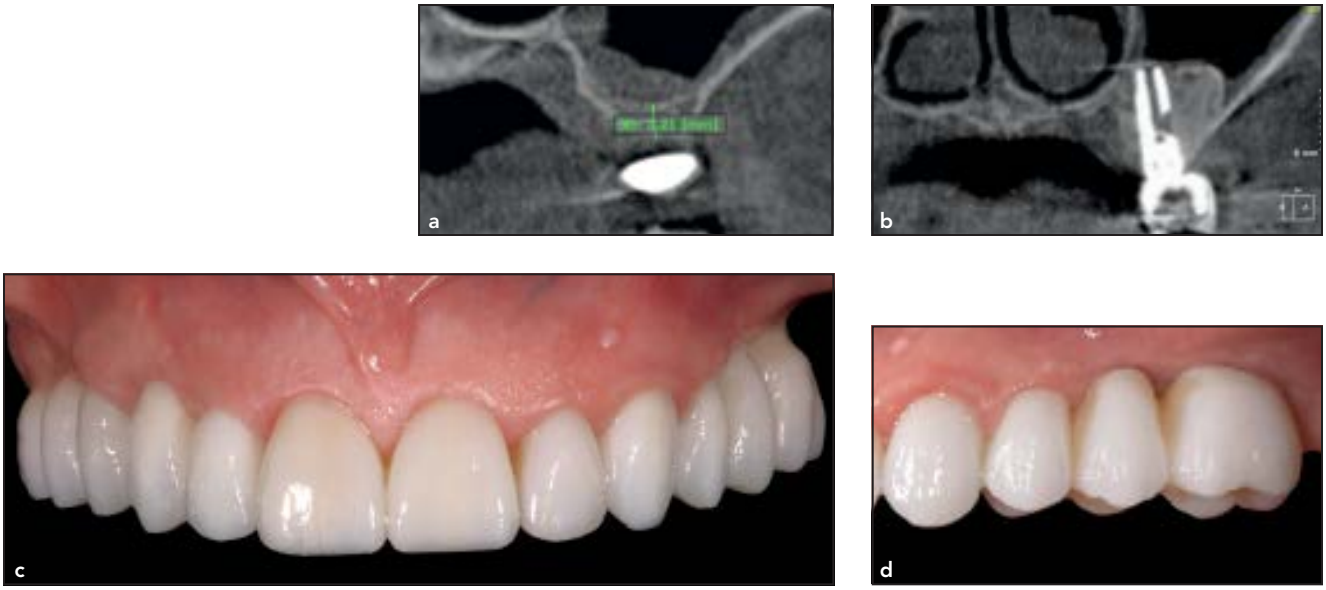


Fig 5 *Sequence of a clinical case.* (a) *Planning.* (b) *Implant placement.* (c, d) *Clinical 1-year follow-up.* (e) *Radiographic 1-year follow-up.*

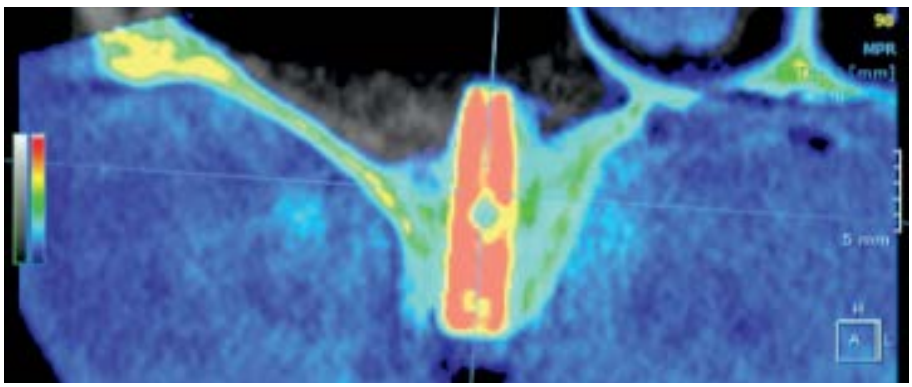


Fig 6 *Superimposition of the immediate postoperative scan with the 6-month follow-up scan. Physiologic bone resorption was noted.*

Mean MBL experienced during the 6 months of submerged healing was 0.18 ± 0.73 mm (P = .4706). By 6 months after the procedure, the mean bone gain was 12.78 ± 2.18 mm (range: 10.7–14.23 mm; 95% CI: 11.54–14.38 mm; P = .0000).

Along the basic reference planes, the mean bone gain measured around implants was as follows: axial area = 239.7 ± 57.68 mm^2 (range:

Table 3 Summary of the main results

Measurement	Implant placement (mean ± SD [range])	6 mo (mean ± SD [range])	Difference (mean ± SD [range])	*P*
Marginal bone level (mm)	–0.3 ± 1.02 (–1.06–0.26)	–0.09 ± 1.45 (–1.05–0.86)	0.18 ± 0.73 (–0.37–0.57)	.4706
Axial mean bone gain (mm^2)	244.9 ± 57.0 (239.5–314.0)	239.7 ± 57.68 (208.1–283.5)	5.2 ± 13.68 (–6.4–11.4)	.2892
Sagittal mean bone gain (mm^2)	304.5 ± 69.7 (254.1–345.3)	257.0 ± 60.83 (227.3–306.8)	47.5 ± 50.26 (23.3–88.9)	.0219
Coronal mean bone gain (mm^2)	165.1 ± 22.9 (150.4–180.4)	143.3 ± 29.46 (136.2–174.6)	21.8 ± 24.22 (–0.6–31.1)	.0271
Graft volume (mL)	2.38 ± 0.26 (2.18–2.52)	2.05 ± 0.24 (1.83–2.14)	0.33 ± 0.29 (0.06–0.44)	.0090
Graft density	322.0 ± 100.42 (246.40–377.60)	1,062.0 ± 293.7 (876.12–1,259.88)	740.0 ± 295.35 (426.04–811.96)	.0001
ISQ	65.5 ± 4.78 (62.88–69.12)	74.1 ± 5.25 (72.57–79.43)	8.6 ± 5.42 (6.96–14.04)	.0000

ISQ = implant stability quotient.

164.3–318.7 mm^2; 95% CI: 208.1–283.5 mm^2); sagittal area = 257.0 ± 60.83 mm^2 (range: 130.3–322.2 mm^2; 95% CI: 227.3–306.8 mm^2); coronal area = 143.3 ± 29.46 mm^2 (range: 90.3–171.4 mm^2; 95% CI: 136.2–174.6 mm^2). The grafted bone showed a physiologic contraction from its original volume (Fig 6) of 2.1% in axial area (*P* = .2892), 15.6% in sagittal area (*P* = .0219), and 13.2% in coronal area (*P* = .0271).

The mean volume of the grafted bone was 2.38 ± 0.26 mL (95% CI: 2.18–2.52 mL) at baseline. After 6 months of bone maturation, the main volume was 2.05 ± 0.24 mL (95% CI: 1.83–2.14 mL). A physiologic contraction of 13.9% of original volume occurred after bone maturation. The difference was not statistically significant (0.33 ± 0.29 mL; 95% CI: 0.06–0.44 mL; *P* = .0090).

Likewise, graft density improved during healing from 322.0 ± 100.42 HU (range: 177–449 HU; 95% CI: 246.4–377.6) to 1,062.0 ± 293.7 HU (range: 573–1,489 HU; 95% CI: 876.12–1,259.88). The difference was statistically significant (740.0 ± 295.35 HU; range: 324–1,231; 95% CI: 426.04–811.96; *P* = .0001).

The mean ISQ value was 65.5 (range: 59–76) at implant placement and increased to 74.1 (range 62–78) at the 6-month examination. The difference was statistically significant (*P* = .0014). A summary of the main results is reported in Table 3.

Regarding patient quality of life, 12 out of 18 patients (66.6%) experienced no pain and 10 out of 18 patients experienced no swelling (55.5%). In the other patients, pain and swelling was moderate. No severe pain or swelling was reported. The mean quantity of analgesic tablets consumed was 0.78 ± 0.67.

Surgical time, calculated from anesthesia induction to the last suture, was 24.0 ± 4.07 minutes (95% CI: 21.84–27.16).

Discussion

The aim of this study was to present the preliminary data on a novel implant system that allows for improved simultaneous sinus graft and implant placement using a minimally invasive transcrestal approach.

Because it was designed as a proof-of-concept of a larger multicenter single cohort study, the primary limitations were the lack of a control group and the sample size. Another limitation is the lack of histologic analysis. Nevertheless, the

present study is one of the first measuring the 3D volume changes of bone material grafted by transcrestal sinus lift approach using the iRaise implants system. These factors make it difficult to compare the present results with other studies.

The major clinical consideration of this prospective study was that detachment and elevation of the sinus membrane can be performed using hydraulic pressure directly through the implant channel, allowing for bone grafting and implant placement at the same time.

The main limitation of hydraulic pressure is possible fluid leakage during insertion. The conical-connection, silicone-coated tube connector is screwed onto the implant hole, allowing a tight seal. However, complete preparation of the maxillary sinus floor and a minimal implant stability are needed before the tube connector is screwed to the implant to ensure the liquid flow.

In the present study, the mean volume of the grafted bone was 2.38 ± 0.26 mL. A physiologic contraction after bone maturation of 13.9% of its original volume was seen. A recent systematic review by Shanbhag et al[24] on 234 sinus augmentation procedures performed with a conventional lateral approach reported reductions in augmentation volumes during early healing of about 45% using autogenous bone. The reductions ranged from 18% to 22% in cases using bone substitutes, with no significant differences between grafting materials. Nevertheless, the same review stated that augmentation volume loss does not seem to compromise implant survival.[24] Accordingly, a retrospective investigation on 16 patients with 25 maxillary sinuses augmented by a lateral approach reported shrinkage of about 26% 6 months after surgery.[25] In this study, different graft materials were used. The mean augmented bone volume was 3.02 ± 1.18 mL (95% CI: 1.4–5.56 mL) immediately after implant placement and 2.28 ± 1.07 mL (95% CI: 0.92–4.46 mL) after 6 months.[25] In accordance with the present research, all the studies reported a physiologic reduction in graft volume after maxillary sinus augmentation. Superimposition was used in all the investigated procedures. This involves superimposing multiple CBCT scans to see the differences between them. Although different approaches were used to augment the sinus cavity, a similar amount of bone was grafted, allowing the iRaise implant system to provide greater sinus augmentation.

Maxillary sinus floor elevation with a transcrestal approach is advocated as minimally invasive because of the minimal surgical flap required, maintaining an intact lateral sinus wall and reducing postoperative morbidity.[9,26] This technique is widely documented and supported by several longitudinal studies that attest to an average implant survival rate close to 92% in the medium-term follow-up.[4,27–29] Some authors investigating transcrestal osteotomes technique for sinus floor augmentation recorded high rates of patient satisfaction.[4,16,30] Recent publications show that transalveolar sinus floor elevation is a reliable method for implant placement in the posterior maxilla, even at sites with ≤ 4 mm of residual alveolar bone height.[19,31–33] The main concerns related to the transcrestal approach compared with the lateral surgical approach are the inability to directly visualize the sinus cavity and sinus membrane, the limited bone augmentation achieved, and the high risk of inadvertent perforation of the sinus membrane during the fracture of the sinus floor with osteotomes or burs, with or without stop drills, without the possibility to repair the torn membrane.[12,34] However, a sinus membrane perforation can occur at any time during the sinus lift procedure, independent of the surgical method used.[35] The main difference is that with the lateral approach perforations can be repaired, while with the transcrestal approach this option is not available. In the present study, no complications were experienced and the mean bone gain was 12.78 ± 2.18 mm. These results are in accordance with a previous report investigating the same procedure that found a mean bone gain of 11.2 mm on 18 patients with 23 procedures.[19] Both studies reported minimal patient discomfort following the iRaise implant system procedure.

Conversely, the conventional approach to the sinus lift creates a lateral opening in the external wall of the maxillary sinus to dissect the sinus membrane for its apical displacement. The space underneath the lifted sinus mucosa is filled with bone graft, and implants can be inserted simultaneously or delayed. In a meta-analysis conducted by Pjetursson et al,[4] a 3-year implant

survival rate of 90.1% (95% CI: 86.4%–92.8%) was reported. Nevertheless, the 3-year failure rate analyzed at patient level was 16.6% (95% CI: 10.9%–24.6%). High patient discomfort and complications at the treated sites (eg, sinusitis, infection, hemorrhage, swelling) were the major concerns, with a possible need for more days of rest after surgery.[2,6,36]

Different 3D techniques using CBCT scans have been described for assessment of the augmented bone volume.[24,25] All studies reported reductions in augmentation volumes during early healing times. Substantial volume reduction was higher for autogenous bone than for bone substitutes, with no significant differences among graft materials.[25] Although its reliability in objectively assessing the density of maxillary bones has not been properly studied in human clinics, preoperative estimation of density values by CBCT is a reliable tool to objectively determine bone density.[21,37,38] Patients underwent three CBCT scans in 9 months according to the guidelines published by the European Association of Osseointegration,[39] but all control radiographs were taken with a lower field of view, providing an overall effective absorbed dose that was lower than that for the first diagnostic CBCT scan.

Conclusions

A closed major sinus floor augmentation using a novel system that allows simultaneous hydraulic elevation of the sinus membrane, injection of a flowable bone replacement graft, and dental implant placement may provide a new option for minimally invasive transcrestal sinus surgery with minimal patient discomfort. A physiologic contraction of 13.9% of the original volume of the bone graft was experienced during healing. Long-term clinical studies are needed to confirm these preliminary results.

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Clarification

In the article by Chu et al (Flapless Postextraction Socket Implant Placement, Part 2: The Effects of Bone Grafting and Provisional Restoration on Peri-Implant Soft Tissue Height and Thickness—A Retrospective Study), in Volume 35, Number 6 (November/December), 2015, a clarification is needed. Part 1 of the study (Tarnow et al, Flapless Postextraction Socket Implant Placement in the Esthetic Zone: Part 1. The Effect of Bone Grafting and/or Provisional Restoration on Facial-Palatal Ridge Dimensional Change—A Retrospective Cohort Study, in Volume 34, Issue 3 [May/June], 2014) states that "Forty-nine patients with anterior maxillary extraction sockets were treated with postextraction socket implant placement." Part 2 says that "As reported in Part 1 of this study, 45 anterior maxillary extraction sockets in 44 patients were treated with immediate implant placement." The reason for the discrepancy in number of extraction sites is that for the second article, data was not available for five of the sites included in Part 1.