KEY WORDS
atrophic maxilla, sinus lift, patient morbidity, patient preference

Randomised controlled trial

CRESTAL *VERSUS* LATERAL SINUS LIFT: ONE-YEAR RESULTS FROM A WITHIN-PATIENT RANDOMISED CONTROLLED TRIAL

ERTA XHANARI, DDS
Department of Implantology and Prosthetic Aspects, Aldent University and private practice, Tirana, Albania

MARCO TALLARICO, DDS, MSC
Adjunct Professor Department of Implantology and Prosthetic Aspects, Master of Science in Dentistry Programme, Aldent University, Tirana, Albania, and private practice, Rome, Italy

SILVIO MARIO MELONI, DDS, MSC, PHD
Assistant Professor, Surgical, Medical and Experimental Science Department, University of Sassari, Sassari, and private practice in Arzachena, Italy

ZAMIRA KALEMAJ, DDS, PHD, MSC
Private practice, Milan, Italy

FRANCESCO MATTIA CERUSO, DDS
Assistant Professor, Department of Dentistry "Fra G.B. Orsenigo - Ospedale San Pietro F.B.F.", Rome, Italy

EDLIRA DEDAJ, DDS, PHD
Researcher, Restorative Dentistry, Endodontics and Periodontology Department, Dental Sciences Faculty, Aldent University, Tirana, Albania

MARCO ESPOSITO, DDS, PHD
Freelance researcher and Associate Professor, Department of Biomaterials, The Sahlgrenska Academy at Göteborg University, Göteborg, Sweden

Correspondence to:
Marco Esposito
Casella Postale 34, 20862 Arcore (MB), Italy
Email: espositomarco@hotmail.com

PURPOSE. To compare the effectiveness of and patient preference for crestal *versus* lateral sinus lift.

MATERIALS AND METHODS. Fifteen partially edentulous patients missing bilateral maxillary molars and/or premolars and having 2 to 6 mm of residual crestal height below the maxillary sinuses were randomised to receive one to three implants placed in sinuses crestally or laterally lifted with bone substitutes according to a split-mouth design. Implants were submerged and loaded after 6 months with definitive screw-retained metal-ceramic prostheses, and patients were followed-up to 1 year after loading.

RESULTS. Twenty crestal implants were placed *versus* 23 lateral ones. One patient dropped out and one lateral implant failed (n = 14; difference = 0.07, 95% CI from -0.28 to 0.13; P = 0.99). No prosthesis failed. Three patients were affected by three complications at crestal *versus* three patients by four complications at lateral sites. The difference was not statistically significant (n = 14; Diff = 0.07; 95% CI -0.24 to 0.38; P-value = 0.99). Statistically significantly less time was required to place crestal implants (28.2 *versus* 62.2 minutes on average; Diff = 33.4; SD = 12.1; 95% CI -40.4 to 26.4; P = 0.001). Eight patients preferred the crestal procedure and six had no preference. Crestal implants lost 0.99 mm (SD = 0.55) of peri-implant bone height *versus* 1.02 mm (SD = 0.57) for lateral ones, the difference being not statistically significant (0.03 mm; 95% CI of difference -0.52 to 0.59; P = 0.89)

CONCLUSIONS. Both techniques produced successful outcomes, but the crestal technique required less surgical time and was preferred by patients.

CONFLICTS OF INTEREST STATEMENT. This trial was partially supported by Maxillent (Herzliya, Israel), the manufacturer of the implants employed in this investigation; however, data belonged to the authors and the manufacturer by no means interfered with the conduct of the trial or the publication of the results.

INTRODUCTION

Reduced bone volumes below the maxillary sinuses limit the possibility of placing dental implants for supporting fixed prostheses. However, the bone inside the maxillary sinus can be augmented using sinus lift procedures to solve this problem. The first of these sinus lift procedures was described in 1980[1]; a lateral window is opened into the maxillary sinus, the sinus epithelium is carefully lifted up, and autogenous bone (or bone substitute) is placed into the sinus and allowed to heal for about 6 months or more before placing the implants. The lateral window sinus lift technique is one of the most commonly performed augmentation procedures and is considered one of the most reliable, particularly when autogenous bone is used[2,3].

Doi: 10.36130/CTD.01.2019.06

While patients with extremely atrophic subantral bone could be good candidates for major sinus lift procedures[4], there is some controversy on how to treat patients with "intermediate" amounts of bone below the maxillary sinuses. A less invasive technique for sinus augmentation was described by Tatum[5] in 1986 and modified by Summers[6] in 1994. The main difference with the lateral window technique is that the sinus membrane is lifted through the crestal bone using osteotomes of increasing diameters, and implants are inserted directly into the prepared sites[7]. The crestal approach technique has since been modified by Cosci[8] who introduced a series of atraumatic lifting drills of varying lengths to reduce the risk of perforation of the sinus lining during drilling of the implant site**.** These are only two of the numerous techniques currently used to augment the sinus through a crestal approach[9]. Another of these crestal sinus lift techniques consists of the elevation of the sinus membrane, via hydraulic pressure, using the implant itself, which, in addition, enables the insertion of bone graft material via the implant body (iRaise, Maxillent, Herzliya, Israel)[10].

While the crestal approach is less invasive, there are some potential disadvantages associated with this technique, such as the limited amount of bone that can be gained vertically, and the minimal amount of crestal bone height (about 3 mm) that is recommended to stabilise the implant at placement[8], even though absolute figures are still questionable. Hence, clinical research is now focussing on evaluating simpler and less invasive sinus lift procedures.

It is unclear whether any of the various crestal sinus lift procedures currently used is advantageous or superior to the others[11]. It would be interesting, therefore, to investigate whether a potentially less invasive technique for crestally lifting maxillary sinuses with residual bone heights between 2 to 5 mm could provide as good results or even better than the lateral window technique. The aim of this randomised controlled trial (RCT) of split-mouth design was therefore to compare the patient preference for and effectiveness of two different techniques for lifting the maxillary sinus: the crestal approach *versus* the lateral window approach. The present article is reported according to the CONSORT statement (http://www.consort-statement.org/) and its extension checklist for reporting within-person randomised trials (http://www.consort-statement.org/extensions/overview/withinperson) to improve the quality of reports of within-person randomised controlled trials.

MATERIALS AND METHODS

Trial design

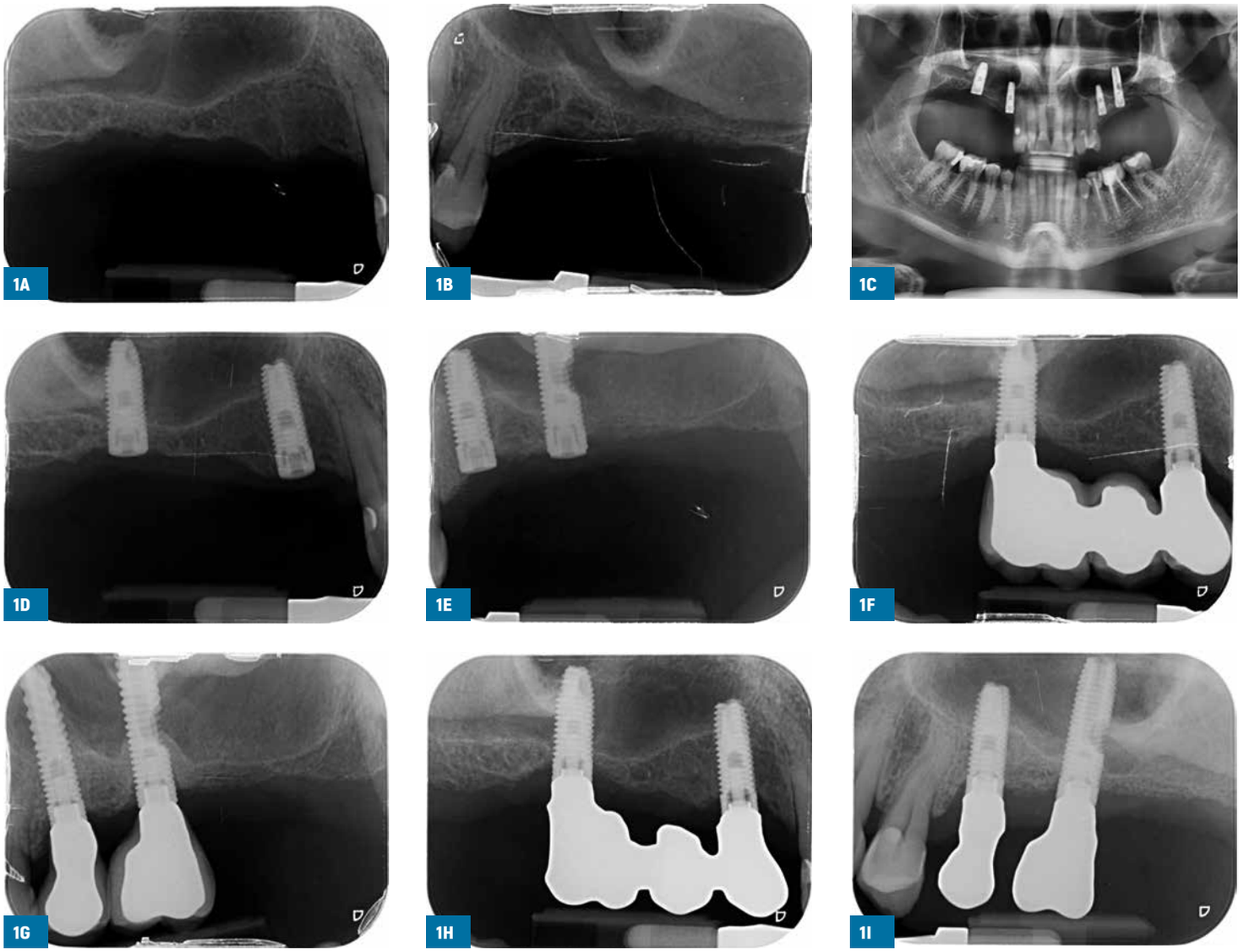
This was a single centre RCT of within-person design evaluating two different interventions with blind assessment. Each patient had both sides of the posterior maxilla randomised to receive one partial fixed prosthesis supported by one to three implants placed either with a crestal or with lateral window sinus lift procedure **(FIGS. 1A-I)**.

Eligibility criteria for participants

Any partially edentulous patient having bilateral edentulism in the posterior maxillae (premolars and/or molars) with a similar degree of bone resorption requiring one to three implants, being 18 years or older, and able to understand and sign informed consent was considered eligible. Only healed implant sites were considered (at least 3 months after tooth extraction). The vertical bone height at the implant sites to be included had to be between 2 to 6 mm, alongside bone thickness of at least 6 mm, as measured on cone-bean computed tomography (CBCT) scans.

Patients were not included in the study if any of the following exclusion criteria was present:

- General contraindications to implant surgery;
- Any irradiation of the head and neck area;



Figs. 1A-I: *Preoperative periapical radiographs of one patient treated in the study: A) the right quadrant was randomly allocated to the lateral sinus lift and, consequently, B) the left quadrant to the crestal sinus lift procedure; C) postoperative panoramic radiograph showing two study implants (the distal ones) and two additional implants. This patient represents a protocol deviation since the study implant at the lateral window treated side should not have been connected to the additional implant under the same prosthesis; D) and E) baseline periapical radiographs; F and G) periapical radiographs at initial loading with the definitive prostheses; H) and I) periapical radiographs at 1 year after loading.*

- Immunosuppression or immunocompromised;
- Past or ongoing treatment with intravenous aminobisphosphonates;
- Poor oral hygiene and motivation;
- Untreated periodontal disease;
- Uncontrolled diabetes;
- Pregnancy or breast-feeding;
- Substance misuse;
- Psychiatric problems;
- Unrealistic expectations;

- Lack of opposing occluding dentition, or prosthesis in the area intended for implant placement;
- Acute or chronic infection/inflammation in the area intended for sinus augmentation/implant placement;
- Referrals for implant placement alone (unavailability for rehabilitation and follow-up at the study treatment centre);
- Inability to attend a 5-year post-loading follow-up.

Smokers were included, and patients were categorised into three groups according to their declarations: 1) non-smokers; 2) moderate smokers, if smoking up to 10 cigarettes/day; 3) heavy smokers, if smoking more than 10 cigarettes/day.
Patients were recruited and treated in one private practice in Tirana, Albania by two operators: Marco Tallarico (MT), who performed all surgical interventions, and Erta Xhanari (EX), who performed all prosthetic and maintenance procedures.
The principles outlined in the Declaration of Helsinki on clinical research involving human subjects were adhered to. The study protocol was approved by the Ethics Committee of Our Lady of Good Counsel University in Tirana on 26th July 2016 (Protocol n° 1/2016). All patients received thorough explanation and signed an informed written consent form prior to their enrolment in the trial. After informed consent was signed, the operator selected one maxilla side of their choice as side number 1.

Surgical procedures

Intranasal spray antibiotic (thiamphenicol glycinate acetylcysteinate, TGA, 810 mg/4 mL) and cortisone (betamethasone 1 mg) was administered twice a day starting the day before surgery. Patients received further prophylactic antibiotics: 2 g of amoxicillin (875 mg) + clavulanic acid (125 mg), or clyndamicin 600 mg if allergic to penicillin, one hour before the intervention. Patients rinsed for one minute with chlorhexidine mouthwash 0.2% prior to any clinical procedures, and were treated under local anaesthesia using articaine with 1:100,000 adrenaline. Both sinuses were to be treated during the same surgical session.

Opening of the sealed envelopes and group allocation

The sealed envelope containing the group allocation code corresponding to the recruitment number of the patient was opened, and the surgeon treated site number one with the technique (crestal or lateral sinus lift) indicated. After the procedure was completed, the contralateral side was treated with the other technique, during the same session.
A crestal incision coupled to one or two buccal releasing incisions was made to expose the alveolar ridge, and a full-thickness flap was raised. Implant position and inclination were guided by surgical templates.

Crestal sinus lift

Only one iRaise Sinus Lift implant (Maxillent, Herzliya, Israel) was used in each augmented side. iRaise implants have a tapered body with a specific internal l-shaped channel allowing the hydraulic lifting of the sinus membrane and the delivery of bone substitute gel. The channel has a diameter of 1.5 mm, and is isolated from the prosthetic connection and the oral cavity. These implants, made of titanium-6 aluminum-4 vanadium alloy, have a surface treated via grit-blasting using an apatitic calcium phosphate media, followed by acid etching, and have an internal hexagonal connection. Additional conventional iSure implants (Maxillent) were also placed in the same quadrant, and those placed in 2 to 6 mm of subantral bone height were included in the study.

Implant sites were marked with the marking drill at 800 rpm. To begin the osteotomy, an Initial drill was used at 800 rpm up to 3 mm deep, until it stopped or reached the cortical bone. When necessary, iRaise Drill Stoppers were used to limit the drilling depth. The flat drill was then used until the sinus floor cortex was reached. A flat depth guide was used to check the osteotomy depth and angulation. Finally, the cortex drill was used to abrade the remaining sinus cortex at 2000 rpm. The integrity of the sinus lining was assessed visually, using a blunt instrument and the Valsalva manoeuvre. Any laceration or perforation of the Schneiderian membrane was to be recorded, and the intervention aborted. The length of the iRaise implants (14.5 and 16 mm, the latter used only in the presence of 5 to 6 mm subantral bone height) had previously been selected based on the residual bone height at the planned implant sites from the bone crest to the floor of the sinus; residual bone heights were measured on the preoperative CBCT scans along the planned implant axis.

iRaise implants were inserted into the osteotomy site up to their entire working lengths, leaving the lateral tubing port outside the bone. The single-use tube connector was screwed to the implant tubing port **(FIG. 2)**. With the exception of the silicone ring, the connector did not touch the implant. Two to 3 cm^3 of saline solution was gently injected into the sinus through the internal L-shaped channel, and then aspirated back into the syringe; next, a syringe filled with a flowable bone graft material (Micro-Macroporous Biphasic Calcium phosphate, MBCP Gel, Biomatlante, Vigneux-de-Bretagne, France) was connected to the same port. Two syringefuls, each of 1 ml (2 cm^3 total volume), of bone graft material with a granulometry ranging from 80–200 μm were slowly injected through the implant channel into the sinus, after mixing with 0.2 cc of 0.9% sterile saline solution; this graft material is a 100% synthetic injectable bone substitute composed of 60% biphasic calcium phosphate and 40% of hydroxyapatite, suspended in a soluble polymer. After completing the grafting procedure, the hydraulic system was disconnected from the implant, and the full length of the implant was inserted until the coronal portion was flush with the surrounding crestal bone. After having placed the iRaise implants, additional iSure implants (Maxillent) were placed; those inserted in subantral bone heights of greater 6 mm were not considered in the present investigation.

Fig. 2: *Example on how i-Raise implants were used at crestally lifted sites, The tube connector was screwed to the implant tubing port to allow the passage into the sinus, through the internal L-shaped channel of saline solution first and then of the flowable bone graft.*

Lateral window sinus lift

A window was delineated on the lateral wall of the sinus with a bur, under abundant saline irrigation. The bone was gently removed, layer by layer, using a piezo-surgical device (Piezotome 2 Acteon, Novaxa SPA, Milan, Italy), until a bluish line, indicating the sinus membrane, appeared around the entire outline of the window **(FIG. 3)**. The bone in the window was gently tapped with a blunt instrument until it fractured completely, and was then internally displaced after having carefully detached the maxillary membrane from the sinus bone using proper curettes, starting from the borders of the window and then proceeding towards the floor of the sinus. The sinus membrane was lifted, allowing the placement of implants of length at least 10 mm.

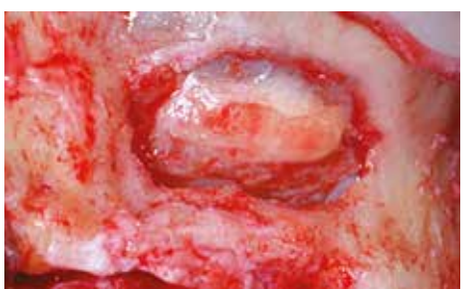


Fig. 3: *Preparation of the lateral sinus window.*

Once the implant sites had been prepared, the sinus lining was examined for any perforations, as discussed above. In the presence of laceration of the Schneiderian membrane, the established protocol required placement of a resorbable collagen barrier (Bio-Gide, Geistlich Pharmaceutical, Wolhusen, Switzerland) in order to contain the graft. If this was not possible, the operation was to be aborted and repeated after a healing period of at least 2 months. The space between the base of the sinus bone and the sinus membrane was filled with granules of anorganic bovine bone (Bio-Oss, small granules, 0.25 to 1 mm, Geistlich Pharmaceutical). One to three 10 to 13 mm-long iSure (Maxillent) implants were inserted, until the coronal portion was flush with the surrounding crestal bone; these implants are similar to the iRaise

implants but do not have the specific internal L-shaped channel. After having completely seated the iSure study implants, additional implants were placed in sites with subantral bone height greater than 6 mm, but these were not be considered in the present investigation. The remaining empty spaces in the sinus cavity were gently packed with Bio-Oss, and resorbable collagen membranes (BioGide) were used to seal the lateral windows.

Cover screws were placed, and all implants were submerged. Flap closure was achieved using Vicryl 4.0 (Ethicon, Padua, Italy). Periapical radiographs and clinical photographs of the study implants were taken. If the peri-implant marginal bone levels were distorted or not clearly visible, a second radiograph was to be taken.

Patients were instructed to continue the prophylactic antibiotic therapy, 875 mg amoxicillin + 125 mg clavulanic acid or 300 mg clindamycin if allergic to penicillin, twice a day for 6 days. Ibuprofen 400 mg analgesic tablets (or 1 g paracetamol if allergic to ibuprofen) were prescribed, to be taken 2 to 4 times a day during meals as long as required. Patients were also prescribed intranasal spray (thiamphenicol glycinate acetylcysteinate 810 mg/4 mL) and cortisone (betamethasone 1 mg) for 10 days after the sinus lift procedure, and instructed to avoid blowing the nose and using drinking straws, and to try to keep the mouth open when sneezing in order to decrease intra-sinus pressure. Patients were also instructed to use 0.2% chlorhexidine mouthwash for one minute twice a day for 2 weeks, to avoid brushing or trauma at surgical sites, and not to wear any removable dentures that could press on the areas operated on for 1 month.

Patients were seen after 1 week for suture removal, and were asked about their preference regarding the two procedures. One month after implant placement, patients were checked again, and were again asked which of the two procedures they preferred.

After 6 months of submerged healing, local anaesthesia was given and implants were exposed via a crestal incision 2 mm palatal to the centre of the implants, and manually tested for stability. Healing abutments and, if needed, sutures were placed. Patients were instructed to rinse with chlorhexidine mouthwash 0.2% for 1 minute twice a day for 2 weeks, and to take 400 mg ibuprofen, or 1 g paracetamol if allergic to ibuprofen, 2 to 4 times a day during meals if they experienced pain. After 2 weeks, occlusion was registered, and impressions with the pick-up impression copings at implant level were taken using a polyether material (Impregum 3M/ESPE, Neuss, Germany) and customised resin impression trays. Models were made with grade 4 precision plaster and mounted in a standard articulator. Within 1 week, definitive screw-retained metal-ceramic crowns or partial fixed prostheses rigidly joining the two or three study implants were delivered. Additional implants in more than 6 mm of bone height were not to be joined under the same fixed prosthesis together with the study implants, and were not evaluated in the present study. The occlusal ceramic surface was in slight contact with the opposing dentition. Periapical radiographs and clinical pictures of the study implants were taken, and oral hygiene instructions delivered as required. One week after, the prostheses were checked, and patients were given additional oral hygiene instructions. Patients were enrolled in an oral hygiene maintenance programme with recall visits every 4 months.

Outcome measures

This study tested the null hypothesis that there would be no differences between the two procedures against the alternative hypothesis of a difference. Outcome measures are listed below.

- Prosthesis failure: planned prosthesis which could not be placed due to implant failure(s), loss of the prosthesis secondary to implant failure(s), or a prosthesis that had to be remade for any reason.

- Implant failure: implant mobility, removal of stable implants dictated by progressive marginal bone loss or infection, implant fracture, or any other mechanical complication rendering the implant unusable. The stability of each individual implant was measured with the prosthesis removed at the abutment junction at delivery of the permanent prostheses and at 1 year after loading, by tightening the implant abutment screws with a torque of 20 Ncm or by assessing the stability of individual crowns using the handles of two metallic instruments.
- Any biological or prosthetic complications occurring during the entire follow-up period. Complications were assessed and treated by EX, who was not masked to group allocation.
- Patient preference, as assessed 1 week and 1 month after surgery, and 1 year after loading, by a blinded independent assessor asking patients which treatment they preferred; possible answers were: 1) the side treated with the crestal technique, 2) the side treated with the lateral technique, 3) none, both treatments were equally good, 4) none, both treatments were equally bad.
- Time necessary to complete the augmentation procedures (expressed in minutes) starting from the surgical incision to application of the last suture, including the additional implants.
- Peri-implant marginal bone level changes, as assessed on digital periapical radiographs taken using the paralleling technique at implant placement **(FIGS. 1D-E)**, prosthesis delivery **(FIGS. 1F-G)** and 1 year after loading **(FIGS 1H-I)** using a digital appliance (CS 2100, Carestream Dental, Rochester, NY, US). In the event of a radiograph not being properly readable, the radiograph was to be taken again. Radiographs were stored in TIFF format with 600-dpi resolution in a personal computer. Peri-implant marginal bone levels were measured using DFW 2.8 software for Windows (Soredex, Tuusula, Finland). The software was calibrated for each single image using the known implant diameter. The distance between marginal bone level and implant/abutment junction was measured to the nearest 0.01 mm at both mesial and distal sides and averaged. Bone level changes at single implants were averaged at both sinus and group level. Reference points for the linear measurements were: the coronal margin of the implant collar, and the most coronal point of bone-to-implant contact.

Two dentists (Edlira Dedaj and Onani Xhanari) not involved in the treatment of the patients made all clinical and radiographic measurements, respectively, without knowing group allocation; both outcome assessors were therefore masked.

Sample size calculation and randomisation

Sample size was calculated to detect a preference of one group over another against the alternative hypothesis that the treatments would be equally preferred. This reduces to a simple one-sample proportion scenario. A single-group chi-square test with a 0.050 two-sided significance level has 80% power to detect the difference between the null hypothesis proportion of 0.500 and the alternative proportion of 0.900 when the sample size is 10. Fifteen partially edentulous subjects with bilateral posterior maxillary atrophy were included in this study to compensate for possible drop-outs. A restricted randomisation list was computer generated. Only one of the investigators (Marco Esposito), not involved in the selection and treatment of the patients, was aware of the randomisation sequence, and had access to the randomisation list, stored in his password-protected laptop. The random codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. The sealed envelope containing the random code was opened after having anaesthetised the patient at site number 1. Site number 1 was treated as indicated in the envelope. The contralateral site was to be treated

with the other intervention during the same session; treatment allocation was therefore concealed from the investigators in charge of enrolling and treating the patients.

Statistical analyses

All data analysis was carried out according to a pre-established analysis plan. A dentist (Zamira Kalemaj) experienced in dental statistics analysed the data without knowing the group codes. Differences in the proportion of patients with prosthesis failures, implant failures, and complications (dichotomous outcomes) were compared between groups using the McNemar chi-square test (one implant failure or complication counted as a failure for that group within that patient). Differences between continuous outcomes such as operation time or marginal bone levels were evaluated using a paired t-test. A single-sample test of proportions was used to estimate differences in intervention preferences at 1 week, 1 month and 1 year post-intervention. Comparative tests were estimated at a 0.05 level of significance. All statistical analyses were conducted using Stata 13 (Stata Statistical Software, release 13.0, StataCorp).

RESULTS

Sixteen patients were screened for eligibility, but one patient could not be enrolled in the trial because he declared he was unable to attend the follow-ups regularly. Fifteen patients were considered eligible and were consecutively enrolled in the trial. Patients were recruited and subjected to the sinus lift procedures from October 2016 to September 2017. The follow-up of all patients was 1 year after initial prosthetic loading.

All patients were treated according to the allocated interventions. One patient dropped out having moved to Asia just after prosthesis delivery, and failed to attend the 1-year follow-up; however, that patient was contacted by phone and reported that everything was fine. Data from all remaining patients were evaluated in the statistical analyses. The following deviations from the protocol were observed: originally, only patients with sites having subantral bone heights of 2 to 5 mm were to be included, but clinicians decided to include also patients having up to 6 mm bone height (seven crestal and five lateral sides); due to this increase in bone height, 16 mm-long iRaise implants were also used, while it was originally planned to use only 13 and 14.5 mm-long implants. In addition, the actual residual subantral bone height of the study implants to be included in the study should have been measured clinically at implant placement, but this was not performed, and instead bone heights were estimated on preoperative CBCT. At crestal sides, five patients had study implants joined under the same prosthesis with additional implants. For one patient, panoramic radiographs instead of periapical radiographs were taken at loading and 1 year after loading. Measurements were not made on the panoramic radiographs. At lateral window sites, only 13 mm-long implants should have been used; however only one 13 mm-long implant was placed, all the others being 10 and 11.5 mm long. Five patients had study implants joined under the same prosthesis with additional implants (for four patients this protocol deviation was bilateral). Two patients in the lateral window sinus lift group did not receive implants at the same time as sinus floor augmentation due to the lack of primary implant stability; one implant in each patient was unstable and therefore removed. These patients received their implants 6 months later than planned. For one patient in this group, panoramic radiographs instead of periapical radiographs were taken at loading and 1 year after loading.

The mean patient age at the time of the augmentation procedure was 51.5 years (range 36 to 76), and there were five females and 10 males. Three patients declared they smoked up to 10 cigarettes per day, two more than 10, and 10 declared themselves to be non-smokers. The implant sites characteristics are summarised in **TABLE 1**. In total, 29 implants were placed in

crestal sites and 30 at lateral sites (two additional implants were removed at placement, being unstable); however, there were 20 and 23, study implants, meaning those placed in 2 to 6 mm subantral bone height, respectively, and these were the only implants assessed in the present study. The residual mean bone height at the study implant sites, estimated on preoperative CBCT scans, was 4.8 mm (SD = 1.15) at crestal sites and 4.2 mm (SD = 1.14) at lateral sites, with no significant difference between sites (P = 0.13). However, implants placed at crestally lifted sites were longer that those placed in sinuses lifted with the lateral window technique (n = 15, Diff. = 4.32 mm, CI 3.4 to 5.2; P-value = 0.001).

- Implant and prosthesis failures: one implant from the lateral group, in position 26, failed. It was found to be painful and mobile at second-stage surgery and was therefore removed. It was replaced 2 months later. There were no difference in implant failures between the two groups (n = 14; difference = 0.07, 95% CI from -0.28 to 0.13; P = 0.99). No prosthesis failed.
- Complications: three patients were affected by three complications at crestal *versus* three patients by four complications at lateral sites. The difference was not statistically significant (n = 14; Diff. = 0.07; 95% CI -0.24 to 0.38; P-value = 0.99). In addition to the pain reported at the failed implant in the lateral group, two patients experienced the same bilateral complication: pain for 4 weeks after implant placement. They were merely treated with analgesics and were checked every 3 to 4 days until spontaneous resolution of the symptoms. Moreover, one patient in each group showed a minor cusp chipping noticed 1 year after loading; these were treated with chairside polishing. The chip noted at the lateral side affected one of the patients who had previously experienced prolonged bilateral pain after sinus lift. Only one complication occurred at implants not examined in the study. One prosthesis screw loosened 7 months after prosthesis delivery (crestal group). It was replaced with a new screw.

TABLE 1 BASELINE INTERVENTION CHARACTERISTICS OF THE 15 PATIENTS INCLUDED

	Crestal sinus lift	Lateral window
Total number of inserted implants	29	30 + 2 removed since unstable at insertion
Total number of implants inserted in 2 to 6 mm of subantral bone height (study implants)	15 iRaise + 5 iSure	23 iSure
Sites receiving 1 study implant	10	8
Sites receiving 2 study implants	5	6
Sites receiving 3 study implants	0	1
Number of 14.5 mm-long iRaise implants	7	0
Number of 16 mm-long iRaise implants	8	0
Number of 10 mm-long iSure implants	4	19
Number of 11.5 mm-long iSure implants	0	3
Number of 13 mm-long iSure implants	1	1
Number of 3.75 mm-diameter implants	1	2
Number of 4.2 mm-diameter implants	14	20
Number of 5 mm-diameter implants	5	1
Mean residual bone height (mm) at implant sites (SD) on preoperative CBCT scans	4.8 (1.15)	4.2 (1.14)

SD = standard deviation.

- Patient preference: one week after surgery, eight out of 15 patients reported preferring the side treated with the crestal technique and seven had no preference (two patients disliking both interventions). One month after surgery, seven out of 14 patients preferred the side treated with the crestal technique, and seven had no preference (two patients disliking both interventions). One year after loading, eight out of 14 patients preferred the side treated using the crestal technique and six had no preference (one patient disliking both interventions). A single-sample proportion test indicated the crestal technique as the preferred intervention at all time-points (1-week P-value=0.004, 1-month P-value=0.008, 1-year P-value=0.004).
- Time necessary to complete the augmentation procedures: the operating time was on average 28.8 minutes (SD = 5.1) for the crestal technique and 62.2 minutes (SD = 12.3) for the lateral technique, the difference of an average 33.4 minutes (SD = 12.1) being statistically significant in favour of the crestal technique (P = 0.001; 95% CI -40.4 to 26.4).
- Peri-implant marginal bone level changes: at implant placement, baseline peri-implant bone levels were 0.42 mm (SD = 0.61) for crestal and 0.31 mm (SD = 0.41) for lateral window sites **(TABLE 2)**. The difference between baseline values was not significant (t-test P-value = 0.49). Both groups lost significant peri-implant marginal bone up to 1 year in function (0.99 mm; SD=0.55 for crestal and 1.02 mm; SD = 0.57 for lateral) with no statistically significant differences between the groups (difference 0.03 mm; 95% CI of difference -0.52 to 0.59; P = 0.89; **TABLE 3**).

TABLE 2 MEAN PERI-IMPLANT BONE LEVELS BETWEEN GROUPS AND TIME POINTS

	Placement	Loading	1-year
	N Mean (SD)	N Mean (SD)	N Mean (SD)
Crestal lift	15 0.42 (0.61)	13 1.18 (0.64)	13 1.41 (0.59)
Lateral window	15 0.31 (0.41)	13 1.18 (0.49)	13 1.33 (0.56)
Mean difference (SD)	0.11 (0.16)	0 (0.14)	0.08 (0.2)
95% CI of difference	-0.47 to 0.24	-0.32 to 0.31	-0.53 to 0.38
P values	0.498	0.991	0.723

TABLE 3 MEAN PERI-IMPLANT CHANGES BETWEEN GROUPS AND TIME POINTS

	Placement-loading	Placement-1 year
	N Mean (SD)	N Mean (SD)
Crestal lift	13 0.77 (0.53)	13 0.99 (0.55)
Lateral window	13 0.88 (0.59)	13 1.02 (0.57)
Mean difference (SD)	0.11 (0.21)	0.33 (0.26)
95% CI of difference	-0.34 to 0.56	-0.52 to 0.59
P values	0.597	0.894

DISCUSSION

This split-mouth RCT was designed to evaluate which sinus lift technique, crestal or lateral window, would be more effective and preferred by patients. The split-mouth design made it possible for patients to express their preference, since they could experience both procedures. Both techniques were clinically successful, and able to achieve the planned goals, with no major complications occurring in either case. However, the crestal technique required half an hour less to be completed on average, and was preferred by patients. From a clinical point of view, to reduce the surgical component of the intervention by half an hour is surely appreciated by patient, as reflected by the patient preference.

Patient preference remained substantially stable over the entire follow-up period, with slightly more than half of the patients preferring the crestal approach and none preferring the lateral approach. The remaining patients showed no preference for either of the techniques. Clinicians should take into serious consideration patient preference when opting for alternative techniques providing similar clinical outcomes. Indeed, taking all these factors in consideration, we would choose to treat patients requiring a sinus lift with the faster procedure that gives patients the least discomfort, as the final clinical outcome appears to be similar. Interestingly there is one 5-year follow-up RCT[12] that compared a modified Cosci crestal sinus lift procedure with a 1-stage lateral window sinus lift procedure. The results of this trial also suggested that the less invasive crestal sinus procedure and 8 mm-long implants can achieve similar, if not better, results than a more invasive procedure involving the placement of longer implants, even when implants were loaded early, 6 weeks after their placement.

The main limitations of the present trial are some of the deviations from protocol, especially the inclusion of sites based on preoperative CBCT scans instead of intrasurgical measurement, and the inclusion of subantral bone heights up to 6 mm, etc., which could have been treated with less invasive procedures like short implants[13-18]. Another limitation was the small number of patients included. All that being said, both sinus lift techniques, as well as the implants used in the present investigation, had good clinical outcomes with few complications and failures. Both techniques were tested under real clinical conditions, and patient inclusion criteria were rather broad, meaning that the results of the present trial are likely generalisable to patients having similar characteristics. However, the operating surgeon was very experienced in both techniques, and this factor might limit generalisation of the findings.

CONCLUSIONS

Within the limits of this trial, both sinus lift procedures produced successful results over a 1-year follow-up period, but the crestal technique required less surgical time and was preferred by patients.

ACKNOWLEDGEMENTS

We thank Dr. Doniano Xhanari for assessing the periapical radiographs.

REFERENCES

1. Boyne PJ, James RA. Grafting of the maxillary sinus floor with autogenous marrow and bone. Journal of Oral Surgery 1980;38:613-6.
2. Wallace SS, Froum SJ. Effect of maxillary sinus augmentation on the survival of endosseous dental implants. A systematic review. Annals of Periodontology 2003;8:328-43.
3. Del Fabbro M, Testori T, Francetti L, Weinstein R. Systematic review of survival rates for implants placed in the grafted maxillary sinus. The International Journal of Periodontics and Restorative Dentistry 2004;24:565-77.
4. Brånemark PI, Gröndahl K, Öhrnell LO, Nilsson P, Petruson B, Svensson B, Engstrand P, Nannmark U. Zygoma fixture in the management of advanced atrophy of the maxilla: technique and long-term results. Scandinavian Journal of Plastic and Reconstructive Surgery 2004;38:70-85.
5. Tatum HJ. Maxillary and sinus implant reconstructions. Dental Clinics of North America 1986;30:207-29.
6. Summers RB. A new concept in maxillary implant surgery: the osteotome technique. Compendium of Continuing Education in Dentistry 1994;15:152-8
7. Emmerich D, Att W, Stappert C. Sinus floor elevation using osteotomes: a systematic review and meta-analysis. Journal of Periodontology 2005;76:1237-51.
8. Cosci F, Luccioli M. A new sinus lift technique in conjunction with placement of 265 implants: a 6-year retrospective study. Implant Dentistry 2000;9:363-8.
9. Esposito M, Cannizzaro G, Cosci F, Soardi E, Felice P. Cosci *versus* Summers technique for crestal sinus lift: 3-year results from a randomised controlled trial. European Journal of Oral Implantology 2014;7(2):129-37.
10. Tallarico M, Cochran DL, Xhanari E, Dellavia C, Canciani E, Mijiritsky E, Meloni SM. Crestal sinus lift using an implant with an internal L-shaped channel: 1-year after loading results from a prospective cohort study. European Journal of Oral Implantology 2017;10:325-36.
11. Esposito M, Felice P, Worthington HV. Interventions for replacing missing teeth: augmentation procedures of the maxillary sinus. Cochrane Database of Systematic Reviews 2014. Chichester, UK: John Wiley & Sons, Ltd.
12. Cannizzaro G, Felice P, Minciarelli AF, Leone M, Viola P, Esposito M. Early implant loading in the atrophic posterior maxilla: 1-stage lateral *versus* crestal sinus lift and 8 mm hydroxyapatite-coated implants. A 5-year randomised controlled trial. European Journal of Oral Implantology 2013;6:13-25.
13. Felice P, Barausse C, Pistilli R, Ippolito DR, Esposito M. Five-year results from a randomised controlled trial comparing prostheses supported by 5 mm long implants or by longer implants in augmented bone in posterior atrophic edentulous jaws. International Journal of Oral Implantology 2019;12:25-37.
14. Felice P, Pistilli R, Barausse C, Piattelli M, Buti J, Esposito M. Posterior atrophic jaws rehabilitated with prostheses supported by 6 mm long 4 mm wide implants or by longer implants in augmented bone. Five-year post-loading results from a randomised controlled trial. International Journal of Oral Implantology 2019;12:57-62.
15. Esposito M, Barausse C, Pistilli R, Piattelli M, Di Simone S, Ippolito DR, Felice P. Posterior atrophic jaws rehabilitated with prostheses supported by 5x5 mm implants with a nanostructured calcium-incorporated titanium surface or by longer implants in augmented bone. Five-year results from a randomised controlled trial. International Journal of Oral Implantology 2019;12:39-54.
16. Guljé FL, Raghoebar GM, Vissink A, Meijer HJA. Single crowns in the resorbed posterior maxilla supported by either 11-mm implants combined with sinus floor elevation surgery or by 6-mm implants: a 5-year randomised controlled trial. International Journal of Oral Implantology 2019;12:315-26.
17. Gastaldi G, Felice P, Pistilli R, Barausse C, Ippolito DR, Esposito M. Posterior atrophic jaws rehabilitated with prostheses supported by 5x5 mm implants with a nanostructured calcium-incorporated titanium surface or by longer implants in augmented bone. Three-year results from a randomised controlled trial. European Journal of Oral Implantology 2018;10:49-61.
18. Bolle C, Felice P, Barausse C, Pistilli R, Trullenque-Eriksson A, Esposito M. Four mm-long *versus* longer implants in augmented bone in posterior atrophic jaws: One year post-loading results from a multicentre randomised controlled trial. European Journal of Oral Implantology 2018;10:31-47.