KEY WORDS
Full arch prosthesis, Immediate loading, Maxillary atrophy, Tilted implants, Trans-sinus implant

Randomized controlled trial

IMMEDIATE FIXED REHABILITATION OF SEVERE MAXILLARY ATROPHY USING TILTED TRANS-SINUS IMPLANTS WITH OR WITHOUT SINUS BONE GRAFTING: FOUR-YEAR RESULTS FROM A RANDOMIZED CONTROLLED TRIAL

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PURPOSE. The aim of this trial was to compare the clinical outcomes of tilted trans-sinus implants with or without simultaneous sinus lift for immediate full arch rehabilitation of severe maxillary atrophy.

MATERIALS AND METHODS. Thirty-two subjects were enrolled in this trial for an immediately loaded fixed restoration supported by four or six implants. They were randomized to receive at least one trans-sinus implant without simultaneous bone grafting (group 1, n = 16) or one trans-sinus implant with sinus lift bone grafting (group 2, n = 16). Primary outcomes considered were prosthesis and implant failures, while secondary outcomes were complications and peri-implant marginal bone level changes.

RESULTS. Forty-one trans-sinus implants (23 trans-sinus implants without simultaneous bone grafting and 18 trans-sinus implants with sinus lift), 23 conventional tilted implants and 84 axial implants were inserted. No drops-out occurred. Four years after loading, no prosthesis was lost. One trans-sinus implant failed in the sinus lift group, but there was no statistically significant difference in implant failure between the two groups at patient level (0.0% *vs.* 6.3%, difference 6.3 %; 95% CI -4.7, 17.3; P = 0.99). No conventional tilted implants or conventional straight implants were lost. Complications occurred in nine patients in the group without bone grafting *versus* ten patients in the sinus lift group. No statistically significant differences were found in this regard either between groups (patient level, 9/16 *vs.* 10/16, 56.2% *vs.* 62.5%, difference 6.3%; 95% CI: -12.9, 25.8; P = 0.99) or the four different centres (50% *vs.* 62.5% *vs.* 50% *vs.* 75%, P = 0.99). Similarly, there were no significant differences in peri-implant marginal bone level changes between either groups (P = 0.67; difference 0.25 mm; 95% CI -0.23, 0.63) or centres (P = 0.695). Considering only trans-sinus implants, no statistically significant difference between the two treatment strategies was observed in peri-implant bone loss (P = 0.55).

CONCLUSIONS. No statistically or clinically significant differences were observed in outcomes between tilted trans-sinus implants supporting cross-arch immediately loaded fixed prostheses in atrophic maxillae placed either without simultaneous bone-grafting or with sinus lift four years after loading. However, longer follow-ups on a larger sample are needed.

CONFLICT OF INTEREST STATEMENT
Tommaso Grandi serves as a consultant for JDentalCare. This study was completely self-financed, and no funding was either sought or obtained, not even in the form of free materials.

INTRODUCTION

Progressive maxillary atrophy caused by loss of teeth, periodontal disease, pneumatization of the sinus, maxillectomy operations or anatomical anomalies may lead to functional deficiency, chewing difficulties, and aesthetic issues to due to changes in the facial features. Rehabilitation of an edentulous maxilla by means of dental implants can be easily implemented in the presence of sufficient bone volume[1], but is challenging in severe atrophy due to the scarce quantity of residual bone[2]. In cases of reduced bone volume, possible solutions are the use of short implants[3], cantilevered prostheses[4], tilted implants, pterygoid implants, zygomatic implants, and augmentation procedures, including sinus floor augmentation[5]. To overcome insufficient bone volume, grafting procedures are performed prior to or simultaneously with implant placement[6], but these have some potential disadvantages like prolonged healing time, complications such as infection, high costs, and increased patient morbidity.

Pterygoid implants, zygomatic implants, trans-sinus implants and tilted implants have been used as alternatives to sinus augmentation procedures[7-18]. These treatment options are based on anchoring implants in the remaining native bone, and may be considered for patients who cannot undergo bone grafting procedures for financial, psychological or clinical reasons. However, the choice of the most appropriate solution for treating severe maxillary atrophy depends on patient anatomy, and the location and availability of the residual alveolar bone.

Recently, a new technique in which posterior implants are angled forward, passing through the sinus to engage the nasal cortical bone, has been reported. This technique may be useful when the insertion of conventional tilted implants is not possible, before resorting to zygomatic implants[14-19]. In particular, this treatment is suggested when there is insufficient bone height posterior to the canines to anchor and stabilize the implants, and when between 4 and 6 mm of residual crestal bone is present under the sinus floor in the premolar area. Trans-sinus implants can be and loaded immediately, after insertion either without sinus bone grafting, or with simultaneous sinus lift.

The aim of this randomized controlled trial (RCT) was to compare the clinical outcomes of tilted trans-sinus implants inserted with or without simultaneous sinus lift bone grafting to support immediately loaded prostheses for rehabilitation of the atrophic maxilla (**FIG. 1**). This report presents data recorded after four years of function, and is the continuation of a previous report published one year after loading[21], in which no statistically significant differences were observed between the two treatment strategies. The data is reported according to the CONSORT statement for improving the quality of RCT reports (http://www.consort-statement.org/).

MATERIALS AND METHODS

This was a multicentre RCT of parallel-group design conducted in four different private practices in Modena, Padua, Piacenza (Italy) and in Byblos (Lebanon). Thirty-two patients with either complete maxillary edentulism or terminal dentition with maxillary sinus pneumatization were selected to be treated using all-on-4 (four immediately loaded implants) or all-on-6 (six immediately loaded implants) procedures.

These maxillae had a particular anterior sinus wall anatomy that precluded the insertion of a tilted implant fully inside the bone in the premolar and molar regions on at least one side. Patients were randomly allocated into two groups to receive at least one trans-sinus implant inserted in either one side or both sides, depending on the maxillary anatomy, with or without simultaneous sinus lift bone augmentation.

Eligible patients were included in the study if the following criteria applied:

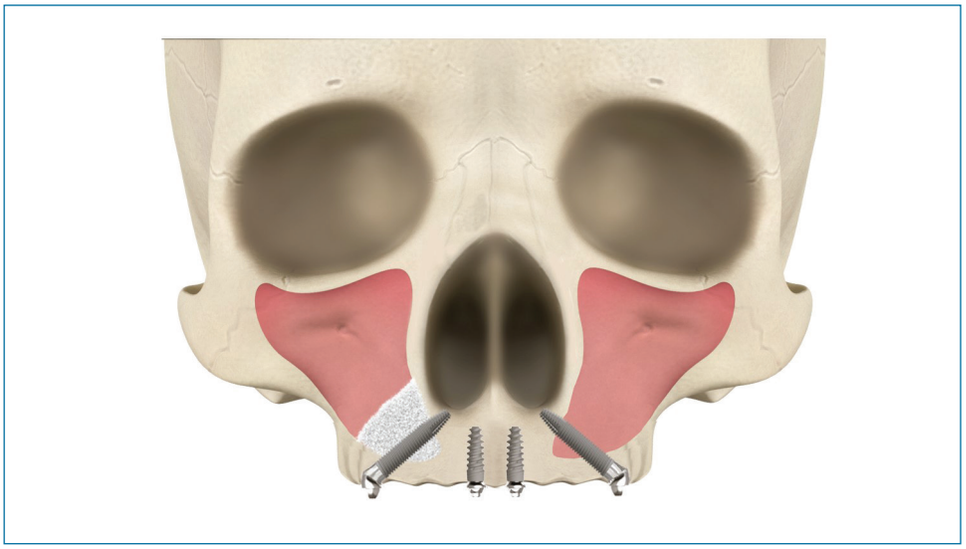


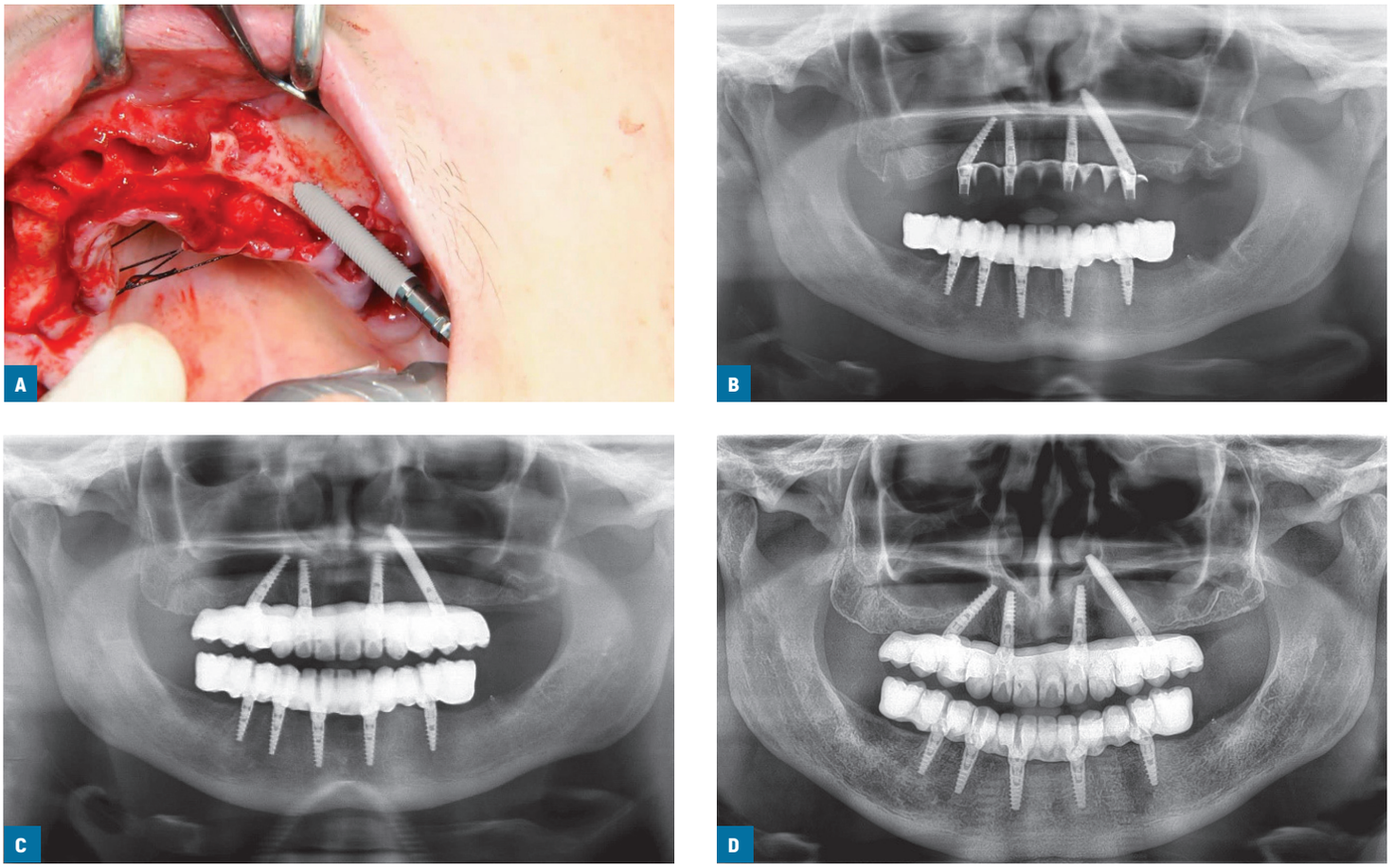
FIG. 1: *Illustration representing tilted trans-sinus implants. The implants crossed the bone crest just anterior to the sinus wall, passed through the sinus and back into the maxilla, engaging the nasal cortical bone at the canine pillar. It is possible to place the trans-sinus implant without a simultaneous bone graft (implant position #25) or with sinus-lift procedures (implant position #15). Trans-sinus implants are indicated in presence of residual bone height of minimum 4 mm and maximum 6 mm available under the sinus floor to anchor the implant head, as measured on computerised tomography (CT) scans.*

- edentulous patients or patients with terminal dentition in need of immediate maxillary rehabilitation supported by four or six implants without sufficient bone height posterior to the canines to anchor and stabilize the implants on at least one side;
- a minimum of 4 mm and a maximum of 6 mm of residual bone height available under the sinus floor to anchor the implant head, as measured on computed tomography (CT) scans;
- curvature of the anterior sinus wall that precluded placement of a tilted implant fully inside the bone using the standard protocol of between 30- and 45-degree angulation;
- and/or the inferior corner of the anterior sinus wall positioned anterior to the first premolar.

Patients were not enrolled in the study if they met any of the following criteria:

- preoperatively diagnosed sinusitis;
- uncontrolled systemic disease that could represent a general contraindication to implant dentistry;
- emotional instability;
- prior maxillary radiation therapy;
- previous or ongoing treatment with intravenous aminobisphosphonates;
- substance abuse;
- prior bone grafting procedures at the planned implant sites;
- sufficient bone height bilaterally in the posterior maxilla to allow the insertion of tilted implants via the standard protocol.

All patients received detailed explanation and signed an informed written consent form prior to enrolment in the trial. Patients were categorized into three groups according to their de-

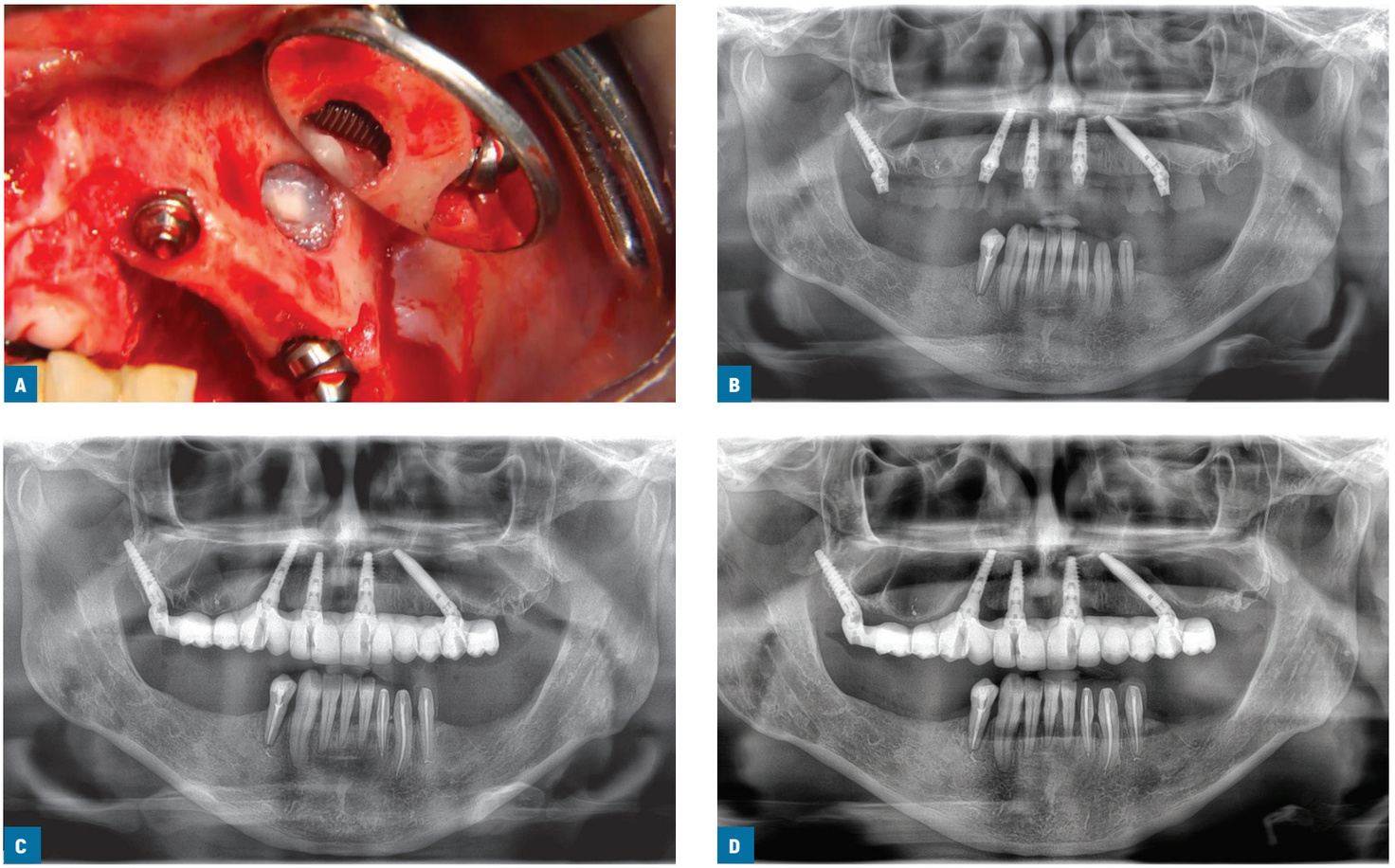


FIGS. 2A-D: *Treatment sequence of one patient randomly allocated to the no-graft group: surgical procedure. The Schneider membrane was ruptured to insert the tilted trans-sinus implant. No additional surgical measures were taken when intra-sinus fenestration occurred (A); post-operative panoramic x-ray showing trans-sinus implant inserted with double bicortical anchorage (implant anchor in both maxillary and nasal cortices) in position #25 (B); panoramic x-ray at 1 year after loading (C); panoramic x-ray at 4 years after loading (D).*

clared smoking habits: non-smokers, moderate smokers (up to 10 cigarettes per day) and heavy smokers (more than 10 cigarettes per day).

Before the intervention, all patients underwent at least one session of oral hygiene instructions and professionally delivered debridement when required. Antimicrobial prophylaxis was obtained with 1 g of amoxicillin + clavulanic acid (or clarithromycin 500 mg if allergic to penicillin) twice a day for 7 days, starting the night before the intervention. On the day of surgery, patients were treated under local anaesthesia using articaine with adrenaline 1:100,000. Tooth extractions, when needed, were performed as atraumatically as possible, attempting to preserve the buccal alveolar bone. Extraction sockets were carefully cleaned of any granulation tissue.

An incision was made along the crest with vertical releasing incisions to obtain access to the mesial wall of the sinus. Once a full-thickness flap was raised, the operator opened the sequentially numbered sealed envelope corresponding to the patient recruitment number to determine whether the trans-sinus implant was to be placed without simultaneous bone grafting (**FIGS. 2A-D**) or with sinus lift (**FIGS. 3A-D**). In patients from the no-graft group, the sinus membrane was ruptured to insert the tilted trans-sinus implant. No additional surgical measures were taken when intra-sinus fenestration occurred.



FIGS. 3A-D: *Treatment sequence of one of patient randomly allocated to the sinus-lift group: surgical procedure, with a small antrostomy being performed close to the mesial sinus wall, the membrane detached from the anterior wall and distally displaced and the implant positioned in the space delineated by the anterior sinus wall, nasal wall, residual maxillary crest and collapsed membrane, adding particles of bone substitute (A); post-operative panoramic x-ray showing implant position #15 inserted trans-sinus and with double bicortical anchorage (implant anchored to both maxillary and nasal cortical bone) (B); panoramic x-ray at 1 year after loading (C); panoramic x-ray at 4 year after loading (D).*

Tilted trans-sinus implants were inserted as follows: an under-preparation protocol was used to achieve an insertion torque of at least 45 Ncm before final implant seating; the 2-mm twist drill generally crossed the bone crest just anterior to the sinus wall, passing through the sinus and back into the maxilla, engaging the nasal cortical bone at an angle of up to 45 degrees. Implant length was determined according to the drilling length. Site preparation was followed by 2.4/2.8 mm and 3.2/3.6 mm step drills, depending on bone density. In cases of high bone density, 3.6/4 mm step drills were used only in the cortical bone. The bone available just posterior to the anterior sinus wall and inferior to the sinus floor was used to anchor the implant head, the body of the tilted implant was inside the sinus, and the implant tip was anchored in the bone between the anterior sinus wall and the nasal cortical bone. If necessary, the nasal cortical bone was engaged to achieve double bicortical anchorage.

In patients from the sinus lift group, a small antrostomy was opened parallel to the anterior sinus wall, usually 4 mm mesiodistally and 7 to 8 mm apicocoronally. The sinus membrane was detached from the anterior wall and distally displaced. The space was limited by the anterior wall of the sinus, the nasal wall, the residual maxillary crest, and the collapsed membrane. The first implant bur was visually checked through the antrostomy, and then the implant site was

prepared to the apical part of the anterior sinus wall in the cortical layer. The implant went through the residual crestal bone, proceeded into the sinus with the membrane previously displaced distally, and engaged the anterior sinus wall in the apical part. After implant placement, a xenograft was inserted (Bio-Oss, Geistlich Pharma, Wolhusen, Switzerland).

All trans-sinus implants were tapered implants (JDNasal, JDentalCare, Modena, Italy) 4 mm in diameter. The operators were free to choose implant lengths (20, 22, 24 and 26 mm) according to the drilling length. Other implants (JDEvolution Plus, JDentalCare) were oriented vertically. The decision to place four or six implants was based on the available bone; six implants were placed if a minimum inter-implant distance of 3 mm was available. The anterior implant was placed in the lateral incisor position in cases requiring four implants, while the central and lateral incisor positions were the preferred locations in cases requiring six implants. Implant positions were carefully selected to avoid contact with the tilted posterior implant tips, which normally reached the canine area. With this implant arrangement, the operators aimed to achieve good implant anchorage, a large inter-implant distance, and short cantilever, with the posterior tilted implants typically emerging at the first/second premolar position. Implants were to be inserted with a torque of at least 45 Ncm to be included in the study, and patients with implants that did not reach that insertion torque were not to be included. Final insertion torque was measured with a calibrated torque wrench (JDTorque, JDentalCare) able to measure torque within a range of 15 to 80 Ncm with 5 Ncm intervals. After suturing the flap with 4/0 non-resorbable sutures, abutments were connected, and a provisional screw-retained restoration was placed. Provisional restorations were made of metal reinforced acrylic resin, or were milled from polymethyl methacrylate (PMMA). Definitive screw-retained metal-composite prostheses were delivered 6 months after surgery. All participants were given a hygiene plan with recall visits every 4 months for the entire duration of the study.

The primary outcome measures were:

- prosthesis failure. A prosthesis was considered a failure if it had to be replaced by a new prosthesis;
- implant failure. Any implant mobility or removal of stable implants dictated by progressive marginal bone loss or infection and/or any mechanical complication that made the implant unusable (e.g., implant fracture or deformation of the connecting platform). Implant stability assessment was performed after having removed the prosthesis by tightening the implant abutment screw with a 30-Ncm force. After fitting the definitive restorations, prostheses were not removed to assess clinical mobility of individual implants.

The secondary outcomes were:

- complications. Any biological or mechanical complication that occurred during follow-up was recorded and reported per study group. Examples of biological complications were: peri-implant mucositis (heavily inflamed soft tissue without bone loss) and peri-implantitis (bone loss with suppuration or heavily inflamed tissues), fistulas and sinusitis (patient-reported complaints). Examples of mechanical complications were: fracture or loosening of prosthodontic components, as assessed clinically and radiographically, fracture of the framework, or detachment of resin teeth;
- peri-implant marginal bone level changes. These were evaluated on periapical radiographs taken with the paralleling technique at implant placement, and at one year and four years after loading. All measurements were taken by an independent blinded assessor (WV). Radiographs were scanned, digitized in JPG format, converted to TIFF format with a 600-dpi resolution, and Image J 1.42 software (National Institute of Mental Health, MD, USA) was

used to measure peri-implant marginal bone levels. The software was calibrated for every single image, based on the known implant diameter. Measurements of the mesial and distal crestal bone levels adjacent to each implant, parallel to the implant axis, were made to the nearest 0.01 mm, and averaged at patient level and then group level. The most coronal margin of the implant collar and the most coronal point of bone-to-implant contact were taken as reference points for the linear measurements. The measurements of each implant were averaged at implant level, patient level and group level.

No sample size calculation was performed for this study. During the definition of the protocol, it was decided that eight patients should be recruited at each centre (32 patients in total), whereby 16 patients were to be randomized to each group. The randomization was performed using computer-generated random numbers by the investigator who performed the statistical analyses (GG). The random codes were enclosed in sequentially numbered, opaque, sealed envelopes, which were opened on the day of the surgery, once the flap was raised and before trans-sinus implant site preparation, thereby concealing treatment allocation to the investigators in charge of enrolling and treating the patients.

Marginal bone level changes were assessed by a single centralized blinded assessor (WV), while implant stability, prosthesis failure and complications were assessed by the treating clinicians, who were therefore not blinded.

All data analyses were carried out according to a pre-established analysis plan. The patient was the statistical unit of the analyses. An doctor with competence in medical statistics (GG) analysed the data. Statistical analyses were performed using the statistical package StatView (Version 5.01.98, SAS Institute, Cary, NC, USA). Mean between-group differences in continuous outcomes were compared at patient level by t test. Within-group comparison was performed by means of paired t-test. Differences in marginal bone level between the two study groups were evaluated using Student's t test. Comparisons among centres were performed by one-factor analysis of variance (ANOVA). Differences in the proportion of patients with implant failures were compared between treatment groups by Fisher's Exact test, and among centres using chi-squared test. Differences among centres in crestal bone levels were compared using ANOVA. When necessary, prevalence of patient characteristics was compared by contingency tables and chi-squared test. All statistical comparisons were conducted at the 0.05 level of significance.

RESULTS

A total of thirty-two patients were enrolled in the trial (8 per centre) and randomized into two groups: 16 patients received trans-sinus implants without simultaneous bone grafting, while 16 patients received trans-sinus implants with sinus lift procedures and bone grafting (16 *vs.* 16, 4 *vs.* 4 per centre). Further information about non-eligible patients has been provided in a previous article[21]. All patients were recruited and treated from January 2017 to December 2017. The follow-up for all patients was four years post-loading (last follow-up December 2021).

The main baseline patient characteristics are shown in **TABLE 1**. A total of 148 implants were placed: 22 subjects had four implants and 10 had six implants supporting a maxillary full-arch fixed prosthesis. All trans-sinus implants had a diameter of 4 mm, 36.6% (15/41) were 22 mm long, 53.7% (22/41) were 24 mm long and 9.7% (4/41) were 26 mm long (**TABLE 1**). The mean bone height of the residual crest at insertion was similar between groups (4.9±0.8 mm for the sinus-lift group and 5.2±0.7 mm for the no-graft group). In total, 41 trans-sinus implants (23 trans-sinus implants without bone-grafting and 18 trans-sinus implants with sinus lift bone grafting), 23 conventional tilted implants and 84 axial implants were placed. All implants were

TABLE 1 CHARACTERISTICS OF THE SUBJECTS BY STUDY GROUP

	With sinus bone grafting (n = 16)	Without sinus bone grafting (n = 16)
Males, n (%)	10 (62.5%)	8 (50%)
Females, n (%)	6 (37.5%)	8 (50%)
Mean age at insertion, y (range)	64.4 (52-75)	67.8 (54-78)
Smokers (≤10 cigarettes/die), n (%)	4 (25.0%)	5 (31.3%)
Controlled diabetes type 2, n (%)	1 (6.3%)	3 (18.5%)
Hypertension, n (%)	8 (50.0%)	7 (43.7%)
Trans-sinus implants, 4 mm diameter (n)	n = 18 22 mm long n = 8 24 mm long n = 8 26 mm long n = 2	n = 23 22 mm long n = 7 24 mm long n = 14 26 mm long n = 2
Mean bone height of the residual crest (mm) ± SD	4.9±0.8	5.2±0.7

inserted with a torque greater than 45 Ncm and immediately loaded. **FIGS. 2** and **3** show the treatment sequence of one patient from each group, respectively.

At the 4-year recall appointment no patients had dropped out.

- *Prosthesis failure*: no prosthesis was lost.
- *Implant failure*: one trans-sinus implant in the sinus-lift group (one patient out of 16, 6.3%) failed after 6 months due to infection. This was an immediate post-extraction implant inserted in a premolar area of a female heavy smoker. The patient reported pain and inflammation at the sinus, together with a nasal discharge. The situation was resolved through the administration of anti-inflammatory and antibiotic drugs and removal of the trans-sinus implant. There was no statistically significant difference in implant failures between the two groups at patient level (0.0% *vs*. 6.3%, difference 6.3 %; 95% CI -4.7, 17.3; P= 0 .991). No conventional tilted implants or conventional straight implants were lost.
- *Complications*: nine patients in the no-graft group had one complication and ten patients from the sinus-lift group experienced one complication each. There was no statistically significant difference in complication rate between either groups (patient level: 9/16 *vs*. 10/16, 56.2% *vs*. 62.5%, difference 6.3%; 95% CI: -12.9, 25.8; P = 0.99) or the four different centres (50% *vs*. 62.5% *vs*. 50% *vs*. 75%, P = 0.99). Most of the complications occurred during the first year of follow up.

  The following complications were recorded in patients from the no-graft group without bone grafting:

  - four patients experienced peri-implant mucositis either five, six or 10 months post-implantation, which was resolved by a curettage and 0.2% chlorhexidine mouthwash;

- two patients experienced provisional restoration screw loosening three months after loading. Both patients presented an implant-supported fixed prosthesis as opposing dentition and bruxism. The problem was solved by adjusting the occlusion and providing a night guard;
- two patients' provisional prosthesis fractured one month and three months after loading, respectively. Prosthesis repair, occlusion adjustment and recommending a soft diet resolved the issue;
- one patient's definitive ceramic prosthesis chipped three years after loading. The prosthesis was unscrewed and repaired in the laboratory.

The following complications occurred in patients from the sinus-lift group:

- six patients experienced peri-implant mucositis either eight, 10, 12 or 24 months post-implantation, which resolved after curettage and 0.2% chlorhexidine mouthwash;
- one patient had peri-implantitis 6 months after trans-sinus implant placement, reporting pain, inflammation at the sinus, and nasal discharge. The implant was removed;
- three patients' provisional restoration screw loosened either three or five months after loading.

- *Peri-implant marginal bone level changes*: both groups had gradually lost a statistically significant amount of peri-implant marginal bone (P <0.001) by both one and four years after implant placement (**TABLE 2**). After one year, patients from the no-graft group had lost an average of 0.4 mm (95% CI 0.24, 0.66) of peri-implant bone, *versus* 0.35 mm (95% CI 0.07, 0.63) of patients from the sinus-lift group. After four years, patients from the no-graft group had lost an average of 1.2 mm (95% CI 0.87, 1.58) of peri-implant bone, as compared to 0.95 mm (95% CI 0.74, 1.41) in the sinus-lift group. There were no statistically significant differences between the two groups in peri-implant bone level changes at either one year (P = 0.604; difference 0.05 mm; 95% CI -0.24, 0.15) or four years (P = 0.67; difference 0.25 mm; 95% CI -0.23, 0.63). There were also no statistically significant differences in bone level changes between centres (P = 0.695). Considering only trans-sinus

TABLE 2 MEAN RADIOGRAPHIC PERI-IMPLANT BONE LOSS BY STUDY GROUP AT DIFFERENT TIMEPOINTS AT AT AXIAL, CONVENTIONAL TILTED AND TRANS-SINUS IMPLANTS

	With sinus bone grafting		Without sinus bone grafting		
Time points	**Mean bone level (SD)**	**Time points**	**Mean bone level (SD)**	**Difference between groups (95% CI)**	**P value intergroup**
Implant placement (n = 16)	0.02 (0.04)	Implant placement (n = 16)	0.01 (0.03)	0.01 (0.04)	
1 year (n = 16)	0.35 (0.28)	1 year (n = 16)	0.40 (0.26)	0.05 (0.26)	0.84
4 years (n = 16)	0.95 (0.55)	4 years (n = 16)	1.2 (0.64)	0.25 (0.59)	0.91
Difference between placement-4 years Mean (95% CI)	0.93 (0.58)		1.19 (0.70)	0.26 (0.65)	
P value intragroup	<0.0001		<0.0001		

TABLE 3 MEAN RADIOGRAPHIC CRESTAL BONE LOSS AVERAGED AT PATIENT LEVEL AND THEN AT GROUP LEVEL AT DIFFERENT TIMEPOINTS BY STUDY GROUP (TILTED TRANS-SINUS IMPLANTS PLACED WITH OR WITHOUT SIMULTANEOUS BONE GRAFTING)

Trans-sinus implants	Implant placement	1 year	4 years	Difference between placement-4 years	
	Mean±SD (95% CI)	Mean±SD (95% CI)	Mean±SD (95% CI)	Mean ±SD (95% CI)	P value intragroup
With sinus bone grafting (n = 16)	0.03±0.04 (-0.01; 0.07)	0.34±0.3 (0.04; 0.64)	0.99±0.32 (0.71; 1.23)	0.96±0.35 (0.61; 1.21)	<0.0001
Without sinus bone grafting (n = 16)	0.02±0.03 (-0.01; 0.05)	0.39±0.3 (0.09; 0.69)	1.32±0.25 (0.88; 1.47)	1.30±0.27 (1.03-1.57)	<0.0001
Difference between groups (95% CI)	0.01±0.02 (-0.01; 0.03)	0.05±0.3 (-0.25; 0.35)	0.33±0.29 (0.04; 0.62)		<0.0001
Intergroup p-value		0.61	0.64		

implants, no statistically significant difference in peri-implant bone loss was observed between the two treatment strategies (P = 0.55; **TABLE 3**).

DISCUSSION

This trial was designed to evaluate the 4-year outcomes of tilted trans-sinus implants placed without simultaneous bone grafting *versus* sinus lift augmentation procedures in subjects with severe maxillary atrophy. In this study, implants were inserted with a torque greater than 45 Ncm and immediately loaded, supporting a full-arch restoration. High primary stability was achieved in all patients because the implants engaged three layers of cortical bone, namely the cortical layers at the residual crest of the alveolar process, the floor of the maxillary sinus, and the nasal bone.

Trans-sinus implants may be inserted with[22-24] or without[19] bone grafting. In this trial, the implant survival and marginal bone resorption outcomes are comparable with those previously reported[21] (at one year) and data from other studies using the same rehabilitation procedure[19,22,23]. Two previous studies suggested the placement of trans-sinus implants to support immediately loaded cross-arch fixed prostheses simultaneously with a bone graft using xenograft or bone morphogenic protein 2 (BMP-2), reporting respective survival rates of 100% and 94.8% after one year[22,23]. In a retrospective clinical study on 70 patients, Malò et al. reported a 95.7% survival rate for trans-sinus implants placement without sinus bone grafting to support immediately loaded all-on-4 maxillary prostheses after three years; those patients lost 0.96 mm of bone after one year and 1.14 mm after three years[19]. To date, no other RCTs comparing trans-sinus implant placement with or without simultaneous grafting has been published, so no meaningful comparisons can be made.

However, according to the findings of the present study, operators can expect comparable outcomes from grafting or not the sinus when placing trans-sinus implants supporting immediately loaded cross-arch fixed prostheses. Rupturing the sinus membrane in the absence

of preoperative sinusitis did not seem to significantly influence the prevalence of complications and sinus infections. This is in line with Tabrizi et al.[25] and Jung et al.'s[26] finding on implants placed in conjunction with maxillary sinus with or without raising the sinus membrane, namely that there were no signs or symptoms of sinusitis in either. That being said, it would be ethically preferable to avoid grafting in order to reduce any associated risk of morbidity, which would need to be quantified by further RCTs on larger samples. What is certain, however, is that placing trans-sinus implants without bone graft simplifies the procedure, reducing surgical time and treatment costs.

Trans-sinus implants are useful when it is not possible to rehabilitate the atrophic posterior maxilla through standard techniques with conventional tilted implants, and should be considered before choosing more complex techniques such as zygomatic implants or bone grafting procedures. For their application, however, residual bone height of minimum 4 mm and maximum 6 mm needs to be available under the sinus floor to anchor the implant head.

The limitations of this study include the short follow-up period (four years) and the small sample size. Other limitations were that neither the time required to complete the two different procedures nor the post-operative discomfort experienced by the patients were recorded. Moreover, the sinuses were not assessed to determine pathological changes in the sinus membrane. Nonetheless, both procedures were tested under real clinical conditions and the patient inclusion criteria were rather broad. Therefore, the results of the present trial can be generalised to patients having similar characteristics.

CONCLUSIONS

In this study, no statistically significant differences were observed in outcomes of tilted trans-sinus implants supporting cross-arch immediately loaded fixed prostheses placed with or without simultaneous bone-grafting in atrophic maxillae.

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