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Immediate fixed rehabilitation of severe maxillary atrophies using trans-sinus tilted implants with or without sinus bone grafting: One-year results from a randomised controlled trial

KEY WORDS

full arch prosthesis, immediate loading, maxillary atrophy, tilted implants, trans-sinus implant

ABSTRACT

Background: To compare the clinical outcomes between tilted trans-sinus implants inserted without simultaneous bone grafting versus sinus elevation procedures with bone grafting to support immediately loaded prostheses for the rehabilitation of the atrophic maxilla.

Materials and methods: Thirty-two subjects were selected to receive an immediately loaded fixed restoration supported by four or six implants and randomised to receive at least one trans-sinus implant without simultaneous bone grafting (group 1, n = 16) or at least one trans-sinus implant with sinus elevation procedures and bone grafting (group 2, n = 16). Primary outcomes were prosthesis and implant failures. 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 elevation procedures), 23 conventional tilted implants and 84 axial implants were inserted. No drop-outs occurred. At 1 year after loading no prosthesis was lost. One patient treated with sinus graft lost one implant (0.0% vs. 6.3%, difference 6.3%; 95% CI: –4.7 to 17.3; $P = 0.99$). There were no statistically significant differences in implant failures between the two groups. Complications occurred in eight patients in the group without bone grafting and in nine patients in the group with sinus elevation and bone augmentation. No statistically significant differences were found in complications (50.0% vs. 56.3%, difference 6.3%; 95% CI: –12.7 to 25.3; $P = 0.99$), and in peri-implant marginal bone level changes (difference 0.05 mm; 95% CI: –0.24 to 0.34; $P = 0.604$).

Conclusions: In this study, no statistically significant differences were observed between subjects treated with tilted trans-sinus implants without simultaneous bone-grafting or with sinus elevation procedures supporting cross-arch immediately loaded fixed prostheses in atrophic maxillae. Longer follow-ups are needed and alternative procedures such us short implants or crestal sinus elevation procedures should be compared since they could be less invasive.

Conflict of interest statement: *Tommaso Grandi and Rawad Samarani serve as consultants for JDentalCare. This study was completely self-financed and no funding was sought or obtained, not even in the form of free materials.*

Introduction

The fixed rehabilitation of a totally edentulous maxilla is often associated with anatomical limitations, generally due to a decreased bone volume in the posterior area, especially when immediate function is implemented. Bone atrophy evolves rapidly during the first year after tooth extraction and then progresses in an unpredictable manner. The other factors that can affect the quantity of available bone are mainly the progressive maxillary sinus pneumatisation and the use of removable prostheses[1].

When bone volumes are not sufficient for implant placement, bone augmentation procedures can be performed[2,3]. However, alternative treatments should be considered, in particular tilted implants, pterygoid and zygomatic implants[4-8]. These alternative treatments could be indicated in patients who cannot undergo bone graft procedures for different financial, psychological or clinical reasons. Recently, a new technique was documented in which posterior implants are angled forward, passing trans-sinus to fixate in the nasal cortical bone. The trans-sinus implants can be inserted without sinus bone grafting or simultaneously with bone grafting and placed into immediate function, achieving good success rates up to 3 years[10-13]. Trans-sinus implants may be used when the insertion of conventional tilted implants is not possible, before considering the use of pterygoid and zygomatic implants or bone grafting procedures. In one study the sinus membrane was ruptured to insert trans-sinus implants and no bone grafting was performed[10]. In other studies the sinus membrane was not ruptured: a lateral window was opened in the maxilla above the residual bone crest, the sinus membrane was elevated before inserting the implant and the residual space was filled with a bone substitute[11-13]. The published data belong to uncontrolled case series or retrospective studies; therefore, it would be interesting to know whether there are advantages by grafting or not the sinus simultaneously to trans-sinus implant placement to support cross-arch immediately loaded fixed prostheses.

The aim of this randomised controlled trial (RCT) was to compare the clinical outcomes between tilted trans-sinus implants inserted without simultaneous bone grafting versus sinus elevation procedures with bone grafting to support an immediately loaded prosthesis for the rehabilitation of the atrophic maxilla. The null hypothesis was that there would be no difference in the outcomes between the two treatments' strategies, against the alternative hypothesis of a difference. This article is reported according to the CONSORT statement for improving the quality of RCT reports (http://www.consort-statement.org/) and presents data up to 1 year after loading. This RCT was designed to have a 5-year post-loading follow-up.

Materials and methods

This was a multicentre RCT of parallel-group design and was conducted in four different private practices in Modena, Padova, Piacenza (Italy) and in Byblos (Lebanon).

Maxillary edentulous patients or patients with a terminal dentition who presented a maxillary sinus pneumatisation were selected to receive an immediately loaded fixed restoration supported by four or six implants. These maxillae had a particular anterior sinus wall anatomy that did not allow insertion of a tilted implant fully inside the bone in the premolar and molar regions at least in one side. Patients were randomly allocated to receive at least one trans-sinus implant without simultaneous bone grafting or at least one trans-sinus implant with sinus elevation procedures and bone augmentation. In every patient one trans-sinus implant was inserted in one side or in both sides depending on the maxillary anatomy.

Patient selection

The inclusion criteria were edentulous patients or patients with a terminal dentition in need of a maxillary immediate rehabilitation supported by four or six implants without having, at least in one side, sufficient bone height posterior to the canines to anchor and stabilise the implants, as reflected in the following anatomical criteria (Fig 1):

- presence of a residual bone height measured on computed tomography (CT) scans of minimum 4 mm and maximum 6 mm available under the sinus floor to anchor the implant head
- an anterior sinus wall that, due to its curvature, did not allow placement of a tilted implant through the standard protocol using between a 30- and 45-degree angulation fully inside the bone
- and/or the inferior corner of the anterior wall of the sinus positioned anterior to the first premolar.

The following exclusion criteria were used:

- sinusitis diagnosed preoperatively
- the presence of systemic uncontrolled diseases that could represent a general contraindication to implant dentistry
- emotional instability
- undergoing maxillary radiation therapy
- undergoing active chemotherapy or aminobisphosphonates
- substance abusers
- patients who underwent bone grafting procedures at the planned implant sites
- patients with sufficient bone height bilaterally in the posterior maxilla that allowed the insertion of tilted implants through the standard protocol.

All patients received detailed explanations and signed a written informed consent form prior to enrolment in the trial. Patients were categorised into three groups according to what they declared: non-smokers, moderate smokers (up to 10 cigarettes per day) and heavy smokers (more than 10 cigarettes per day).

All patients underwent at least one session of oral hygiene instructions and professionally delivered debridement when required prior to the intervention. Antimicrobial prophylaxis was obtained with 1 g of amoxicillin + clavulanic acid (or clarithromycin 500 mg if allergic to penicillin) starting the night before the intervention, twice a day, for 7 days.

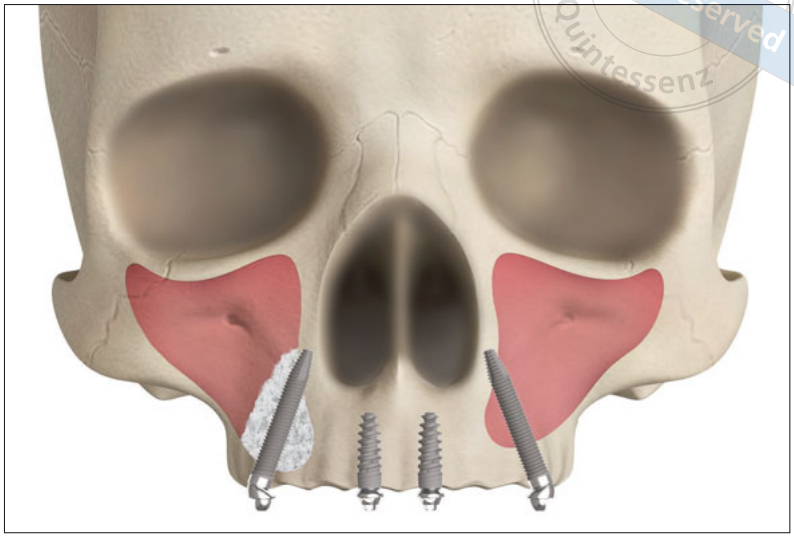


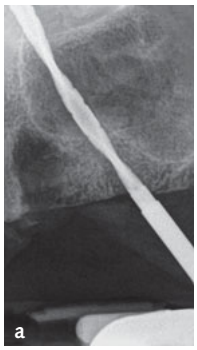
Fig 1 Illustration representing implants inserted trans-sinus. Implants cross the bone crest immediately anterior to the sinus wall, pass inside the sinus and enter again in the maxilla, engaging in the nasal cortical bone. It is possible to place the trans-sinus implant without a simultaneous bone graft (implant position 25) or with sinus elevation procedures (implant position 15). Trans-sinus implants are indicated in presence of a residual bone height measured on computed tomography (CT) scans of minimum 4 mm and maximum 6 mm available under the sinus floor to anchor the implant's head.

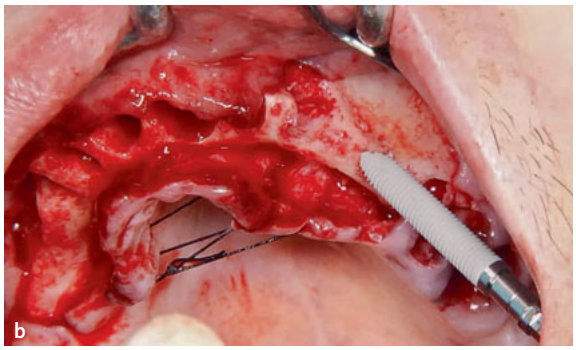
Procedures

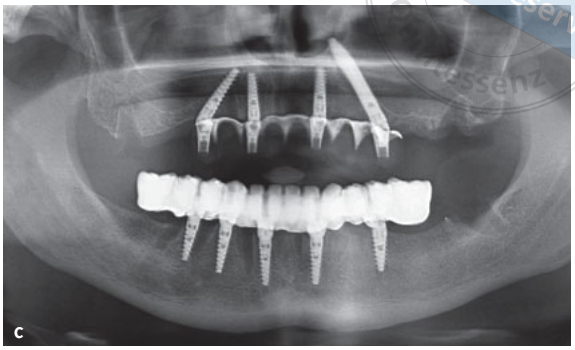
On the day of surgery, patients were treated under local anaesthesia using articaine with adrenaline 1:100,000. Tooth extractions, when needed, were performed as atraumatically as possible, attempting to preserve the buccal alveolar bone. Extraction sockets were carefully cleaned from any granulation tissue.

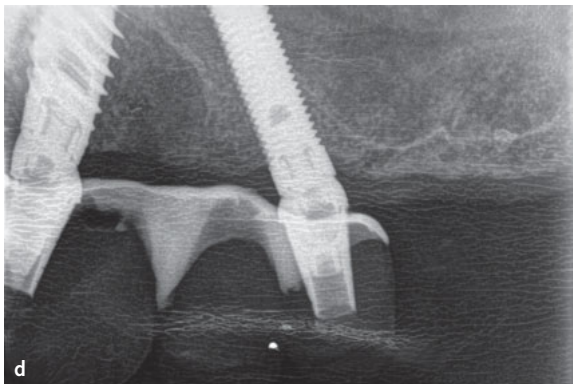
An incision was made along the crest with vertical releasing incisions to obtain access to the mesial wall of the sinus. Once a full-thickness flap was elevated, the operator was informed whether the trans-sinus implant had to be placed without simultaneous bone grafting (Fig 2) or with sinus elevation procedures (Fig 3) by opening the sequentially numbered sealed envelope corresponding to the patient recruitment number.

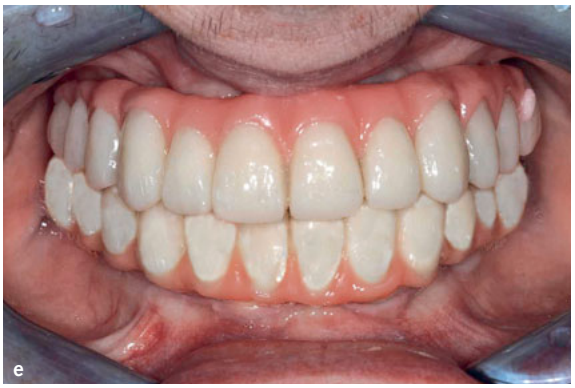
In patients allocated to the group without bone grafting, the sinus membrane was ruptured to insert the tilted trans-sinus implant. No additional surgical care was taken when intra-sinus fenestration occurred. The insertion of the tilted trans-sinus implant was as follows: an under preparation protocol was used to achieve an insertion torque of at

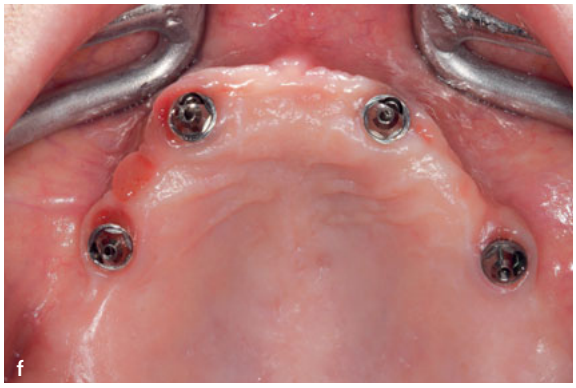


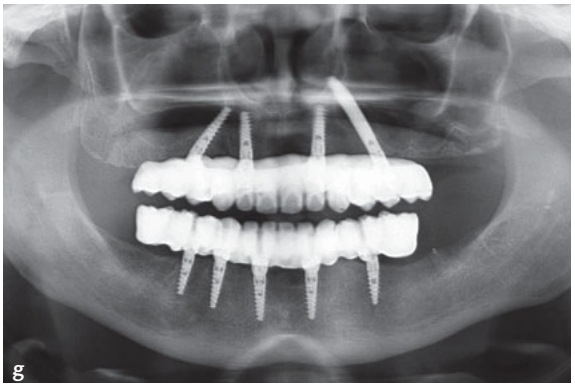


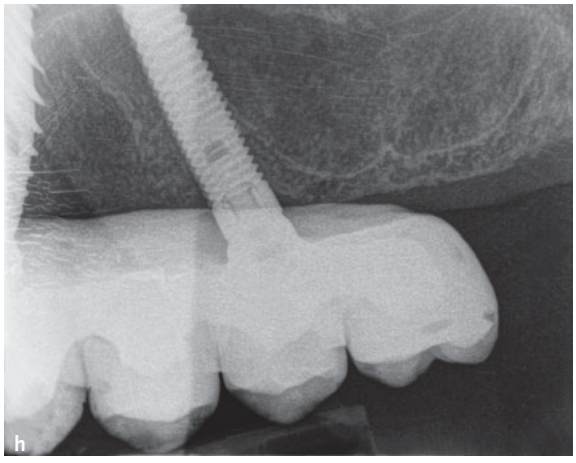




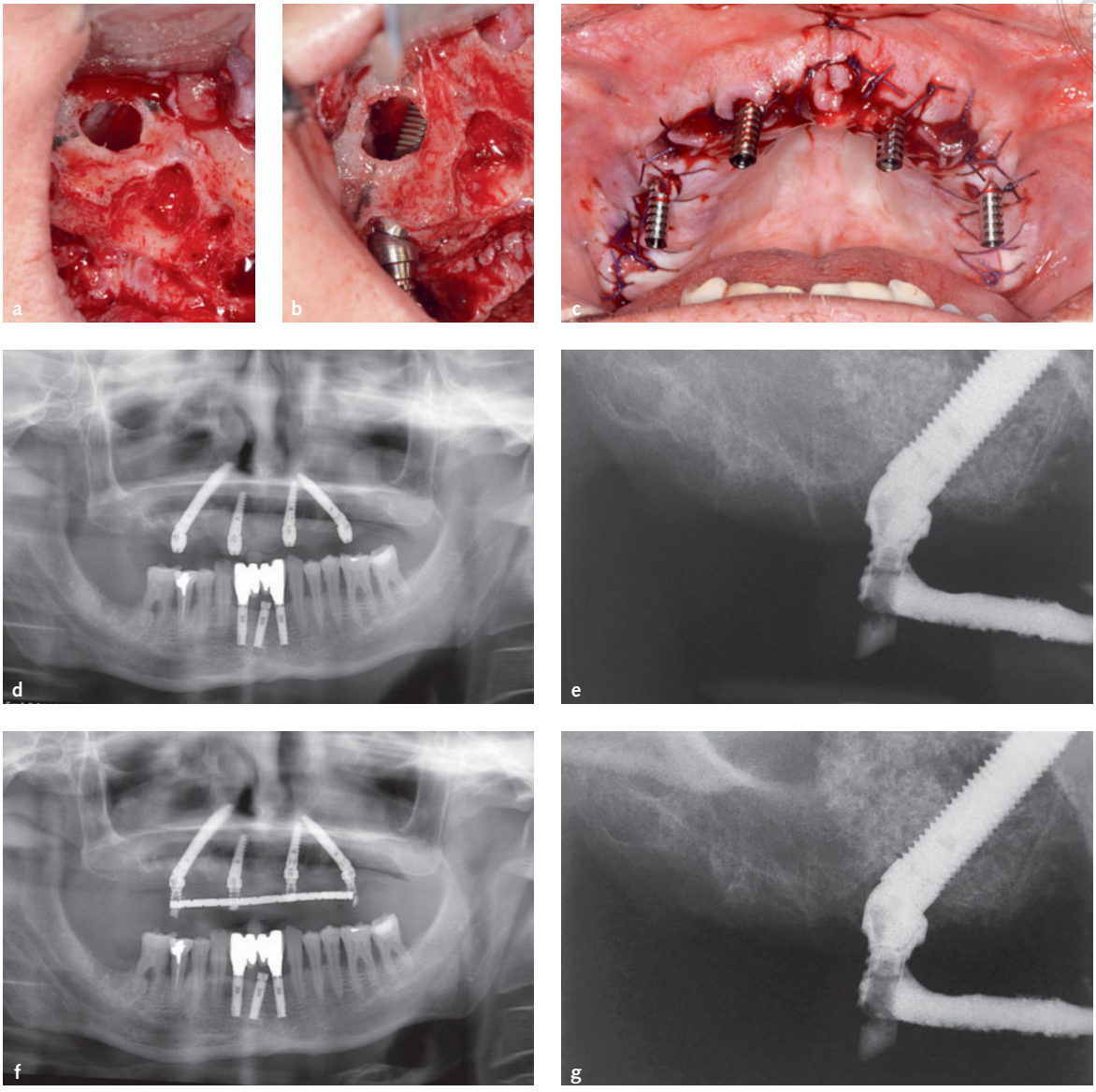








Figs 2a–h Treatment sequence of one of Dr Grandi's patients randomly allocated to the group without bone grafting. **(a)** Surgical procedure. The 2-mm twist drill crossed the bone crest immediately anterior to the sinus wall, passed inside the sinus and entered again in the maxilla, engaging in the nasal cortical bone. **(b)** The sinus membrane was ruptured to insert the tilted trans-sinus implant. No additional surgical care was taken when intra-sinus fenestration occurred. **(c)** Postoperative panoramic radiograph showing implant position 25 inserted trans-sinus and with bicortical anchorage (implant anchored to both maxillary and nasal corticals). **(d)** Baseline radiograph at trans-sinus implant placement. **(e)** Clinical view at the 1-year recall appointment. **(f)** Soft tissue healing at 1 year after loading. Some inflammation was observed in the right side due to excessive prosthesis compression. **(g)** Panoramic radiograph of the same patient at 1 year after loading. **(h)** Periapical radiograph of the trans-sinus implant at 1 year after loading.



Figs 3a–g Treatment sequence of one of Dr Faustini's patients randomly allocated to the group with sinus elevation procedures. **(a)** Surgical procedure. A small antrostomy was performed close to the sinus mesial wall, the membrane was detached from the anterior wall and distally displaced. **(b)** The implant was positioned in the space limited by the anterior wall of the sinus, the nasal wall, the residual maxillary crest and the collapsed membrane. The area was grafted with a granular xenograft. **(c)** Postoperative clinical view. **(d)** Postoperative panoramic radiograph showing implant position 15 inserted trans-sinus and with bicortical anchorage (implant anchored to both maxillary and nasal corticals). **(e)** Baseline radiograph at trans-sinus implant placement. **(f)** Panoramic radiograph of the same patient at 1 year after loading. **(g)** Periapical radiograph of the trans-sinus implant at 1 year after loading.

least 45 Ncm before final seating of the implant. The 2-mm twist drill usually crossed the bone crest just anterior to the sinus wall, passed inside the sinus and entered again in the maxilla, engaging in the nasal cortical bone with an angulation up to 45 degrees. Implant length was determined according to the drilling length. The 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 density bone, 3.6-/4.0-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 apex was anchored in the bone between the anterior sinus wall and the nasal

cortical. The nasal cortical was used, if necessary, to achieve a double bicortical anchorage.

In patients allocated to the group with sinus elevation procedures, a small antrostomy, usually 4 mm mesiodistally and 7 to 8 mm apicocoronally, was carried out parallel to the anterior sinus wall. 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 preparation of the implant site was carried out to the apical part of the anterior sinus wall in the cortical layer. After implant placement, a xenograft was inserted (Bio-Oss, Geistlich Pharma, Wolhusen, Switzerland). 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.

All trans-sinus implants were 4 mm in diameter. The operators were free to choose implant lengths (20, 22, 24 and 26 mm) according to the drilling length. Tapered implants specially designed (JDNasal, JDentalCare, Modena, Italy) with internal connection and airborne-particle abraded and acid-etched treated surface were used.

The other implants were oriented vertically (JDEvolution Plus, JDentalCare). The anterior implant was placed in the lateral incisor position if four implants were planned; if the placement of six implants was planned, the central and lateral incisor positions were the preferred locations. The decision to place four versus six implants was based on the available bone. Six implants were placed if a minimum inter-implant distance of 3 mm was available. Care was taken in the selection on the implant positions not to come in conflict with the apex of the tilted posterior implants, which normally reached the canine area. With this implant arrangement, the authors aimed at allowing good implant anchorage, a large inter-implant distance, and short cantilever length with the posterior tilted implants typically emerging at the first/second premolar position. During the protocol-formulation phase it was decided that trans-sinus and anterior implants should attain insertion torque of at least 45 Ncm to be included in the study. If implants did not reach an insertion torque of at least 45 Ncm, patients were to be excluded from the study. Final insertion torque was measured with a calibrated torque wrench (JDTorque, JDentalCare). The wrench used was able to perform torque measurements within a range of 15 to 80 Ncm, with 5% precision. After closing and suturing the flap with 4/0 non-resorbable sutures, abutments were connected and a provisional screw-retained restoration was placed. Provisional restorations were made by metal reinforced acrylic resin or milled from polymethyl methacrylate (PMMA). Final screw-retained metal-composite prostheses were delivered 6 months post-surgically. Patients were enrolled in an oral hygiene programme with recall visits every 4 months for the entire duration of the study.

Outcome measures

Patients underwent the 1-year recall appointment to assess the following outcome measures.

The primary outcomes were:

- Prosthesis failure: a prosthesis was considered a failure if it needed to be replaced by an alternative prosthesis.
- Implant failure: implant mobility and removal of stable implants dictated by progressive marginal bone loss or infection and/or any mechanical complication rendering the implant unusable (e.g. implant fracture or deformation of the connecting platform). Implant stability was assessed after having removed the prosthesis by tightening the implant abutment screw with a 30-Ncm force.

The secondary outcomes were:

- Complications: any biological and mechanical complications that occurred during the entire follow-up time were 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 assessed

clinically and radiographically, fracture of the framework and 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 1 year after loading. All measurements were taken by an independent blinded assessor (LS). Radiographs were scanned, digitised in JPG format, converted to TIFF format with a 600 dpi resolution and stored in a personal computer. Peri-implant marginal bone levels were measured using ImageJ 1.42 software (National Institute of Mental Health, Maryland, USA). The software was calibrated for every single image using the known implant diameter. Measurements of the mesial and distal crestal bone levels adjacent to each implant were made to the nearest 0.01 mm and averaged at patient level and then group level. The measurements were taken parallel to the implant axis. Reference points for the linear measurements were the most coronal margin of the implant collar and the most coronal point of bone-to-implant contact. The measurements of each implant were averaged at implant level and then at patient level and finally at group level.

Sample size, random sequence, allocation concealment and blinding

No sample size calculation was performed for this study. During the protocol-formulation phase it was decided that eight patients should be recruited at each centre (32 patients in total), whereby 16 patients had to be randomised to each group. The randomisation list was provided using computer-generated random numbers by the doctor who performed the statistical analyses (GG). The random codes were enclosed in sequentially numbered, opaque, sealed envelopes. The envelopes were opened once the flap was elevated before starting placement of the trans-sinus implant, therefore treatment allocation was concealed to the investigators in charge of enrolling and treating the patients. Implant stability, prosthesis failure and complications were assessed by the treating clinicians who were therefore not blinded. Marginal bone level changes were assessed by a single centralised blinded assessor (LS).

Statistical analysis

All data analysis was carried out according to a pre-established analysis plan. The patient was the statistical unit of the analyses. A doctor with expertise in statistics analysed the data without knowing group allocation (GG). Statistical analyses were performed using the statistical package StatView (version 5.01.98, SAS Institute, Cary, NC, USA). Differences of mean at patient level for continuous outcomes between groups were compared by *t* test. Within-group comparison was performed with *t* test for paired data. The Student *t* test was used to evaluate differences in resorption between the two study groups. Comparisons among centres were performed by one-factor analysis of variance (ANOVA). Differences in the proportion of patients with implant failures were compared among the treatment groups by Fisher exact test and among the centres using chi-square test. Differences in crestal bone levels were compared among the centres using ANOVA test. When necessary, prevalence of patient characteristics was compared by contingency tables and the chi-square test. All statistical comparisons were conducted at the 0.05 level of significance.

Results

A total of 40 subjects were screened for eligibility, but eight subjects were not included for the following reasons: four subjects were hesitant to receive implant treatment, two patients declined the treatment for economic reasons, one was treated with amino-bisphosphonates orally and intravenously and one was a substance abuser.

A total of 32 subjects (56.3% men) with a mean age of 65.2 (± 9.1) (range 52 to 78 years) years old were considered eligible and were consecutively enrolled in the study (eight patients at each centre) and randomised to receive a trans-sinus implant without simultaneous bone grafting or a trans-sinus implants with sinus elevation procedures

Table 1 Characteristics of the subjects included in the study in group with (n = 16) or without (n = 16) sinus bone grafting

Characteristic		With sinus bone grafting (n = 16)	Without sinus bone grafting (n = 16)
Gender, n (%)	Male	10 (62.5)	8 (50.0)
	Female	6 (37.5)	8 (50.0)
Mean age at insertion, y (range)		64.4 (52–75)	67.8 (54–78)
Smokers	(≤ 10 cigarettes/day), n (%)	4 (25.0)	5 (31.3)
	(> 10 cigarettes/day), n (%)	1 (6.3)	1 (6.3)
Controlled diabetes type 2, n (%)		1 (6.3)	3 (18.5)
Hypertension, n (%)		8 (50.0)	7 (43.7)
Conventionally placed implants (n)		14	9
Axially placed implants (n)		44	40
Trans-sinus implants diameter 4 mm (n)	All	18	23
	22 mm long	8	7
	24 mm long	8	14
	26 mm long	2	2
Mean bone height at trans-sinus implants (mm) ± SD		4.9 ± 0.8	5.2 ± 0.7

SD, standard deviation.

and bone grafting (16 vs. 16, 4 vs. 4 per centre). Patients were recruited and operated from January 2017 to December 2017. All patients were treated according to the allocated interventions. Thirty-two patients with 148 implants placed (22 subjects with four implants and 10 with six implants) received a maxillary full-arch fixed prosthesis supported by axial and trans-sinus tilted implants. 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). At the 1-year recall appointment no patients dropped out.

The main baseline patient features are reported in Table 1. There were no apparent differences in baseline characteristics between the two groups. Patients were generally healthy, although 15 patients (46.9%) had medication-controlled hypertension and four (9.7%) patients had controlled type 2 diabetes. Eleven of the included patients were smokers: nine were moderate smokers (up to 10 cigarettes per day) and two were heavy smokers (more than 10 cigarettes per day).

In total 41 trans-sinus implants (23 trans-sinus implants without bone grafting and 18 trans-sinus implants with sinus elevation procedures and bone grafting), 23 conventional tilted implants and 84 axial implants were inserted. All implants were inserted with a torque superior to 45 Ncm and were all immediately loaded.

The mean (± standard deviation) bone height at insertion by study group was similar: 4.9 ± 0.8 mm in sinus with bone grafting at trans-sinus implants and 5.2 ± 0.7 mm without bone grafting (mean difference 0.3 mm; 95% CI: –0.78 to 0.18; $P = 0.22$).

Primary outcomes

- Prosthesis failure: No prosthesis was lost.
- Implant failure: one trans-sinus implant inserted with sinus elevation procedures (one patient out of 16, 6.3%) failed for infection after 6 months. It was inserted as an immediate post-extractive implant in a premolar area in the maxilla in a heavy smoker female. 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 the extraction of the trans-sinus implant. 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 to 17.3; $P = 0.99$). No conventional tilted implants and conventional straight implants were lost.

Secondary outcomes

- Complications occurred in eight patients in the group without bone grafting and in nine patients in the group with sinus elevation and bone augmentation procedures, the difference being not statistically significant (50% vs. 56.3%, difference 6.3%; 95% CI: –12.7 to 25.3; $P = 0.99$) (see the details about biological and mechanical complications in the paragraphs below).

  Biological complications occurred in four patients in the group without bone grafting and in six patients in the group with sinus elevation and bone augmentation procedures, the difference being not statistically significant (25% vs. 37.5%, difference 12.5 %; 95% CI: –18.5 to 40.6; $P = 0.44$). In brief all these complications were peri-implant mucositis and were solved by a curettage and 0.2% chlorhexidine mouthwash, except for one patient in the group with sinus elevation procedures who reported pain, inflammation at the sinus and nasal discharge which determined implant removal 6 months after its placement.

  Mechanical complications occurred in four patients without bone grafting and three patients with bone grafting with no statistically significant difference between the two groups (25.0% vs. 18.8%, difference 6.2%; 95% CI: –22.2 to 33.6; $P = 0.99$). Screw loosening occurred in two patients in the group without bone grafting and in three patients in the group with sinus elevation procedures. All the patients presented an implant-supported fixed prosthesis as opposite dentition and bruxism. These problems were solved by adjusting the occlusion and manufacturing a night guard. The fractures of the provisional prosthesis occurred in two patients in the group without bone grafting and were solved by mending the prosthesis, adjusting the occlusion and further re-instruction about not overloading the prosthesis.
- Peri-implant marginal bone level changes: the measurements of each implant were averaged at implant level and then at patient level and finally at group level. There was no statistically significant difference between the two treatment groups at implant placement in bone levels (difference 0.01 mm; 95% CI: –0.02 to 0.04; $P = 0.43$). One year after loading there was no statistically significant difference between the two groups for peri-implant bone levels (difference 0.02 mm; 95% CI: –0.19 to 0.23; $P = 0.849$) (Table 2). The difference between placement and 12 months was similar (difference 0.05 mm; 95% CI: –0.24 to 0.34; $P = 0.604$). Both treatment groups lost statistically significant marginal peri-implant bone at 1-year post-loading ($P = 0.0001$). The trans-sinus implants in the group without bone grafting lost an average of 0.51 mm peri-implant bone, versus 0.66 mm of implants in the group with sinus elevation procedures. By comparing the outcomes of the four different centres, no statistically significant differences can be observed for failures (12.5% vs. 0.0% vs. 0.0% vs. 0.0%, $P = 0.38$) or complications (25.0% vs. 25.0% vs. 25.0% vs. 12.5%, $P = 0.91$) and bone loss (0.36 ± 0.26 vs. 0.38 ± 0.30 vs. 0.41 ± 0.24 vs. 0.33 ± 0.27 mm, $P = 0.695$).

Table 2 Mean radiographic crestal bone loss and changes between groups and time periods

	Implant placement, mean ± SD (95% CI)	12 mo after loading, mean ± SD (95% CI)	Difference from placement to 12 mo, mean ± SD (95% CI)	*P* value intragroup
With sinus bone grafting (n = 16)	0.02 ± 0.04 (–0.02; 0.06)	0.32 ± 0.28 (0.04; 0.60)	0.35 ± 0.28 (0.07; 0.63)	0.0001
Without sinus bone grafting (n = 16)	0.01 ± 0.03 (–0.02; 0.04)	0.30 ± 0.31 (–0.01; 0.61)	0.40 ± 0.26 (0.24; 0.66)	0.0001
Difference (95% CI)	0.01 (–0.02; 0.04)	0.02 (–0.19; 0.23)	0.05 (–0.24; 0.34)	
P value intergroup	0.430	0.849	0.604	

Discussion

This RCT was designed to evaluate whether there are advantages by grafting or not the sinus simultaneously to trans-sinus implant placement to support cross-arch immediately loaded fixed prostheses in the atrophic maxilla. One year after loading no statistically significant differences for implant failures, prosthesis failures, complications and peri-implant marginal bone loss were observed between the two treatment strategies. On the one hand, due to the relatively small sample size of this study and moreover, to the short follow-up (only 1 year after loading), it would be hazardous to conclude that there are no differences between the two treatment strategies. In order to draw more reliable conclusions, longer follow-ups and larger sample sizes are required, since the differences, which were not apparent at 1 year, may become evident over time.

The trans-sinus approaches described in this study provided evidence that implants can be tilted through the sinus and can still be immediately loaded provided that the implants are inserted with a good primary stability and a cross-arch-stabilised prosthesis is made. All the implants were inserted with torque superior to 45 Ncm to be immediately loaded, as previously described for single implants[14,15]. The primary stability required was easily reached in all the patients because implants were inserted in three layers of cortical bone: the cortical layer at the residual crest of the alveolar process, the cortical layer at the floor of the maxillary sinus and the cortical layer of the anterior wall of the sinus. The nasal cortical was used, if necessary, to increase stability in case of soft bone.

Implant survival and marginal bone resorption results are comparable to other studies using the same rehabilitation procedure[10-12]. In a retrospective study including 70 patients, Malò et al[10] reported trans-sinus implants placement without sinus bone grafting to support immediately loaded All-on-4 maxillary prostheses. After 3 years, trans-sinus implants had a survival rate of 95.7%, and lost 0.96 mm of bone after 1 year and 1.14 mm after 3 years. Two other recent studies proposed the placement of trans-sinus implants simultaneously with a bone graft using xenograft or bone morphogenetic protein 2 (BMP-2) to support cross-arch immediately loaded fixed prostheses, and reported survival rates of 100% and 94.8% respectively after 1 year[11,12]. There are no other published RCTs comparing grafting or not in sinuses simultaneously to trans-sinus implant placement, so meaningful comparisons with other similar RCTs cannot be made at the present stage.

The authors recommend the use of trans-sinus implants when it is not possible to rehabilitate posterior atrophic maxillae through standard techniques with conventional tilted implants, and before choosing more complex techniques such as pterygoid and zygomatic implants or bone grafting procedures. According to the findings of the present study, operators can choose to graft or not the sinus simultaneously to trans-sinus implant placement supporting cross-arch immediately loaded fixed prostheses. If these results are confirmed by longer follow-ups, it should be better to avoid any graft, in order to reduce the morbidity and the cost of the treatment and to simplify and reduce the time of the procedure. Tabrizi et al[16], in a retrospective study with 13 patients and 18 implants with radiographic evidence of implant exposure to the maxillary sinuses, reported absence of signs or symptoms of sinusitis owing to the avoidance of membrane tearing. Jung et al[17] evaluated nine patients with 23 implants that had been inserted into the maxillary sinus without elevating the sinus membranes and found no clinical signs of sinusitis in any patient 6 to 10 months after implant insertion. The present study reached a similar result, as rupturing the sinus membrane in the absence of preoperative sinusitis did not seem to influence significantly the prevalence of complications and sinus infections. Moreover, placing trans-sinus implants without bone graft reduced the surgery time and decreased the treatment cost. However, these are simply hypotheses that need to be verified in further RCTs.

Trans-sinus implants are indicated in presence of a residual bone height of minimum 4 mm and maximum 6 mm available under the sinus floor to anchor the implant's head. Alternative less invasive

treatments should be considered, in particular short implants or crestal sinus elevation procedures[18-20]. These alternative treatments could be indicated in patients who cannot undergo complex surgery for different clinical or psychological reasons and in presence of sinusitis. On the other hand, such alternative procedures could reduce the possibility to reach a good primary stability of the implant in most of the cases and this could represent a limitation in presence of a specific patient's request for an immediately loaded restoration as tested in this trial.

The major limitations of the present study were the small sample size and the short follow-up. Other limitations were that the time required to complete the two different procedures and postoperative discomfort of the patients were not recorded and moreover the sinuses were not evaluated to determine pathological changes in the sinus membrane.

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

No statistically or clinically significant differences were observed between tilted trans-sinus implants with and without simultaneous bone grafting supporting cross-arch immediately loaded fixed prostheses in the atrophic maxilla. Longer follow-ups of larger patient populations are needed in order to draw more reliable conclusions.

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