CLINICAL ORAL IMPLANTS RESEARCH

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Short (6-mm) dental implants versus sinus floor elevation and placement of longer (≥10-mm) dental implants: a randomized controlled trial with a 3-year follow-up

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Abstract

Objectives: To investigate whether short (6-mm) dental implants could be an alternative to sinus floor elevation (SFE) and placement of longer (≥10-mm) implants in the posterior maxilla.

Materials and methods: Over a 3-year period, all patients presenting with partial edentulism in the posterior maxilla were considered for inclusion in this randomized controlled trial. Patients were randomly chosen either to receive short (6-mm) implants (test group [TG]) or to undergo SFE with simultaneous placement of standard-length (≥10-mm) implants (control group [CG]). SFE was performed using the lateral technique. In both groups, tapered implants (AnyRidge, MegaGen, Gyeongbuk, South Korea) were placed. All implants were loaded after 4 months of healing. At each annual follow-up session, clinical and radiographic parameters were assessed. Primary outcomes were implant survival, stability (measured with the implant stability quotient [ISQ]), marginal bone loss (MBL), and complications; secondary outcomes were patient satisfaction and treatment time and cost.

Results: Thirty-three patients were assigned to the TG and 20 to the CG. Forty-five implants were inserted in each group. At 3 years, implant survival rates were 100% and 95.0% for the TG and CG, respectively; this difference was not statistically significant ($P = 0.38$). The mean ISQ values of the TG and CG did not differ at placement (68.2 vs. 67.8, $P = 0.1$), at delivery of the final restoration (69.5 vs. 69.4, $P = 0.9$), and after 1 year (71.0 vs. 71.5, $P = 0.1$); at 3 years, the CG had a significantly higher mean ISQ than the TG (72.4 vs. 71.6, $P = 0.004$). Mean MBL was significantly higher in the CG than in the TG, both at 1 year (0.14 mm vs. 0.21 mm, $P = 0.006$) and at 3 years (0.20 mm vs. 0.27 mm, $P = 0.01$). A few complications were reported. Surgical time and cost were significantly higher in the CG than in the TG ($P < 0.0001$). Patient satisfaction was high in both groups.

Conclusions: In this randomized controlled trial, results for short (6-mm) implants were similar to those for longer (≥10-mm) implants in augmented bone. Short implants might be preferable to SFE, because the treatment is faster and less expensive. Long-term randomized controlled trials are required to confirm these results.

Dental implants are a viable solution for the prosthetic rehabilitation of the posterior maxilla (Pabst et al. 2015; Simion et al. 2015). However, the edentulous posterior maxilla is often characterized by reduced bone volume, due to severe post-extraction alveolar crest resorption coupled with age-linked sinus pneumatization (Aghaloo & Moy 2007; Chan et al. 2014). This anatomic limitation is a problem that can affect osseointegration and the fabrication of a functional and esthetic implant-supported restoration, dictating the need for reconstructive osseous surgery in order to restore a sufficient bone for implant insertion (Aghaloo & Moy 2007; Chan et al. 2014).

Different bone augmentation techniques have been introduced to overcome this problem (Tong et al. 1998; Papaspyridakos et al. 2013). Among these, maxillary sinus floor elevation has become the more reliable, commonly used procedure to increase bone height in the posterior maxilla (Nkenke & Stelzle 2009; Duttenhoefer et al. 2013). Although maxillary sinus floor elevation can be successfully employed to regenerate bone and allow the placement of implants of

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standard length (Tetsch et al. 2010; Oliveira et al. 2012; Mangano et al. 2013), recent studies have pointed out that this surgical intervention increases treatment duration and cost (Esposito et al. 2014a; Lee et al. 2014). In addition, complications (such as postoperative sinusitis, partial or total graft failure) may occur after sinus floor elevation (Barone et al. 2006; Nkenke & Stelzle 2009; Chan & Wang 2011; Lee et al. 2013). Consequently, patients are often reluctant to undergo this procedure (Pommer et al. 2014).

The placement of short (<10-mm) dental implants represents a viable, minimally invasive alternative treatment solution for the prosthetic restoration of the posterior maxilla with limited amount of bone (Atieh et al. 2012; Mertens et al. 2012; Lai et al. 2013; Bratu et al. 2014; Mangano et al. 2014a). The use of short implants simplifies the restoration: in fact, no sinus floor elevation is required, reducing the risk of complications and treatment time and cost and, thus, increasing the patient's acceptance of the treatment (Atieh et al. 2012; Mertens et al. 2012; Lai et al. 2013; Bratu et al. 2014; Esposito et al. 2014a; Lee et al. 2014; Mangano et al. 2014a). Survival and success rates for short dental implants are comparable to those for standard-length implants, as reported by several systematic reviews (Atieh et al. 2012; Lee et al. 2014; Monje et al. 2014) and clinical studies (Mertens et al. 2012; Lai et al. 2013; Bratu et al. 2014; Mangano et al. 2014a).

However, only a few randomized controlled trials have compared the clinical outcomes of short dental implants with those of longer fixtures inserted in the posterior augmented maxilla (Pistilli et al. 2013a,b; Esposito et al. 2014b; Guljé et al. 2014); most of these were based on a limited number of patients with short follow-up times.

The aim of the 3-year follow-up randomized clinical trial described here was to evaluate whether short (6-mm) dental implants placed in the posterior atrophic maxilla are a viable alternative to sinus floor elevation and placement of longer (≥10-mm) fixtures. The primary outcomes of the study were implant survival, stability, marginal bone loss, and complications associated with the two treatment options; secondary outcomes included treatment time and cost and patient satisfaction.

Material and methods

Patient selection

In the period between January 2010 and December 2012, all patients referred for treatment with dental implants were considered for enrollment in the present study. The inclusion criteria were as follows: (1) partial edentulism in the posterior atrophic maxilla; (2) post-extraction or healed sites (at least 4 months after extraction) with residual bone height ≥4 mm and width ≥5 mm under the maxillary sinus; (3) one to four adjacent implants required; (4) dentition in the posterior mandible for occlusal contacts; (5) age ≥18; and (6) ability to sign an informed consent form. Patient eligibility in terms of bone dimensions was determined on orthopantomography (OPT) and cone beam computed tomography (CBCT) scans. Exclusion criteria were as follows: (1) severe systemic diseases that might contraindicate intervention; (2) uncontrolled diabetes mellitus; (3) immunocompromised status; (4) coagulation disorders; (5) radiotherapy; (6) chemotherapy; (7) alcohol or drug abuse; (8) pregnancy or lactation; (9) use of oral and/or intravenous amino-bisphosphonates; (10) untreated active periodontal infections; (11) active infection in the site of implant placement; (12) acute or chronic sinusitis; (13) history of sinus surgery; and (14) bruxism. Smoking, history of periodontal disease, and bruxism were recorded, but only the latter was an exclusion criterion. Patients were informed that smoking (Moy et al. 2005; Lin et al. 2012) and history of periodontal disease (Stanford 2010; Ramanauskaite et al. 2014) can be associated with an increased risk of implant failure. Patient questionnaires, clinical examination, and electromyography were used for the diagnosis of bruxism (Lobbezoo et al. 2013). All patients signed an informed consent form, after being informed in details on the planned treatment. The Ethics Committee for Human Clinical Trials at Guarulhos University approved the study protocol, which was conducted in accordance with the principles defined in the Declaration of Helsinki on experimentation involving human subjects, as revised in 2008.

Preoperative study

A careful preoperative clinical and radiological assessment was performed in each patient. Orthopantomography (OPT) was the basic examination. If requested by the surgeon, OPT was followed by CBCT scan. CBCT scans were used to accurately assess the bone volume at each implant site, including height, width, density, and ridge angulation. The preoperative assessment was completed by an accurate study of the residual anatomy using plaster models and prosthetic wax-up.

Study design

This study was designed as a prospective, randomized, controlled study. Before starting, operators met to reach a consensus on the protocol to be adopted. Patients were randomly assigned either to receive one to four short (6-mm) implants (test group) or to undergo augmentation procedures and simultaneous placement of one to four standard-length (≥10-mm) implants (control group). Within the same group, patients could undergo bilateral treatment (i.e., short implants in the right and left posterior maxilla or bilateral maxillary sinus augmentation and placement of standard-length implants). Randomization was performed prior to surgery by opening a sequentially numbered sealed envelope corresponding to the patient recruitment number. In both groups of patients, dental implants featuring a tapered design with strong self-cutting threads (AnyRidge Implants, MegaGen Implant, Gyeongbuk, South Korea) were used. These implants have an internal hexagon combined with a 5-mm-deep conical connection (10°), providing a tight seal and high mechanical strength, with built-in platform switching designed to maintain crestal bone and to increase soft tissue volume (Luongo et al. 2014). The implants feature a novel nanostructured calcium-incorporated surface (Lee et al. 2012). In the control group, the augmentation procedures consisted of the insertion of collagenated porcine particulate bone graft (OsteoBiol GenOs, Tecnoss Dental, Turin, Italy) in a lateral window below the lifted membrane, with simultaneous implant placement.

Surgical procedures

One hour before surgery, each patient was given a prophylactic antibiotic, 500 mg amoxicillin plus clavulanic acid (Augmentin; GlaxoSmithkline Beecham, Brentford, UK); the patients were subsequently asked to rinse with chlorhexidine 0.2% mouthwash (OralB, Boston, MA, USA) for 1 min. Anesthesia was administered by infiltrating articaine (4%) with 1 : 100,000 adrenaline (Ubistesin; 3M Espe, St. Paul, MN, USA).

The test group (short implants) included both fresh post-extraction sites and healed sites (defined as sites with at least 4 months of undisturbed healing after tooth extraction). In fresh post-extraction sockets, a flapless approach was used. The failing teeth were extracted as atraumatically as possible. Sockets were debrided of remaining granulation tissue with an excavator and irrigated with sterile saline.

Subsequently, the extraction socket was carefully examined with a periodontal probe, to verify the integrity of the alveolar walls. Afterward, the preparation of the osteotomy was performed using an adapted surgical protocol based on the bone quality of the implant site. In brief, bone quality was evaluated at drilling, according to the clinician's judgment, and the final drill size was based on bone quality, so that the fixtures were inserted in underprepared osteotomies, deepened beyond the alveolar apex, to engage the apical bone and increase primary stability. Saline irrigation was used throughout the drilling procedure. No specific precautions were taken to preserve the Schneiderian membrane from perforation in this phase. In healed sites, a midcrestal incision was made, connected to two releasing incisions, and then a full-thickness flap was raised. The implant sites were prepared according to the aforementioned surgical protocol, based on the bone density of the implant sites. Drills of increasing diameter were used. Implant sites were slightly underprepared. In both fresh post-extraction sockets and healed sites, the surgeon had to place short (6-mm) implants, but was free to choose from the available implant diameters (4–8 mm) according to clinical indications and his preferences. All fixtures were placed at the bone crest level.

In the control group (standard-length implants in augmented sites), the maxillary sinuses were augmented using the lateral approach. After crestal incision and flap elevation, a lateral window was outlined and moved internally. After careful elevation of the Schneiderian membrane, the sinus cavity was partially filled with a collagenated porcine particulate bone graft; then, one to four 10-, 11.5-, 13-, or 15-mm fixtures were inserted, according to the previously described protocol. Again, the operator was free to choose appropriate implant diameters (4–8 mm) on the basis of clinical indications and his preferences. Finally, the sinus cavity was completely packed and overfilled with bone graft particles, and the lateral window was covered with a pericardium porcine resorbable collagen membrane (Osteobiol Evolution, Tecnoss Dental, Turin, Italy).

In both groups, all implants were placed using a manual ratchet and then exposed to evaluate primary stability with a resonance frequency analysis (RFA) instrument (Osstell Mentor; Ostell, Goteborg, Sweden; Kim et al. 2015). Implant stability quotient values were measured from the four sites (mesial, distal, buccal, and lingual sites) for each implant. An average value was calculated from the four measurements, rounded to a whole number, and regarded as the final ISQ of the implant. A submerged healing protocol was selected for implants with an ISQ <60, whereas a non-submerged healing protocol (with placement of healing abutments) was selected in implants with an ISQ ≥60. The mucoperiosteal flaps were repositioned and sutured over the cover screws (submerged healing) or around the healing abutments (non-submerged healing) using resorbable sutures.

After surgical procedures, all patients were prescribed oral antibiotics, 500 mg amoxicillin plus clavulanic acid (Augmentin; GlaxoSmithkline), every 8 h (three times per day) for 6 days. Postoperative pain was controlled with 600 mg ibuprofen (Actron; Bayer Scherig Pharma, Berlin, Germany) every 12 h for 2 days. Detailed instructions on oral hygiene were provided; chlorhexidine 0.2% mouth rinse (OralB) twice a day and a soft diet were recommended for 2 weeks. Patients were recalled and checked 3 days, 10 days (suture removal), and 1 month postoperation; they were not allowed to wear removable dentures up to 1 month postoperatively.

Prosthetic procedures

All implants were left unloaded to achieve osseointegration over a period of 4 months; then, where necessary, the implants were uncovered and the cover screws were replaced with healing abutments. Impressions were taken, and provisional acrylic resin restorations, consisting of cemented or screw-retained single crowns (SCs) and fixed partial dentures (FPDs), were provided. The provisional remained *in situ* for 4 months, after which definitive restorations were provided. The definitive restorations comprised single crowns (SCs) and fixed partial dentures (FPDs). All definitive restorations were ceramometallic, screwed or cemented with temporary zinc oxide–eugenol cement. An accurate control of occlusion was performed, and protrusion and laterotrusion were evaluated on the articulator and intra-orally. Maintenance care was given every 6 months. All patients were included in an annual recall program.

Outcome measures

At each annual inspection, an experienced, calibrated, independent examiner performed a careful clinical examination of the fixtures, peri-implant tissues, and prostheses. The primary outcome measures were implant survival, stability, marginal bone loss, and complications.

Implant survival

All implant losses were considered as failures. Implant mobility in the absence of signs of infection, persistent/recurrent infections (with pain, suppuration, bone loss), progressive marginal bone loss caused by mechanical overload, and implant fracture were indications for implant failure. Implant losses were divided into "early" (before the connection of the prosthetic abutment) and "late" (after the connection of the prosthetic abutment) failures.

Implant stability

Resonance frequency analysis was employed to measure implant stability with a dedicated instrument (Osstell Mentor; Osstell; Kim et al. 2015). For each implant, ISQ values were measured from the four sites (mesial, distal, buccal, and palatal sites). The mean of all measurements was rounded to a whole number and regarded as the final ISQ of the implant. Afterward, the abutments were repositioned and installed on the implants, so that the prostheses could be re-inserted. ISQ values were obtained after implant insertion, at the delivery of the final restoration, and at the 1- and 3-year follow-up examinations.

Peri-implant marginal bone loss

Orthopantomographies were taken of each patient at baseline (immediately after implant insertion), delivery of the final restoration, and 1 and 3 years after implant placement. Radiographs were digitized, converted to TIFF (600-dpi resolution), and saved in a dedicated folder. Peri-implant marginal bone levels were then measured using dedicated software (Scion Image; Scion, Frederick, MD, USA). Marginal bone levels were measured on the mesial and distal sides of each implant (Galindo-Moreno et al. 2014). Reference points for the linear measurements were the coronal margin of the implant shoulder and the most coronal point of bone-to-implant contact; to adjust for distortions, the software was calibrated for every single image using the known distance of two consecutive implant threads. Accordingly, MBL was calculated as modification in the peri-implant marginal bone levels at different periods; the average of the mesial and distal calculations was used as the final value (Galindo-Moreno et al. 2014). All radiographic measurements were taken

by the same experienced independent examiner.

Complications

Complications were biological and/or prosthetic. Biological complications included intraoperative complications (intraoperative bleeding), immediate postoperative complications (pain and swelling after surgery, acute sinus infection), late postoperative complications (chronic sinus infection, partial or complete graft failure), and problems in the function caused by an infectious process affecting the peri-implant tissues (peri-implant mucositis or peri-implantitis). Peri-implant mucositis is characterized by soft tissue inflammation, pain, or swelling, with no peri-implant bone loss; peri-implantitis is characterized by peri-implant infection with pain, suppuration/exudation, fistula formation, discomfort on occlusion, and advanced peri-implant bone loss. The threshold to define peri-implantitis was set at a probing pocket depth ≥6 mm with bleeding on probing/suppuration and peri-implant bone loss >3.0 mm (Shibli et al. 2008).

Prosthetic complications included failures or complications of prefabricated implant components (abutment loosening and abutment fracture) and superstructure-related failures (such as fracture of the metallic framework of the restoration, decementation/loss of retention, and ceramic fracture/chipping; Mangano et al. 2014b).

The evaluation of complications included identification of any complications that had affected the restorations over the 3-year follow-up period. The secondary outcomes were treatment time and cost and patient satisfaction.

Treatment time and cost

The time required for placement of one single implant, with both treatments (short implants and sinus floor elevation with placement of longer implants) was calculated as follows. The time required for the entire surgical procedure (from anesthesia to sutures) was assessed for each patient and divided by the number of installed fixtures. The ratio of the time required for placement of a single short implant to the time required for a sinus floor elevation procedure in combination with a longer implant was calculated and expressed as a percentage.

Finally, to assess the cost of the treatments, the costs associated with both treatments for the placement of one single implant (limited to the surgery, without prosthetic treatment) was calculated by dividing the overall fee paid by each patient by the number of installed implants. The ratio of the cost for implant therapy with a short implant to the cost for sinus floor elevation procedure and placement of a longer implant was calculated and expressed as a percentage.

Patient satisfaction

Patient satisfaction with both treatments (short implants and sinus floor elevation with placement of longer implants) was assessed. All patients were asked to give their perception of the received therapy by completing the following questionnaire concerning function, esthetics, cleaning of the implant-supported restorations, satisfaction, and cost.

1. Does my implant-supported restoration(s) function well?
2. Do I feel secure biting/chewing on my implant-supported restoration(s)?
3. Am I pleased with the esthetic result?
4. Can I clean my implant-supported restoration(s) well?
5. Am I satisfied with the treatment?
6. Would I undergo this treatment again, if requested?
7. Would I recommend this treatment to a relative/friend?
8. Is the cost of treatment justified?

The questions were evaluated using a three-grade scale: "yes I am fully satisfied," "yes I am quite satisfied," "no, I am not satisfied".

Statistical analysis

All collected data were inserted in a sheet for statistical analysis (Excel 2003; Microsoft, Redmond, WA, USA). Frequency distributions were calculated for patient demographics (gender, age group, smoking status, and history of periodontal disease) and implant characteristics (implant position, length, and diameter); we used the Fisher's exact test to compare the distributions. Implant survival was calculated both at the implant level and at the patient level. In the patient-based analysis, in the case of multiple indications (with the same patient receiving more than one implant), the patient was classified as a failure even if there was only one implant loss. We compared the failure frequencies in the two study groups with Fisher's exact test. Means and 95% confidence intervals (95% CIs) were calculated for quantitative variables, such as ISQ and MBL. To estimate the mean change over time in ISQ by group, we used a repeated-measures linear regression model including ISQ at placement, treatment group, the visit, and the interaction between visit and group as covariate. The within-patient correlation due to multiple implants and to repeated measurements over time was modeled using a compound-symmetry variance–covariance structure. Sensitivity analyses modifying the variance–covariance structure did substantially confirm the results. The analysis was also repeated taking into consideration trends in short implant subtype. A similar repeated-measures approach was used to estimate the mean difference and its 95% confidence interval in MBL at 1 and 3 years for the control and test groups. Complications were described using descriptive statistics, and their frequencies in the study groups compared using Fisher's exact test. Finally, secondary outcomes like treatment time and cost and patient satisfaction were summarized using descriptive statistics, and their distribution in the two study groups was compared using a nonparametric approach (Fisher's test for patient satisfaction and Wilcoxon's rank test for treatment time and cost assessment). The level of significance was set at 0.05. All computations were carried out with statistical analysis software (SAS 9.4 release; SAS, Cary, NC, USA).

Results

Patient population and implant-supported restorations

Fifty-three patients (19 males and 34 females) aged between 21 and 76 years (mean age: 48.1 ± 15.1 years, median: 48, 95% CI: 44.0–52.1) were included in this study. Among these, 15 (28.3%) were smokers. According to the study design, the patients were randomly divided into two groups: 33 patients (10 males and 23 females) aged between 21 and 76 years (mean age: 47.5 ± 16.2 years, median: 48, 95% CI: 42.0–53.0) were assigned to the test group (short implants without sinus floor elevation), and 20 patients (9 males, 11 females) aged between 28 and 75 years (mean age: 49.2 ± 13.4, median: 47.5, 95% CI: 43.0–55.0) were assigned to the control group (sinus floor elevation with standard-length implants). Patient demographics are summarized in Table 1. Baseline demographics (gender, age, smoking habits, history of periodontal disease) did not reveal significant differences between the two groups. Twenty-one of the 53 enrolled patients had multiple indications for implant treatment (13 patients received 2 implants, 2 patients received 3 implants, 4 patients received 4 implants, and

Table 1. **Patient demographics**

		Groups (%)		
	All patients	Test group	Control group	*P**
N	53	33	20	–
Gender, *n*				
Males	19	10 (30.3)	9 (45.0)	0.4
Females	34	23 (69.7)	11 (55.0)	
Age, *n*				
25–44 years	24	15 (45.5)	9 (45.0)	0.9
45–64 years	18	11 (33.3)	7 (35.0)	
65–84 years	11	7 (21.2)	4 (20.0)	
Smoke, *n*				
Non-smokers	38	26 (78.8)	12 (60.0)	0.2
Smokers	15	7 (21.2)	8 (40.0)	
History of periodontal disease, *n*				
No history	35	24 (72.7)	11 (55.0)	0.2
History	18	9 (27.3)	9 (45.0)	

*Fisher's exact test.

2 received 5 implants), so a total of 90 implants were installed. Forty-five implants were finally inserted in each group of patients.

In the test group, 33 patients received 45 implants (25 patients received 1 implant, 6 patients received 2 implants, 1 patient received 3 implants, and 1 patient received 5 implants); in the control group, 20 patients received 45 implants (7 patients received 1 implant, 7 patients received 2 implants, 1 patient received 3 implants, 4 patients received 4 implants, and 1 patient received 5 implants). In the test group, 36 implants were inserted in healed sites (at least 4 months after teeth extraction) of 25 patients, whereas 9 implants were inserted in the extraction sockets (immediate implant placement) of 8 patients. Among the test implants placed in healed sites, 24 (15 patients) were placed in ridges with a residual height of 4 mm, whereas 12 (10 patients) were placed in healed ridges with a residual height of 5–6 mm; among the control implants, 25 (10 patients) were placed in healed ridges with a residual height of 4 mm, whereas 20 (10 patients) were placed in healed ridges with a residual height of 5–6 mm. In the test group, the most frequent indication was the restoration of single tooth gaps (24 implants were placed to support SCs); the least frequent indication was the restoration of partially edentulous patients with FPDs (21 implants were placed to support 11 FPDs). Conversely, in the control group, 21 implants were placed to support SCs, and 24 implants were inserted to restore partially edentulous patients (12 FPDs). The distribution of the implants with respect to position, length, diameter, and type of supported restoration is outlined in Table 2. There was a significant difference in the distribution of the implants between the two groups with respect to implant diameter (implant diameter was narrower in the control group than in the test group, $P < 0.0001$); there were no significant differences in the distribution of implants between the two groups with respect to implant position and type of supported restoration.

Table 2. **Implant characteristics**

		Groups (%)		
	All implants	Test group	Control group	*P**
N	90	45	45	–
Position, *n*				
Second premolar	7	3 (6.7)	4 (8.9)	0.3
First molar	48	28 (62.2)	20 (44.4)	
Second Molar	35	14 (31.1)	21 (46.7)	
Implant length, *n*				
6.0 mm	45	45 (100)	–	–
10.0 mm	5	–	5 (11.1)	
11.5 mm	24	–	24 (53.3)	
13.0 mm	11	–	11 (24.5)	
15.0 mm	5	–	5 (11.1)	
Implant diameter, *n*				
4.0	21	1 (2.2)	20 (44.5)	<0.0001
4.5	28	10 (22.2)	18 (40)	
5.0	34	28 (62.2)	6 (13.3)	
> 5.0	7	6 (13.4)	1 (2.2)	
Type of restoration, *n*				
SCs	45	24 (53.3)	21 (46.7)	0.7
FPDs	45	21 (46.7)	24 (53.3)	

*Fisher's exact test.

Implant survival

Over the 3-year period after surgery, only two implant failures occurred, both in the same patient (control group). This patient was a 55-year-old male smoker with a history of periodontal disease; the failed implants were 4 mm in diameter × 11.5 mm in length, placed in the first and second molar positions with the intention to support a FPD. These failures occurred 2 months after surgery (before connection of the prosthetic abutment) and were classified as "early failures": they were caused by chronic sinus infection with loss of integration/implant stability. No further implant failures were observed in the control group after the delivery of prosthetic restorations. No implant failures occurred in the test group. Overall, 1-year survival rates of 97.8% (implant-based) and 98.2% (patient-based) were found. In the test group, the implant survival rate was 100% at the implant (45/45) and patient (33/33) levels; in the control group, the survival rates were 95.6% (43/45) at the implant level and 95.0% (19/20) at the patient level. There were no significant differences in the 1-year implant survival rate between the groups at both the implant level ($P = 0.49$) and patient level ($P = 0.38$). One 76-year-old male patient in the test group (one implant) died 2.5 years after implant placement and was consequently lost to follow-up: this patient was considered a dropout and was excluded from the study. No other patients dropped out of this study, so 52 patients were available for the 3-year follow-up examination. Overall, 3-year survival rates of 97.8% (implant-based) and 98.1% (patient-based) were reported. The test group had a 100% implant survival rate at both the implant level (44/44) and patient level (32/32); the control group had a 95.6% survival rate (43/45) at the implant level and a 95.0% survival rate (19/20) at the patient level. There were no significant differences between the two groups at the 3-year follow-up at both the implant level ($P = 0.49$) and patient level ($P = 0.38$).

Implant stability

The mean ISQ values of the test and control groups did not differ at placement (test 68.2

vs. control 67.8, $P = 0.1$), at delivery of the final restoration (test 69.5 vs. control 69.4, $P = 0.9$), and after 1 year (test 71.0 vs. control 71.5, $P = 0.1$); however, at 3 years, the control group had a significantly higher mean ISQ than the test group (72.4 vs. 71.6, $P = 0.004$). On the basis of the mean change over time, the ISQ did increase between placement and delivery by 1.6 and 1.2 units in the control and test groups, respectively, and by an additional 2.1 and 1.5 units between delivery and 1 year. The mean change between 1 and 3 years was <1 unit in both the control and test groups. Significant differences in the trends were not observed. However, considering the cumulative change from placement, ISQ increased more in the control group than in the test group, both at 1 year (3.7 vs. 2.8 units, $P = 0.002$) and at 3 years (4.6 vs. 3.3 units, $P < 0.0001$). The mean (95% CI) ISQ values at placement, at delivery of final restorations, and after 1 and 3 years of follow-up in the two groups, with a trend assessment over time, are listed in Table 3.

Peri-implant marginal bone loss

Overall, a mean MBL values of 0.18 ± 0.09 mm (median: 0.15, range: 0–0.41) and 0.24 ± 0.11 mm (median: 0.23, range: 0–0.5) were found at the 1- and 3-year follow-up evaluations, respectively. Minimal bone changes around implants were observed with time; however, this difference was significant ($P < 0.0001$). Mean MBL was significantly higher in the control group than in the test group, both at 1 year (0.14 mm vs. 0.21 mm, $P = 0.006$) and at 3 years (0.20 mm vs. 0.27 mm, $P = 0.01$). With respect to the short implant subtypes, the MBL of implants placed in the post-extraction socket was significantly lower than that of control implants, both at 1 year ($P = 0.03$) and at 3 years ($P = 0.02$). MBL of implants placed in healed ridges with 3–4 mm of residual bone was significantly lower than that of control implants, both at 1 year ($P = 0.003$) and at 3 years ($P = 0.005$); however, in the 5- to 6-mm subtype, mean MBL did not differ from the values for the control group at 1 year ($P = 0.5$) and 3 years ($P = 0.6$). Finally, with respect to the short implants, there were no statistically significant differences in MBL between the different subtypes at 1 year ($P = 0.2$) and 3 years ($P = 0.12$). MBL values of the different groups and subgroups are summarized in Table 4.

Complications

No complications were reported for the test group. In the control group, 19 biological complications occurred: 3 were intraoperative (intraoperative bleeding) and 16 were immediately postoperative (1 patient experienced pain and swelling after surgery, and 14 patients experienced swelling alone); finally, one patient experienced a late postoperative complication (chronic sinus infection with complete graft loss) which led to the loss of two implants. Significant differences were reported between the two groups with respect to intraoperative bleeding ($P = 0.049$) and swelling after surgery ($P < 0.0001$). Peri-implant mucositis or peri-implantitis was not reported. All implant-supported restorations were free from prosthetic complications; no mechanical or technical complications were reported over the 3-year period. The complications that occurred in both groups are reported in Table 5.

Treatment time and cost

In the test group (short implants), the mean time needed for placement of one single implant was 19.1 ± 7.1 min (median: 15, 25th–75th percentile: 15–20 min), whereas in the control group (sinus floor elevation with longer implants), the mean time needed was 32.2 ± 8.5 min (median: 30; 25th–75th percentile: 25–35 min). The calculated ratio (short implant/sinus grafting with longer implant) was 59%. The sinus floor elevation

Table 3. **Mean (95% CI) values of ISQ at placement, at delivery of final restoration, and after 1 and 3 years of follow-up in the control and in the test group, and over time trend assessment**

	Control group		Test group			
Time	Mean (95% CI)	Δ (95% CI)‡	Mean (95% CI)	Δ (95% CI) ‡	*P**	*P*†
At placement	67.8 (67.4–68.2)	–	68.2 (67.9–68.6)	–	0.1	–
At delivery of final restoration	69.4 (69.0–69.8)	1.6 (1.2–2.0)	69.5 (69.1–69.8)	1.2 (0.8–1.6)	0.9	0.2
At 1 year	71.5 (71.1–71.9)	2.1 (1.7–2.5)	71.0 (70.6–71.4)	1.5 (1.1–1.9)	0.1	0.1
At 3 years	72.4 (72.0–72.8)	0.9 (0.4–1.3)	71.6 (71.2–71.9)	0.6 (0.2–1.0)	**0.004**	0.3
1-year change from placement	–	3.7 (3.3–4.1)	–	2.8 (2.3–3.2)	–	**0.002**
3-year change from placement	–	4.6 (4.1–5.0)	–	3.3 (2.9–3.7)	–	**<0.0001**

Mean (95% CI) from a repeated-measures model with ISQ at placement as covariate, allowing for a nonzero correlation between implants in the same object.
**P* value for testing the hypothesis of no difference in ISQ mean values between control and test groups at each time period.
†*P* value for testing the hypothesis of no difference in ISQ mean change values between control and test groups.
‡Incremental change in mean ISQ from a repeated-measures model with ISQ at placement as covariate.

Table 4. **Detailed data of changes in peri-implant marginal bone levels between groups at different time periods (implant level) in mm**

	MBL at 1 year			MBL at 3 years		
	N	Mean (95% CI)	*P* value*	*N*	Mean (95% CI)	*P* value*
Control group	43	0.210 (0.176–0.244)	–	43	0.273 (0.232–0.313)	–
Test group						
Healed ridges 3–4 mm	24	0.126 (0.08–0.167)	**0.003**	24	0.180 (0.131–0.229)	**0.005**
Healed ridges 5–6 mm	12	0.188 (0.135–0.240)	0.5	12	0.255 (0.193–0.317)	0.6
Post-extraction sockets	9	0.135 (0.08–0.195)	**0.03**	8	0.173 (0.100–0.248)	**0.02**
All implants	45	0.146 (0.117–0.175)	**0.006**	44	0.201 (0.166–0.236)	**0.01**

Mean (95% CI) from a repeated-measures model, allowing for a nonzero correlation between implants on the same patient.
*Hypothesis of no difference in MBL between the test and the control groups, and between each short implant subtype and the control group (*t*-test).

Table 5. **Detailed data about complications encountered in the two groups of patients, over a 3-year period**

	All patients (n = 53)	Groups (%)		P*
		Test group (n = 33)	Control group (n = 20)	
Biological complications				
Intraoperative bleeding	3/53	0/33 (0.0)	3/20 (15)	**0.049**
Pain	1/53	0/33 (0.0)	1/20 (5)	0.4
Swelling	15/53	0/33 (0.0)	15/20 (75)	**<0.0001**
Acute sinus infection	–	–	–	–
Chronic sinus infection	1/53	0/33 (0.0)	1 (5)	0.4
Peri-implant mucositis	–	–	–	–
Peri-implantitis	–	–	–	–
Prosthetic complications				
Mechanical complications	–	–	–	–
Technical complications	–	–	–	–

*Fisher's exact test.

procedure almost doubled the time needed for the intervention. The difference between the two groups was statistically significant ($P < 0.0001$).

The cost of both treatment modalities was calculated for one single implant limited to the surgery (without prosthetic treatment). The cost for the placement of one single implant in the short implant group was 700 EUR, whereas in the longer implant group, the mean cost was 1322 ± 490 EUR (median: 1700, 25th–75th percentile: 700–1700 EUR). The calculated ratio (short implant/sinus grafting with longer implant) was 52%. The sinus floor elevation procedure almost doubled the price for the intervention. The difference between the two groups was statistically significant ($P < 0.0001$).

Patient satisfaction

The two statements addressing function and biting/chewing comfort yielded very high patient satisfaction; the vast majority of patients in both the test (29/32, 90.6%) and control (17/20, 85.0%) groups were very satisfied. Three patients each in the test (3/32, 9.4%) and control (3/20, 15.0%) groups stated they were sufficiently satisfied with function; no patients said they were dissatisfied. There were no significant differences between the two groups with respect to satisfaction with function ($P = 0.7$). The majority of patients were highly satisfied with esthetics (test group: 27/32, 84.4%; control group: 15/20, 75.0%). Five patients each in the test (5/32, 15.6%) and control (5/20, 25.0%) groups stated they were sufficiently satisfied with the esthetic results; no patients said they were dissatisfied with the esthetic outcome. Again, there were no significant differences between the two groups of patients with respect to their perceptions of esthetic outcome ($P = 0.5$). No patients had problems cleaning the implant-supported restorations: the vast majority were fully (test 30/32, 93.8%; control 18/20, 90.0%) or sufficiently (test 2/32, 6.2%; control 2/20, 10.0%) satisfied with cleaning. There were no significant differences between the groups ($P = 0.6$). The majority of patients in both the test (29/32, 90.6%) and control (17/20, 85.0%) groups indicated that the outcome fully satisfied their expectations; 3 patients each in the test (3/32, 9.4%) and control (3/20, 15.0%) groups stated they were sufficiently satisfied; and no patients indicated they were dissatisfied. Accordingly, the same majority of patients (test 29/32, 90.6%; control 17/20, 85.0%) would be willing to undergo the same treatment again and would even recommend such treatment to relatives or friends, if indicated. There were no significant differences between the groups with respect to overall satisfaction with the treatment ($P = 0.7$). The cost for implant therapy was deemed to be justified and reasonable to many patients. In the test group, the majority of patients were fully satisfied with the cost (27/32: 84.4%) and five patients were sufficiently satisfied (5/32, 15.6%). Fewer patients in the control group were fully satisfied with the cost (11/20, 55.0%), and nine patients (9/20, 45.0%) were sufficiently satisfied. Although no patients indicated they were dissatisfied with the cost of treatment, perception of the cost of the therapy statistically significantly differed between the groups ($P = 0.03$). Patient satisfaction in the two groups is summarized in Table 6.

Discussion

Although survival rates of fixtures inserted simultaneously with sinus floor elevation (Peleg et al. 2006) or staged after a period of 6 months (Tong et al. 1998; Oliveira et al. 2012; Mangano et al. 2013) are high, complications (sinusitis, partial or total loss of bone graft) associated with this procedure have been reported (Barone et al. 2006; Nkenke & Stelzle 2009; Chan & Wang 2011; Lee et al. 2013; Esposito et al. 2014b). The results from systematic reviews, including clinical studies in which the lateral window approach and simultaneous implant placement were used, indicated that complications occur in up to 38% of patients (Stricker et al. 2003) and implants fail in up to 17% of patients within 3 years (Pjetursson et al. 2008).

Short dental implants can be used as an alternative to longer implants in purposely augmented bone, to support fixed prostheses in the rehabilitation of patients with an atrophic posterior maxilla (Atieh et al. 2012; Mertens et al. 2012; Lai et al. 2013; Bratu et al. 2014; Mangano et al. 2014a; Monje et al. 2014). At present, the use of short implants is widespread in posterior maxillary regions, and several studies have indicated that it is possible to place these fixtures without compromising the short- and long-term outcomes of implant prosthetic rehabilitation (Atieh et al. 2012; Mertens et al. 2012; Lai et al. 2013; Bratu et al. 2014; Mangano et al. 2014a; Monje et al. 2014). However, only a few randomized controlled studies have compared the two treatment alternatives (Pistilli et al. 2013a,b; Esposito et al. 2014b; Guljé et al. 2014; Thoma et al. 2015), and still no clear evidence is available as to whether short implants are preferable to sinus floor elevation with placement of longer implants.

In a recent 1-year follow-up randomized controlled trial, the authors (Thoma et al. 2015) tested whether the use of short (6-mm) fixtures results in a survival rate similar to that for sinus grafting with placement of long implants (11–15 mm). In total, 101 patients with a posterior maxillary bone height of 5–7 mm randomly received short (6-mm) implants (short group) or sinus grafting with long (11- to 15-mm) implants (graft group; Thoma et al. 2015). One hundred and thirty-seven implants were placed (67 short, 70 long) and loaded after a period of 6 months. All implants were reconstructed with single non-splinted crowns. The primary outcome of the study was implant survival; secondary outcomes included treatment time and cost, safety, and patient satisfaction. At the end of the study, no implants failed. Both treatments were suitable; however, short implants were considered more favorable with respect

Table 6. **Patient satisfaction in the two groups**

	Yes, I am fully satisfied (%)	Yes, I am quite satisfied (%)	No, I am not satisfied (%)	*P**
Do my implant-supported restoration/s function well?				
Test group†	29 (90.6)	3 (9.4)	0 (0.0)	0.7
Control group	17 (85.0)	3 (15.0)	0 (0.0)	
Do I feel secure biting/chewing on my implant-supported restoration/s?				
Test group†	29 (90.6)	3 (9.4)	0 (0.0)	0.7
Control group	17 (85.0)	3 (15.0)	0 (0.0)	
Am I pleased with the esthetic result?				
Test group†	27 (84.4)	5 (15.6)	0 (0.0)	0.5
Control group	15 (75.0)	5 (25.0)	0 (0.0)	
Can I clean my implant-supported restoration/s well?				
Test group†	30 (93.8)	2 (6.2)	0 (0.0)	0.6
Control group	18 (90.0)	2 (10.0)	0 (0.0)	
Am I satisfied with the treatment?				
Test group†	29 (90.6)	3 (9.4)	0 (0.0)	0.7
Control group	17 (85.0)	3 (15.0)	0 (0.0)	
Would I undergo this treatment again?				
Test group†	29 (90.6)	3 (9.4)	0 (0.0)	0.7
Control group	17 (85.0)	3 (15.0)	0 (0.0)	
Would I recommend this treatment to a relative/friend?				
Test group†	29 (90.6)	3 (9.4)	0 (0.0)	0.7
Control group	17 (85.0)	3 (15.0)	0 (0.0)	
Is the cost of treatment justified?				
Test group†	27 (84.4)	5 (15.6)	0 (0.0)	**0.03**
Control group	11 (55.0)	9 (45.0)	0 (0.0)	

*Fisher's exact test.
†Data not available for one patient in the test group.

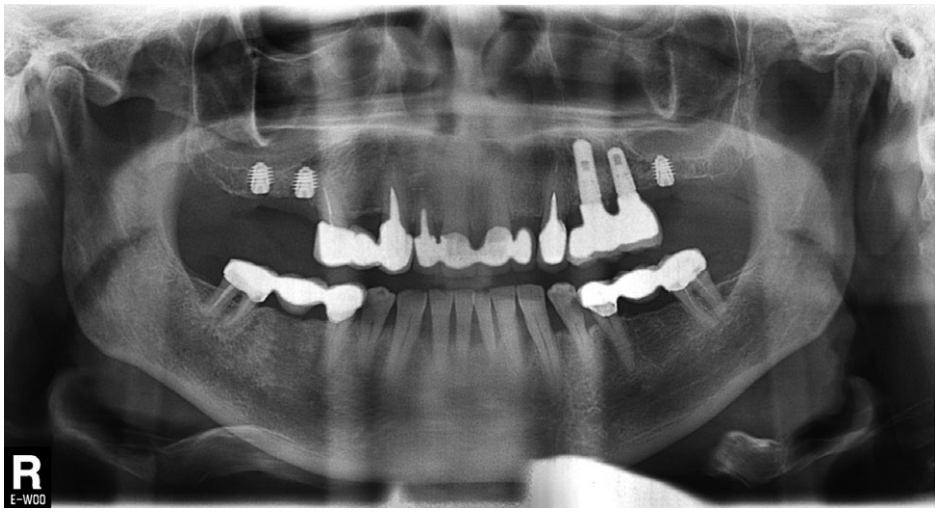

Fig. 1. Test group. Panoramic radiograph at implant placement.

to short-term patient morbidity and treatment time and cost (Thoma et al. 2015). In another randomized controlled trial with a 3-year follow-up, the authors (Esposito et al. 2014b) investigated short (5-mm) dental implants as an alternative to sinus augmentation with anorganic bovine bone and placement of long (≥10-mm) implants. Fifteen patients with bilateral atrophic maxillae (4–6 mm of bone height below the maxillary sinus) and a bone width ≥8 mm were randomized, according to a split-mouth design, to receive one to three short (5-mm) fixtures or long (≥10-mm) fixtures in augmented sinus (Esposito et al. 2014b). A submerged healing period of 4 months was established. The implants were restored with single crowns and fixed partial dentures. The outcome measures were implant failures, complications, and marginal bone loss. At the end of the study, there were no significant differences in implant survival and complications between the groups. However, patients lost, on average, 1.02 mm at short implants and 1.54 mm at long implants: this difference was statistically significant (Esposito et al. 2014b). Because the results for 5-mm-long implants were similar to those for the longer implants in augmented bone, the authors concluded that short implants may be preferable to sinus floor elevation, as the treatment is faster and less expensive (Esposito et al. 2014b). Similar results were obtained in another randomized controlled trial (Guljé et al. 2014), where the authors concluded that 6-mm implants and 11-mm implants combined with sinus floor elevation were equally successful in supporting single crowns in the resorbed posterior maxilla.

Our investigation was designed as a prospective randomized clinical trial based on data from 53 patients treated with short (6-mm) dental implants or sinus floor elevation and placement of longer (≥10-mm) dental implants. Thirty-three patients received short implants (test group), and 20 patients underwent sinus floor augmentation (control group) and placement of longer implants. In total, 45 implants were inserted in each group. Baseline demographics and the distribution of implants did not reveal statistically significant differences between the two groups, except in implant diameter. In the test group, the final restorations were 24 single crowns and 11 fixed partial dentures; in the control group, the final restorations were 21 single crowns and 12 fixed partial dentures. The distribution of the restorations was similar between the two groups. After 3 years of loading, only two implants failed, in the same patient (control group). These failures were attributed to a severe chronic sinus infection with complete graft loss. No implant failures were reported in the test group. Accordingly, a 100% survival rate was reported for short implants, and 95.6% (implant-based) and 95.0% (patient-based) survival rates were reported, respectively, for longer implants in combination with sinus floor elevation. The difference between the two groups was not statistically significant, in agreement with previous studies (Esposito et al. 2014b; Guljé et al. 2014; Thoma et al. 2015). Primary stability is paramount in the survival of dental implants. The implant stability quotient (ISQ) is the world standard for measuring implant stability. Measured with the RFA technique, the ISQ scale ranges from 1 to 100, but the acceptable stability range is 55–85. In the present study, sufficiently high stability was achieved immediately after placement of the implants, in both groups (test: 68.2, control: 67.8); the mean ISQ values of the test and control groups did not differ at placement.

It is well known that primary stability depends by bone quality/quantity, implant design, surface roughness, surgical technique,

and operator skill (Luongo et al. 2014). The threads of the fixtures used in the present study were designed to provide high insertion torque by increasing their dimensions toward the coronal end of the implant: this specific macrotopographic feature may allow for axial and radial bone compression during implant insertion, and it may be particularly useful in increasing primary stability. In this study, ISQ values increased with time in both groups. In accordance with the current literature, in fact, primary mechanical stability is enforced by new bone apposition on the implant surface (osseointegration) with time (Lee et al. 2012; Luongo et al. 2014). Implant surface properties have long been identified as an important factor in promotion of osseointegration: the implants used in this study featured a novel nanostructured calcium-incorporated surface that may have the potential to promote bone healing (Lee et al. 2012; Luongo et al. 2014). At the 3-year follow-up, mean ISQ values of 71.6 and 72.4 were reported for the test and control groups, respectively, in agreement with the current literature, in which the average ISQ value of all successful implants has been reported to be around 70 (Kim et al. 2015). In the present study, minimal bone changes around implants were observed with time; however, mean marginal bone loss was significantly higher in patients who underwent sinus floor elevation with placement of long implants than in patients who received short implants, as previously reported (Esposito et al. 2014b). Anyhow, peri-implant MBL has been calculated on panoramic radiographs (Figs 1–4): this represents a limit of the present study, as panoramic radiographs are *per se* subject to a certain degree of distortion. No mechanical complications were reported in our study; however, the control group had a significantly higher incidence of specific biological complications (intraoperative bleeding and swelling after surgery) compared with the test group. Several variables can alter the outcome of sinus floor elevation, such as the surgical technique, the timing of implant insertion in relation to grafting, the type of grafting material, and the use of barrier membranes (Tong et al. 1998; Nkenke & Stelzle 2009; Tetsch et al. 2010; Oliveira et al. 2012; Duttenhoefer et al. 2013; Mangano et al. 2013). Although maxillary sinus membrane perforation has been commonly described in the literature as an intraoperative complication in sinus floor elevation (Tong et al. 1998; Nkenke & Stelzle 2009; Tetsch et al. 2010; Oliveira et al. 2012; Duttenhoefer et al. 2013), we did not consider perforation

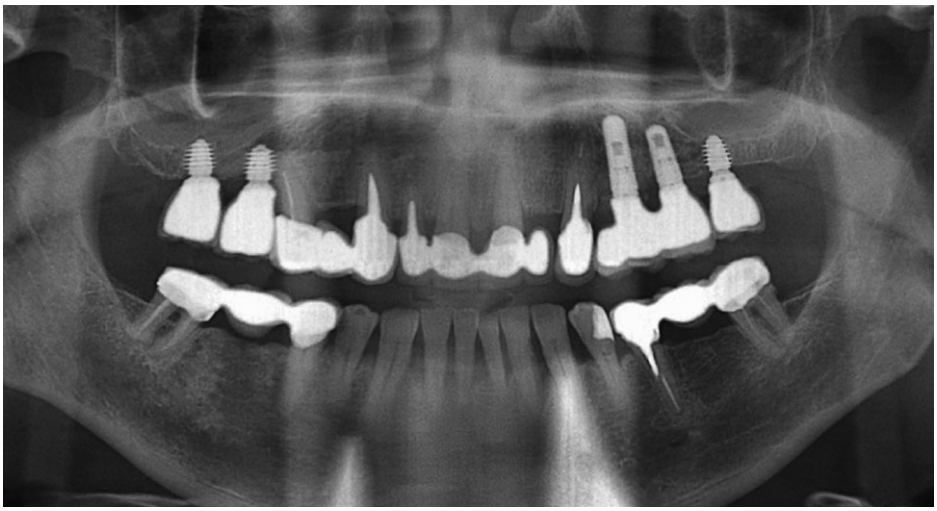

Fig. 2. Test group. Panoramic radiograph 3 years after implant placement.

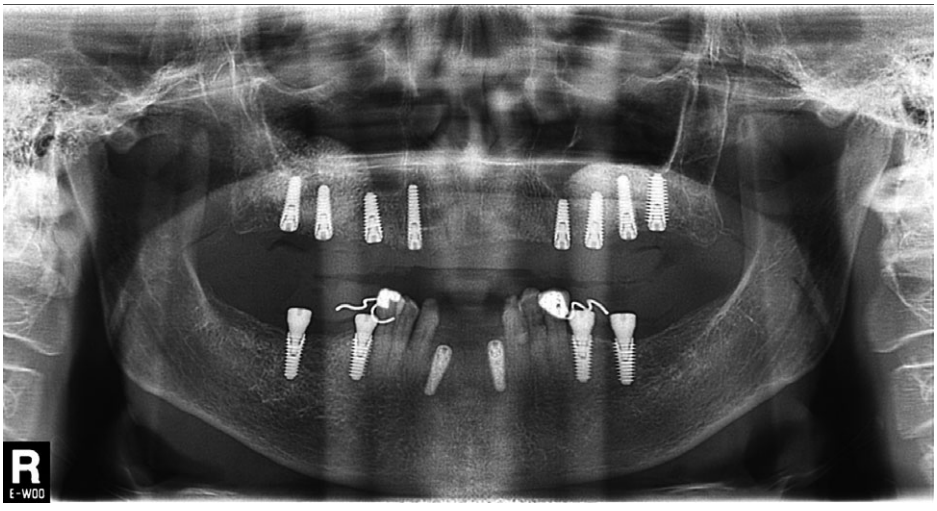

Fig. 3. Control group. Panoramic radiograph at placement.

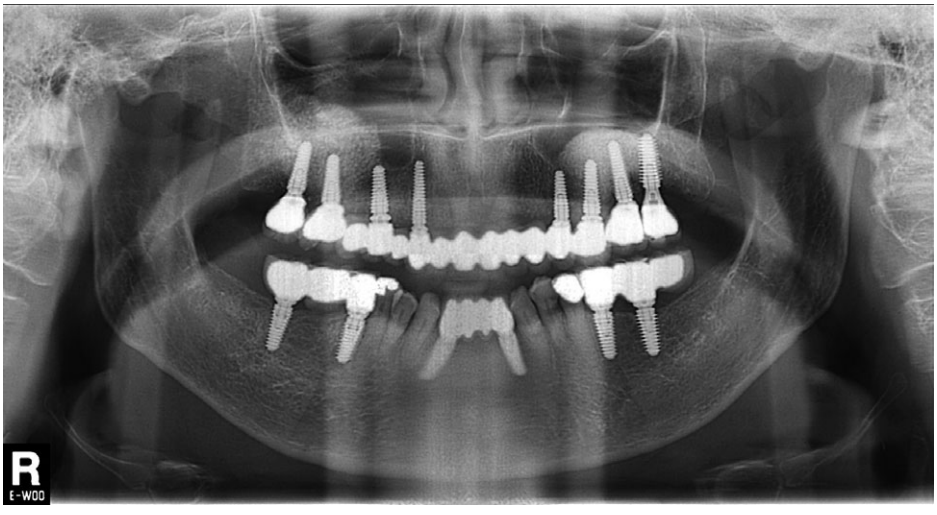

Fig. 4. Control group. Panoramic radiograph 3 years after implant placement.

as a complication *per se*. A recent study (Froum et al. 2013) evaluated the percentage of vital bone and implant survival in perforated and non-perforated sinuses. The authors found no differences in implant survival between the perforated and non-perforated groups and concluded that maxillary sinus membrane perforation does not seem to be an adverse complication *per se*, in terms of bone apposition or implant survival (Froum et al. 2013). Our results seem to confirm this conclusion. In our study, in fact, the membrane perforations described in the test group did not result in acute or chronical sinusitis (no graft material was used with short implants); however, one of the perforations that occurred in the control group resulted in the dispersion of grafted material inside the sinus, which led to chronic sinus infection, complete graft loss, and implant failure, as previously described (Nolan et al. 2014). Finally, sinus floor elevation almost doubled treatment time and cost for the intervention, so that surgical time and cost per implant were significantly higher in the control group than in the test group, as reported by previous studies (Esposito et al. 2014b; Guljé et al. 2014; Thoma et al. 2015). Nevertheless, patient satisfaction with function and esthetics was high in both groups.

Our present study has limits, such as the limited number of patients treated and the short follow-up time (3 years); further, long-term studies on a larger sample of patients are needed to validate our results.

Conclusions

In the present randomized clinical trial, both short (6-mm) dental implants and longer (≥10-mm) dental implants in combination with sinus floor elevation provided good results up to 3 years after loading; however, with 6-mm short implants, the treatment was faster and less expensive. Further, long-term randomized controlled trials on larger samples of patients are needed to confirm these results.

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Conflict of interests

The authors have no conflict of interest in relation to this work.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. CONSORT 2010 checklist of information to include when reporting a randomised trial.