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Randomised controlled trial

SHORT IMPLANTS *VERSUS* BONE AUGMENTATION AND LONGER IMPLANTS IN ATROPHIC MAXILLAE. FIVE-YEAR POST-LOADING RESULTS OF A RANDOMISED CONTROLLED TRIAL

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PURPOSE. To evaluate whether short (5 to 8.5 mm) dental implants could be a suitable alternative to longer (at least 11.5 mm long) implants for supporting dental prostheses placed in atrophic fully edentulous maxillae augmented with autogenous bone.

MATERIALS AND METHODS. Twenty-eight patients with fully edentulous atrophic maxillae having 5 to 9 mm of residual crestal bone height at least 5 mm thick, as measured on CT scans, were randomised into two groups, either to receive four to eight short (5 to 8.5 mm) implants (15 patients) or autogenous bone from the iliac crest to allow the placement of at least 11.5 mm-long implants (13 patients). Both bone blocks and windows at lifted maxillary sinuses were covered with rigid resorbable barriers. Grafts were left to heal for 4 months before placing implants, which were submerged. After 4 months, provisional reinforced acrylic prostheses or bar-retained overdentures were delivered. Provisional prostheses were replaced after 4 months by definitive screw-retained metal-resin cross-arch restorations. Outcome measures were: augmentation, prosthesis or implant failures, any complications, peri-implant marginal bone level changes, and patient satisfaction. Patients were followed-up until 5 years after loading.

RESULTS. All patients could be rehabilitated with implant-supported prostheses, but four patients dropped-out from the augmentation group and three from the short implant group. One bilateral sinus lift procedure failed due to infection, though short implants could be placed. Four implants failed in four patients from the augmentation group *versus* three short implants in three patients (Fisher's exact test P = 0.6500; difference in proportions = -0.17; 95% CI -0.51 to 0.21). No prosthesis failed. Significantly more complications occurred in augmented patients: 12 complications occurred in nine augmented patients *versus* one complication in the short implant group (Fisher's exact test P = 0.0003; difference in proportions = -0.82; 95% CI -0.97 to -0.41). Periapical radiographs of only four patients were readable, so no bone level could be measured at 5 years after loading. With the exception of three patients from the augmentation group, who were only partially satisfied with function, all remaining patients were fully satisfied with the treatment (P = 0.0957); all would have the treatment again.

CONCLUSIONS. This study showed that in patients with fully edentulous atrophic maxillae, short implants can be a preferable alternative to longer implants placed in bone augmented with autogenous bone, the treatment being less invasive, cheaper, faster and associated with fewer complications.

CONFLICT OF INTEREST STATEMENT. MegaGen partially supported this trial and donated the implants and prosthetic components used in the present investigation. However, data property belonged to the authors and MegaGen by no means interfered with the conduct of the trial or the publication of its results.

INTRODUCTION

The rehabilitation of fully edentulous atrophic maxillae can be challenging. The missing dentition can be replaced by dentures, which may not always be appreciated by patients due to their instability, discomfort and negative psychological impact. The ideal solution would be an implant-supported prosthesis, but the lack of sufficient bone volume to place at least four dental implants of "sufficient" length due to advanced bone resorption could be a problem. Bone heights of between 10 and 12 mm are generally considered the minimal amount of bone required to place implants of sufficient length (9 to 11 mm long) to be able to guarantee good long-term prognosis. Unfortunately, however, often the residual amount of maxillary alveolar bone is less than 10 mm, especially below the maxillary sinuses, and implant-supported prostheses in such cases are considered to be at a higher risk of failure[1].

There are three main options for rehabilitating patients with atrophic maxillae via implant-supported prostheses: i) augmenting the maxillary bone, which can be achieved by means of several different techniques[2,3]; ii) using zygomatic implants[4], which can also be loaded immediately[5]; or iii) using short implants (4 to 8 mm long). Unfortunately, however, there are no randomised controlled trials (RCTs) evaluating the effectiveness of short implants in comparison with longer implants in augmented jaws of fully edentulous atrophic maxillae, with the exception of the 1-year data from the present trial[6], of another single RCT comparing the use of zygomatic implants with conventional implants in augmented jaws[7], and there is scarce evidence about bone grafting techniques[8,9].

The definition of "short" implants is controversial, since some authors consider short all those implants with a length ranging between 7 to 10 mm[1], whereas other authors consider "short" those implants with a designed intra-bony length of 8 mm or less[10]. It is commonly perceived that implants 7 mm or shorter do not have good long-term prognosis when compared to longer implants. However, the perception about the minimal implant length that could be used clinically is gradually changing, and nowadays implants as short as 4 mm long are in clinical use. Indeed, short implants could be a simpler, cheaper and faster alternative to augmentation procedures than zygomatic implants, being easier to place and to remove if necessary, provided they could provide similar success rates. In fact, several RCTs have shown that short implants are an effective alternative to various bone augmentation procedures in both posterior atrophic mandibles and maxillae[6,11-17].

The aim of this randomised controlled trial was to compare effectiveness of total maxillary prostheses implant-supported by 5- to 8.5-mm "short" implants *versus* prostheses supported by implants at least 11.5 mm long placed in atrophic maxillae augmented with autogenous bone. The test hypothesis was that there would be no differences between the two procedures, against the alternative hypothesis of a difference. This report presents data up to 5 years after loading. Reports with data at 5 months and 1 year post-loading have previously been published[6,18]. The present article is reported in line with the CONSORT statement for improving the quality of reports of parallel-group randomised trials (http://www.consort-statement.org/).

MATERIALS AND METHODS

This trial was designed as a multicentre randomised controlled trial of parallel-group design with blind assessment, with the exception of complications which were assessed by the treating dentists.

Any fully edentulous patient with an atrophic maxilla, 18 years or older and able to understand and sign informed consent, was eligible for inclusion in this trial. Maxillae were to be able to receive four to eight short (5 to 8.5 mm long) implants. The residual vertical bone height at

the implant sites had to be 5 to 9 mm, and bone thickness of at least 5 mm, as measured on preoperative CT scans.

Patients were not admitted to the study if any of the following exclusion criteria was applicable:

- General contraindications to implant surgery;
- Subjected to irradiation in the head and neck area;
- Immunosuppression or immunocompromised status;
- Past or ongoing treatment with intravenous aminobisphosphonates;
- Untreated periodontitis;
- Poor oral hygiene and motivation;
- Severe intermaxillary discrepancies;
- Uncontrolled diabetes;
- Pregnancy or breast-feeding;
- Substance misuse;
- Psychiatric problems or unrealistic expectations;
- Lack of opposing occluding dentition/prosthesis;
- Acute/chronic infection/inflammation in the area intended for implant placement;
- Participation in other trials, if precluding adherence to the present protocol;
- Referrals for implant placement alone;
- Extraction sites with less than 3 months of healing time.

Patients were categorised into three groups according to their declarations: non-smokers, moderate smokers (up to 10 cigarettes per day), and heavy smokers (more than 10 cigarettes per day).

Patients were recruited and treated at two different centres: Oral and Maxillofacial Unit, Sant'Orsola Malpighi Hospital, University of Bologna, Bologna, Italy (Pietro Felice, PF; 14 patients) and the San Filippo Neri Hospital in Rome (Roberto Pistilli, RP; 14 patients) by the same operators, using similar standardised procedures.

All patients received a thorough explanation and signed an informed written consent form prior to being enrolled in the trial. After consent was given, eligible patients were randomised, according to a parallel-group design, to receive either 5 to 8.5 mm-long implants (**FIG. 1**) or autogenous bone from the iliac crest to allow placement of identical implants at least 11.5 mm long (**FIG. 2)**.

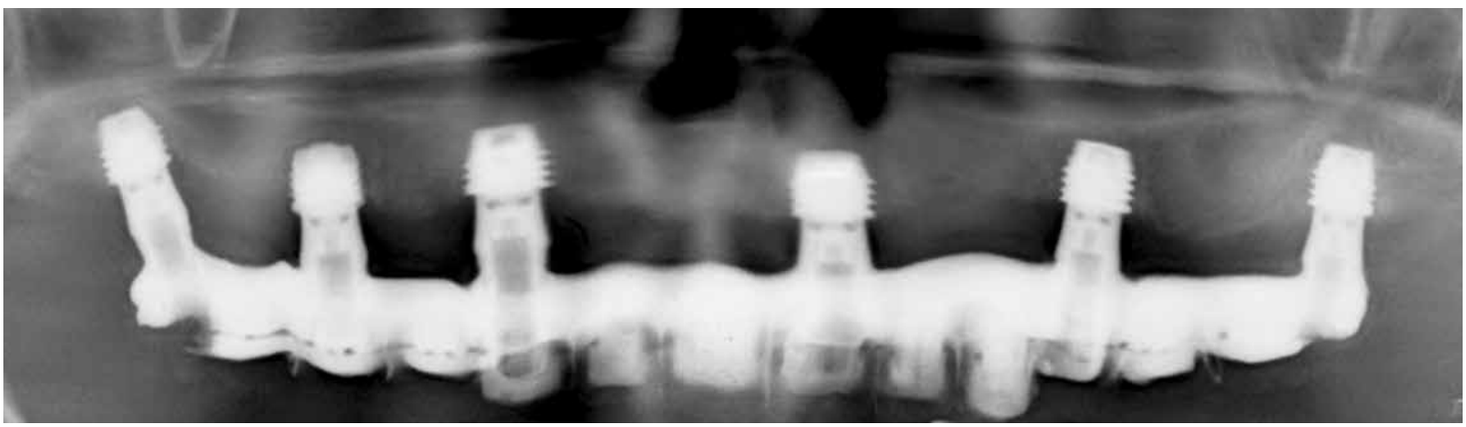

Fig. 1: *Panoramic radiograph taken 5 years after loading of one of the patients randomly allocated to the short implant group and rehabilitated with six 5-mm-long implants. Virtually no significant marginal peri-implant bone loss occurred.*

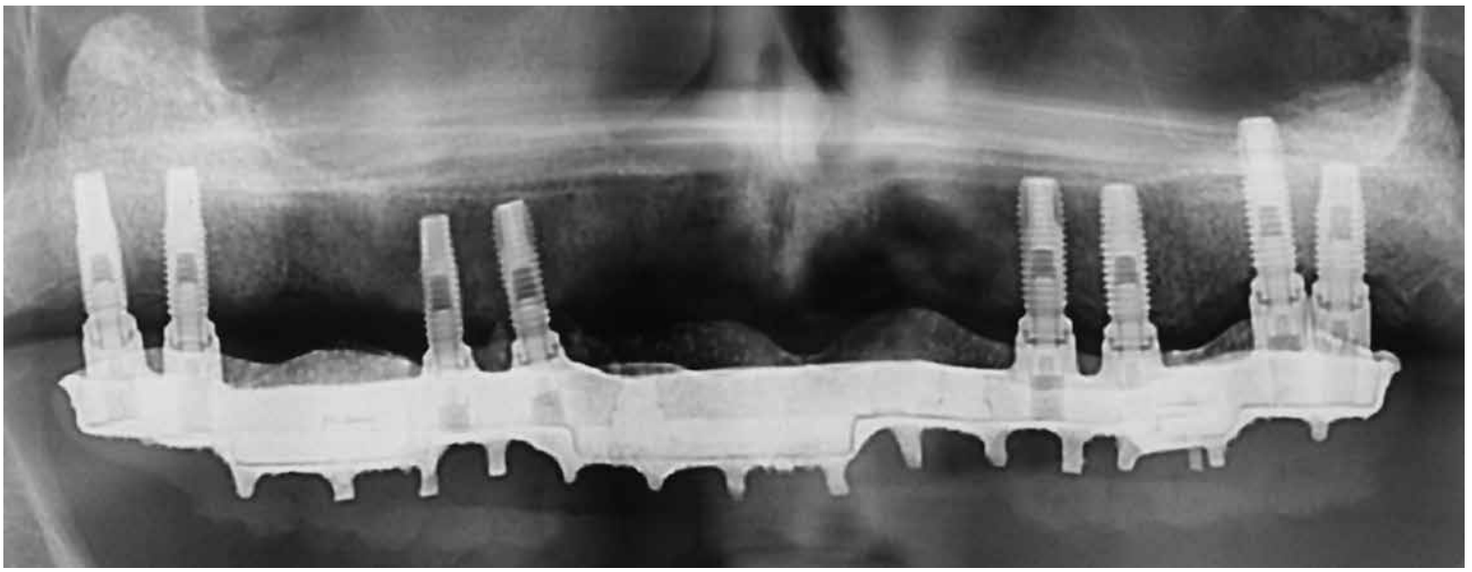

Fig. 2: *Panoramic radiograph taken 5 years after loading of one of the patients randomly allocated to the augmentation procedure, placement of at least 11.5-mm-long implants, and rehabilitated with eight long implants.*

Bone grafting procedures were performed following this protocol: before undergoing general anaesthesia, patients rinsed with chlorhexidine mouthwash 0.2% for 1 minute. Patients received 2.2 mg of amoxicillin with clavulanic acid (Augmentin, GlaxoSmithKline, Brentford, UK) intravenously. Local anaesthesia was delivered using articaine with 1:100,000 adrenaline.

The iliac crest donor site was infiltrated with local anaesthesia (lidocaine 1%) and the non-scalpel-bearing hand was used to displace the skin medially before the incision was made. A 3-cm long incision was started 1 cm behind the anterior superior iliac spine, through the displaced skin directly over the crest. Dissection was continued following the axis of the iliac crest, through the subcutaneous tissues, fascia of Scarpa and periosteum, directly over the crest. Then, the periosteum and the muscles overlying the top of the crest and the medial aspect of the ilium were dissected. Corticotomy of the medial portion of anterior iliac crest was performed using a fissure bur or reciprocating saw: two vertical cuts defined a bone portion 5 to 7 cm long; these two vertical cuts (about 1 cm long) were connected by a horizontal cut along the medial portion of the top of iliac crest (above), and with a second horizontal cut (below) in the medial surface of the iliac bone. The osteotomy of cancellous portion was completed using chisels, obtaining a rectangular corticocancellous bone block. A portion of the harvested block was reduced to particulate using a bone crusher (KLS Martin Group, Tuttlingen, Germany). The soft tissues overlying the osteotomy site were closed with three layers of sutures, and drained for 2 days.

After crestal incision and flap raising, bilateral sinus lifts were performed and, if necessary, onlay bone blocks were placed in the anterior maxilla. First, the sinuses were lifted according to a lateral window technique; after internal displacement of a bony window prepared with a piezosurgical device (Mectron Piezosurgery Device, Mectron, Carasco, Italy), the maxillary linings were carefully raised, and their integrity assessed visually and with a blunt instrument. Any laceration or perforation was noted. Sinuses were then loosely packed with granular autogenous bone from the iliac crest.

Once the sinus lift procedures had been completed, the anterior maxillae were augmented when necessary. Bone blocks were adjusted with the aim of achieving the best adaptation on

the maxilla. Blocks were trimmed with diamond discs and stainless steel laboratory burs (Horico Dental, Berlin, Germany) under profuse saline irrigation. It was ensured that the blocks had a sufficient width and that vertical augmentation would be sufficient to allow the placement of implants at least 11.5mm-long. Several holes were made with a 0.9 mm-diameter bur at the recipient sites to stimulate bleeding. The blocks were placed on the recipient bone and were fixed with two titanium screws (Gebrüder Martin, Tuttlingen, Germany) of 1.5-mm diameter. The screw heads were slightly submerged into the blocks to prevent their protruding. After all blocks were fixed, they were ground to remove any sharp edges. Residual gaps between blocks and the recipient bone site were filled with particulated bone from the iliac crest. The bone blocks and maxillary windows were then covered with resorbable 30 x 40 mm barriers (Inion GTR Biodegradable Membrane System, Tampere, Finland), used as recommended by the manufacturer. Inion membranes are rigid barriers made of a synthetic co-polymer (trimethylene carbonate l-lactide polyglycolide) which become malleable after being immersed in a plasticising solution for 30 seconds and a curing solution for 10 minutes. This allowed the membranes to be cut and moulded to fit the area exactly, and membranes then naturally stiffen in contact with water.

Periosteal incisions were made to release the flaps as coronally as needed, and the flaps were sutured back with Vicryl 4.0 sutures (Ethicon FS-2, St-Stevens-Woluwe, Belgium) until the incisions were perfectly sealed. All patients remained hospitalised for 3 days, and at the hospital were given 2.2 mg amoxicillin plus clavulanic acid intravenously twice a day. On the first day, patients received 4 mg betamethasone (Bentalan, Defiante Farmaceutica, Funchal, Portugal) intravenously both in the morning and in the evening. The following day they were given 4 mg in the morning only, and on last day in hospital they received 2 mg in the morning only. Patients also received 40 mg omeprazole (Antra, AstraZeneca, London, UK) intravenously in the morning for gastric protection. At hospital discharge, patients were prescribed 1 g of amoxicillin with clavulanic acid twice a day for 4 days, and ibuprofen 600 mg 4 times a day during meals for 1 week, not to be taken in the absence of pain. Patients were instructed to use chlorhexidine gel 1% twice a day, and to ingest a soft diet for the following 2 weeks, avoiding brushing and trauma to the surgical sites. Dentures were not allowed for 1 month, after which they were rebased and given back to the patients. Patients were reviewed after 3 and 10 days, when sutures were removed. All patients were recalled for additional postoperative reviews at 1, 2 and 3 months after the augmentation procedure. Four months after augmentation, a second CT scan was obtained to plan the implant placement operation.

The implant placement and prosthetic procedures were identical in both groups. All patients received 2 g of amoxicillin + clavulanic acid 1 hour prior to the intervention as prophylactic antibiotic therapy, and rinsed with 0.2% chlorhexidine mouthwash for 1 minute. All patients were treated under local anaesthesia using articaine with 1:100,000 adrenaline. No intravenous sedation was used. After crestal incision, flap raising, and removal of the titanium screws holding the bone grafts in the augmentation group, four to eight dental implants, either 5 to 8.5 mm long (short implant group) or longer than 11.5 mm (augmentation group) when possible, were inserted with the aid of a surgical guide.

The dental implants placed in the short implant group were ExFeel implants and/or Rescue implants with external hexagon connection (MegaGen Implant, Gyeongbuk, South Korea). For ExFeel implants, operators were free to choose between lengths of 7 and 8.5 mm, and diameters of 4 and 5 mm, according to clinical indications and their preference. For Rescue implants, operators were free to choose between implant lengths of 5 and 6 mm with a diameter of 6 mm, according to clinical indications and their preferences. ExFeel implants with external hexagon connection were used in the augmentation group. Operators were free to choose

implant lengths (11.5 or 13 mm) and diameters (4 or 5 mm) according to clinical indications and their preference.

Implant sites were slightly underprepared to increase the insertion torque, and the motor was set with a torque of 25 Ncm. Implants were placed with the neck flush to the bone. A submerged technique was used**,** cover screws were placed, and flap closure was achieved using Vicryl 4.0 sutures. Periapical radiographs (baseline) were obtained using the paralleling technique. In cases in which bone levels around the study implants were hidden or difficult to estimate, a second radiograph was taken. Ibuprofen 400 mg was prescribed to be taken two to four times a day during meals as long as required. Patients were instructed to use 0.2% chlorhexidine mouthwash for one minute twice a day for 2 weeks, to eat a soft diet for one week, and to avoid brushing and trauma to the surgical sites. No denture was allowed for 1 month. Sutures were removed after 10 days.

After 4 months of submerged healing, implants were exposed, manually tested for stability using a torque of 15 Ncm, and impressions with the pick-up impression copings were taken using a polyether material (Impregum 3M/ESPE, St. Paul, MN, USA). The vertical dimensions were registered, and models were made out of class 4 precision plaster and mounted in a standard articulator. Patients scheduled to receive a one-piece bar-retained overdenture were given their final prostheses at this time; otherwise they received a provisional screw-retained full acrylic reinforced restoration rigidly joining all the implants on temporary abutments within 3 weeks. Intraoral radiographs and clinical pictures of the study implants were taken at prostheses delivery. Four months after delivery of the provisional prostheses, implants were manually tested for stability using a torque of 15 Ncm, and definitive screw-retained metal-resin cross-arch prostheses, rigidly joining the implants, were delivered on definitive standard titanium abutments. One month later, patient were recalled for check-up and to evaluate their satisfaction.

Patients were enrolled in an oral hygiene programme with recall visits at least every 6 months for the entire duration of the study. Follow-ups were conducted up to the third year in function by an independent outcome assessor (Dr. Soardi) and thereafter by other two independent assessors (Dr. Di Simone in Bologna and Dr. Maranesi in Rome) together with the surgical operators.

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

Outcome measures were the following.

- Augmentation procedure failure**.**
- Prosthesis failure: planned prosthesis which could not be placed due to implant failure(s), prosthesis loss secondary to implant failure(s), or replacement of the definitive prosthesis for any reason.
- Implant failure: implant mobility, removal of stable implants dictated by progressive marginal bone loss or infection, or any mechanical failure rendering the implant unusable, such as implant fracture or deformation of the implant–abutment connection. Stability of individual implants was measured at abutment connection (4 months after implant placement), at delivery of the provisional prostheses, at delivery of the definitive prostheses (4 months after delivery of the provisional prostheses) and at 1 and 5 years after loading, by tightening abutment screws using a torque of 15 Ncm.
- Any biological or prosthetic complications at donor and recipient sites, including prolonged postoperative pain at the donor site.
- Peri-implant marginal bone level changes, as evaluated on intraoral radiographs taken via the paralleling technique at implant placement, at delivery of the provisional pro-

stheses, and at 1 and 5 years after loading. In the case of poorly readable radiographs, new radiographs were taken. A blind outcome assessor (Dr. Barausse) scanned non-digital radiographs in TIFF format with 600-dpi resolution, and stored the radiograph files on a personal computer; peri-implant marginal bone levels were measured using Scion Image (Scion Corporation, Frederick, MD, USA) software, calibrated for each single image using the known distance of two consecutive coronal threads. Measurements of the mesial and distal bone crest levels adjacent to each implant were made to the nearest 0.01 mm. Reference points for the linear measurements were: the coronal margin of the implant collar and the most coronal point of bone-to-implant. Implants with bone up to the coronal margin of the implant collar were ascribed a value of zero. Mesial and distal measurements of each implant were averaged, and a mean calculated for each patient and group.

- Patient satisfaction: five months, and 1 and 5 years after loading, the independent outcome assessor asked the patients the following questions: "are you satisfied with the function of your implant-supported prosthesis?" and "are you satisfied with the aesthetic outcome of your implant-supported prosthesis?". Possible answers were: "yes, absolutely", "yes, partly", "not sure", "not really", and "absolutely not". Patients were also asked "would you undergo the same treatment again?" Possible answers were: "yes" or "no".

Three dentists (Dr. Soardi up to the third year in function and thereafter Dr. Di Simone in Bologna and Dr. Maranesi in Rome), not involved in the treatment of the patients, performed all clinical assessments without knowing group allocation; the outcome assessors were therefore blind, but the radiographic outcome assessor could not be blinded as the different implant lengths would be readily apparent.

The sample size was calculated for the primary outcome measures (implant failure): a two-group continuity-corrected chi-square test with a 0.050 two-sided significance level will have 80% power to detect the difference between a proportion of 0.100 and a proportion of 0.300 for patients experiencing at least one implant failure (odds ratio of 3.857) when the sample size in each group is 72. However, it was decided to recruit only 14 patients in each group. A computer-generated restricted randomisation list was created. Only one of the investigators (Dr. Esposito), not involved in the selection and treatment of the patients, was aware of the randomisation sequence and could have access to the randomisation list stored in his password-protected portable computer. The randomised codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially after eligible patients signed the informed consent form to be enrolled in the trial. Therefore, treatment allocation was concealed to the investigators in charge of enrolling and treating the patients.

All data analysis was carried out according to a pre-established analysis plan. The patient was the statistical unit of the analyses, and an intention-to-treat analyses was performed. A dentist with expertise in statistics (Dr. Buti) analysed the data without knowing group allocation. Differences in the proportions of patients with prosthesis failures, implant failures and complications (dichotomous outcomes) were compared between groups and centres using Fisher's exact probability test. Paired t-tests were used to compare the mean radiographic values at implant placement, initial loading and 1 year after loading. Sample t-tests were used to compare the mean radiographic marginal bone level changes between the groups. The Mann-Whitney U test was to be used to compare the medians of the two groups for patient satisfaction. All statistical comparisons were conducted at the 0.05 level of significance.

RESULTS

Twenty-eight patients were considered eligible and were consecutively enrolled in the trial. Following the research protocol, each centre enrolled 14 patients, who were to be randomly allocated to two equal groups of seven patients each. An additional 18 patients were screened for eligibility, but seven refused to participate in the trial since they were not willing to donate their own bone from the iliac crest. Nine patients had an intermaxillary discrepancy judged by the operators to be too severe to receive short implants, and two patients were undergoing treatment with intravenous aminobisphosphonates. Fourteen patients should have been allocated to each group, but due to a communication mistake with the Rome centre, 15 patients received short implants and 13 were augmented for longer implants. Another major protocol deviation was that the periapical radiographs at the 5-year follow-up of only four patients (two per group) were available. This was because either the patient refused to have them taken because of discomfort, or because when taken the radiographs were not assessable. Panoramic radiographs were taken instead, but their image quality did not permit precise peri-implant marginal bone level assessment, and we were therefore forced to abandon the planned 5-year peri-implant bone-level assessment.

At five years after loading, four patients dropped-out from the augmentation group, and three patients from the short implant group. Reasons for dropping out from the augmentation group were:

- One patient (Bologna) moved to another town. Last seen at 6-month follow-up. Contacted by phone, reported having functional implant-supported prosthesis and being satisfied with the treatment;
- One patient (Bologna) was no longer reachable by phone. Last seen at 1-year-6-month follow-up;
- One patient (Bologna), who dropped out at 1-year follow-up, returned at 4 years and 2 months with one loose implant affected by peri-implantitis;
- One patient (Rome) moved to another town. Last seen 1 year and 8 months after loading. Contacted by phone, reported having functional implant-supported prosthesis and being satisfied with the treatment;
- One patient (Bologna) moved to another town. Last seen at 2-year follow-up. Contacted by phone, reported having functional implant-supported prosthesis and being satisfied with the treatment.

Reasons for dropping out from the short implant group were:

- One patient (Bologna) changed dentist and was unable to come to the follow-up appointments. Last seen at 1-year follow-up. Contacted by phone, reported having functional implant-supported prosthesis and being satisfied with the treatment;
- One patient (Bologna) was no longer reachable by phone. Last seen at 2-year follow-up;
- One patient (Rome) was no longer reachable by phone. Last seen at 2-year-6-month follow-up.

Data from all remaining patients were evaluated in the statistical analyses. Patients were recruited and treated from June 2009 to April 2010. The follow-up of all patients was 5 years after implant loading.

The main baseline patient characteristics are presented in **TABLE 1**. All 13 patients in the augmentation group were treated with bilateral sinus lifts, and 10 patients received additional onlay blocks. Ninety-two implants were placed in the augmentation group, and 86 in the short implant group. With the exception of gender and number of implants, there were no signifi-

TABLE 1 PATIENT AND INTERVENTION CHARACTERISTICS

	Augmentation (n = 13)	Short implant (n = 15)
Females	8 (62%)	4 (27%)
Mean age at implant insertion (range)	52 (29-65)	56 (41-65)
Smokers (all moderate smokers)	1 (8%)	4 (27%)
Total number of inserted implants	92	86
Average number of implants in each patient	7.1	5.7
# implants placed with less than 25 Ncm torque	67 (7 patients)	86 (15 patients)
Mean length of placed implants (SD)	11.6 (1.3) mm	7.6 (1.2) mm
Mean diameter of the placed implants (SD)	4.07 (0.25) mm	4.49 (0.76) mm
# overdentures	2 (15%)	9 (60%)
# metal-resin fixed cross-arch prostheses	11 (85%)	6 (40%)
# prostheses supported by 4 implants	1 (8%)	3 (20%)
# prostheses supported by 5 implants	0 (0%)	2 (13%)
# prostheses supported by 6 implants	3 (23%)	6 (40%)
# prostheses supported by 7 implants	2 (15%)	4 (27%)
# prostheses supported by 8 implants	7 (54%)	0 (0%)

cant differences apparent between the two groups at baseline. **TABLE 2** presents the frequencies of the implant lengths and diameters used in the sample.

The main results are summarised in **TABLE 3**. One **augmentation** procedure (bilateral sinus lift) was unsuccessful, and it was therefore not possible to place implants with the planned

TABLE 2 LENGTH AND DIAMETERS OF THE IMPLANTS

Implant length	Augmentation (n = 92)	Short implant (n = 86)
5 mm	0	10
6 mm	0	2
7 mm	5	23
8 mm	0	3
8.5 mm	0	48
10 mm	3	0
11.5 mm	61	0
13 mm	23	0
Implant diameter	**Augmentation (n = 92)**	**Short implant (n = 86)**
4 mm	86	57
5 mm	6	17
6 mm	0	11
7 mm	0	1

TABLE 3 SUMMARY OF THE MAIN RESULTS UP TO 5 YEARS AFTER LOADING.

	Augmentation	Short implant	Differences in proportions	95% CI	P-value
Drop-outs	4 out of 13 patients	3 out of 15 patients	-0.11	-0.41 to 0.21	0.6703
Patients with augmentation failures	1 out of 13 patients	Not applicable	Not applicable	Not applicable	Not applicable
Patients with prosthesis failures	0 out of 11 patients	0 out of 13 patients	Not applicable	Not applicable	Not applicable
Patients with implant failures	4 out of 10 patients	3 out of 13 patients	-0.17	-0.51 to 0.21	0.6500
Patients with complications	9 out of 10 patients had 12 complications	1 out of 12 patients	-0.82	-0.97 to -0.41	0.0003*
Patients with postop pain at 1 week	13 out of 13 patients	0 out of 15 patients	-1	-1.04 to -0.71	<0.0001*
Patients with postop pain at 1 month	5 out of 13 patients	0 out of 15 patients	-0.38	-0.61 to -0.07	0.0131*
Patients with postop pain at 2 months	2 out of 13 patients	0 out of 15 patients	-0.15	-0.37 to 0.09	0.2063

**Statistically significant difference*

length of at least 11.5 mm. Instead, five 7-mm and three 10-mm-long implants had to be placed. All prostheses could be fitted and were successful 5 years after loading.

- Four patients from the augmentation group lost one implant each *versus* three implants in three patients from the short implant group. The difference in proportions of implant failures was not statistically significant (Fisher's exact test P = 0.6500; difference in proportions = -0.17; 95% CI -0.51 to 0.21). One implant in the augmentation group that failed (4 x 11.5 mm) was in position 26, and was found not to be osseointegrated at the abutment connection; this implant was not replaced. The other three implant failures in this group, in positions 22, 13 and 23, were caused by peri-implantitis, after 3 years and 5 months, 4 year and 1 month, and 4 years and 2 months, respectively; they were not replaced.
  In the short implant group, one implant (4 x 7 mm), in position 14, was found not to be osseointegrated at the abutment connection and was replaced by a 5 x 8.5 mm implant. Another failed implant (4 x 8.5 mm) was in position 25, and was placed slightly supracrestally. However, it became exposed and was found to be mobile 2 months after its placement; it was painful at palpation, and was probably lost due to the overload caused by the denture. It was replaced with another 4 x 8.5 mm implant. The last implant to fail (5 x 8 mm), in position 27, was noticed to be painful at 3 years and 4 months after loading. It was lost due to peri-implantitis, and was not replaced, but the prosthesis was shortened to the 26.
- There were significantly more patients experiencing complications in the augmentation group (Fisher's exact test P = 0.0003; difference in proportions = -0.82; 95% CI -0.97 to -0.41). Indeed, twelve complications occurred in nine patients from the augmentation group *versus* only one complication in the short implant group. Specifically, in the augmentation group, one patient subjected to bilateral sinus lift alone developed, after 2 weeks, two areas of buccal dehiscence (one per side) in proximity to the sinus windows. The authors suspected an infectious aetiology and prescribed antibiotics (ceftriaxone, 1 mg intramuscularly twice a day for 1 week), anti-inflammatory beclomethasone (Clenil-A, 0.8 mg aerosol) twice a day for 15 days, antiseptic and decongestant (Argotone nasal drops) twice a day for 15 days, and another decongestant, xylometazoline (Otrivine) nasal spray, 3 times a day for one week. After one week the particulated bone from both sinuses was removed, but after debridement both dehiscences worsened. Both dehiscences

were still present at implant placement, 4 months after sinus lift, though the patient never experienced any swelling, pain or symptoms of sinusitis. Five 7-mm and three 10-mm-long implants were able to be placed, and during the submerged healing periods of the implants both dehiscences healed. Another patient developed an early dehiscence in the palate, which spontaneously healed within 2 weeks. With regard to post-operative pain at the donor sites (the iliac crest) after 1 week, all 13 patients complained of pain, and were still taking analgesics. Five patients also complained of pain 1 month after the grafting procedure, and were still taking analgesics. Two months after grafting, two patients were still in pain and taking analgesics. We considered postoperative pain at donor sites one month after the harvesting procedure as complications. As previously described, three patients from the augmentation group developed peri-implantitis and lost one implant each. Finally, 4 years and 5 months after loading, one patient displayed chipping of the prosthetic lining around tooth 26, which was repaired chairside.

The only complication reported in the short implant group was one case of peri-implantitis, as already described in the implant failure section.

- Peri-implant bone levels at all implant surfaces could be measured on periapical radiographs at implant placement, loading and 1 year after loading. Unfortunately, the periapical radiographs of only four patients were available for the 5-year follow-up, so it was not possible to calculate meaningful marginal bone levels. Nonetheless, there were no statistically significant differences in bone levels between the two groups at either implant placement, loading or 1-year after loading (**TABLE 4**). However, both groups gradually lost statistically significant marginal peri-implant bone (P <0.0001) (**TABLE 4**); at 1-year post-loading, patients with short implants lost -1.05±0.20 mm, as compared with -1.01±0.16 mm for longer implants in augmented bone, the difference between groups not being statistically significant (P = 0.59; mean difference -0.04 mm; 95% CI -0.22 to 0.14; **TABLE 4**).
- Five months and one year after loading, all patients declared to the independent outcome assessor that they were highly satisfied with both the function and aesthetics of their implant-supported prostheses, and said that they would undergo the same treatment again. New to this study, similar results were recorded at 5 years, with the excep-

TABLE 4 COMPARISON OF MEAN MARGINAL BONE LEVELS (SD) IN MM AT IMPLANT PLACEMENT, LOADING AND 1 YEAR AFTER LOADING BETWEEN THE TWO GROUPS, AND CHANGES FROM BASELINE WITHIN EACH GROUP. RELIABLE DATA AT 5 YEARS NOT AVAILABLE

	Short implants	Implants in augmented bone	Mean difference	95% CI of the difference	P-value from unpaired sample t-test
	N mean (SD)	N mean (SD)			
At implant placement	15 0.21 (0.18)	13 0.20 (0.21)	0.01	-0.19 to 0.21	0.86
At loading	15 0.55 (0.26)	13 0.55 (0.28)	0.00	-0.26 to 0.26	0.96
1-year post-loading	15 1.26 (0.21)	11 1.24 (0.24)	0.02	-0.20 to 0.24	0.84
Mean changes at 1-year	15 -1.05 (0.20)	11 -1.01 (0.16)	-0.04	-0.22 to 0.14	0.59
P-value from paired t-test from placement to 1-year	<0.0001	<0.0001			
95% CI of the difference (1-year)	15 -0.85; -1.25	11 -0.85; -1.17			

tion of 3 out of 12 patients from the augmentation group, who declared being only partially satisfied with the function of their prostheses (P = 0.0957).

There were no differences in implant failures or complications between the two centres during the 5-year follow-up period. Specifically, three implants failed in three patients treated in Bologna *versus* four implants in four patients from Rome (Fisher's exact test P = 1; difference in proportions = 0.07; 95% CI -0.25 to 0.37). Five patients experienced seven complications in Bologna *versus* five patients experiencing six complications in Rome (Fisher's exact test P = 1; difference in proportions = 0; 95% CI -0.34 to 0.34).

DISCUSSION

This trial was designed to provide preliminary data on the most effective implant support for prostheses in the rehabilitation of fully edentulous atrophic maxillae with 5 to 9 mm of residual bone height. Specifically, five to seven 8.5 mm-long implants were compared with longer implants (at least 11.5 mm long), the latter secured in bone augmented with autogenous bone from the iliac crest via lateral-window sinus-lift procedures and onlay bone blocks. Autogenous bone grafting is generally considered the gold standard procedure for augmenting atrophic jaws; however, our results suggest that similar, excellent medium-term clinical outcomes can be achieved using shorter implants with no augmentation in half the time (in about 5 months *versus* nine months), at a lower cost (one surgical procedure in general anaesthesia less and fewer implants placed) and less postoperative discomfort (all augmented patients were in pain after one week *versus* none of those who received short implants, and about 40% were still in pain one month after the augmentation procedure), not to mention far fewer complications. Indeed, all but one of the complications we encountered occurred in the augmentation group. It should also be noted that the augmentation procedure is by far more technically demanding than placing short implants, requiring a skilful maxillofacial surgeon and specialised auxiliary staff.

The major potential drawback of short dental implants is the unknown long-term prognosis when compared to longer implants, which may be expected to have a better prognosis. In fact, the RCTs[11,14,17,19,20] with the longest follow-up comparing short *versus* longer implants in maxillae have only 3- to 5-year post-loading follow-up to date. Another aspect which could potentially put short implants at a disadvantage when compared to longer implants in augmented maxillae is the lower number of implants which could be placed per patient. In fact, on average, only 5.7 short implants were placed per patient *versus* 7.1 longer implants in the augmentation group. This baseline imbalance was due to the fact that there was not sufficient bone to place more short implants, especially since the 5-mm-long implants available for this study had a diameter of 6 mm, which is too large to be inserted in the anterior area, and is often even difficult to use in the posterior areas[21,22]. In contrast, the augmentation procedure not only successfully allowed the placement of longer implants, but also the placement of a greater number of implants. That being said, our results do not support the idea that a better prognosis is linked to a greater number of implants supporting a prosthesis.

Another interesting aspect is that, irrespective of the treatment received, all patients were completely satisfied with both the function and aesthetics of their implant-supported prostheses, and declared that they would undergo the same treatment again at 5 months, and 1 and 5 years after initial loading. The only exceptions were three patients from the augmentation group who reported being only partially satisfied 5 years after loading. This uniform response is surprising, especially when considering the two patients who had to take analgesics for 2 months after augmentation, and especially the patient who had to have revision

surgery at both sinuses due to infection. One possible explanation, however, could be that the satisfaction of having a fixed prosthesis obviated all the pain the patient had experienced.

It is difficult to compare these results with those of similar trials, since there were no other trials investigating alternative options to treat fully edentulous maxillae that we could find. However, there are several RCTs comparing the use of short implants *versus* longer implants in sinus-lifted posterior maxillae[11,12,14-17,19,20], which, supported by a Cochrane review[3], all suggest that short implants may represent a valid alternative to sinus lift procedures, at least in the medium term. The real question now, therefore, is whether the positive functional outcomes of short implants demonstrated thus far can be maintained for decades, but only longer follow-up will shed light on this issue.

At the present time, however, it is possible to make some additional considerations. For instance, in case of sinus lift procedures, we know that bone substitutes can be a valid alternative to autogenous bone[23,24], which means less morbidity for the patient. In contrast, using blocks of bone substitute for reconstructing a maxilla has been shown to be less predictable than using autogenous bone[9]. Another consideration is that, with the exception of those failures which occurred before implant loading, all failures occurring after loading in bone groups were attributed to peri-implantitis, suggesting that peri-implantitis is the main problem to be solved in terms of improving the long-term success of dental implants.

The main limitation of the present trial is the small sample size, as this study was designed to provide preliminary evidence of the outcome of the comparison. That being said, the sample size was large enough to disclose a significant difference in post-augmentation complications between the two procedures, in favour of the less invasive approach. When data from other RCTs become available, it should be possible to combine the data presented here with those from similar trials in a meta-analysis; such larger samples sizes should provide a more precise estimate of the real-world clinical picture.

Another limitation was the lack of 5-year post-loading periapical radiographs. The majority of those taken were of poor quality, and often patients refused to allow better ones be taken despite our repeated attempts; panoramic radiographs were taken instead. It was therefore decided not to try to calculate peri-implant marginal bone levels at 5 years. This is undoubtedly a missed opportunity. Finally, there was an error in patient allocation. In fact, one patient erroneously received short implants when he should have been assigned to the augmentation group. After investigation, we discovered that the error was a purely casual human mistake which occurred when communicating the group allocation for that patient by phone from the main centre, where the envelopes were stored, to the surgical unit in Rome. There were no serious ramifications on the validity of the study arising from this error, apart from a further reduction in sample size.

Both techniques were tested in real-world clinical conditions and patient inclusion criteria were rather broad; therefore, the results of the present investigation can be generalised with confidence to a wider population with similar characteristics. However, both surgeons were experienced in both techniques, and this factor might limit extrapolation of the results.

CONCLUSIONS

Five years after loading, both techniques yielded effective outcomes; however, short implants were the preferable option, since the treatment was faster, cheaper and associated with less morbidity than placing longer implants in augmented bone.

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