KEY WORDS
inlay graft, bone substitute, short dental implants,
sinus lift, vertical augmentation

Randomised controlled trial

FOUR-MM-LONG *VERSUS* LONGER IMPLANTS IN AUGMENTED BONE IN ATROPHIC POSTERIOR JAWS: THREE-YEAR POST-LOADING RESULTS FROM A MULTICENTRE RANDOMISED CONTROLLED TRIAL

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PURPOSE. To evaluate whether 4-mm-long dental implants could be an alternative to bone augmentation with xenografts and placement of implants of length at least 10 in posterior atrophic jaws.

MATERIALS AND METHODS. Forty patients with atrophic posterior (premolar and molar areas) mandibles having 5 to 6 mm bone height above the mandibular canal and 40 patients with atrophic maxillae having 4 to 5 mm bone height below the maxillary sinus were randomised according to a parallel-group design to receive one to three 4.0-mm-long implants or one to three implants of length at least 10 mm in augmented bone at two centres. All implants had a diameter of 4.0 or 4.5 mm. Mandibles were vertically augmented with interpositional equine bone blocks and resorbable barriers. Implants were placed 4 months after grafting. Maxillary sinuses were augmented with particulated porcine bone via a lateral window covered with resorbable barriers, and implants were placed simultaneously. Implants were not submerged. Four months later, screw-retained reinforced acrylic restorations were fitted, and replaced after 4 months by definitive screw-retained metal-composite prostheses. Patients were followed up to 3 years post-loading. Outcome measures were: prosthesis and implant failures, any complications, and peri-implant marginal bone level changes.

RESULTS. Nine patients dropped out, six from the augmentation group and three from the short implant group. In six augmented mandibles (30%) it was not possible to place implants of length at least 10.0 mm, so shorter implants had to be placed instead. In mandibles, two implants from the augmentation group failed in two patients, *versus* two 4.0-mm-long implants in two patients from the short implant group. In maxillae, four short implants failed in three patients *versus* seven long implants in four patients (two long implants and one short implant dropped into the maxillary sinus). Three prostheses on short implants (one mandibular and two maxillary) failed or were placed at a later stage due to implant failure, *versus* eight prostheses (three mandibular and five maxillary) at augmented sites. There were no statistically significant differences in implant failures (P [Fisher's exact test] = 0.159; difference in proportion = 0.05; CI 95% -0.11 to 0.21) or prostheses failures (P [Fisher's exact test] = 0.919; difference in proportion = 0.02; CI 95% -0.14 to 0.18). There were more patients affected by complications in the augmentation group (18 patients affected by 30 complications *versus* 8 patients affected by 10 complications), but the difference was not statistically significant (P [Fisher's exact test] = 0.587; difference in proportion = -0.72; CI 95% -0.29 to 0.14). At 3 years post-loading, average peri-implant bone loss was 0.62 mm at 4-mm-long mandibular implants, 0.71 mm at 10-mm or longer mandibular implants, 1.14 mm at short maxillary implants and 0.73 mm at long maxillary implants. The difference was not statistically significant in mandibles (mean difference -0.08 mm, 95% CI -0.37 to 0.20, P [ANCOVA] = 0.568), but was significant in maxillae, with greater bone loss at short implants (mean difference 0.41 mm, 95% CI -0.04 to 0.87, P [ANCOVA] = 0.037).

CONCLUSIONS. Three years after loading, 4.0-mm-long implants yielded similar, if not better, results than longer implants in augmented jaws, but were affected by fewer complications. Hence, short implants may be preferable to bone augmentation, especially in mandibles, since the treatment is less invasive, faster, cheaper, and associated with less morbidity. However, 5- to 10-year post-loading data will be necessary to make reliable recommendations.

CONFLICT OF INTEREST STATEMENT. GlobalD (Brignais, France) partially supported this trial and donated the implants and prosthetic components, while OsteoBiol (Tecnoss, Giaveno, Italy) kindly donated the biomaterials and membranes; however data properties belong to the authors, and GlobalD or OsteoBiol by no means interfered with the conduct of the trial or the publication of the results.

INTRODUCTION

Dental implants are used to replace missing teeth for rehabilitating the function and aesthetics of edentulous patients. However, in many patients it is not possible to place dental implants of "adequate" length because there is less than 8 mm of residual vertical bone height due to the resorption of the crestal bone. Clinicians, therefore, are faced with the dilemma of whether to attempt an augmentation procedure or to place short implants having an intra-bony length of 8 mm or less[1]. Until a few years ago, 7-mm-long or shorter implants were associated with lower success rates when compared to longer implants placed in non-augmented bone[2]. However, this comparison may be inappropriate because when adequate amounts of bone are available, dentists usually place longer implants. Therefore, in the absence of bone of adequate height, it would be more meaningful to compare the clinical outcome of short implants with that of longer implants placed in augmented bone.

Various techniques are currently used for bone augmentation, though just a few of these techniques have been evaluated in randomised controlled trials (RCTs)[3,4]. Augmentation procedures are more technically demanding, and therefore require skilled operators. Moreover, they have been associated with significant postoperative morbidity and complications, as well as being more expensive and potentially entailing longer times (up to 1 year) before patients are able to chew on their implant-supported prostheses[3,4]. If, on the other hand, short implants could provide similar clinical outcomes to longer implants placed in augmented bone, they would be a simpler, cheaper, less invasive and faster alternative for rehabilitating edentulous patients with reduced bone height.

Several RCTs and systematic reviews have compared short implants with longer implants in augmented bone[5-14]. Results from all these RCTs suggest that 5.0- to 8.0-mm-long implants may be a good alternative to augmentation procedures, but the question of what will happen if the atrophy is advanced to the extent that only the placement of 4.0-mm-long implants is possible remains. Data from one RCT on 4.0-mm-long implants suggests that these ultra-short implants perform well up to 3-year post-loading[15], but no other RCT has yet compared 4.0-mm-long implants *versus* longer implants in augmented bone.

Hence, the aim of this RCT was to compare the outcomes of single-implant-supported crowns and partial fixed prostheses supported by 4-mm-long tapered, transmucosal implants (Twinkon, Universal SA2, GlobalD, Brignais, France) with prostheses supported by identical implants of at least 10 mm in length placed in posterior jaws augmented either with mandibular interpositional collagenated blocks of cancellous equine bone (OsteoBiol Sp-Block, Tecnoss, Giave-

no, Italy) or a mix of cancellous and cortical granular collagenated porcine-derived bone (OsteoBiol Gen-Os, Tecnoss), placed through a lateral window below raised maxillary sinus epithelium. This report presents the clinical outcome data at up to 3 years after loading. Data at 4 months[16] and 1 year[17] post-loading have previously been published, and we ultimately aim to follow up the patients up to the tenth year of function to compare the outcome of both procedures over time. This article has been drafted according to the CONSORT statement for improving the quality of reports of parallel-group randomised trials (http://www.consort-statement.org/).

MATERIALS AND METHODS

The study was designed as a randomised controlled multicentre trial of parallel-group design with two arms. Any partially edentulous patient missing teeth in the premolar and/or molar area, requiring one to three dental implants, being 18 years or older and able to understand and sign an informed consent form was eligible for inclusion in this trial. Vertical bone heights at implant sites had to be 5 to 6 mm above mandibular canals, and 4 to 5 mm below maxillary sinuses. Bone thickness had to be at least 5 mm, as measured on cone-beam computed tomography (CBCT) scans. Each patient was treated on only one side of the jaw, according to the parallel-group design.

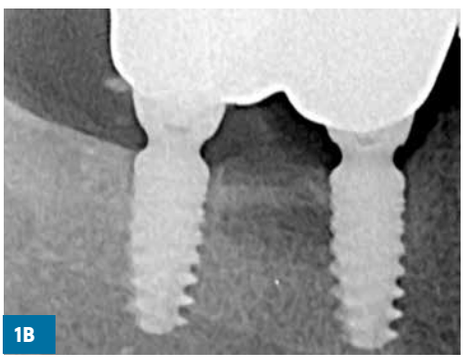
Exclusion criteria were the following.

- General contraindications to implant surgery.
- Irradiation in the head and neck area.
- Immunosuppressed or immunocompromised status.
- Prior or ongoing treatment with intravenous aminobisphosphonates.
- Untreated periodontitis.
- Poor oral hygiene and motivation.
- Uncontrolled diabetes.
- Pregnancy or breast-feeding.
- Substance misuse.
- Psychiatric problems.
- Unrealistic expectations.
- Lack of occluding dentition opposite the area intended for implant placement.
- Acute or chronic infection/inflammation in the area intended for implant placement.
- Participation in other studies precluding adherence to the present protocol.
- Referral for implant placement alone, i.e., having the prosthesis or maintenance procedures performed at other treatment centres.
- Extraction sites with less than 3 months of healing.
- Unavailability for 10-year follow-up.

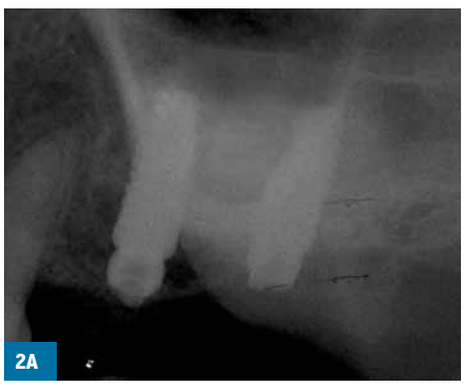
Patients were categorised into three groups according their declared smoking status: non-smokers, moderate smokers (up to 10 cigarettes per day), and heavy smokers (more than 10 cigarettes per day). Patients were recruited and treated at different Italian centres by two different operators. One operator (Dr. Felice, PF) treated patients in one university hospital and two private practices, while the other operator (Dr. Pistilli, RP) treated patients in one hospital and one private practice. Both operators followed similar standardised protocols.

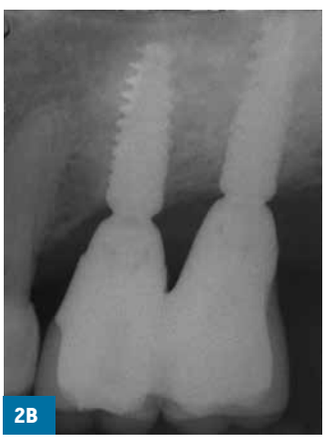
The principles outlined in the Declaration of Helsinki on clinical research involving human subjects were adhered to. The study was approved by the Ethics Committee of the Ospedale Maggiore in Bologna, Italy on 14th June 2013 (Prot. N.554/CE). All patients received thorough explanation and signed an informed written consent form prior to being enrolled in the trial.

After signing the informed consent forms, patients were randomly allocated to treatment groups by opening a sequentially numbered envelope corresponding to the patient recruitment number; on the basis of their allocation, patients received either an augmentation procedure to allow placement of one to three implants of at least 10 mm in length (control procedure; **FIGS. 1A, B AND FIGS. 2A, B**) or one to three ultra-short 4.0-mm-long implants (test procedure; **FIGS. 3A, B AND FIGS. 4A, B**). Augmentation procedures involved the use of interpositional blocks of collagenated cancellous equine bone in mandibles, or a mix of cancellous and cortical granular (250-1000 micron) collagenated porcine-derived bone inserted in a lateral window below the raised maxillary sinus membrane. The same bone substitute was also used to fill gaps between bone blocks and the surrounding mandibular bone.

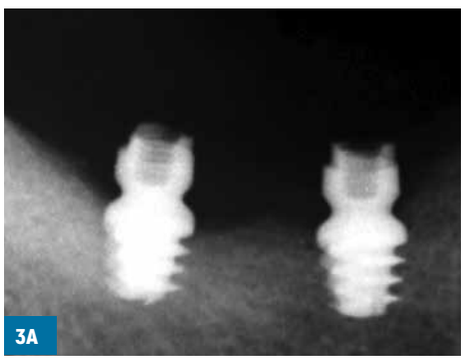


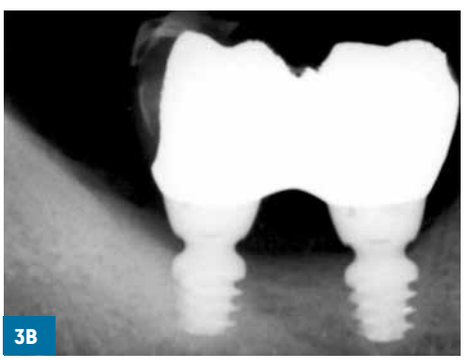
FIGS. 1A, B: *Treatment sequence of one of the patients randomly allocated to mandibular vertical augmentation and long implants: periapical radiographs just after implant placement (A) and 3 years after loading (B).*



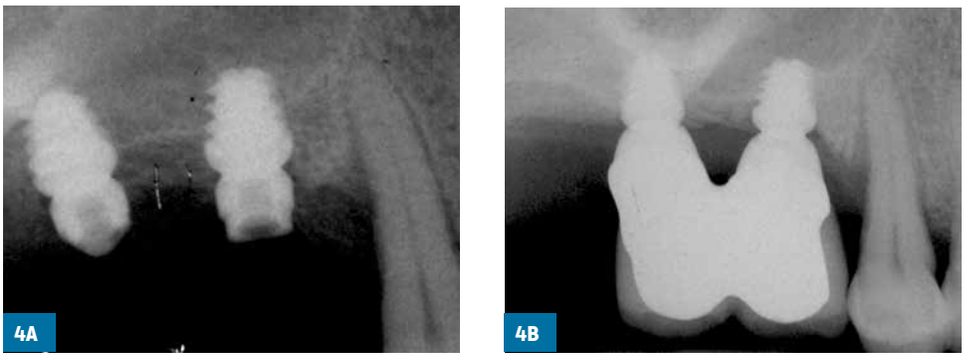


FIGS. 2A, B: *Treatment sequence of one of the patients randomly allocated to sinus lift and long implants: periapical radiographs just after implant placement (A) and 3 years after loading (B).*





FIGS. 3A, B: *Treatment sequence of one of the patients randomly allocated to 4-mm-long mandibular implants: periapical radiographs just after implant placement (A) and 3 years after loading (B).*



FIGS. 4A, B: *Treatment sequence of one of the patients randomly allocated to 4-mm-long maxillary implants: periapical radiographs just after implant placement (A) and 3 years after loading (B).*

Augmentation and implant placement procedures

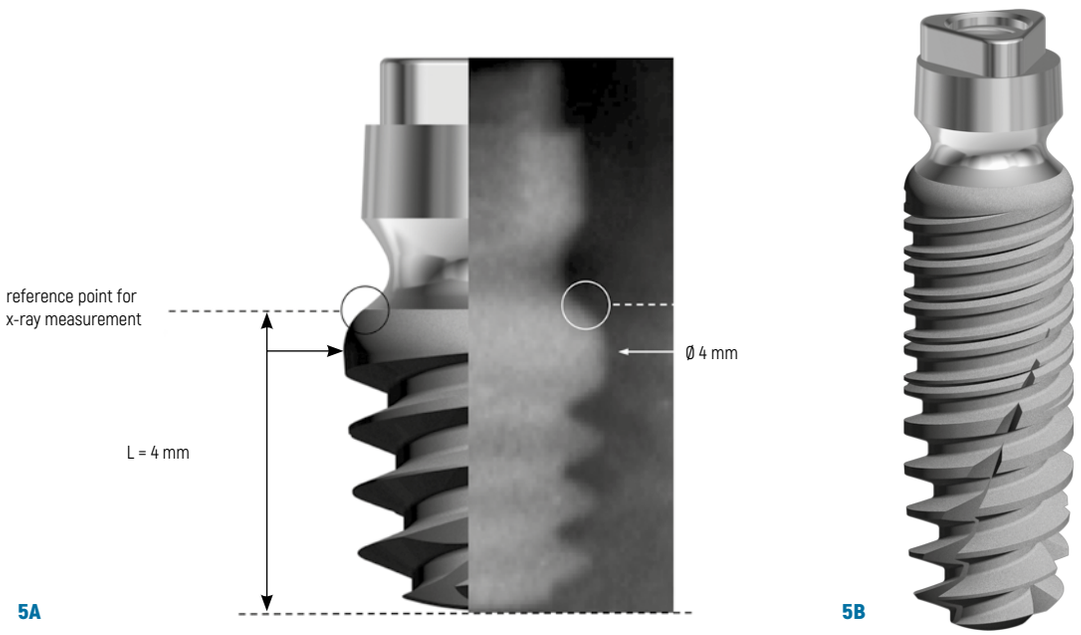
Within the 10 days before augmentation and implant placement, all patients underwent at least one session of oral hygiene instruction/debridement if required. Patients received prophylactic antibiotic therapy: 2 g of amoxicillin (or clindamycin 600 mg if allergic to penicillin) one hour prior to augmentation, and rinsed for one minute with chlorhexidine 0.2%. Patients were treated under local anaesthesia (articaine with adrenaline 1:100.000). No intravenous sedation was used.

For mandibles randomly allocated to vertical augmentation, surgical guides were prepared to help operators determine more precisely the amount of vertical augmentation required. A paracrestal incision was made through the buccal area to expose the alveolar ridge, respecting the emergence of the mental nerve. A mucoperiosteal flap was carefully retracted to try to minimise tension on the mental nerve. A horizontal osteotomy was performed approximately 2 mm above the mandibular canal using piezosurgery (Piezosurgery 3, Mectron, Carasco, Genoa, Italy). Two oblique cuts were made in the coronal third of the mandible, with the mesial cut at least 2 mm distal to the last tooth in the arch; the height of the osteotomised segment had to be at least 2 mm to minimise the risk of fracture when inserting the stabilizing screws. The bone segment was then raised in a coronal direction, sparing the lingual periosteum, and a 35x10x5 mm collagenated cancellous equine bone block was modelled, under saline solution cooling, to the desired height and shape; the block was then interposed between the raised bony fragment and the mandibular basal bone, and fixed to both the basal bone and the osteotomised crestal bone with 0.6-mm-thick titanium miniplates and 1.5-mm diameter miniscrews (Titanium Minitek-Microtek, GlobalD). Gaps between the block and the mandibular bone were filled using granular porcine bone. The grafted areas were covered with resorbable collagen membranes derived from equine pericardium (Fine 30 x 30 mm, OsteoBiol Evolution, Tecnoss). Incisions were made into the vestibular periosteum to release flaps as coronally as needed.

Flaps were sutured with Vicryl 4.0 sutures (Ethicon FS-2, St-Stevens-Woluwe, Belgium), until the incisions were perfectly sealed. Ice packs were provided, and 1 g amoxicillin (or 300 mg clindamycin) was prescribed to be taken twice a day for 7 days. Ibuprofen 400 mg (or 1 g paracetamol in case of allergy to non-steroidal anti-inflammatory drugs) was prescribed to be taken 2 to 4 times a day during meals as long as required. Patients were instructed to use chlorhexidine gel 1% twice a day for 2 weeks, to have a soft diet for one week, and to avoid brushing or trauma to the surgical sites. Patients were advised not to wear any removable prostheses. Patients were seen after 3 days, and sutures were removed after 10 days. Patients were recalled for additional postoperative check-ups monthly after the augmentation procedure. Mandibular grafted areas were left to heal for 4 months before placing the implants.

Four months after the inlay procedures, CBCT scans were taken to evaluate bone volumes for planning implant surgery. One hour prior to implant placement, 2 g of amoxicillin (or 600 mg clindamycin) was administered and patients rinsed for one minute with 0.2% chlorhexidine mouthwash. Infiltration anaesthesia (articaine with adrenaline 1:100.000) was administered. After crestal incision and flap raising, the miniplates were removed. One to three 10.0-mm-long tapered transmucosal implants (TwinKon Universal SA2; GlobalD; **FIGS. 5A, B**) having a diameter of 4.0 or 4.5 mm and a brand-specific external connection, were to be inserted under guidance of surgical stents to optimise implant positioning. Operators were allowed to place shorter implants (4.0, 6.0 and 8.5 mm) at augmented sites if the augmentation procedure was not successful. Each missing tooth was replaced by one dental implant. The standard placement procedure, as recommended by the manufacturer, was implemented. Drills with stops of increasing diameters were used to prepare implant sites, which were slightly underprepared. The surgical unit motor was set with a torque of 25 Ncm during implant insertion. Implants were placed with the transitional portion of the neck at crestal level and were not submerged. Flap closure around the neck of the implants was achieved using vicryl 4.0 sutures. Baseline periapical radiographs of the study implants were taken; if the peri-implant marginal bone levels were not measurable, a new radiograph was taken. Implants were left to heal for 4 months before being functionally loaded. The previously described postoperative instructions were given, and patients were seen after 3 and 10 days (suture removal) and at 1 month. Mandibles allocated to short implants received one to three 4.0-mm-long implants following exactly the same treatment procedures, barring augmentation, as the augmented group.

Maxillae allocated to sinus lift procedures were treated with a crestal incision, flap raising, and preparation of a lateral window with piezosurgery (Mectron), which was carefully displaced internally after elevation of the maxillary sinus epithelium. The sinus cavity below the respiratory epithelium was partially packed with a mix of cancellous and cortical granular (250-1000 micron) collagenated porcine-derived bone substitute (Gen-Os), and then one to three 10.0-mm or longer (11.5 and 13.0 mm) transmucosal TwinKon implants with a diameter



FIGS. 5A, B: *Illustration of the 4-mm (A) and 13-mm (B) conical transmucosal GlobalD TwinKon Universal SA2 implants used in this study. Implants are made of Ti4V6Al alloy, have a sand-blasted acid-etched surface and a proprietary external connection.*

of 4.0 or 4.5 mm were inserted. Each missing tooth was replaced by one dental implant. Implant sites were prepared using drills of increasing diameters, and sites characterised by soft bone were underprepared. Implants were inserted with the motor unit set at 25 Ncm and the transitional portion of the neck at crestal level, and were not submerged. The sinus was loosely packed and overfilled with granular Gen-Os bone substitute, and the lateral window was covered with an Evolution resorbable collagen barrier. Flaps were sutured with Vicryl 4.0 sutures until the incisions were perfectly sealed around the transmucosal portion of the implant necks. Baseline periapical radiographs of the study implants were taken; if the peri-implant marginal bone levels were not measurable, a new radiograph was taken. The postsurgical instructions described above were given. Patients were seen after 3 days and sutures were removed after 10 days. All patients were recalled for one additional postoperative check-up at 1 month after sinus lift. Implants were left to heal unloaded for 4 months. In patients randomly allocated to the short implant group, 4-mm-long implants were placed following similar procedures to those previously described.

Prosthesis fitting and follow-up procedures

After 4 months of unloaded healing, implants were manually tested for stability, and impressions were taken with pick-up impression copings using a polyether material (Impregum 3M/ESPE, Neuss, Germany) and customised resin impression trays. Provisional screw-retained or cemented reinforced acrylic restorations rigidly joining the implants or single crowns were delivered within one week after impressions. In some cases, definitive metal frameworks covered with a provisional acrylic resin coating, to be replaced by a composite coating 4 months after loading, were fitted. The occlusal surfaces were in slight contact with the opposing dentition. Periapical radiographs of the study implants were taken. Four months after delivery of the provisional prostheses, implants were manually tested for stability, and definitive metal-composite or metal-resin prostheses, rigidly joining the implants, were either screw-retained or cemented with provisional cement (Implacem, Dentalica, Milan, Italy by PF or TempBond, Kerr Italia, Scafati, SA, Italy by RP) onto titanium abutments, and oral hygiene instructions were reinforced, if necessary.

Patients were enrolled in an oral hygiene programme with recall visits every 6 months for the entire duration of the study. This report presents data recorded 3 years after prosthesis loading.

Outcome measures

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

Outcome measures were the following.

- Prosthesis failure: planned prostheses which could not be placed due to implant failure(s) or loss of prosthesis secondary to implant failure(s), or replacement of a definitive prosthesis for any reason.
- Implant failure: implant mobility, removal of stable implants dictated by progressive marginal bone loss or infection, and any mechanical complications rendering the implant unusable (e.g., implant fracture). The stability of each individual implant was measured after removing the restorations at delivery of the provisional (4 months after implant placement) and definitive prostheses (4 months after delivery of the provisional prostheses) by removing the prosthesis and tightening the abutment screws using a manual wrench with a 15 Ncm force. At follow-ups 1 and 3 years after loading, only partial fixed prostheses were removed to evaluate individual implant stability, whereas the stability of

implant-supported crowns was tested by rocking the implants using the metal handles of two dental mirrors.

- Any biological or prosthetic complication.
- Peri-implant marginal bone level changes, evaluated on periapical radiographs taken with the paralleling technique at implant placement, delivery of the provisional prostheses, and at 4 months, and 1 and 3 years after loading. Non-digital radiographs were scanned into TIFF format with 600 dpi resolution and stored on a personal computer. Peri-implant marginal bone levels were measured using OsiriX (Pixmeo Sarl, Bernex, Switzerland) software, calibrated for each single image using the known implant diameter. Measurements of the mesial and distal crestal bone levels adjacent to each implant were made parallel to the implant axis to the nearest 0.01 mm, and averaged for implants, patients and groups. Reference points for the linear measurements were the apical margin of the implant collar (**FIG. 5A**) and the most coronal point of bone-to-implant contact.

Methodological aspects

One dentist not involved in the treatment of the patients (Dr. Masi at PF's centre up to 1-year follow-up, when replaced by Dr. Berti; and Dr. Cassoni at RP's centre) performed implant stability assessments at each centre without knowing group allocation. Complications were dealt with and reported by the treating clinicians, who were not blinded. One experienced assessor (Dr. Barausse), not involved in treating the patients, performed all radiographic assessments without knowing group allocation; however, augmented sites could be easily identified on radiographs due to the different implant lengths.

No sample size calculation was performed, since no data on similar 4.0-mm-long implants was available when this trial was conceived. Eighty partially edentulous patients with posterior jaw atrophy were included: 40 patients were partially edentulous in the upper and 40 in the lower jaw.

One computer-generated restricted randomisation list was created for each centre. Only one of the investigators (Dr. Esposito), not involved in the selection and treatment of patients, was aware of the random sequence and had access to the randomisation list stored in his password-protected laptop. The information on how to treat each patient was enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially after patients agreed to participate in the trial and signed informed consent. Hence, 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. A dentist with expertise in statistics (Dr. Kalemaj) analysed the data without knowing the group codes. The patient was the statistical unit of the analyses. Differences in the proportion of patients with prosthesis failures, implant failures and complications (dichotomous outcomes) were compared using Fisher's exact test. Differences in patient means for continuous outcomes (radiographic bone levels) were compared between groups using a t-test for independent samples. Comparisons between each time point and the baseline measurements were performed using paired t-tests to detect any changes in marginal peri-implant bone levels. Analysis of covariance was used to compare the mean radiographic values at loading, and at 4 months and 1 and 3 years after loading, with the baseline value as a covariate. Fisher's exact tests were used to compare the number of graft failures, prosthesis failures, implant failures, complications and drop-outs, and a t-test for independent samples was applied to compare the marginal bone level changes between centres. All statistical comparisons were conducted at a 0.05 level of significance, and data for upper and lower jaws were analysed

separately. Statistical analyses were performed using Stata 13 (Stata Statistical Software, release 13.0, Stata Corporation).

RESULTS

One hundred patients were screened for eligibility, but 20 patients were not included in the trial for the following reasons: 12 patients had insufficient bone height or width, and eight patients had more bone than required by the inclusion criteria. Eighty patients were considered eligible and were consecutively enrolled in the trial. As per the protocol, 40 patients should have been enrolled at each centre, 20 with partially edentulous posterior atrophic mandibles and 20 with partially edentulous posterior atrophic maxillae. However, since RP's centre had unplanned difficulties in recruitment, PF recruited and treated 57 patients (31 mandibles and 26 maxillae) and RP recruited and treated 23 patients (9 mandibles and 14 maxillae). Patients were recruited and subjected to surgical procedures from September 2013 to October 2015. All patients were treated according to the allocated interventions.

Drop-outs

Nine patients dropped out before 3-year post-loading follow-up, three from the short implant group and six from the augmentation group.

Reason for dropping out were the following.

Short implant group:

- Patient 23 (PF, maxilla): moved to USA (last seen at prosthesis delivery);
- Patient 2 (PF, mandible): no longer reachable (last seen at 1-year post-loading);
- Patient 72 (RP, maxilla): moved away (last seen at 1 year post-loading). Contacted by phone and subjectively reported feeling fine, with no implant-related problems.

Augmentation group:

- Patient 3 (PF, mandible): moved to China (last seen at 4 months post-loading);
- Patient 75 (PF, maxilla): dissatisfied with the treatment due to one implant failure. The implant would have been replaced free of charge, but the patient decided to go to another dentist (last seen at 5 months post-loading);
- Patient 14 (PF, mandible): decided to see another dentist. No problems reported up to the third year of follow-up (last seen 3 months after the augmentation procedure);
- Patient 40 (PF, maxilla): after failures of all three implants, the patient decided to see another dentist (last seen 1 month after placement of the replacement implants, which occurred 16 months after placement of the study implants);
- Patient 5 (RP, mandible): moved away. Contacted by phone and sent a panoramic radiograph taken at 3 years after loading which revealed distal implant loss (last seen at 1-year post-loading);
- Patient 46 (RP, mandible): moved away. Contacted by phone and subjectively reported feeling fine with no implant-related problems (last seen at 1 year and 6 months post-loading).

Deviations from the original research protocol

Apart from the previously described imbalance in the number of patients, the following deviations from the protocol were reported.

Short implant group:

- Patient 39 (PF, maxilla): received three implants, of which the intermediate implant failed; the patient refused a replacement and asked to be rehabilitated on the two

remaining implants. The 3-year post-loading periapical radiograph was taken at 3 years and 4 months;
- Patients 1 and 19 (PF, mandible): had the 3-year post-loading periapical radiographs taken at 3 years and 5 months;
- Patients 9 (PF, mandible) 21, 38 and 79 (PF, maxilla): no periapical radiographs taken 3 years after loading;
- Patient 24 (PF, maxilla): the distal surface of implant #26 was not measurable on the 3-year post-loading periapical radiograph;
- Patient 18 (PF, mandible): the 3-year post-loading periapical radiograph was taken at 3 years and 4 months;
- Patient 44 (RP, mandible): the 3-year post-loading periapical radiograph was taken at 3 years and 6 months.

Augmented group:
- Patient 33 (PF, maxilla): received two implants in positions #24 and #25; after having worn the provisional prosthesis, requested a longer prosthesis without undergoing implant surgery again, so tooth 26 was employed as a cantilever for the definitive prosthesis;
- Patients 15, 53 (PF, mandible) and 22 (PF, maxilla): no periapical radiographs taken 3 years after loading;
- Patient 49 (RP, mandible): the 3-year post-loading periapical radiograph was taken at 3 years and 4 months;
- Patient 20 (PF, mandible): the 3-year post-loading periapical radiograph was taken at 3 years and 5 months.

Data from all remaining patients were suitable for statistical analyses.
The main baseline patient and intervention characteristics, divided by study group and location, are presented in **TABLE 1** (mandibles) and **TABLE 2** (maxillae). Eighty-seven implants were allocated to the augmentation group and 80 to the short implant group. There were no baseline differences between the two groups, with the exception of more smokers in the augmentation group (eight *versus* two smokers, respectively, all treated in mandibles). In six (30%) patients there was insufficient bone to place 10-mm-long implants after vertical bone augmentation of the mandible as planned, and 4.0-to 8.5-mm-long implants had to be used instead.
The follow-up reported here was conducted 3 years after initial loading. The main results are summarised in **TABLE 3**, and were as follows.

Implant failures

Six patients from the augmentation group lost nine implants, *versus* five patients from the short implant group, who lost six implants (P [Fisher's exact test] = 0.159 difference in proportion = 0.05; CI 95% -0.11 to 0.21). In mandibles, two patients from the augmentation group lost one implant each, *versus* two patients from the short implant group who lost one implant each (P [Fisher's exact test] = 0.342 difference in proportion = 0.04; CI 95% -0.21 to 0.29). In maxillae, three patients lost four short implants, *versus* four patients who lost seven long implants (P [Fisher's exact test] = 0.934; difference in proportion = 0.05; CI 95% -0.15 to 0.25). The difference between the two groups in the proportions of patients with implant failures was not statistically significant. Regarding the 4-mm-long group, two mandibular implants were found not to be osteointegrated in two patients at abutment connection; one was successfully replaced (prosthesis delivered with a 4-month delay) whereas the other implant was not (it was an intermediate implant and the prosthesis was regularly fitted on the two remai-

TABLE 1 PATIENT AND INTERVENTION CHARACTERISTICS FOR MANDIBLES

	Long implants (n = 20)	Short implants (n = 20)
Females	8 (40%)	13 (65%)
Mean age at recruitment (range)	63.25 (46-72)	59.35 (47-73)
Moderate smokers (up to 10 cig/day)	5 (25%)	2 (10%)
Heavy smokers (more than 10 cig/day)	3 (15%)	0
# implants	46	43
# 4.0-mm-long implants	6 (13%)	43 (100%)
# 6.0-mm-long implants	2 (4.3%)	0
# 8.5-mm-long implants	6 (13%)	0
# 10.0-mm-long implants	20 (43.5%)	0
# 11.5-mm-long implants	12 (26.1%)	0
# 13.0-mm-long implants	0	0
# 4.0-mm diameter implants	46 (100%)	38 (88.4%)
# 4.5-mm diameter implants	0	5 (11.6%)
# implants placed with < 25 Ncm torque	2 (10%) in two patients	6 (14%) in four patients
# patients receiving one implant	0	4 (20%)
# patients receiving two implants	14 (70%)	9 (45%)
# patients receiving three implants	6 (30%)	7 (35%)

TABLE 2 PATIENT AND INTERVENTION CHARACTERISTICS FOR MAXILLAE

	Long implants (n = 20)	Short implants (n = 20)
Females	11 (55%)	10 (50%)
Mean age at recruitment (range)	56.40 (36-71)	60.75 (25-77)
Moderate smokers (up to 10 cig/day)	6 (30%)	3 (15%)
Heavy smokers (more than 10 cig/day)	1 (5%)	1 (5%)
# implants	41	37
# 4.0-mm-long implants	0	37 (100%)
# 6.0-mm-long implants	0	0
# 8.5-mm-long implants	0	0
# 10.0-mm-long implants	15 (36.6%)	0
# 11.5-mm-long implants	24 (58.5%)	0
# 13.0-mm-long implants	2 (4.9%)	0
# 4.0-mm diameter implants	41 (100%)	31 (83.8%)
# 4.5-mm diameter implants	0	6 (16.2%)
# implants placed with < 25 Ncm torque	11 (26.8%) in eight patients	11 (29.7%) in nine patients
# patients receiving one implant	4 (20%)	6 (30%)
# patients receiving two implants	11 (55%)	11 (55%)
# patients receiving three implants	5 (25%)	3 (15%)

TABLE 3 SUMMARY OF THE MAIN OUTCOMES EXPRESSED AS NUMBER OF PATIENTS EXPERIENCING AT LEAST ONE NEGATIVE EVENT IN MANDIBLES AND MAXILLAE UP TO 3 YEARS AFTER LOADING

	Long implants	Short implants	Difference in proportions	95% CI	P-value
Failure to place implants of length at least 10 mm in mandibles (= graft failure)	6 (40 patients)	Not applicable	-	-	-
Failure to place implants of length at least 10 mm in maxillae (= graft failure)	0 (40 patients)	Not applicable	-	-	-
Failure of mandibular prostheses	3 (18 patients)	1 (19 patients)	-0.02	-0.26, 0.23	0.984
Failure of maxillary prostheses	5 (20 patients)	2 (19 patients)	0.05	-0.15, 0.25	0.832
Total number of patients with failed prostheses	8 (38 patients)	3 (38 patients)	0.02	-0.14, 0.18	0.919
Patients with failed mandibular implants [number of implants]	2 [2] (18 patients)	2 [2] (19 patients)	0.04	-0.21, 0.29	0.342
Patients with failed maxillary implants [number of implants]	4 [7] (20 patients)	3 [4] (19 patients)	0.05	-0.15, 0.25	0.934
Total number of patients with failed implants [number of implants]	6 [9] (38 patients)	5 [6] (38 patients)	0.05	-0.11, 0.21	0.159
Patients with complications in mandibles [number of complications]	10 [14] (18 patients)	4 [4] (19 patients)	-0.04	-0.35, 0.27	0.580
Patients with complications in maxillae [number of complications]	8 [16] (20 patients)	4 [6] (19 patients)	-0.1	-0.4, 0.2	0.891
Total number of patients with complications [number of complications]	18 [30] (38 patients)	8 [10] (38 patients)	-0.72	-0.29, 0.14	0.587

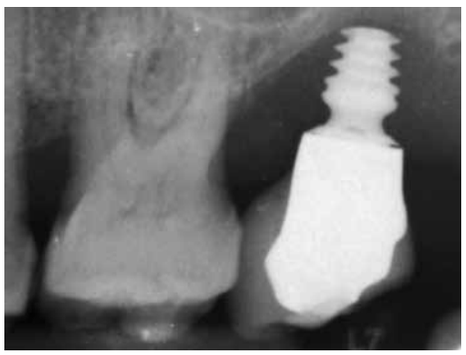


FIG. 6: *Patient 67 (maxilla), who presented at 3-year follow-up complaining of discomfort and crown mobility at #27. Clear periapical radiolucency surrounded the entire implant.*

ning implants). In the maxilla, one 4-mm-long implant was found to be mobile 3 months after placement, and was replaced with an implant of a different shape (i-RES Shape 1t Tissue Level, Lugano, Switzerland); this type of implant is locked into the bone by its shape, and is less likely to fall into the maxillary sinus. The following month, the same patient lost her second implant, which had migrated into the sinus. This implant was removed via a lateral window and replaced, in the same session, with a second i-RES Shape 1t implant; patient reported that she was in the habit of touching both implants with her tongue. Another patient complained of some discomfort and mobility at the distal of the three short implants placed 2 weeks previously; the implant appeared mesially tilted, and was removed but not replaced, in accordance with the patient's wishes. The prosthesis was regularly loaded on the two remaining implants in positions #14 and #15, using tooth #16 as cantilever. Finally, one patient presented to the 3-year follow-up complaining of discomfort and crown mobility at implant #27. Radiograph revealed a clear radiolucent periapical area around the implant (**FIG. 6**). The implant was removed and the patient decided not to have it replaced.

The following implants from the augmentation group failed: in the mandible, one patient lost his interpositional graft due to infection; the graft was removed and the same day three 4-mm-long implants were placed. A few days later the mandible fractured, and 10 days afterwards was stabilised using osteosynthesis plates. Eight months after its placement, the mesial implant was found to be infected and mobile, and was therefore removed. The patient originally did not want to proceed with the rehabilitation, but later on changed his mind and received one additional TwinKon 4-mm-long implant and was successfully rehabilitated (**FIG. 7**).

In the maxilla, one patient whose sinus lining was perforated while being detatched presented with one mobile implant two months after its placement, and it was therefore removed. Two months later, the second implant was also found to be mobile and was removed. At the same session two replacement implants were placed, and the patient was prosthetically rehabilitated with a delay of four months.

In another patient, one implant migrated into the maxillary sinus 3 months after placement, without the patient noticing it. It was retrieved using a lateral window approach, and two i-Res implants were placed during the same session. The patient was prosthetically rehabilitated with a delay of 8 months.

Another patient showed up with two out of three implants being mobile three months after their placement. Despite being advised not to do so, the patient had worn her partial removable denture since implant placement. The patient was initially unwilling to proceed with the therapy, but 13 months after the implant failures she changed her mind and had, on her specific request, two 10-mm-long implants placed (NobelActive, NobelBiocare, Goteborg, Sweden). During the placement procedures, it was observed that the third original TwinKon implant had also failed, and this was removed. The patient is not yet prosthetically rehabilitated.

One patient complained of prosthesis instability and discomfort while chewing and speaking five months after loading. The implant in position 16 was found to be mobile. The patient was told that the failed implant had to be replaced, but she refused the proposed free replacement and went to another dentist.

Finally, one patient dropped out 1 year after loading, but after our repeated requests sent us a panoramic radiograph taken at 3 years after loading. On the radiograph it was apparent that she had lost the distal implant #47 and that the prosthesis was reduced to a single crown on #46. The patient reported that she had begun to experience discomfort about 2 years and 7 months after loading.

Prosthesis failures

Also considering as prosthesis failures those prostheses which could not be delivered because of implant failures (even though a prosthesis was successfully placed on replacement implants at a later stage), prosthesis failures were as follows: two prostheses on short implants (one mandibular and one maxillary) were placed at a later stage due to implant failures, and one maxillary crown (**FIG. 6**) failed at the 3-year post-loading follow-up, *versus* eight prostheses (three mandibular and five maxillary) at augmented sites, which were placed later (five prostheses), not delivered at all (one prosthesis), failed (one prosthesis), or were reduced to a single crown due to the failure of one of the two supporting implants (one prosthesis). There was no statistically significant difference in prosthesis failures between the two groups (P [Fisher's exact test] = 0.019; difference in proportion = 0.02; CI 95% -0.14 to 0.18; **TABLE 3**). In particular, two patients from the augmentation group (both maxillary implants) and one patient from the short implant group (maxillary) were not wearing a prosthesis at the time of writing this report.

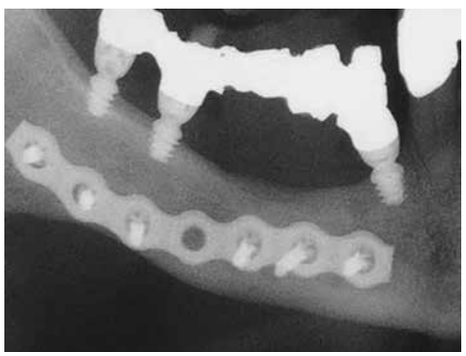


FIG. 7: *Definitive prosthesis delivered to Patient 14 (augmentation group, mandible) at 3-year follow-up. Three months after inlay grafting, the graft became infected. The graft was removed and three 4-mm-long implants were placed. After a few days, the mandible had a spontaneous fracture, treated with an osteosynthesis plate. Implant in position #44 failed, and was successfully replaced. The patient was ultimately rehabilitated using a partial fixed prosthesis.*

Complications

More complications occurred at augmented sites: eight patients from the short implant group were affected by ten complications, *versus* 30 complications in 18 patients from the augmentation group, but the difference was not statistically significant (P [Fisher's exact test] = 0.587; difference in proportion = -0.72; CI 95% -0.29 to 0.14; **TABLE 3**). More specifically, in mandibles ten augmented patients were affected by 14 complications, *versus* four complications in four patients treated using short implants (P [Fisher's exact test] = 0.580; diffe-

rence in proportion = -0.04; CI 95% -0.35 to 0.27; **TABLE 3**). In maxillae, eight sinus-lift patients had 16 complications *versus* four patients rehabilitated with maxillary short implants with six complications (P [Fisher's exact test] = 0.891; difference in proportion = -0.01; CI 95% -0.42 to 0.2; **TABLE 3**). A detailed description of the complications and their treatment is presented in **TABLE 4** (**FIG. 7**).

Peri-implant marginal bone levels

At implant placement, there was no difference in bone levels between short and long implants when evaluating both mandibular and maxillary implants together (**TABLE 5**); however, for mandibular implants alone there was a statistically significant difference of 0.04 mm (P = [t-test] = 0.020) in favour of short implants (**TABLE 5A**). There were significant

TABLE 4 DESCRIPTION OF COMPLICATIONS AND THEIR OUTCOMES UP TO 3 YEARS

Patient number	Time	Complication	Treatment and outcome
Patients allocated to 4-mm-long implants			
64, max (RP)	2w.pi	Discomfort at #16, implant mobile and mesially inclined	Implant removal, patient refused replacement; prosthesis loaded on #14 and 15 with #16 as cantilever
23, max (PF)	3m.pi	Implant at #16 painful and mobile	Removed
	4m.pi	Implant at #17 migrated into the sinus	Removed via lateral window and replaced
67, max (RP)	1m.pl	Provisional crown on #27 loose	Retightened
	3y.pl	Discomfort at #27: implant mobile and painful upon pressure	Implant removal, patient refused replacement
13, mand (PF)	3m.pl	Discomfort at #46. Implant stable but slightly painful at percussion, no radiographic sign of failure	Implant removed from occlusion but prosthesis left on #45 and #47; loaded again after 10 months
48, mand (RP)	10m.pl	Chipping of the prosthetic composite lining at #37	Repaired chairside
34, max (PF)	1y.pl	Screw loosening at #26 crown	Retightened
59, mand (PF)	3y.pl	Chipping of the prosthetic composite lining at #36	Repaired chairside
41, mand (RP)	3y.pl	Prosthetic screw loosening at #47 crown	Retightened
Patients allocated augmentation procedures and 10-mm-long or longer implants			
22, max (PF)	0	Minor maxillary sinus epithelium perforation	Used Evolution collagen membrane
30, max (PF)	0	Minor maxillary sinus epithelium perforation	Used Evolution collagen membrane
77, max (PF)	0	Minor maxillary sinus epithelium perforation	Used Evolution collagen membrane
	3m.pi	Implant #26 mobile and painful at pressure	Removed
	4m.p.i	Implant #25 mobile and painful at pressure	Removed and two new implants placed in position #26 and #27; prosthetic rehabilitation delayed by 4 months

Patient number	Time	Complication	Treatment and outcome
50, mand (PF)	0	Paraesthesia	Spontaneous healing in 1 week
57, mand (PF)	0	Paraesthesia	Spontaneous healing in 3 days
45, mand (RP)	5w.pl	Symptomless lingual dehiscence of about 3 mm	Osteoplasty; healed in 2 weeks
63, max (RP)	4d.pi	Lost healing screw at #16	Retightened
37, max (PF)	1w.pi 3m.pl 3y.pl	Pain, swelling and bad odour After 1 week no pain resolution After 2 weeks no pain resolution Loosening of prosthetis screw at #27 Loosening of both prosthesis screws	One additional week of amoxicillin + betamethasone x 4 days Painkillers No pathological signs on CBCT: suspected pain of neurological origin: anaesthesia of the infraorbital nerve which induced an almost pain-free condition: arnica ointment for 2 weeks, symptomatology improved but not resolved, 2 months' delay in prosthetic rehabilitation Retightened Retightened
16, mand (PF)	10d.pg	Asymptomatic vestibular wound dehiscence	Treated with chlorhexidine rinse 2% and gel 1%; dehiscence reduced in size but still present; at implant placement the graft was partially resorbed and not integrated: removed; three 4-mm-long implants placed
14, mand (PF)	3m.pg 3m.pi 8m.pi	Pain, swelling and exudate Major pain in the area a few days after implant placement: mandible fracture Pain at #48 Pain at #44	Graft removal and placement of three 4 mm-long implants Placement of osteosynthesis plates Spontaneous healing Implant removed and replaced, patient rehabilitated (**FIG. 7**)
42, mand* (RP)	4m.pg	The planned vertical augmentation was not achieved	Used implants shorter than 10 mm
49, mand* (RP)	4m.pg	The planned vertical augmentation was not achieved	Used implants shorter than 10 mm
60, mand* (PF)	4m.pg	The planned vertical augmentation was not achieved	Used implants shorter than 10 mm
20, mand* (PF)	4m.pg	The planned vertical augmentation was not achieved Post-implantation paraesthesia	Placement of two 8.5-mm-long implants Spontaneous healing in 1 week
40, max (PF)	3m.pi 16m.pi	Implants #24 and 25 were painful and mobile; the patient wore her mobile partial denture immediately after implantation Implant at #26 painful at stability testing	Both implants removed Removed

Patient number	Time	Complication	Treatment and outcome
36, max (PF)	3m.pi	Implant at #15 disappeared: migrated into the maxillary sinus; no symptoms and the patient did not realise it	Implant removed from the sinus via a lateral window and replaced the same day by two implants of different shape (i-RES Shape 1t Tissue Level) which were locked into the bone by their shape and were less likely to fall into the maxillary sinus
23, max (PF)	3m.pi 4m.pi	Discomfort at #16: implant mobile and painful upon pressure Patient referred disappearance of implant #17: the implant had migrated into the maxillary sinus	Removed and replaced the same day with one implant as above Implant removed from the sinus via a lateral window and another implant placed, as above
75, max (PF)	5m.pl	Prosthesis instability and discomfort when chewing and speaking; implant at #16 mobile	Free implant replacement proposed but patient opted to see another dentist
5, mand (PF)	2y+7m.pl	Discomfort at #47: implant mobile and painful at pressure	Implant removal and prosthesis cut and left on the residual implant #46

Max = maxilla; mand = mandible; d.pg = days post-grafting; w.pi = weeks post-implantation; m.pl = months post-loading; y.pl = years post-loading

**These were considered complications even though there was no discomfort, symptoms or additional treatment.*

TABLE 5 MEAN RADIOGRAPHIC PERI-IMPLANT MARGINAL BONE LEVELS BETWEEN GROUPS AND TIME PERIODS AT BOTH MANDIBULAR AND MAXILLARY IMPLANTS

	Implant placement	Loading	4 months post-loading	1 year post-loading	3 years post-loading
	N Mean (SD) [95% CI]	N Mean (SD) [95% CI]	N Mean (SD) [95% CI]	N Mean (SD) [95% CI]	N Mean (SD) [95% CI]
Short implants	40 0.03 (0.03) [0.02 to 0.04]	39 0.25 (0.10) [0.22 to 0.28]	39 0.43 (0.12) [0.39 to 0.48]	39 0.57 (0.16) [0.52 to 0.62]	32 0.89 (0.65) [0.38 to 2.03]
Long implants	39 0.05 (0.05) [0.03 to 0.06]	36 0.33 (0.09) [0.29 to 0.36]	36 0.51 (0.12) [0.47 to 0.55]	34 0.75 (0.23) [0.67 to 0.83]	32 0.76 (0.43) [0.32 to 1.89]
Difference	-0.02 [-0.04 to 0.001]	-0.07 [-0.12 to -0.03]	-0.07 [-0.13 to -0.02]	-0.18 [-0.27 to -0.09]	-0.13 [-1.47 to 0.41]
P-value	0.068	0.001*	0.010*	<0.001*	0.351

**Statistically significant difference*

TABLE 5A MEAN RADIOGRAPHIC PERI-IMPLANT MARGINAL BONE LEVELS BETWEEN GROUPS AND TIME PERIODS AT MANDIBULAR IMPLANTS ALONE

	Implant placement	Loading	4 months post-loading	1 year post-loading	3 years post-loading
	N Mean (SD) [95% CI]	N Mean (SD) [95% CI]	N Mean (SD) [95% CI]	N Mean (SD) [95% CI]	N Mean (SD) [95% CI]
Short implants	20 0.03 (0.03) [0.01 to 0.04]	20 0.24 (0.11) [0.19 to 0.28]	20 0.40 (0.12) [0.34 to 0.45]	20 0.51 (0.16) [0.44 to 0.58]	17 0.62 (0.58) [0.50 to 0.75]
Long implants	19 0.06 (0.06) [0.03 to 0.09]	19 0.34 (0.08) [0.30 to 0.38]	19 0.52 (0.10) [0.47 to 0.57]	18 0.77 (0.21) [0.67 to 0.87]	15 0.71 (0.13) [0.42 to 0.99]
Difference	-0.04 [-0.07 to -0.01]	-0.11 [-0.17 to -0.04]	-0.12 [-0.19 to -0.04]	-0.26 [-0.38 to -0.14]	-0.09 [-0.39 to 0.19]
P-value	0.020*	0.001*	0.002*	<0.001*	0.470

**Statistically significant difference*

TABLE 5B MEAN RADIOGRAPHIC PERI-IMPLANT MARGINAL BONE LEVELS BETWEEN GROUPS AND TIME PERIODS AT MAXILLARY IMPLANTS ALONE

	Implant placement	Loading	4 months post-loading	1 year post-loading	3 years post-loading
	N Mean (SD) [95% CI]	N Mean (SD) [95% CI]	N Mean (SD) [95% CI]	N Mean (SD) [95% CI]	N Mean (SD) [95% CI]
Short implants	20 0.03 (0.03) [0.02 to 0.05]	19 0.27 (0.09) [0.23 to 0.31]	19 0.47 (0.12) [0.42 to 0.53]	19 0.63 (0.15) [0.56 to 0.70]	15 1.14 (0.22) [0.67 to 1.62]
Long implants	20 0.03 (0.04) [0.01 to 0.05]	17 0.31 (0.10) [0.25 to 0.36]	17 0.50 (0.13) [0.43 to 0.57]	16 0.72 (0.25) [0.59 to 0.85]	17 0.73 (0.78) [0.57 to 0.89]
Difference	0.0005 [-0.02 to 0.02]	-0.04 [-0.10 to 0.02]	-0.03 [-0.11 to 0.06]	-0.09 [-0.23 to 0.05]	0.41 [-0.07 to 0.85]
P-value	0.966	0.213	0.528	0.193	0.079

differences in bone levels between the two groups at implant loading, 4 months and 1 year after loading (P [t-test] = 0.001; P [t-test] = 0.010, and P [t-test] < 0.001 respectively; **TABLE 5**) but not at 3 years after loading (P [t-test] = 0.351). For mandibular implants alone, there were significant differences at loading, and at 4 months and 1 year after loading (P [t-test] = 0.001; P [t-test] = 0.002; P [t-test] < 0.001, respectively; **TABLE 5A**), but not at 3-year post-loading (P [t-test] = 0.470). There were no significant differences in bone levels at any time for maxillary implants alone (**TABLE 5B**).

At 3 years after loading, both groups lost a statistically significant amount of bone; short implants lost 0.87 mm of bone and long implants 0.72 mm. The difference was not statistically significant (mean difference 0.15 mm, 95% CI -0.13 to 0.0, P [ANCOVA] < 0.290; **TABLE 6**). More specifically, mandibular short implants lost 0.62 mm of bone and long implants 0.71 mm (mean difference -0.08 mm, 95% CI -0.37 to 0.20, P [ANCOVA] = 0.568; **TABLE 6A**). There was statistically significantly more bone loss at short maxillary implants (1.14 mm) than at

TABLE 6 COMPARISON OF MEAN CHANGES IN PERI-IMPLANT MARGINAL BONE LEVELS AT LOADING AND 3 YEARS AFTER LOADING FOR BOTH MANDIBULAR AND MAXILLARY IMPLANTS, USING ANCOVA WITH BASELINE BONE LEVELS AS COVARIATE

	Baseline - loading	Baseline - 4-month post-loading	Baseline - 1-year post-loading	Baseline - 3-year post-loading
	N Mean (SE) [95% CI]	N Mean (SE) [95% CI]	N Mean (SE) [95% CI]	N Mean (SE) [95% CI]
Short implants (all)	39 0.25 (0.02) [0.22 to 0.28]	39 0.43 (0.02) [0.40 to 0.47]	39 0.57 (0.03) [0.51 to 0.63]	32 0.87 (0.66) [0.3 to 2.03]
Long implants (all)	36 0.32 (0.02) [0.29 to 0.35]	36 0.51 (0.02) [0.47 to 0.55]	34 0.75 (0.03) [0.68 to 0.81]	32 0.72 (0.42) [0.22 to 1.85]
Difference	-0.07 [-0.11 to -0.02]	-0.08 [-0.13 to -0.02]	-0.18 [-0.27 to -0.08]	0.15 [-0.13 to 0.0]
P-value	0.003*	0.010*	< 0.001*	0.290

All changes from baseline statistically different (P [paired t-test] < 0.001)
**Statistically significant difference.*

TABLE 6A COMPARISON OF MEAN CHANGES IN PERI-IMPLANT MARGINAL BONE LEVELS AT LOADING AND 3 YEARS AFTER LOADING AT MANDIBULAR IMPLANTS ALONE, USING ANCOVA WITH BASELINE BONE LEVELS AS COVARIATE

	Baseline - loading	Baseline - 4 month post-loading	Baseline - 1 year post-loading	Baseline - 3 years post-loading
	N Mean (SE) [95% CI]	N Mean (SE) [95% CI]	N Mean (SE) [95% CI]	N Mean (SE) [95% CI]
Short implants (all)	20 0.24 (0.02) [0.20 to 0.29]	20 0.40 (0.03) [0.34 to 0.45]	20 0.51 (0.04) [0.42 to 0.60]	17 0.62 (0.24) [0.2 to 1.14]
Long implants (all)	19 0.33 (0.02) [0.29 to 0.38]	19 0.52 (0.03) [0.46 to 0.57]	18 0.77 (0.04) [0.68 to 0.86]	15 0.71 (0.52) [0.22 to 1.90]
Difference	-0.09 [-0.15 to -0.02]	-0.12 [-0.20 to -0.04]	-0.26 [-0.39 to -0.13]	-0.08 [-0.37 to 0.20]
P-value	0.011*	0.006*	< 0.001*	0.568

All changes from baseline statistically different (P [paired t-test] < 0.001)
**Statistically significant difference.*

TABLE 6B COMPARISON OF MEAN CHANGES IN PERI-IMPLANT MARGINAL BONE LEVELS AT LOADING AND 3 YEARS AFTER LOADING AT MAXILLARY IMPLANTS ALONE, USING ANCOVA WITH BASELINE BONE LEVELS AS COVARIATE

	Baseline - loading	Baseline - 4 month post-loading	Baseline - 1 year post-loading	Baseline -3 years post-loading
	N Mean (SE) [95% CI]	N Mean (SE) [95% CI]	N Mean (SE) [95% CI]	N Mean (SE) [95% CI]
Short implants (all)	19 0.27 (0.02) [0.22 to 0.31]	19 0.48 (0.03) [0.42 to 0.54]	19 0.63 (0.05) [0.53 to 0.72]	15 1.14 (0.86) [0.50 to 3.77]
Long implants (all)	17 0.31 (0.02) [0.26 to 0.36]	17 0.50 (0.03) [0.43 to 0.56]	16 0.72 (0.05) [0.62 to 0.83]	17 0.73 (0.32) [0.22 to 1.48]
Difference	-0.04 [-0.11 to 0.03]	-0.02 [-0.10 to 0.07]	-0.09 [-0.24 to 0.05]	0.41 [-0.04 to 0.87]
P-value	0.243	0.711	0.196	0.037*

All changes from baseline statistically different (P [paired t-test] < 0.001)
**Statistically significant difference*

TABLE 7 COMPARISON OF THE OUTCOMES BETWEEN THE TWO STUDY CENTRES UP TO 3 YEARS AFTER LOADING

	PF 57 patients	RP 23 patients	Differences in proportions	95% CI	P-value
Drop-outs	6	3	-0.03	-0.18 to 0.13	0.769
Patients with graft failures	4 (N = 57)	2 (N = 23)	-0.02	-0.15 to 0.12	0.769
Patients with implant failures (# of implants)	8 (12) (N = 54*)	3 (3) (N = 21)	0.03	-0.15 to 0.20	0.447
Patients with prosthesis failures	9 (N = 54*)	2 (N = 21)	-0.12	-0.31 to 0.08	0.280
Patients with complications (# of complications)	18 (31) (N = 54*)	8 (9) (N = 21)	-0.18	-0.43 to 0.06	0.982
	N Mean (SE) [95% CI]	**N Mean (SE) [95% CI]**	**Difference**	**95% CI**	**P-value**
Peri-implant bone loss	44 0.73 (0.58) [0.62 to 0.85]	20 0.92 (0.18) [0.54 to 1.30]	-0.18	-0.48 to 0.11	0.218

**Four out of the nine drop-outs had complications, implant or prosthesis failures*

long maxillary implants (0.73 mm), the mean difference being 0.41 mm (95% CI -0.04 to 0.87, P [ANCOVA] = 0.037; **TABLE 6B**).
No significant differences were found in outcomes between the two operators (**TABLE 7**).

DISCUSSION

This trial was designed to evaluate whether 4-mm-long implants could be a feasible alternative for the rehabilitation of atrophic posterior jaws using implant-supported crowns or partial fixed prostheses. The control procedures were augmentation techniques already evaluated in several other trials, namely vertical bone augmentation with interpositional blocks of xenograft[s5-7,9,18] for atrophic mandibles and one-stage sinus lift with lateral window approach using 100% bone substitute[6,9,12,14]. However, the difference between the present trial and previous RCTs is that in this study patients with even more severely atrophic jaws were included (5 to 6 mm of bone above the mandibular canal or 4 to 5 mm below the maxillary sinus), testing both augmentation procedures and short implants to their limits. This may explain the slightly higher number of complications and failures reported. Nevertheless, all tested interventions provided satisfactory results, and only three patients (two augmented in the maxilla and one with 4.0-mm short maxillary implants) are not wearing a fixed prosthesis at the time of writing this article.
The most technically demanding procedure proved again to be the rehabilitation of the posterior mandible with an interpositional bone substitute graft. In fact, in six patients (30%) the desired bone height needed to allow placement of at least 10-mm-long implants was not achieved. In the best-case scenario, these patients could be rehabilitated with short implants. In the worst-case scenario, serious complications could have occurred, such as the spontaneous fracture of the mandible seen in one of our patients, whose mandible, which was already atrophic and weakened by the grafting procedure, graft infection and associated inflammation, fractured after implant placement.
Another peculiar complication was implant migration into the maxillary sinus. This occurred in three patients, and in a fourth patient the implant tilted mesially. There are two possible cofactors which may have helped bring about this complication, both possibly linked to the design of the implants used in this study, namely the transmucosal design and the shape of the implant collar. Indeed, transmucosal implants are more likely to receive unwanted loading forces during mastication or simply upon pressure by the tongue. Many patients use their tongues to explore new objects present in their mouths, such as the head of an implant. Such movements may have gradually pushed the implant into the sinus cavity, and this process could have also been facilitated by the reduced bone height of soft quality and the insufficient primary implant stability at insertion (all these implants were inserted with torques of lower than 25 Ncm). Moreover, the design of the implant neck might have played a role, since the reduced collar diameter might not be sufficient to engage adequately with the surrounding bone at the crestal level if the implant is pushed apically. By being aware of this potential problem, clinicians could pre-emptively place wide healing cover screws or choose alternative implant designs in the atrophic posterior maxilla.
Bone augmentation procedures to create new supporting bone are generally more technically demanding than placing short implants; they are also often associated with higher postoperative morbidity, complications, longer treatment periods and an increased number of surgeries. Data from other RCTs[5-9,11-14] and a systematic review[10], together with the present findings, suggest that short implants may be an appealing alternative to augmentation of the posterior jaws, at least up to 5 years after loading. Nevertheless, it should be emphasised that the long-term prognosis of short implants is not sufficiently known, and

the sample size of the present and of other published RCTs are still too small to draw definitive conclusions. More RCTs with larger sample sizes and longer follow-ups are needed. In particular, it would also be interesting to test 4-mm-long implants with a bone-level design, which at the moment seem to be missing from the market, and other bone augmentation techniques such as guided bone regeneration[19].

Regarding peri-implant marginal bone level changes, using implant placement as baseline, 3 years after loading short implants lost on average 0.87 mm, and long implants about 0.72 mm, the difference not being statistically significant. However, at maxillary implants specifically, short implants lost on average 1.14 mm and long implants about 0.73 mm. This difference was statistically significant, and might indicate a less favourable long-term prognosis of 4-mm-long maxillary implants compared to longer implants placed in lifted maxillary sinuses. Another interesting observation is that implants may need as little as 3.1 mm of bone height on average to be able to support a prosthesis, though the current follow-up is too short to predict the long-term outcome.

The main limitation of the present investigation is the small sample size; however, the study should be considered as a pilot study, since the degree of atrophy of the included patients was really at the limits of the feasibility of all tested interventions. The second limitation is represented by the seven patients for whom 3-year periapical radiographs were not taken. Indeed, such large patient attrition may have affected the results, hiding statistically significant differences. The third limitation is the short follow-up, but we plan to follow this cohort of patients up to 10 years after loading.

Both operators were very experienced with all the rehabilitation procedures evaluated in this trial, and this might limit extrapolation of the present results; however, all interventions were tested in real clinical conditions and the inclusion criteria were sufficiently broad. Therefore, the results of the present trial may be generalised with confidence to a wider population with similar characteristics.

CONCLUSIONS

Three years after loading, 4.0-mm-long implants achieved similar results as longer implants in augmented jaws, but were affected by fewer complications. Short implants might therefore be preferable to bone augmentation, especially in mandibles, since the treatment is less invasive, faster, cheaper, and associated with less morbidity. However, 5 to 10-year post-loading data from larger trials will be necessary before we are able to produce reliable recommendations.

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