

POSTERIOR JAW REHABILITATION USING PARTIAL PROSTHESES SUPPORTED BY IMPLANTS 4.0 X 4.0 MM OR LONGER: THREE-YEAR POST- LOADING RESULTS OF A MULTICENTRE RANDOMISED CONTROLLED TRIAL



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PURPOSE. To evaluate whether 4.0 x 4.0-mm dental implants could be viable alternatives to implants of length at least 8.5 mm when placed in posterior jaws with adequate bone volumes.

MATERIALS AND METHODS. One hundred and fifty patients with posterior (premolar and molar areas) jaws having at least 12.5 mm bone height above the mandibular canal or 11.5 mm below the maxillary sinus, as applicable, were randomised according to a parallel-group design and received one to three 4.0 mm-long implants or one to three implants which were at least 8.5 mm-long at three treatment centres. All implants had a diameter of 4.0 mm. Implants were loaded with permanent screw-retained prostheses after 4 months. Patients were followed-up until 3-year post-loading, and outcome measures considered were prosthesis and implant failure, any complications, and changes in peri-implant marginal bone levels.

RESULTS. Seventy-five patients were randomly allocated to each group. Drop-outs at 3-year post-loading assessment were five patients from the long implant group and three from the short implant group. Up to 3 years post-loadings, three patients lost one 4.0 mm-long implant each, in comparison to two patients who lost one long implant each (difference in proportion = -0.013; 95% CI: -0.079 to 0.054; P = 1). All failures occurred before loading; failed implants were replaced, delaying delivery of two prostheses in each group by several months (difference in proportion = 0; 95% CI: -0.061 to 0.062; P = 1). Five short-implant patients experienced six complications *versus* the three complications seen in three long implant patients (difference in proportion = -0.026; 95% CI: -0.103 to 0.053; P = 0.719). There were no statistically significant differences between groups in prosthesis failures, implant failures or complications. Patients with short implants lost on average 0.55 mm of peri-implant bone, and patients with longer implants lost 0.61 mm. There were no statistically significant differences between short and long implants in bone level changes up to 3 years (mean difference = 0.05 mm; 95% CI: -0.05 to 0.16; P = 0.221).

CONCLUSIONS. Outcomes 3 years after loading were similar with 4.0 x 4.0 mm-long implants and 8.5 x 4.0 mm or longer implants in posterior jaws, in the presence of adequate bone volumes. However, 5 to 10-year post-loading data will be necessary before reliable recommendations can be made.

CONFLICT OF INTEREST STATEMENT. Global D (Brignais, France) partially supported this trial and donated the implants and prosthetic components. OsteoBiol (TecnoSS, Giaveno, Italy) donated the biomaterials used for bone augmentation. However, the data property belonged to the authors and neither Global D nor OsteoBiol interfered in any way with the conduct of the trial or the publication of the results.

INTRODUCTION

Rehabilitation of atrophic edentulous jaws with implant-supported prostheses is challenging because of inadequate bone volumes. However, several randomised controlled trials (RCTs) and systematic reviews have shown that in the presence of 4 to 8 mm of bone height, short implants can be successfully used as an alternative to the more invasive bone augmentation procedures required for placement of longer implants¹⁻¹¹. In particular, findings of ongoing trials with a follow-up up to 8-years that 4.0 to 8.5-mm long implants can be a viable, if not better, alternative to augmentation procedures, especially in posterior sectors of both jaws. This raises the clinical issue of whether short implants might also be a viable option in situations in which long implants are possible, and just how short an implant could be in order to be able to provide good long-term outcomes.

There are at least two manufacturers (Straumann and Global D) marketing 4.0 mm-long transmucosal implants, and one of these implant types has been evaluated in a non-controlled single-cohort multicentre prospective 2-year post-loading study¹². In this study, 100 4.0 mm-long implants were placed in the posterior jaws of 32 partially edentulous patients (three or four implants in each patient). Seven implants failed before loading in four patients, and two additional patients were excluded for unclear reasons (most likely because of implant failures), so only 26 patients received their prostheses. Two years after loading, one patient had died, and one requested to have all his implants removed¹². This meant that 2 years after loading, the treatment with short implants had failed in 23% (seven out of 31) of the treated patients.

Despite this less than encouraging preliminary report, the aim of this RCT was to compare the outcomes of partial fixed prostheses supported using 4.0 x 4.0-mm implants with respect to those of length at least 8.5 x 4.0 mm when placed in posterior jaws with bone volumes sufficient for placement of medium-to-long implants. This report presents the clinical outcomes up to 3 years' post-loading, according to the original research protocol and following the previous publication of 4-month¹³ and 1-year post-loading data¹⁴. The present article has been drafted 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 study was designed as a multicentre randomised controlled trial of parallel-group design with two arms, using blinded outcome assessors whenever possible.

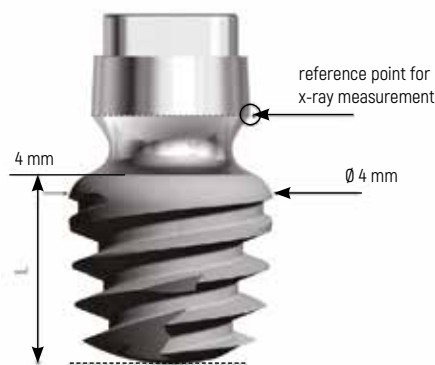
Any partially edentulous patient missing teeth in the premolar and molar areas requiring one to three dental implants aged 18 years or older and able to sign an informed consent form was eligible for inclusion in this trial. Vertical bone heights at implant sites had to be at least 12.5 mm above the mandibular canals and 11.5 mm below the maxillary sinuses, as applicable. Bone thickness had to be at least 6.0 mm, as measured on cone-beam computed tomography (CBCT) scans. Each patient was treated on only one side of the jaw, and received one prosthesis only, according to a parallel-group design.

Exclusion criteria were:

- General contraindications to implant surgery;
- Any irradiation to the head and neck area;
- Immunosuppressed or immunocompromised status;
- Previous or ongoing treatment with intravenous aminobisphosphonates;
- Untreated periodontitis;
- Poor oral hygiene and motivation;
- Uncontrolled diabetes;
- Pregnancy or breast-feeding;

- Substance misuse;
- Psychiatric problems or unrealistic expectations;
- Lack of opposite occluding dentition to the area intended for implant placement;
- Acute or chronic infection/inflammation in the area intended for implant placement;
- Participation in other trials, if precluding adherence to the present protocol;
- Referral solely for implant placement, and having the prosthesis or maintenance procedures performed at other treatment centres;
- Inability to attend follow-up visits for 3 years after loading;
- Post-extraction sockets, if upper portion of the buccal wall was 4 mm lower than the palatal wall.

Patients were categorised into three groups according to their declared smoking habits: non-smokers, moderate smokers (up to 10 cigarettes per day), and heavy smokers (more than 10 cigarettes per day). Patients were to be recruited and treated in three different centres (50 patients per centre) by three different operators. However, one operator recruited and treated only four patients, so his remaining quota of patients was taken over by one of the two other operators (Pietro Felice, PF), who treated patients in two Italian private practices and one university hospital, whereas the other operator (Roberto Pistilli, RP) treated patients in both a hospital and a private practice. All operators followed a similar, standardised, protocol. The principles outlined in the Declaration of Helsinki on clinical research involving human subjects were adhered to, and the study design was approved by the ethical committee of the Ospedale Maggiore in Bologna, Italy, on 14th June 2013 (Prot.N.554/CE). All patients received thorough explanation and provided informed written consent prior to being enrolled in the trial. Approximately 10 days before implant placement, patients received at least one professional tooth cleaning session.



1A



1B

Figs. 1A, B: Illustration of a 4.0-mm (A) and a 13.0-mm (B) conical transmucosal Global D TwinKon Universal SA2 implants, as used in this study. Implants are made of Ti4V6Al alloy, have a sand-blasted acid-etched surface and a distinctive external connection.

Implant placement procedures

One hour prior to implant placement, 2 g of amoxicillin (or 100 mg minocycline for patients allergic to penicillin) was administered, and before the procedure patients rinsed for one minute with 0.2% chlorhexidine. The area was locally anaesthetised via infiltration of articaine with 1:100,000 adrenaline. After crestal incision and flap raising, or after curettage of the socket in case of post-extraction implants, patients were randomly allocated, by opening the sequentially numbered envelope corresponding to the patient recruitment number, to receive either one to three 4.0 x 4.0 mm-long implants (**FIG. 1A**) or one to three implants which were at least 8.5 mm-long (8.5, 10, 11.5 and 13-mm long; **FIG. 1B**) and 4.0 mm in diameter, according to the standard procedures as recommended by the manufacturer (TwinKon Universal SA2, Global D, Lyon, France). Surgical stents were used to optimise implant positioning after flap lifting. Drills with stops of increasing diameters (**FIG. 2**) were used to prepare the implant sites, which were slightly under-prepared. At implant insertion, the surgical motor unit was set to a torque of 25 Ncm, and resistance at implant insertion was recorded as up to 25 Ncm or superior to 25 Ncm. The transition portion from machined to roughened surface of the implant neck (**FIGS. 1A, B**) was placed about 2 mm subcrestally.

In the case of post-extraction implants, teeth were extracted using a flapless approach in order to minimise surgical trauma and to spare the buccal wall of the socket. Sockets were carefully debrided from any remnants of granulation tissue. In the presence of a horizontal buccal bone-to-implant gap of 2 mm or more, gaps were filled with 600 to 1000-micron diameter granules of pre-hydrated corticocancellous porcine bone mixed with approximately 10% collagen gel (MP3, OsteoBioI, Tecross, Giaveno, Italy) covered with a resorbable haemosta-



Fig. 2: Sequence of drills used to prepare the implant sites for shorter implants. Please note the presence of stops with the drills.

tic collagen sponge (Spongostan, 1 x 1 x 1 cm, Ethicon, Johnson & Johnson, Somerville, NJ, USA) of porcine origin, blocked with a cross-suture.

Healing abutments were placed on implants not to be submerged, and healing screws on implants to be submerged. Flaps were closed around non-submerged implants or over submerged implants with Vicryl 4/0 sutures (Ethicon). The decision on whether to submerge the implant or not was based on the thickness of the mucosa. Ideally, all implants were to be submerged, but since these implants have a transmucosal design, they could be only submerged when soft tissues were sufficiently thick. Periapical radiographs (baseline) were taken using the paralleling technique. If bone levels around the study implants were hidden or difficult to estimate, a second radiograph was taken.

Ibuprofen 400 mg to be taken 2 to 4 times a day during meals was prescribed for pain relief as long as required. Patients were instructed to place 1% chlorhexidine gel on the wounds twice a day for two weeks, to avoid brushing and trauma to the surgical sites, and advised to ingest a soft diet for one week. No removable prostheses were allowed on treated areas. Sutures were removed after 10 days, and patients were checked at 20 days, and one and two months after placement of dental implants.

Prosthetic procedures

After 3 months of unloaded healing, implants were exposed when necessary, manually tested for stability, and impressions with the pick-up impression copings were taken using a polyether material (Impregum 3M/ESPE, Neuss, Germany) and customised resin impression trays. Impressions of submerged implants were taken after 2 weeks of soft tissue healing. Four months after placement, implants were manually tested for stability and definitive metal-composite or metal-resin screw-retained restorations, rigidly joining the implants, were connected directly to the implants in light occlusion with antagonistic dentition. Oral hygiene instructions were delivered. Periapical radiographs of the study implants were taken, and, in the case of unreadable radiographs, new radiographs were taken.

Patients were enrolled in an oral hygiene programme with recall visits every 6 months for the entire duration of the study. Follow-ups were conducted by independent outcome assessors (Vittorio Checchi, VC, at PF's and Luigi Checchi's centres, LC, and Roberto Cassoni, RC, at RP's centre) up to the first year, and thereafter by Cesare Berti (PF's and LC's centres) and Fabrizio Lisotti (RP's centre).

Outcome measures

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

Outcome measures were the following.

- Prosthesis failure: planned prosthesis which could not be placed due to implant failure(s), loss of the prosthesis secondary to implant failure(s), or replacement of the prosthesis for any reason.
- Implant failure: implant mobility, removal of stable implants dictated by progressive marginal bone loss or infection, or any mechanical complications rendering the implant unusable (e.g., implant fracture). The stability of each individual implant was measured at delivery of permanent prostheses (4 months after implant placement) by tightening the abutment screws using a manual wrench at force 25 Ncm. Implant mobility was checked by tightening the abutment screws for fixed partial prostheses 4 months, and 1 and 3 years after initial loading, whereas the stability of single implant-supported crowns was tested by attempting to rock the crown with the handles of two dental instruments.
- Any biological or prosthetic complications.
- Peri-implant marginal bone levels changes, as assessed on periapical radiographs taken with the paralleling technique at implant placement, at prostheses delivery, and at 4 months, and 1 and 3 years after loading. Non digital radiographs were scanned in TIFF format with a 600 dpi resolution and stored in a personal computer. Peri-implant marginal bone levels were measured using OsiriX (Pixmeo Sarl, Bernex, Switzerland) software. The software was calibrated for each single image using the known implant length. Measurements of the mesial and distal bone crest level adjacent to each implant, parallel to the implant axis, were made to the nearest 0.01 mm, and averaged at implant, patient and group levels. Reference points for the linear measurements were the apical margin of the implant collar (**FIGS. 1A, B**) and the most coronal point of bone-to-implant contact.

Methodological aspects

Four dentists (VC at RP's and LC's centres and RC at RP's centre) up to the first year and thereafter Cesare Berti (PF's and LC's centres) and Fabrizio Lisotti (RP's centre) performed all clinical measurements without knowing group allocation. One dentist (Carlo Barausse), not involved in patient treatment, performed all the radiographic assessments; note, however, that the different implant lengths could be easily identified on periapical radiographs.

A sample size calculation was performed using patient experiencing at least one implant failure as the primary outcome measure with 80% power ($\beta = 0.2$) and one-sided $\alpha = 0.05$. No previous study on the same topic had been published at the time that the research protocol was devised. Consequently, the sample size was computed on the basis of a similar study,¹⁵ which reported that 3 years after loading, 7% of patients had lost short implants and 10% long implants. A failure rate of 0.07 was therefore estimated for the control group. The minimal clinically relevant difference was set at 0.08, in agreement with the clinicians' opi-

nions. Based on this consideration, 160 patients would be required in total, but we had only resources to recruit 150 patients.

Hence 150 patients with partial edentulism, or to be rendered partially edentulous, in the posterior jaws were included in the trial: 75 patients received 4.0 x 4.0 mm-long implants (short implant group) and 75 patients in the 8.5 mm-long or longer implants (long implant group). Patients were allocated to groups on the basis of a computer-generated restricted randomisation list. Only one of the investigators (Maria Rosaria Gatto), not involved in the selection or treatment of the patients, was aware of the random sequence and had access to the random list, stored in a password-protected portable computer. Information on how to treat each patient was enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially after flap raising, and treatment allocation was thereby concealed from 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 (Jacopo Buti) analysed the data. The patient was the statistical unit of the analyses. Differences between the two groups in the proportion of patients with prosthesis failures, implant failures and complications (dichotomous outcomes) were compared using Fisher's exact test, and binomial 95% confidence intervals were computed. The non-Gaussian distribution of radiographic bone levels suggested the use of non-parametric tests. Differences between means for radiographic bone levels between groups were compared using Mann-Whitney U test, and bias-corrected and accelerated 95% confidence intervals were computed (IBM-SPSS Statistics Release 21, Armonk NY, USA). Comparisons between each time point and baseline measurements were made using a paired Wilcoxon test, to detect any changes in peri-implant marginal bone levels. A chi-square test was used to compare the number of patients with prosthesis failures, implant failures and complications, and the Kruskal-Wallis H test to compare the marginal bone level changes between centres. All statistical comparisons were conducted at the 0.05 level of significance.

RESULTS

One hundred and sixty-four patients were screened for eligibility, but 14 patients were not included in the trial because they did not want to be randomised, and wished to have long implants. One hundred and fifty patients were considered eligible and were consecutively enrolled in the trial, four patients at LC's centre; 96 at PF's centre, which also treated the remaining 46 patients who should have been treated by LC's centre, and 50 patients at RP's centre. Seventy-five patients were treated using short implants (**FIGS. 3A, B**) and 75 patients using long implants (**FIGS. 4A, B**). All patients were treated according to the allocated interventions.

Eight patients dropped-out during the three years of follow-up, three from the short implant group and five from the long implant group. Reasons for dropping out are listed below.

— Short implant group:

Patient 14 (PF's) was last seen at 1-year follow-up. He changed dentist but was contacted by phone and reported no problems;

Patient 84 (PF's) was last seen at 1-year follow-up. Her phone number was later disconnected;

Patient 98 (PF's) was last seen at 1 year, 8-month follow-up. He moved away and could not come to the 3-year follow-up appointment, but was contacted by phone and reported no problems.

— Long implant group:

Patient 56 (PF's) was last seen at 4-month follow-up. His phone number was later disconnected;



3A



3B

Figs. 3A, B: Sequence of periapical radiographs of a patient randomly allocated to 8.5 x 4.0-mm or longer implants (long implant group) who received an implant in position 25: A) just after implant placement (baseline); B) at 3 years post-loading.



Figs. 4A, B: Sequence of periapical radiographs of a patient randomly allocated to 8.5 x 4.0-mm or longer implants (long implant group) who received an implant in position 35: A) just after implant placement (baseline); B) at 3 years post-loading.

Patient 27 (PF's) was last seen at 1-year follow-up. His phone number was later disconnected; Patient 128 (RP's) was last seen at 1-year follow-up. He moved away and could not come to the 3-year follow-up appointment, but was contacted by phone and reported no problems; Patient 23 (PF's) was last seen at 1½-year follow-up. He moved away and could not come to the 3-year follow-up appointment, but was contacted by phone and reported no problems; Patient 134 (RP's) was last seen at 2-year follow-up. He moved away and could not come to the 3-year follow-up appointment, but was contacted by phone and reported no problems.

Data pertaining to all remaining patients were subjected to statistical analysis. No substantial deviations from the protocol occurred, with the exception that LC treated only four patients out of the 50 patients allocated, and the remaining quota of his patients were therefore treated by PF. In addition, one patient, from the long implant group, from PF's centre initially received a provisional resin prosthesis instead of the permanent one due to financial issues. The permanent prosthesis was delivered at the 1-year post-loading assessment. Patients were recruited and had their implant placed from September 2013 to February 2014. Follow-up was 3-year post-loading in all patients.

The main baseline patient and intervention characteristics are presented in **TABLE 1**. Initially, 124 implants were placed in the short group and 116 in the long group. There were no apparent significant baseline imbalances between the two groups, with the exception that less 4 mm-long implants were placed in maxillae than longer implants.

The main results up to 3-year post-loading are summarised in **TABLE 2**.

- Prosthesis failures: in each group, two prostheses could not be placed when planned because of early implant failures. The difference in observed proportions for prosthesis failures was not statistically significant (difference in proportion = 0; 95% CI: -0.061 to 0.062; $P = 1$; **TABLE 2**). All four prostheses were successfully delivered with a 4-month delay once the failed implants had been replaced.

- Implant failures: five patients experienced one implant failure each: three short and two long implants failed. The difference in proportions for implant failures was not statistically significant (difference in proportion = -0.013; 95% CI: -0.079 to 0.054; $P = 1$; **TABLE 2**). In the short implant group, one implant in position 16, inserted with a torque lower than 25 Ncm, was found to be mobile and painful at percussion 3½ months after insertion. The implant was removed and immediately replaced by an identical implant 11.5-mm long, which was successfully loaded 4 months later. One immediate post-extraction implant, in position 44 and inserted with a torque lower than 25 Ncm, was found to be mobile four months after insertion, and immediately replaced with an identical 10 mm-long implant, which was successfully loaded 4 months later. Another implant, inserted with a torque lower than 25 Ncm in position 36, was found to be mobile and painful at impression-taking and was removed. It was not replaced since there were successful implants in positions 35 and 37. Two long implants failed: one 13 mm-long implant in position 26 was found to be mobile and painful at percussion after 4 months. It was removed and immediately replaced with a short but wider implant (6 x 4.7 mm, I-RES Shape 1, I-RES, Milan, Italy). After 4 months of submerged healing, the replacement implant was successfully loaded. Another 11.5 mm-long implant placed immediately post-extraction in position 35, with an insertion torque lower than 25 Ncm, was found to be mobile and painful 3½ months after placement. The patient confessed to having been worrying the implant with her tongue. The implant was removed and immediately replaced with an identical implant measuring 10.0 x 4.0 mm, inserted with a torque greater than 25 Ncm, and was successfully loaded after at 4 months.

— Complications: eight patients experienced nine complications: six complications occurred in five patients with short implants and three complications occurred in three patients with long implants. There was no statistically significant difference between the two groups in the number of patients experiencing complications rate (difference in proportion = -0.026; 95% CI: -0.103 to 0.053; P = 0.719; **TABLE 2**). The following complications occurred with short implants: two patients experienced some pain when touching the implants. Both implants were mobile and were removed. Another patient lost the cover screw 20 days after surgery, but this was replaced without any consequences. Two years and 8 months after loading, the same patient complained of pain around his implants, in positions 34 and 35. These implants were seen to be surrounded by inflamed mucosa, and

TABLE 1 PATIENT AND INTERVENTION CHARACTERISTICS

	4 mm-long implants (75 patients)	8.5-mm or longer implants (75 patients)
Females	45 (60%)	39 (52%)
Mean age at recruitment (range)	53.7 (20-76)	55.5 (25-86)
Heavy smokers (smoking up to 10 cigarettes per day)	20 (26.7%)	13 (17.3%)
Moderate smokers (smoking >10 cigarettes per day)	1 (1.3%)	6 (8.0%)
# implants	124	116
# implants in upper jaws	46	69
# post-extraction implants	22	34
# of augmented post-extraction implants	14	18
# implants placed with < 25 Ncm torque	17	27
Mean implant length	4.00 mm	9.94 mm
# patients with submerged implants	39	38
# patients receiving 1 implant	32	38
# patients receiving 2 implants	37	33
# patients receiving 3 implants	6	4
# patients rehabilitated with metal-resin prostheses	11 (14.7%)	3 (4.1%)
# patients rehabilitated with metal-composite prostheses	64 (85.3%)	71 (95.9%)

TABLE 2 SUMMARY OF THE MAIN RESULTS EXPRESSED AS NUMBER OF PATIENTS WHO EXPERIENCED AT LEAST ONE NEGATIVE EVENT UP TO 3 YEARS AFTER LOADING. DROP-OUTS WERE EXCLUDED AND NONE EXPERIENCED A NEGATIVE EVEN

	Long implants 70 patients	Short implants 72 patients	Difference in proportions	95% CI	P-value
Patients with failed prostheses	2 (2.9%)	2 (2.8%)	0	-0.061 to 0.062	1
Patients with failed implants	2 (2.9%)	3 (4.2%)	-0.013	-0.079 to 0.054	1
Patients with complications	3 (4.3%)	5 (6.9%)	-0.026	-0.103 to 0.053	0.719

the prosthesis' screws were loose. The prosthesis was therefore removed and healing abutments placed on the implants. The patient was prescribed 1% chlorhexidine gel (Corsodyl, GlaxoSmithKline Consumer Healthcare, Baranzate, Italy) to be applied twice a day for 14 days. After 14 days the mucosa looked healthy, and the prosthesis was adjusted to facilitate oral hygiene procedures. Another patient complained about the mobility of her prosthesis, on implants in positions 35 and 37, at 2 years and 3 months after loading. Part of the resin prosthesis lining was missing. The prosthesis was unscrewed, and the connecting screw of implant 37 was found to be fractured at the level of its apical third. Since the broken portion of the screw could not be removed, it was abraded with a micro-drill. The prosthesis was screwed back into place, to see how it performed, before deciding whether to repair the missing resin lining. Finally, another patient presented with a mobile crown 2½ years after prosthesis loading. The connecting screw was loosened and was retightened at 25 Ncm.

Two implants belonging to the long implant group caused pain when placed under pressure. Both implants were mobile, removed and immediately replaced. Failures were not considered as complications unless pain was present, and these events were therefore both considered as complications. Finally, one patient complained of discomfort at both implants 2 years and 5 months after loading. Both implants were affected by peri-implant mucositis. The prosthesis was unscrewed, the area was cleaned, 1% chlorhexidine gel was applied, and the prosthesis screwed back in place. The chlorhexidine gel was prescribed to be taken 3 times per day for 14 days, and the complication resolved.

- Peri-implant marginal bone level changes (**TABLE 3 AND 4**): both groups had gradually lost statistically significant marginal peri-implant bone ($P < 0.001$) at loading (0.23 mm for short implants and 0.21 mm for long implants), at 4 months after loading (0.38 mm for short implants and 0.39 mm for long implants, at 1 year after loading (0.53 mm for short implants and 0.57 mm for long implants, and at 3 years after loading (0.55 mm for short implants and 0.61 mm for long implants; **TABLE 4**). There was no statistically significant difference between the two groups in terms of peri-implant bone level changes either between implant placement and loading (-0.01; 95% CI: -0.11 to 0.07; $P = 0.304$), implant placement and 4 months after loading (0.01; 95% CI: -0.08 to 0.11; $P = 0.328$), implant placement and 1 year after loading (0.04; 95% CI: -0.07 to 0.14; $P = 0.198$), or between implant placement and 3 years after loading (0.05; 95% CI: -0.05 to 0.16; $P = 0.221$) (**TABLE 4**).

TABLE 3 MEAN RADIOGRAPHIC PERI-IMPLANT MARGINAL BONE LEVELS BETWEEN GROUPS AND TIME PERIODS

	Implant placement	Loading	4 months after loading	1 year after loading	3 years after loading
	N Mean (SD)	N Mean (SD) 95% CI	N Mean (SD) 95% CI	N Mean (SD) 95% CI	N Mean (SD) 95% CI
Short implants	75 0.02 (0.08)	75 0.25 (0.26) 0.20; 0.30	75 0.40 (0.26) 0.35; 0.45	75 0.550 (0.257) 0.492; 0.608	72 0.58 (0.26) 0.52; 0.64
Long implants	75 0.05 (0.27)	74 0.26 (0.173) 0.23; 0.30	74 0.44 (0.25) 0.39; 0.50	73 0.616 (0.262) 0.556; 0.678	69 0.66 (0.30) 0.59; 0.73
Difference	-0.03	-0.02 -0.09; 0.05	-0.04 -0.12; 0.05	-0.066 -0.147; 0.023	-0.08 -0.18; 0.01
Mann-Whitney U-test P-value	0.859	0.131	0.172	0.127	0.133

TABLE 4 COMPARISON OF MEAN CHANGES IN PERI-IMPLANT MARGINAL BONE LEVELS AT LOADING, 4 MONTHS, AND 1 AND 3 YEARS AFTER LOADING

	Placement – loading	Placement – 4 months after loading	Placement – 1 year after loading	Placement – 3 years after loading
	N Mean (SD) 95% CI	N Mean (SD) 95% CI	N Mean (SD) 95% CI	N Mean (SD) 95% CI
Short implants	75 -0.225 (0.213) -0.278; -0.177	75 -0.380 (0.247) -0.447; -0.322	75 -0.528 (0.238) -0.592; -0.470	72 -0.554 (0.240) -0.611; -0.498
Long implants	74 -0.214 (0.254) -0.261; -0.152	74 -0.392 (0.312) -0.463; -0.310	73 -0.566 (0.338) -0.639; -0.479	69 -0.610 (0.368) -0.694; -0.517
Difference	-0.011 -0.109; 0.070	0.013 -0.083; 0.105	0.038 -0.068; 0.138	0.051 -0.052; 0.156
Mann-Whitney U-test P-value	0.304	0.328	0.198	0.221

TABLE 5 COMPARISONS BETWEEN THE THREE STUDY CENTRES AT 3 YEARS AFTER LOADING

	PF 96 patients	RP 50 patients	VC 4 patients	P-value
Drop-outs	6	2	0	0.755
Patients with implant failures	4	1	0	0.728
Patients with prosthesis failures	4	0	0	0.311
Patients with complications	7	1	0	0.352
Mean (95% CI) peri-implant bone level changes in mm from implant placement to 3 years after loading	-0.620 (-0.692; -0.548) A	-0.513 (-0.582; -0.443) B	-0.498 (-0.657; -0.338) AB	0.011*

*Statistically significant difference; centres not connected by the same letter are statistically significant different.

There were no statistically significant difference in failure, complication or drop-out rates across centres, but there was a statistically significant difference in marginal bone level changes between RP's and PF's centres ($P = 0.004$) at 3-year post-loading (**TABLE 5**). Specifically, PF's centre lost 0.1 mm more peri-implant marginal bone than RP's centre; however this difference would not be considered clinically significant.

DISCUSSION

This study assessed whether 4.0 x 4.0-mm implants supporting partial fixed prostheses could be at higher risk of failures than longer implants when placed in posterior jaws with adequate bone volumes. We were particularly interested in evaluating the clinical performance of very short implants (4.0 mm long) with the conventional diameter of 4.0 mm in order to determine the minimal amount of bone able to support functionally loaded dental implants. Previous trials suggested that short implants can achieve clinical results that are as effective, if not more so, than longer implants placed in augmented bone up to 8 years after loading¹⁻¹¹.

However, sometimes surgeons use short implants with wider bodies to compensate for the lack of implant height^{2,10}. While it is still unclear whether this 'compensation' is actually necessary, results of this and many other trials in which 5.0 to 6.6 mm-long implants with diameters of 4.0 to 5.0 mm were used suggest that short implants with diameters of 4.0 to 5.0 mm also perform well, at least up to 8 years post-loading^{1,3-9,11}.

When comparing our data to those from previous similar RCTs¹⁶⁻¹⁸, all trials showed identical trends: there were similar outcomes between 5.0 to 6.0 mm-long implants and 10.0-mm or longer implants up to 10 years post-loading in the presence of adequate bone volumes. In the present trial, five implants were lost in total: three 4 mm-long implants and two longer ones. All failures were detected at abutment connection, and four of the failed implants were replaced. No apparent signs of infection were noted, but failed implants were usually painful at percussion and mobile, indicating that osseointegration had not taken place⁹.

The failures occurring earlier were easier to handle; in fact, four of the mobile implants were immediately replaced with other implants on the same day they were removed, minimising patient discomfort. That being said, in those patients delivery of the prostheses was delayed for up to 4 additional months. In at least one of these cases, the patient declared that she had been continuously touching the transmucosal portion of the implant with her tongue, and most of the failed implants were placed using insertion torques lower than 25 Ncm. It is possible that several undesirable movements disrupted the bone healing around these transmucosal implants, thereby causing fibrointegration¹⁹. To minimise the potential risk of such a complication, therefore, we suggest that a two-piece bone-level 4 mm-long implant be developed, and its clinical performance subsequently compared with that of 4 mm-long transmucosal implants.

Peri-implant marginal bone loss was minimal (about 0.6 mm) at 3 years after loading in both groups. It may be that this minimal bone loss could be partly explained by the lack of an implant-abutment junction at the level of the crest; indeed, such junctions could easily harbour bacteria that could enhance peri-implant marginal bone loss.

The main limitation of the present trial was the short duration of the follow-up, but longer follow-up findings will be presented at a later date. Another limitation is the limited sample size. Nonetheless, at the time of writing, this is the RCT comparing short with longer implants in sufficient bone volumes with the largest sample size ever published. Furthermore, as interventions tested were assessed in real-world clinical conditions and the patient inclusion criteria were rather broad, similar results should be obtained by other experienced operators treating patients with similar characteristics.

CONCLUSIONS

Three years after loading, 4.0 x 4.0 mm-long implants achieved similar results to 8.5 x 4.0 mm or longer implants in posterior jaws in the presence of adequate bone volumes. That being said, 5 to 10 years' post-loading data will be necessary before reliable recommendations can be made.

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