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Posterior jaws rehabilitated with partial prostheses supported by 4.0 x 4.0 mm or by longer implants: Four-month post-loading data from a randomised controlled trial

Key words posterior jaws, short dental implants

Purpose: To evaluate whether 4.0 x 4.0 mm dental implants could be an alternative to implants at least 8.5 mm long, which were placed in posterior jaws in the presence of adequate bone volumes.

Materials and methods: One hundred and fifty patients with posterior (premolar and molar areas) mandibles having at least 12.5 mm bone height above the mandibular canal or 11.5 mm bone height below the maxillary sinus, were randomised according to a parallel group design, in order to receive one to three 4.0 mm-long implants or one to three implants which were at least 8.5 mm long, at three centres. All implants had a diameter of 4.0 mm. Implants were loaded after 4 months with definitive screw-retained prostheses. Patients were followed up to 4-month post-loading and outcome measures were prosthesis and implant failures, any complications and peri-implant marginal bone level changes.

Results: No patients dropped-out before the 4-month evaluation. Three patients experienced the early failures of one 4.0 mm-long implant each, in comparison to two patients who lost one long implant each (difference in proportion = 0.01; 95% CI -0.06 to 0.09; $P = 0.50$). Consequently, two prostheses in each group could not be delivered as planned (difference in proportion = 0; 95% CI -0.07 to 0.07; $P = 0.69$), and one patient from each group is still waiting to have their prostheses delivered. Three short implant patients experienced three complications versus two long implant patients (difference in proportion = 0.01; 95% CI -0.06 to 0.09; $P = 0.50$). There were no statistically significant differences in prosthesis failures, implant failures and complications. Patients with short implants lost on average 0.38 mm of peri-implant bone at 4 months and patients with long mandibular implants lost 0.42 mm. There were no statistically significant differences in bone level changes up to 4 months between short and long implants (mean difference = 0.04 mm; 95% CI: -0.041 to 0.117; $P = 0.274$).

Conclusions: Four months after loading, 4.0 x 4.0 mm implants achieved similar results as 8.5 x 4.0 mm-long or longer implants in posterior jaws, however 5 to 10 years post-loading data are necessary before reliable recommendations can be made.

Conflict-of-interest statement: *Global D (Lyon, France) donated implants and prosthetic components and Tecnos (Coazze, Italy) donated the biomaterials used in this study. Data property belonged to the authors and by no means did the manufacturers interfere with the conduct of the trial or the publication of its results.*



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■ Introduction

Short dental implants are used as an alternative to long implants in intentionally augmented bone, in order to support fixed prostheses in the rehabilitation of patients with atrophic jaws. There are a few randomised controlled trials (RCTs) comparing the effectiveness of dental prostheses supported by short implants with those supported by long implants placed in augmented bone¹⁻¹². The results of these ongoing trials having follow-ups of up to 5-years post-loading, suggest that 5.0 to 8.0 mm-long implants can be a viable, if not a better, alternative to augmentation procedures, especially in posterior mandibles.

More recent clinical questions include whether to use short implants also in those situations where long implants could have been used and how short could an implant be in order to be able to provide a good long-term outcome. There are at least two manufacturers (Straumann and Global D) marketing transmucosal 4.0 mm-long implants, and one of these implant types was evaluated in a multicentre non-controlled single-cohort prospective 2-year post-loading study¹³. In this study 100 4.0 mm-long implants were placed in the posterior region of 32 partially edentulous patients (three or four implants in each patient). Seven implants failed before loading in 4 patients and 2 additional patients were excluded for unclear reasons (most likely because of implant failures) so that only 26 patients received their prostheses. Two years after loading one patient died and one requested to have all his implants removed¹³. This means that the treatment with short implants failed in 23% (seven out of 31) of the treated patients 2 years after loading, and these initial figures are not very promising.

The aim of this RCT was to compare the outcome of partial fixed prostheses supported by 4.0 x 4.0 mm implants with prostheses supported by implants at least 8.5 x 4.0 mm long placed in posterior jaws, which have adequate bone volumes to be treated with medium to long implants. This report presents the preliminary clinical outcome up to 4-month post-loading. The aim was to follow-up these patients to the third year of function. The present article is reported according to the CONSORT (Consolidated Standards of Reporting Trials) statement for improv-

ing the quality of reports of parallel group randomised trials (<http://www.consort-statement.org/>).

■ Materials and methods

This study was designed according to a randomised controlled multicenter trial of parallel group design with two arms, using, whenever possible, a blinded outcome assessor.

Any partially edentulous patient missing teeth in the premolar and molar area requiring one to three dental implants, being 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. Bone thickness had to be at least 6.0 mm as measured on cone beam computer tomography (CT) scans. Each patient was treated at 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;
- subjected to irradiation in the head and neck area;
- immunosuppressed or immunocompromised;
- treated or under treatment with intravenous amino-bisphosphonates;
- untreated periodontitis;
- poor oral hygiene and motivation;
- uncontrolled diabetes;
- pregnant or nursing;
- substance abusers;
- 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 the present protocol could not be properly followed;
- referred only for implant placement and not having the prosthesis or maintenance procedures performed at the treatment centres;
- unable to attend follow-up visits for 3 years after loading;
- post-extractive sockets if the upper portion of the buccal wall was lower than 4 mm when compared to the palatal wall.

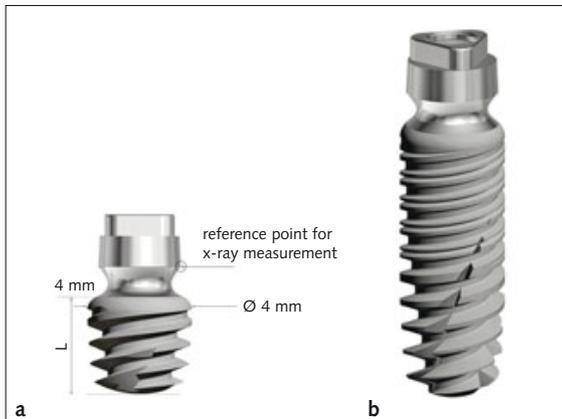


Fig 1 Illustration of 4.0 mm (a) and 13.0 mm (b) conical transmucosal Global D TwinKon® Universal SA2 implants used in this study. Implants are made of Ti4V6Al alloy, have a sand-blasted acid-etched surface and a peculiar external connection.

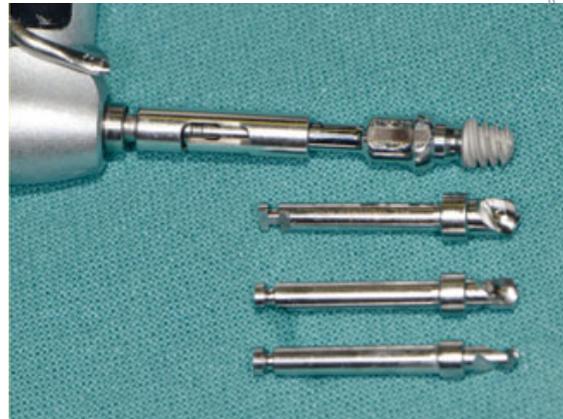


Fig 2 Sequence of drills used to prepare the implant sites for shorter implants. Please notice the presence of stops with the drills.

Patients were categorised into three groups according to what they declared: non-smoker, moderate smoker (up to 10 cigarettes per day) and heavy smoker (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 were taken by one of the two remaining operators (Dr Pietro Felice), who treated patients in two Italian private practices and one university hospital, whereas the other operator (Dr Roberto Pistilli) treated patients both in a hospital and a private practice. All operators followed similar standardised procedures.

The principles outlined in the Declaration of Helsinki on clinical research involving human subjects were adhered to. The study was approved by the ethical committee of the Ospedale Maggiore in Bologna, Italy on 14 June 2013 (Prot.N.554/CE). All patients received thorough explanations and signed a written informed consent form prior to being enrolled in the trial. Approximately 10 days before implant placement patients received at least one session of professional oral hygiene.

■ Implant placement procedures

Two grams of amoxicillin (or 100 mg minocycline for patients allergic to penicillin) were administered 1 h prior to implant placement and patients rinsed

for 1 min with 0.2% chlorhexidine. The area was locally anaesthetised with infiltration of articain with adrenaline 1:100.000. After crestal incision and flap elevation, or in the case of post-extractive implants after curettage of the socket, patients were randomly allocated, by opening the sequentially numbered envelope corresponding to the patient recruitment number, where either they received 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, 10.0, 11.5 and 13.0 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 elevation. Drills with stops and increasing diameters were used to prepare the implant sites, which were slightly underprepared (Fig 2). At implant insertion, the surgical motor unit was set at a torque of 25 Ncm and resistance at implant insertion was recorded as < 25 Ncm or > 25 Ncm. The transition portion from the machined to the roughened surface of the implant neck (Fig 1) was placed about 2 mm subcrestally. In the case of post-extractive implants, teeth were extracted using the flapless approach, in order to try to minimise the surgical trauma as much as possible 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 microns diameter granules of pre-hydrated



cortico-cancellous porcine bone mixed with approximately 10% collagen gel (MP3, OsteoBiol, Tecnos, Coazze, Italy) covered with a haemostatic resorbable collagen sponge (Spongostan, 1 x 1 x 1 cm, Ethicon, Johnson & Johnson, New Jersey, 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 and 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, however since these implants had a transmucosal design, they could only be submerged when the soft tissues were sufficiently thick. Periapical radiographs (baseline) were made with the paralleling technique. If bone levels around the study implants were hidden or difficult to estimate, a second radiograph was made. Ibuprofen 400 mg was prescribed to be taken 2 to 4 times a day during meals, in the presence of pain, as long as required. Patients were instructed to place 1% chlorhexidine gel on the wounds twice a day for 2 weeks, to avoid brushing and trauma on the surgical sites, and were advised to have a soft diet for 1 week. No removable prostheses were allowed on treated areas. Sutures were removed after 10 days, and patients were controlled at 20 days, one and two months after placement of dental implants.

■ Prosthetic procedures

After 3 months of unloaded healing, when necessary, implants were exposed, 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 on the implants, in light occlusion with the antagonistic dentition, and 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 program with recall visits every 6 months for the entire duration of the study. Follow-ups were conducted by independent outcome assessors (Dr Vittorio Checchi at Dr Pietro Felice's and Luigi Checchi's centres and Dr Roberto Cassoni at Dr Roberto Pistilli'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:

- Prosthesis failure: planned prosthesis which could not be placed due to implant failure(s), loss of the prosthesis secondary to implant failure(s) and replacement of the prosthesis for any reasons.
- 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). Stability of each individual implant was measured at delivery of definitive prostheses (4 months after implant placement) and 4 months after initial loading by tightening the abutment screws using a manual wrench with a 25 Ncm force with the removed prostheses.
- Any biological or prosthetic complications.
- Peri-implant marginal bone levels changes evaluated on intraoral radiographs taken with the paralleling technique at implant placement, at delivery of definitive prostheses and 4 months after loading. 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 the OsiriX (Pixmeo Sarl, Bernex, Switzerland) software. The software was calibrated for every single image using the known implant diameter. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.01 mm and averaged at implant level, then at patient level and finally at group level. The measurements were taken parallel to the implant axis. Reference points for the linear measurements were the most coronal margin of the implant collar and the most coronal point of bone-to-implant contact.



■ Methodological aspects

Two clinicians (Dr Vittorio Checchi at Dr Pietro Felice's and Luigi Checchi's centres, and Dr Roberto Cassoni at Dr Roberto Pistilli's centre) not involved in patient treatment performed all clinical measurements without knowing group allocation. One dentist (Carlo Barausse) not involved in the treatment of the patients performed all the radiographic assessments and therefore the different implant lengths could be easily identified on the periapical radiographs.

A sample size calculation was performed using patients whom experienced at least one implant failure as a primary outcome measure with 80% power ($\beta = 0.2$) and one-sided $\alpha = 0.05$. No previous study on the same topic was carried out at the time of the research protocol. Consequently the sample size was computed on the basis of a similar study⁷ that reported that 3 years after loading, 7% of patients lost short implants and 10% long implants. A failure rate of 0.07 in the control group was estimated. The minimal difference which was considered clinically relevant was set at 0.08, in agreement also with the clinicians' opinion. Based on this consideration, 160 patients were needed in total, however we only had sufficient resources to recruit 150 patients. One hundred and fifty 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 received 8.5 mm-long or longer implants (long implant group).

A computer generated restricted randomisation list was created. Only one of the investigators (Dr Maria Rosaria Gatto), not involved in the selection and 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 elevation; therefore, treatment allocation was concealed to the investigators in charge of enrolling and treating the patients.

All data analysis was carried out according to a pre-established analysis plan. A biostatistician with expertise in dentistry (Dr Maria Rosaria Gatto) ana-

lysed the data. The patient was the statistical unit of the analyses. Differences in the proportion of patients with prosthesis failures, implant failures and complications (dichotomous outcomes) between the two groups were compared using the 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. Difference of means for radiographic bone levels between the groups were compared by Mann-Whitney U test and bias was corrected and accelerated 95% confidence intervals were computed (IBM-SPSS Statistics Release 21). Comparisons between each time points and the baseline measurements were made by the Wilcoxon test for paired data, to detect any changes in marginal peri-implant bone levels. A chi-square test was used to compare the number of prosthesis failures, implant failures and complications and the Kruskal-Wallis one-way analysis of variance was used to assess the marginal bone levels amongst the 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 longer implants. One hundred and fifty patients were considered eligible and were consecutively enrolled in the trial, four patients at Dr Checchi's centre; 96 at Dr Felice's centre who also treated those remaining 46 patients who should have been treated by Dr Checchi's centre, and 50 patients at Dr Pistilli's centre. Seventy-five patients were treated with short implants (Figs 3a to 3g) and 75 patients with long implants (Figs 4a to 4f). All patients were treated according to the allocated interventions.

No patient dropped out from the study before the 4-month follow-up and data of all patients were evaluated in the statistical analyses. No substantial deviations from the protocol occurred, except that Dr Checchi treated only four patients out of the 50 patients planned and the remaining quota of his patients were treated by Dr Felice. In addition, one

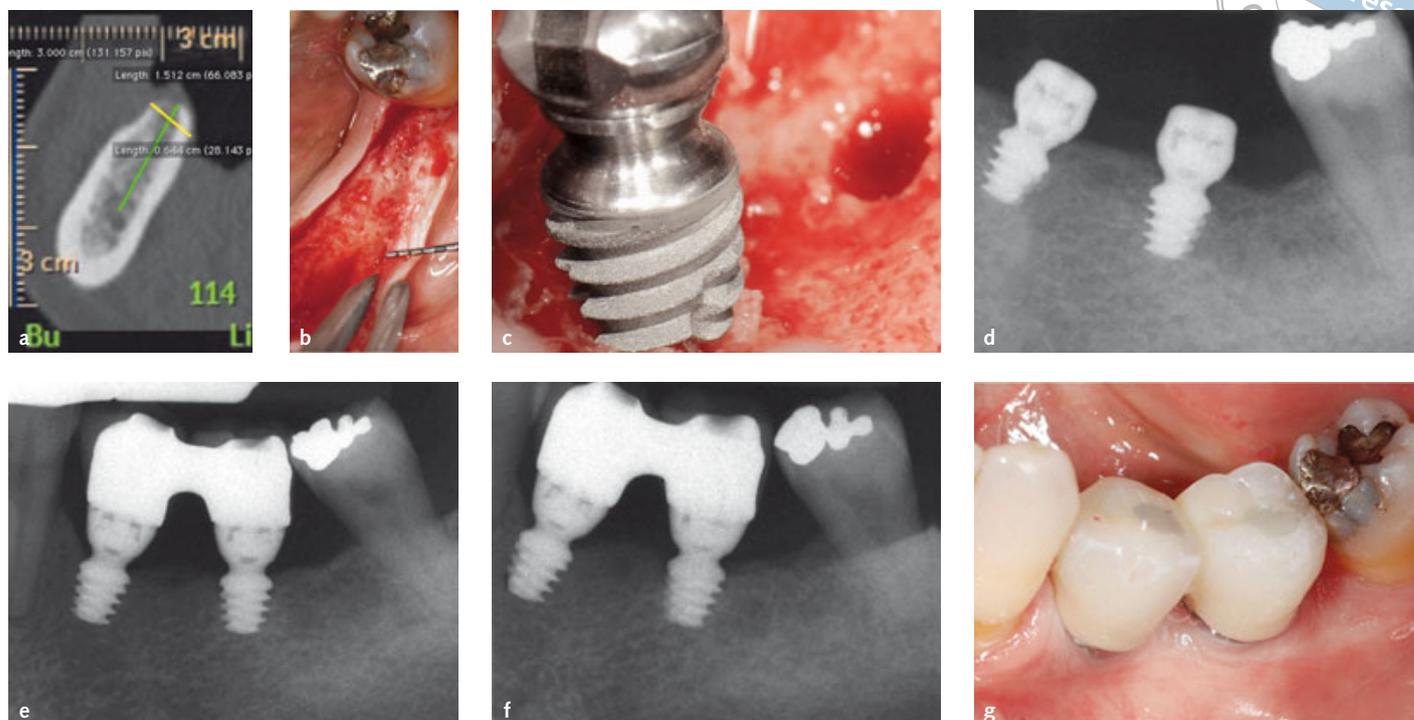


Fig 3 Treatment sequence of a patient with posterior mandibular edentulism randomly allocated to 4.0 x 4.0 mm implants: a) preoperative CBCT showing the measurements to evaluate patient eligibility; b) surgical area after flap elevation; c) 4.0 x 4.0 mm-long implants to be placed; d) baseline periapical radiograph taken after implant placement, showing two 4.0 x 4.0 mm-long implants; e) periapical radiograph taken at delivery of definitive prosthesis 4 months after implant placement; f) periapical radiograph taken 4 months after initial loading; g) clinical view at 4-month post-loading.

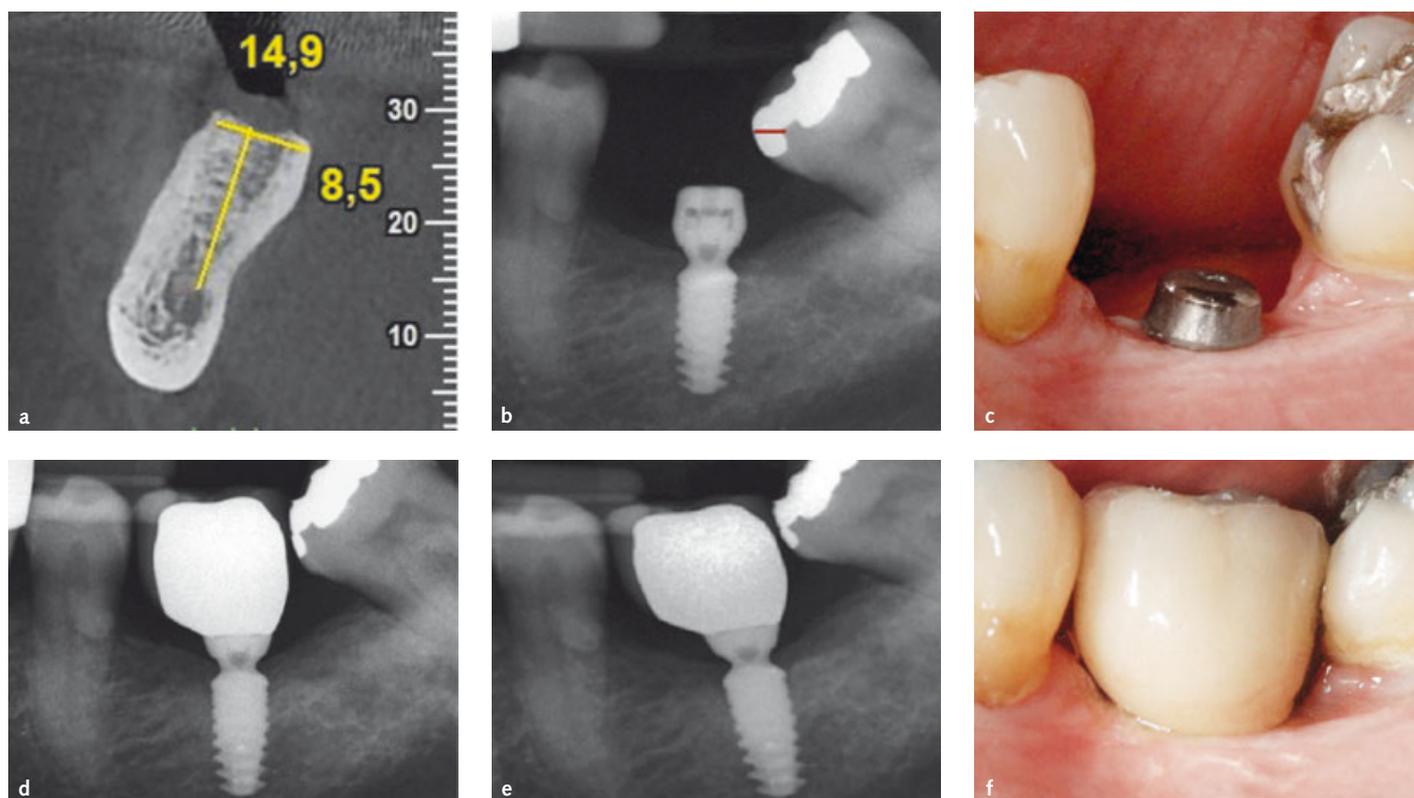
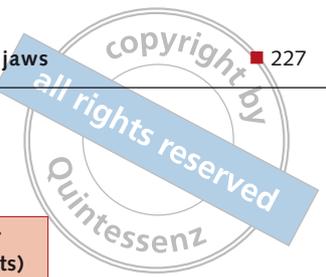


Fig 4 Treatment sequence of a patient with posterior mandibular edentulism randomly allocated to the 8.5 x 4.0 mm or longer implant group: a) preoperative CBCT showing the measurements to evaluate patient eligibility; b) baseline periapical radiograph taken after implant placement showing an 8.5 x 4.0 mm-long implant; c) clinical view after 4 months of non-submerged healing; d) periapical radiograph taken at delivery of definitive prosthesis 4 months after implant placement; e) periapical radiograph taken 4 months after initial loading; f) clinical view at 4-month post-loading.

**Table 1** Patient and intervention characteristics.

	4.0 mm-long implants (75 patients)	8.5 mm or longer implants (75 patients)
Females	45 (60%)	39 (52%)
Mean age at recruitment (range)	54 (20-76)	56 (25-86)
Smokers (smoking >10 cigarettes)	1 (1.3%)	6 (8.0%)
No. of implants	124	116
No. of implants in maxillas	46	69
No. of post-extractive implants	22	34
No. of augmented post-extractive implants	14	18
No. of implants placed with < 25 Ncm torque	17	27
Mean implant length	4.00 mm	9.95 mm
No. of patients with submerged implants	39	38
No. of patients receiving 1 implant	32	38
No. of patients receiving 2 implants	37	33
No. of patients receiving 3 implants	6	4
No. of patients rehabilitated with metal-resin prostheses	11 (15%)	6 (8%)

Table 2 Summary of the main results expressed as number of patients who experienced at least one negative event. All patients had only one negative event each.

	Long implants 75 patients	Short implants 75 patients	Differences in proportions	95% CI	P-value
Patients with failed prostheses	2 (3%)	2 (3%)	0	-0.07 to 0.07	0.69
Patients with failed implants	2 (3%)	3 (4%)	0.01	-0.06 to 0.09	0.50
Patients with complications	2 (3%)	3 (3%)	0.01	-0.06 to 0.09	0.50

patient of Dr Felice's group received a provisional resin prosthesis instead of the definitive one because of financial problems.

Patients were recruited and had their implant placed from September 2013 to February 2014. The follow-up of all patients was 4-month post-loading.

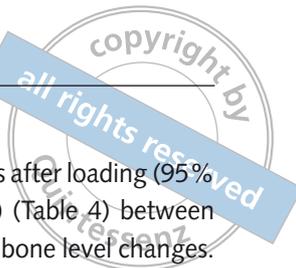
The main baseline patient and intervention characteristics are presented in Table 1. Initially, 124 implants were placed in the short group and 116 in the long group. There were no apparent significant baseline imbalances between the two groups with the exception that more 4.0 mm-long implants were placed in mandibles.

The main results up to 4-month post-loading are summarised in Table 2.

Two prostheses could not be placed when planned because of early implant failures at both groups. The difference in observed proportions for prosthesis failures was not statistically significant (difference in proportion = 0; 95% CI -0.07 to 0.07;

$P = 0.69$; Table 2). Two prostheses (one from each group) were delivered with 4 months delay and two patients (one from each group), at the moment of writing this article, had their replacement implants healing unloaded.

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 = 0.01; 95% CI -0.06 to 0.09; $P = 0.50$; Table 2). In the short implant group one implant in position 16, inserted with a torque < 25 Ncm, was found to be mobile and painful at percussion. The implant was removed and immediately replaced by an identical implant 11.5 mm-long. It was successfully loaded 4 months after. One immediate post-extractive implant in position 44 and inserted with a torque < 25 Ncm, was found to be mobile 4 months after insertion and immediately replaced with an identical implant 10.0 mm long. The implant



has not been loaded yet. Another implant, inserted with a torque < 25 Ncm in position 36, was mobile and painful during impression taking and therefore 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 (4.7 x 6.0 mm, I-RES Shape 1, I-RES, Milan, Italy). After 4 months of submerged healing the implant was successfully loaded. Another 11.5 mm-long implant placed as an immediate post-extractive implant in position 35 with an insertion torque < 25 Ncm was found to be mobile and painful 3.5 months after placement. The patient confessed to playing with the tongue on the implant. The implant was removed and immediately replaced with an identical 10.0 x 4.0 mm implant inserted with a torque > 25 Ncm. The implant was still unloaded at the time of writing this manuscript

Five patients experienced one complication each: three complications occurred for short implants and two for long implants. There was no statistically significant differences with regard to complications between the two groups (difference in proportion = 0.01; 95% CI -0.06 to 0.09; $P = 0.50$; Table 2). The following complications occurred for 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, which was replaced without any consequences. The two implants belonging to the long implant group created pain in patients when under pressure. Both implants were mobile and were removed. Failures were not considered as complications, unless pain was present, therefore, the presence of pain was considered as a complication.

Marginal bone levels are described in Table 3. Both groups gradually lost statistically significant marginal peri-implant bone ($P = 0.001$) at loading (0.28 mm for short implants and 0.24 mm for long implants) and 4 months after loading (0.38 mm for short implants and 0.42 mm for long implants; Table 4). There was no statistically significant difference between implant placement and loading (95% CI: -0.157 to 0.077; $P = 0.324$) and between

implant placement and 4 months after loading (95% CI: -0.041 to 0.117; $P = 0.274$) (Table 4) between the two groups for peri-implant bone level changes.

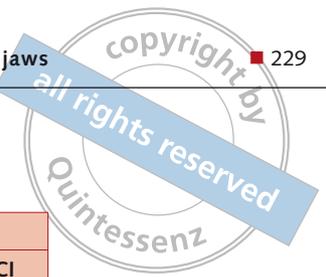
There were no statistically significant differences for failures, complications and marginal bone level changes at 4-month post-loading between the three centres (Table 5).

■ Discussion

This study evaluated whether a 4.0 x 4.0 mm implant supporting a partial fixed prosthesis could be at higher risk of failure than longer implants when placed in posterior jaws with adequate bone volumes. We were interested in assessing the clinical performance of very short implants (4.0 mm long) with a conventional diameter of 4.0 mm in order to understand what is the minimal amount of bone in order to be able to support functionally loaded dental implants.

Previous studies suggested that short implants can achieve clinical results which are as effective, if not better, than long implants placed in augmented bone up to 5 years after loading, however often surgeons use short implants with wider bodies to compensate for the lack of implant height^{3,5,14,15}. While it is still unclear whether this 'compensation' is actually needed, preliminary results of this and many other trials^{8,11,12,15-18} in which 5.0 to 6.0 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 perform well, at least up to 5-years post-loading.

When comparing the present data to those of previous similar RCTs^{16,18,19}, 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 1-year post-loading, in the presence of adequate bone volumes. Obviously follow-ups of at least 5-years post-loading are needed to draw more reliable conclusions. 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 sign of infection were noted but implants were usually painful during percussion and mobile indicating that osseointegration did not take place²⁰. Failures occurring earlier are easier to handle, in fact four of the mobile implants

**Table 3** Mean radiographic peri-implant marginal bone levels between groups and time periods.

	Implant placement	Loading		4 months after loading	
	N Mean (SD)	N Mean (SD)	95% CI	N Mean (SD)	95% CI
Short implants	75 0.021 (0.075)	74 0.298 (0.506)	0.205; -0.414	74 0.399 (0.264)	0.345; -0.457
Long implants	75 0.049 (0.266)	73 0.255 (0.160)	0.218; -0.292	73 0.434 (0.245)	0.377; -0.497
Difference	-0.028	-0.043	-0.164; 0.078	-0.036	-0.118; 0.046
Mann-Whitney U-test P-value	0.859	0.225		0.184	

Table 4 Comparison of mean changes in peri-implant marginal bone levels at loading and 4 months after loading.

	Placement – loading		Placement – 4 months after loading	
	N Mean (SD)	95% CI	N Mean (SD)	95% CI
Short implants	74 -0.277 (0.488)	-0.193; -0.388	74 -0.378 (0.248)	-0.317; -0.439
Long implants	73 -0.237 (0.162)	-0.202; -0.268	73 -0.416 (0.240)	-0.366; -0.465
Difference	-0.040	-0.157; 0.077	0.038	-0.041; 0.117
Mann-Whitney U-test P-value	0.324		0.274	

Table 5 Comparisons between the three study centres at 4 months after loading.

	Dr Felice 96 patients	Dr Pistilli 50 patients	Dr Checchi 4 patients	P-value
Patients with implant failures	4	1	0	0.730
Patients with prosthesis failures	4	0	0	0.310
Patients with complications	4	1	0	0.730
Mean peri-implant bone level changes in mm from implant placement to 4 months after loading	0.44	0.33	0.33	0.062

were immediately replaced with other implants the same day that they were removed, minimising patient discomfort, although the delivery of the prostheses in those patients was delayed for up to 4 additional months. In at least one case the patient declared that she was continuously touching the transmucosal portion of the implant with her tongue and most of the failed implants were placed with insertion torques < 25 Ncm. It is possible that several unwanted movements disrupted the bone healing around these implants and this could have been caused by the fibrointegration of these implants²⁰. On the one hand, a short two-piece 4 mm-long implant without a transmucosal portion, to be positioned at crestal level, could be developed and tested. However, peri-implant marginal bone loss was minimal (about 0.4 mm) for both groups up to 1 year after loading. 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, which could harbour bacteria that could enhance peri-implant marginal bone loss.

The main limitation of the present trial is the short duration of the follow-up, however longer follow-ups will be carried out. The positive aspects of this study are that all treated patients were accounted for with no exclusions and all assessments were done by independent assessors. The tested interventions were evaluated in real 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

Short-term data (4 months after loading) indicate that 4.0 x 4.0 mm implants achieved similar results to 8.5 x 4.0 mm-long or longer implants in the presence of adequate bone volumes, however 5- to 10-years post-loading data from larger trials are necessary before reliable recommendations can be made.

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