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Subcrestal placement of dental implants with an internal conical connection of 0.5 mm versus 1.5 mm: three-year after loading results of a multicentre within-person randomised controlled trial

KEY WORDS

aesthetics, bone level, dental implant, subcrestal placement

ABSTRACT

Purpose: To evaluate whether there are some clinical benefits by placing single dental implants either 0.5 mm or 1.5 mm subcrestally in healed bone crests.

Materials and methods: Sixty partially edentulous patients requiring two single implant-supported crowns had both sites randomly allocated either to 0.5-mm or 1.5-mm subcrestal implant placement according to a split-mouth design at six centres and submerged in aesthetic areas or non-submerged in non-aesthetic areas for 3 months. Provisional acrylic crowns were delivered and were replaced after 2 months by definitive metal-ceramic crowns. Patients were followed to 3 years after loading. Outcome measures were: crown and implant failures, complications, aesthetics assessed using the pink aesthetic score (PES), peri-implant marginal bone level changes and patient preference, recorded by blinded assessors.

Results: One patient dropped out. One patient lost both implants for infection at impression taking. Seven complications affected seven patients of the 0.5-mm group and four complications affected four patients of the 1.5-mm subcrestal group. Three patients had complications at both implants. There were no statistically significant differences for complications between group (OR = 4; 95% CI: 0.45 to 35.79; *P* (McNemar test) = 0.375). At delivery of definitive crowns, 2 months after loading, the mean PES was 11.22 ± 1.91 and 11.12 ± 1.59 for the 0.5- and 1.5-mm groups, respectively. At 1 year after loading, the mean PES was 12.09 ± 1.66 and 12.10 ± 1.52 for the 0.5- and 1.5-mm groups, respectively. At 3 years after loading, the mean PES was 12 ± 1.94 and 12.19 ± 1.78 for the 0.5- and 1.5-mm groups, respectively. There were no statistically significant differences between the two groups at 2 months (*P* = 0.626), at 1 year (*P* = 0.920) or at 3 years (*P* = 0.296). One year after loading, patients of the 0.5-mm group lost on average 0.21 ± 0.51 mm and those of the 1.5-mm group 0.11 ± 0.36 mm, the difference being not statistically significant (difference = 0.10 mm; 95% CI: –0.01 to 0.20; *P* = 0.078). Three years after loading, patients of the 0.5-mm group lost on average 0.34 ± 0.87 mm and those of the 1.5-mm group 0.19 ± 0.54 mm, the difference being statistically significant (difference = 0.15 mm; 95% CI: 0.00 to 0.30; *P* = 0.046). Patients did not prefer any depth of the implant placement over the other. There were no differences in outcomes between centres.

Conclusions: No appreciable clinical differences were noticed when placing implants 0.5 mm or 1.5 mm subcrestally; therefore clinicians can do as they prefer.

Conflict of interest statement: *Anthogyr (Sallanches, France), the manufacturer of the implants used in this investigation, partially funded this trial and donated the implants and the prosthetic components; however, data belonged to the authors and by no means did the sponsor interfere with the conduct of the trial or the publication of its results.*

Introduction

Among the legends circulating in implant dentistry there is the belief that aesthetics can be improved by placing implants in a subcrestal position. The origins of this myth are difficult to track, but some authors attribute this to Buser[1]. His original statement actually referred to ITI transmucosal implants with a polished collar to have the transition portion between the rough section and the polished collar to be placed 1 mm below the bone crest in vertically augmented bone. A dedicated randomised controlled trial (RCT) conducted in non-augmented bone tested this hypothesis[2]. No statistically significant differences were observed in peri-implant marginal bone levels and other secondary parameters 1 year after loading, but the authors concluded anyhow that "From a biological point of view, the placement of the border between the rough and the smooth surfaces into a subcrestal location should not be recommended".

More recently, another RCT[3] evaluated the influence of the placement level of implants with a laser-microtextured collar design on the outcomes of crestal bone and soft tissue levels in case of immediate post-extractive implants. Patients were randomly assigned to have the implant placed at the palatal crest or 1 mm subcrestally. Patients were followed up to 12 months post-surgery (8 months post-loading). No statistically significant differences were observed at 8 months post-loading. The authors concluded that "the level of placement did not influence horizontal and vertical bone and soft tissue changes".

Another RCT[4] evaluated platform-switched implants with a morse taper connection, placed at crestal level, 1 and 2 mm subcrestally. One year after loading, there was a statistically significant difference of 0.27 mm more bone loss for implants positioned at crestal level than those positioned 1 and 2 mm below, but no difference between those placed 1 and 2 mm below the crest. These results were confirmed by another RCT[5] in which platform-switched implants were placed at crestal level or 1 mm below the crest. Three years after loading 0.65 mm significantly more bone loss was observed at crestally placed implants, with no difference for all the remaining parameters evaluated. Finally, in a RCT[6] with a follow-up of only 3 months, using two different implant types that were not even loaded, no significant differences in bone levels and other parameters were found for implants placed crestally or 1.5 to 2 mm subcrestally, though no realistic conclusions can be derived from a study in which implants were not ~~even~~ loaded.

Therefore, it would be interesting to know whether there is a better aesthetic outcome by placing implants 1.5 mm subcrestally or whether similar results are obtained by placing implants 0.5 mm subcrestally.

The aim of this pragmatic multicentre RCT was to evaluate whether there are ~~some~~ clinical benefits by placing single dental implants either 0.5 mm or 1.5 mm subcrestally in healed bone crests. This is the second report of a series presenting data at 3 years after loading. A previous publication presented the 1-year data[7]. At protocol stage, it was planned to follow the patients up to 5 years after loading. The present article is reported according to the CONSORT statement (http://www.consort-statement.org/) and its extension checklist for reporting within-person randomised trials (http://www.consort-statement.org/extensions/overview/withinperson) to improve the quality of reports of within-person randomised controlled trials.

Materials and methods

Trial design

This was a multicentre RCT of split-mouth design and blind assessment. Each patient received two identical implants (one test and one control implant): the test implant was placed 1.5 mm below the crest and the control implant 0.5 mm subcrestally.

Patient selection

Any patient requiring at least two single implant-supported crowns in any arch location, being at least 18 years old and able to sign an informed consent form was eligible for inclusion. The two implant sites could be adjacent and had to allow the placement of two implants at least 6.5 mm long and 3.4 mm wide, leaving at least 1 mm of bone around the implant. For patients with more than two suitable implant sites, the operator chose those two sites with more similar characteristics at the screening visit. The operator coded the selected sites as implant site number 1 and implant site number 2.

Exclusion criteria were:

- general contraindications to implant surgery
- immunosuppressed or immunocompromised patients
- irradiation in the head and/or neck area
- uncontrolled diabetes
- pregnancy or lactating
- untreated periodontitis
- poor oral hygiene and motivation
- substance abusers
- psychiatric disorders
- unrealistic expectations
- acute infection or suppuration at any of the sites intended for implant placement
- need of any type of bone augmentation at implant placement
- post-extractive sites (implants can be inserted after a healing of at least 5 months)
- unable to commit to 5-year follow-up post-loading
- under treatment or had previous treatment with intravenous amino-bisphosphonates
- patients referred only for implant placement if the follow-up cannot be done at the treatment centre
- participation to other clinical studies if the present protocol could not be fully adhered to.

Patients were divided into three groups based on the number of cigarettes they declared to consume per day:

- non-smokers
- moderate smokers (up to 10 cigarettes per day)
- heavy smokers (more than 10 cigarettes per day).

Equal numbers of patients were recruited and treated by six different doctors: Salina, Gualini, Rigotti, Mazzarini, Longhin and Grigoletto in private practices located in Northern Italy using similar and standardised procedures. Each clinician treated 10 patients. Prior to enrolment, all patients were asked to sign an informed consent form to document that they understood the scope of the study (including procedures, follow-up evaluations, and any potential risks involved), were allowed opportunities to ask questions pertaining to this study, and were apprised of treatment alternatives. The study was open to any qualifying patients without regard to sex or race. All patients received thorough explanations and signed a written informed consent form prior to enrolment in the trial.

Clinical procedures

Preoperative radiographs were taken. Investigators were free to choose the most appropriate examination according to the clinical case between periapical radiography, panoramic radiography and cone beam computed tomography (CBCT). All patients underwent at least one oral hygiene session within 10 days prior to the implantation procedure.

Patients received a single dose of prophylactic antibiotic 1 hour prior to the intervention: 2 g of amoxicillin or 500 mg of clarithromycin, if allergic to penicillin. Patients rinsed with chlorhexidine mouthwash 0.2% for 1 minute prior

to the intervention. Patients were treated under local anaesthesia using articaine with adrenaline 1:100,000. No intravenous sedation was used. After crestal incision and flap elevation, the sequentially numbered sealed envelope corresponding to the patient recruitment number was opened and implant site number 1 was treated according to the content of the envelope. Consequently, the other intervention was delivered to implant site number 2, according a split-mouth design (Fig 1a-n). The two study implants were placed in the same surgical session following similar procedures and were restored simultaneously with similar single crowns. Bone quality was subjectively quantified at drilling as: 'hard', 'medium' and 'soft'. Implant sites were prepared using drills with increasing diameters as suggested by the implant manufacturer using burs of different lengths according to the random allocation. Tapping was used in hard bone. Tapered implant Axiom REG (Anthogyr, Sallanches, France) with internal morse tapered connection and platform switching, made of titanium alloy Ti_4V_6Al (grade 5), were used. The surface is airborne-particle-abraded with biphasic calcium phosphate (BCP) bioceramics consisting of a mixture of hydroxyapatite (HA) and ß-TCP (beta-tricalcium phosphate), and then subjected to mild acid treatment. Operators were free to use implant of diameters 3.4 mm (8.0, 10.0, 12.0 and 14.0 mm long), 4.0 mm, 4.6 mm and 5.4 mm (6.5, 8.0, 10.0, 12.0 and 14.0 mm long), according to clinical indications and operator preference.

According to the random allocation, the neck of the implant was sunk subcrestally for 0.5 mm or 1.5 mm using as reference point the apical peak of the surrounding bone. Periapical radiographs were taken and if the peri-implant marginal bone levels were difficult to evaluate they were taken again. Implants in aesthetic areas were submerged and implants in non-aesthetic areas received transmucosal healing abutments. Ibuprofen 400 mg was prescribed to be taken two to four times a day during meals, as long as required. In case of stomach problems or allergy to non-steroidal anti-inflammatory drugs, 1 g of paracetamol was recommended instead. Patients were instructed to use 0.2% chlorhexidine mouthwash for 1 minute twice a day for 2 weeks, and to avoid brushing and possible trauma on the surgical sites. A soft diet was recommended for 2 weeks. After 1 week, patients were checked and sutures were removed. Implants were left to heal unloaded for 3 months, then submerged implants were exposed, the stability of individual implants was assessed by torqueing the abutment screws at 25 Ncm, impressions were taken at implant level, provisional crowns were delivered on provisional titanium abutments, periapical radiographs were taken, and oral hygiene instructions were delivered. Exactly the same procedures were implemented at both implants.

After 2 months, the following definitive standard straight titanium abutments lengths were used: 1.5, 2.5, 3.5 and 4.5 mm. The abutment shoulder was selected to be 0.5 to 1 mm shorter than the buccal gingival margin. The diameters of healing caps and definitive abutments used were 5 mm for implants replacing molars and 3.4 or 4.0 mm for implants replacing other teeth according to clinician evaluation. The provisional restorations were replaced by cemented metal-ceramic definitive crowns provisionally cemented on definitive standard straight titanium abutments. Implant stability was assessed and vestibular and occlusal pictures of the study implants including one adjacent tooth per side were taken together with standardised periapical radiographs of the study implants, which were taken using an individual stent, and oral hygiene motivation was reinforced. Patients were recalled every 6 months for maintenance for the entire duration of the study. Dental occlusion was evaluated at each visit.

Outcome measures

This study tested the null hypothesis that there were no differences in clinical outcome between the two procedures against the alternative hypothesis of a difference. Outcome measures were as follows:

- Implant/crown failures. Implant mobility, removal of stable implants dictated by progressive marginal bone loss or infection, and any mechanical complications rendering the implant not usable (e.g. implant fracture)

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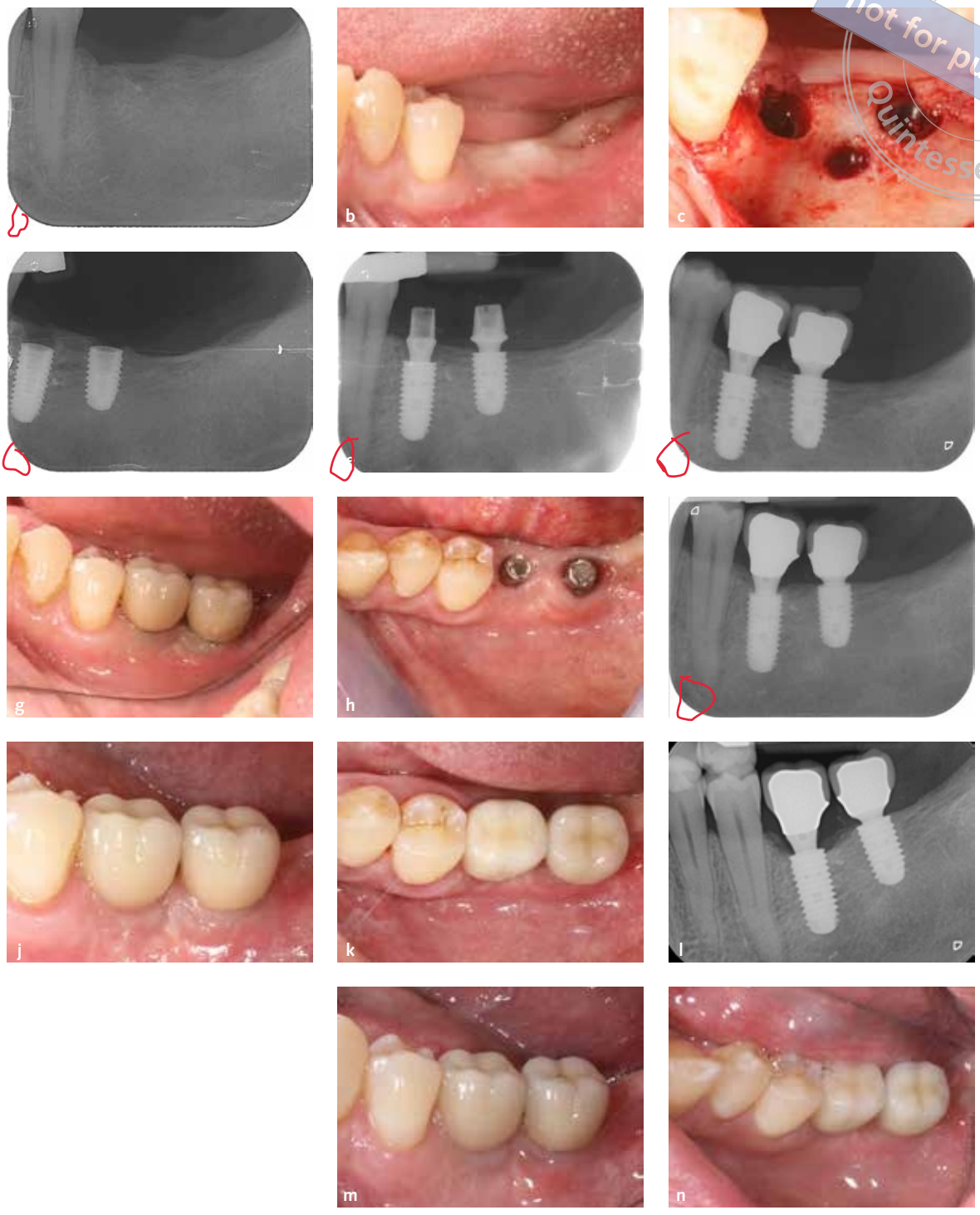

Fig 1a-n Treatment sequence of a representative patient treated by Dr Salina: **(a)** preoperative periapical radiograph and **(b)** clinical view; **(c)** site 36 was randomly allocated to receive an implant with the neck 1.5 mm below the crest and site 37 at 0.5 mm below; **(d)** postoperative baseline periapical radiograph clearly showing the difference in depth positioning; **(e)** periapical radiograph at initial loading; **(f)** periapical radiograph at delivery of definitive crown 2 months after initial loading; **(g)** vestibular and **(h)** occlusal view (without the definitive crowns) at delivery of definitive crown; **(i)** periapical radiograph, **(j)** vestibular, and **(k)** occlusal view at 1 year after loading; **(l)** periapical radiograph, **(m)** vestibular, and **(n)** occlusal view at 3 years after loading.

i j k could be placed on one row together, and l m n below, leaving a space where i is at the moment

were considered implant failures. If a definitive crown had to be replaced for any reason, it accounted as a crown failure. Stability of individual implants was measured at delivery of definitive crowns, 2 months after implant placement, applying a reverse torque of 20 Ncm with a dedicated wrench. Implant stability was re-assessed at 1 and 3 years after loading using the metal handles of two instruments.

- Complications. Any biological or biomechanical complications were recorded. Examples of biological complications are fistula and

peri-implantitis. Examples of biomechanical complications are loosening or fracture of the abutment screws.

- Peri-implant marginal bone level. Peri-implant marginal bone level changes evaluated on peri-apical radiographs taken with the paralleling technique at implant placement, initial loading, and 1 and 3 years after loading. In case of a non-measurable radiograph, a second radiograph was taken. Radiographs were scanned into TIFF format with a 600 dpi resolution, and stored in a personal computer. Peri-implant marginal bone levels were measured using the ImageJ software, version 1.48 (National Institutes of Health, Bethesda, MD, USA). The software was calibrated for every single image using the known distance of the two more coronal consecutive threads and/or the implant diameter. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.01 mm. Reference points for the linear measurements were the coronal margin of the implant collar and the most coronal point of visible bone-to-implant contact. The measurements at mesial and distal sides of each implant were averaged at implant level and then at group level. All radiographic measurements were made by a blinded dentist (Dr Sbricoli).
- Aesthetic evaluation. Aesthetic evaluation of the vestibular and occlusal clinical pictures, including the two adjacent teeth, taken at delivery of the definitive crowns (2 months after initial loading), and 1 and 3 years after loading was performed on a computer screen by a blinded dentist (Dr Sbricoli). The aesthetic evaluation was performed using the pink aesthetic score (PES)[8]. In brief, seven variables were evaluated: mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiencies, soft tissue colour and texture. A 0-1-2 scoring system was used, 0 being the lowest and 2 being the highest value, with a maximum achievable score of 14 per implant.
- Patient preference. One and 3 years after loading the local blind outcome assessors provided a mirror to patients, indicated both implant-supported crowns and asked them which of the crowns they preferred. Possible patient's answers were:
  - crown in implant site number 1
  - crown in implant site number 2
  - I like both crowns the same
  - I dislike both crowns.
  - Patients could express comments on the matter if they wanted.

At each centre there was a local blind outcome assessor who assessed implant stability and recorded patient preference. One blinded dentist (Dr Sbricoli), not involved in the treatment of the patients, evaluated both aesthetic and marginal bone levels, without knowing group allocation, with the exception of complications, which were handled and reported directly by the responsible clinicians who were not blind.

Statistical analysis

No sample size calculation was performed and it was agreed to recruit 60 patients, 10 at each of the six centres that agreed to participate in this trial. Six computer-generated restricted randomisation lists were created. Only one investigator (Dr Esposito), who was not involved in the selection and treatment of the patients, knew the random sequence and had access to the random list stored in a password-protected portable computer. The randomised codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. After flap elevation, the envelope corresponding to the patient recruitment number was opened, and implant site number 1 was allocated to the group determined by the content of the envelope, and other site received the alternative intervention. Therefore, treatment allocations were concealed to the investigators in charge of enrolling and treating the patients.

All data analysis was performed according to a pre-established analysis plan by a clinician (Dr Jacopo Buti) with expertise in statistics who analysed the data without knowledge of the group codes. The implant sites were the statistical unit of

the analyses. Differences between the groups in crown/implant failures and complications (dichotomous outcomes) were compared using a McNemar test. Differences between the groups for continuous outcomes (mean marginal bone level changes and aesthetics assessed by clinician) were compared using a paired *t* test. Comparisons between the various follow-up endpoints and the baseline measurements were made by paired *t* tests, to detect any changes in mean marginal bone level changes for each study group. Differences between centres for continuous outcomes were analysed by the ANOVA test followed by Tukey's HSD post-hoc test to detect differences between groups. For categorical outcomes, the chi-square test or Fisher's exact test were used depending on the count per cell (small cell sizes with values less than 5). Zero cells were handled by adding 0.5 to each of the cells and then calculating the odds ratio (OR) over these adjusted cell counts (Haldane-Anscombe correction). All statistical comparisons were conducted at the 0.05 level of significance.

Results

Sixty-three patients were screened at the six centres and 60 patients were consecutively enrolled in the trial. Three patients were not included because they did not want to participate in the study. All patients were treated according to the allocated interventions. One patient dropped out because he did not want to come back after the delivery of the provisional crowns (Dr Longhin).

The periapical radiographs at 2 months and 1 year after loading of both implants of one patient could not be taken because she was pregnant at both time points (Dr Rigotti); however, assessment of bone levels at 3 years after loading revealed no bone loss occurred so it was possible to estimate with precision the bone levels of the missing radiographs, and the missing data (0 value) were entered. The data of all patients were evaluated in the statistical analyses. The main deviations from the protocol were:

- The centres, at protocol stage, specifically requested to use standardised periapical radiographs using customised stents. This request was not considered necessary by the study coordinator but was incorporated in the original protocol anyway. However, after treatment of the first cases the use of radiographic stents was discontinued because of difficulties in repositioning them over time.
- In one patient both definitive crowns were placed 11 months after loading, because the patient had health problems and did not return for the appointment (Dr Salina).
- In one patient both definitive crowns were placed 9 months after the provisional restoration. The definitive crown delivery, 9 months after loading, was considered as the 1-year post loading visit (Dr Rigotti).
- In one patient only at the implant placed 1.5 mm below the crest, a straight abutment was used instead of standard abutment (Dr Salina).

Patients were recruited and received the implants from June 2013 to April 2015. The follow-up of all remaining patients was to 3 years after implant loading. There were 34 females and 26 males, with a mean age of 53.4 years (range 28 to 81). There were 47 non-smokers, six moderate smokers and seven patients smoking more than 10 cigarettes per day. Implant characteristics by study groups are described in Table 1. There were no apparent significant baseline imbalances between the two groups.

Crowns and implant failures

Two implants failed, one per group, from the same patient. The differences in proportions of implant failures between groups was not statistically significant (OR = 1; 95% CI: 0.02 to 50.41; *P* [Exact McNemar test] = 1.000). Both implants that were initially loaded with provisional crowns showed a fistula, were found mobile at definitive impression taking, and were removed. Both failed implants were successfully replaced but the data of the replaced implants were not recorded since this was outside the scope of the present study.

Table 1 Intervention characteristics, n (%)

Characteristic		0.5-mm group (N = 60)	1.5-mm group (N = 60)
Implant position	Central incisor	0 (0.0%)	0 (0.0%)
	Lateral incisor	0 (0.0%)	0 (0.0%)
	Canine	1 (1.7%)	0 (0.0%)
	First premolar	7 (11.7%)	9 (15.0%)
	Second premolar	15 (25.0%)	16 (26.7%)
	First molar	31 (51.7%)	30 (50.0%)
	Second molar	5 (8.3%)	5 (8.3%)
	Third molar	1 (1.7%)	0 (0.0%)
Implant arch	Maxilla	17 (28.3%)	15 (25.0%)
	Mandible	43 (71.7%)	45 (75.0%)
Implant diameter	3.4 mm	21 (35.0%)	21 (35.0%)
	4.0 mm	35 (58.3%)	35 (58.3%)
	4.6 mm	2 (3.3%)	3 (5.0%)
	5.2 mm	2 (3.3%)	1 (1.7%)
Implant length	6.5 mm	6 (10.0%)	8 (13.3%)
	8.0 mm	24 (40.0%)	30 (50.0%)
	10.0 mm	28 (46.7%)	22 (36.7%)
	12.0 mm	2 (3.3%)	0 (0.0%)
	14.0 mm	0 (0.0%)	0 (0.0%)
Abutment length	1.5 mm	33 (55.0%)	19 (31.7%)
	2.5 mm	20 (33.3%)	31 (51.7%)
	3.5 mm	7 (11.7%)	10 (16.7%)
	4.5 mm	0 (0.0%)	0 (0.0%)
Abutment diameter	3.4 mm	4 (6.7%)	1 (1.7%)
	4.0 mm	31 (51.7%)	37 (61.7%)
	5.0 mm	23 (38.3%)	21 (35.0%)
	6.0 mm	2 (3.3%)	1 (1.7%)
Bone quality	Soft	8 (13.3%)	6 (13.3%)
	Medium	31 (51.7%)	34 (56.7%)
	Hard	21 (35.0%)	20 (33.3%)

Complications

Seven complications occurred in seven patients of the 0.5-mm group versus four complications in four patients of the 1.5-mm group. Three patients had both implants affected by the same complications. There was no statistically significant difference in the number of patients experiencing complications between the two groups (OR = 4; 95% CI: 0.45 to 35.79; *P* (McNemar test) = 0.375).

In the 0.5-mm group, one patient (ID = 13) had permanent postoperative paraesthesia at implant in position 36 (according to FDI notation).

One patient (ID = 33) presented a fistula and implant in position 14, which was mobile at the time of definitive impression taking. It was removed and successfully replaced. Exactly the same problem happened at the other implant of the same patient.

Another patient (ID = 27) presented an inflammatory problem at time of abutment connection around the implant in position 46, which resulted in bone loss at 1 year after loading (peri-implantitis). She was treated with light scaling with a polytetrafluoroethylene (PTFE) tip using the piezoelectric device (Mectron, Carasco, Italy) and curettes, irrigation with physiological saline and injection of a solution of tetracycline hydrochloride (Ambramicina, 250 mg, Scharper, Milan, Italy). This treatment was repeated after 2 weeks.

One patient (ID = 5) had an episode of peri-implant mucositis at implant in position 27 (pocket depth palatally = 4.5 mm). The patient was immediately treated with light ultrasonic treatment using polytetrafluoroethylene (PTFE) tips and one application of 810 nm diode laser (1.2 W for 1 min x 3 times) with simultaneous irrigation of 3% H_2O_2. The peri-implant sulcus was then filled with a gel of chlorhexidine 0.5% (Oralsan, IDS, Genoa, Italy) and azithromycin (Zitromax, Pfizer, Latina, Italy) 500 mg (one tablet per day for 3 days) was prescribed. The situation returned to normality in 20 days. The patient was recalled monthly for 6 months.

One patient (ID = 17) was affected by peri-implantitis 18 months after loading at both implants. Both implants were surgically debrided, and the frequency of maintenance recalls was increased. Marginal peri-implant bone at both implants stabilised after some more bone loss occurred together with some mucosa recession.

One patient (ID = 8) showed peri-implant bone resorption 2 years after loading without inflammation so no treatment was delivered. One patient (ID = 10) was affected at both implant by peri-implant mucositis 2 years after loading, treated with ultrasound debridement, laser, H_2O_2 irrigation, local application of doxycycline (Ligosan 140 mg, Heraeus Kulzer, Milan, Italy). The patients was stable at the time of writing but still inflamed.

Table 2a PES mean (SD) scores at 2 months after loading by groups and by different aesthetic domains

Group	Mesial papilla	Distal papilla	Soft tissue level	Soft tissue contour	Alveolar process deficiencies	Soft tissue colour	Soft tissue texture	Total PES score
0.5 mm deep (N = 58)	1.40 (0.70)	1.00 (0.77)	1.84 (0.37)	1.57 (0.53)	1.81 (0.40)	1.81 (0.40)	1.79 (0.41)	11.22 (1.91)
1.5 mm deep (N = 58)	1.40 (0.67)	0.97 (0.67)	1.86 (0.35)	1.52 (0.57)	1.81 (0.40)	1.79 (0.41)	1.78 (0.42)	11.12 (1.59)
Difference [95% CI]	0.00 [–0.25, 0.25]	0.03 [–0.16, 0.23]	–0.02 [–0.14, 0.11]	0.05 [–0.06, 0.17]	0.00 [–0.07, 0.07]	0.02 [–0.08, 0.11]	0.02 [–0.09, 0.12]	0.10 [–0.32, 0.53]
P value (paired *t* test)	1.000	0.727	0.784	0.370	1.000	0.709	0.742	0.626

SD, standard deviation.

The complications reported for patients of the 1.5-mm group were as follows. One patient (ID = 29) lost the cover screw on tooth 36 one week after its placement; the soft tissues covered the implant and no treatment was necessary. A fistula was present at the mobile implant in position 15 in the same patient who lost this and the adjacent implant (ID = 33).

One patient (ID = 10) was affected at both implant by peri-implant mucositis 2 years after loading, treated with ultrasound debridement, laser, H_2O_2 irrigation, local application of doxycycline (Ligosan 140 mg, Heraeus Kulzer). The patients was stable at the time of writing but still inflamed. One patient (ID = 17) was affected by peri-implantitis 18 months after loading at both implants. Both implants were surgically debrided, and the frequency of maintenance recalls was increased. Both implants become stable, but some more bone loss occurred together with some mucosa recession.

Marginal peri-implant bone at both implants stabilised after some more bone loss occurred together with some mucosa recession.

Aesthetics

Two months after loading, at delivery of the definitive prostheses, the average total PES score, assessed by a blind assessor, was 11.22 ± 1.91 for the 0.5-mm group and 11.12 ± 1.59 for the 1.5-mm group, the difference being not statistically significantly different (*P* [paired *t* test] = 0.626; Table 2a). Regarding the individual aesthetic domains, no statistically significant difference could be observed between the two groups (Table 2a).

One year after loading, the average PES score was 12.09 ± 1.66 for the 0.5-mm group and 12.10 ± 1.52 for the 1.5-mm group, the difference being not statistically significantly different (*P* [paired *t* test] = 0.920; Table 2b). Also evaluating the individual aesthetic domains no statistically significant difference could be observed between the two groups (Table 2b). Three years after loading, the average PES score was 12 ± 1.94 for the 0.5-mm group and 12.19 ± 1.78 for the 1.5-mm group, the difference being not statistically significantly different (*P* [paired *t* test]= 0.296; Table 2c). In terms of the individual aesthetic domains, no statistically significant difference could be observed between the two groups (Table 2c).

Patient preference

Patient preference was assessed at definitive crown delivery (2 months after initial loading), and 1 and 3 years after initial loading only for those patients who did not experience an implant failure. At delivery of definitive crowns, 57 patients had no preferences (liking both crowns the same way) and one patient preferred the 1.5-mm crown. At 1 year after loading, 55 patients had no preference (liking both crowns the same way), two patients preferred the 0.5-mm one and one the 1.5-mm one. At 3 years after loading, 57 patients had no preference (liking both crowns the same way), and one patient preferred the 0.5-mm implant.

Please place 2b and 2c below 2a

Table 2b PES mean (SD) scores at 1 year after loading by groups and by different aesthetic domains

Group	Mesial papilla	Distal papilla	Soft tissue level	Soft tissue contour	Alveolar process deficiencies	Soft tissue colour	Soft tissue texture	Total PES score
0.5 mm deep (n = 58)	1.71 (0.50)	1.33 (0.69)	1.86 (0.35)	1.69 (0.50)	1.81 (0.40)	1.83 (0.38)	1.86 (0.35)	12.09 (1.66)
1.5 mm deep (n = 58)	1.67 (0.57)	1.33 (0.57)	1.90 (0.31)	1.74 (0.48)	1.81 (0.40)	1.83 (0.38)	1.83 (0.38)	12.10 (1.52)
Difference [95% CI]	0.03 [–0.16, 0.23]	0.00 [–0.19, 0.19]	–0.03 [–0.14, 0.08]	–0.05 [–0.17, 0.06]	0.00 [–0.10, 0.10]	0.00 [–0.10, 0.10]	0.03 [–0.06, 0.13]	–0.02 [–0.36, 0.33]
P value (paired *t* test)	0.718	1.000	0.532	0.370	1.000	1.000	0.484	0.920

mean (SD)

Table 2c PES scores at 3 years after loading by groups and by different aesthetic domain s ~~(SD in parenthesis)~~

Group	Mesial papilla	Distal papilla	Soft tissue level	Soft tissue contour	Alveolar process deficiencies	Soft tissue colour	Soft tissue texture	Total PES score
0.5 mm deep (N = 58)	1.66 (0.55)	1.38 (0.62)	1.67 (0.51)	1.81 (0.44)	1.84 (0.37)	1.79 (0.45)	1.84 (0.37)	~~12~~ (1.94)
1 .5 mm deep (N = 58)	1.67 (0.54)	1.47 (0.54)	1.74 (0.52)	1.81 (0.44)	1.83 (0.38)	1.81 (0.44)	1.86 (0.35)	12.19 (1.78)
Difference [95% CI]	–0.02 [–0.25, 0.21]	–0.09 [–0.24, 0.06]	–0.07 [–0.22, 0.08]*	0 [–0.11, 0.11]	0 .02 [–0.09, 0.12]	–0.02 [–0.12, 0.09]	–0.02 [–0.12, 0.09]	–0.19 [–0.55, 0.17]
P value (paired t test)	0.880	0.255	0.350	1.000	0.742	0.742	0.742	0.296

11.99

Peri-implant marginal bone levels

Peri-implant marginal bone levels were evaluated by a blinded outcome assessor on periapical radiographs taken at implant placement, at loading, and at 1 and 3 years after loading (Table 3a). At baseline, all bone level measures equalled 0 for both groups. At initial loading, the average bone levels around 0.5-mm implants were 0.07 ± 0.21 mm versus 0.04 ± 0.13 mm at 1.5-mm implants, the difference being not statistically different (difference = 0.03 mm; 95% CI: –0.02 to 0.07; *P* [paired *t* test] = 0.209). At 1 year post-loading, the average bone levels around 0.5-mm implants were 0.21 ± 0.51 mm versus 0.11 ± 0.36 mm at 1.5-mm implants, the difference being not statistically different (difference = 0.10 mm; 95% CI: –0.01 to 0.20; *P* [paired *t* test] = 0.078). At 3 years post-loading, the average bone levels around 0.5-mm implants were 0.34 ± 0.87 mm versus 0.19 ± 0.54 mm at 1.5-mm implants, the difference being statistically different (difference = 0.15 mm; 95% CI: 0.00 to 0.30; *P* [paired *t* test] = 0.046). Bone level losses at 1 year post-loading were 0.21 ± 0.51 mm at 0.5-mm implants and 0.11 ± 0.36 mm at 1.5-mm implants, the difference was not statistically significant (difference = 0.10; 95% CI: –0.01 to 0.20; *P* [paired *t* test] = 0.078; Table 3b). Bone level losses at

Table 3a Mean radiographic peri-implant marginal bone levels between groups and time periods up to 3 years after loading

Group	Implant placement			Loading			2 mo post loading			1 y post-loading			3 y 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
0.5 mm deep	60	All implants = 0	NA	59	0.07 (0.21)	[0.01, 0.12]	58	0.16 (0.39)	[0.06, 0.26]	58	0.21 (0.51)	[0.07, 0.34]	58	0.34 (0.87)	[0.12, 0.57]
1.5 mm deep	60	All implants = 0	NA	59	0.04 (0.13)	[0.01, 0.07]	58	0.10 (0.38)	[-0.01, 0.20]	58	0.11 (0.36)	[0.02, 0.21]	58	0.19 (0.54)	[0.05, 0.33]
Difference [95% CI]	0			0.03 [–0.02, 0.07]			0.06 [–0.02, 0.15]			0.10 [–0.01, 0.20]			0.15 [0.00, 0.30]		
P value	1.000			0.209			0.152			0.078			0.046*		

NA, not applicable.

*Statistically significant difference.

Table 3b Mean radiographic peri-implant marginal bone level changes between groups and time periods up to 3 years after loading

Group	Baseline–loading			Baseline–2 mo post loading			Baseline–1 y post-loading			Baseline–3 y post-loading		
	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	95% CI	N	Mean (SD)	95% CI
0.5 mm deep	59	0.07 (0.21)	[0.01, 0.12]	58	0.16 (0.39)	[0.06, 0.26]	58	0.21 (0.51)	[0.07, 0.35]	58	0.34 (0.87)	[0.12, 0.57]
1.5 mm deep	59	0 04 (0.13)	[0.01, 0.07]	58	0.10 (0.38)	[-0.01, 0.20]	58	0.11 (0.36)	[0.02, 0.21]	58	0.19 (0.54)	[0.05, 0.33]
Difference [95% CI]	0.03 [–0.02, 0.07]			0.06 [–0.02, 0.15]			0.10 [–0.01, 0.20]			0.15 [0.00, 0.30]		
P value	0.209			0.152			0.078			0.046*		

All changes from baseline statistically different ($P < 0.05$).

*Statistically significant difference.

3 years post-loading were 0.34 ± 0.87 mm at 0.5-mm implants and 0.19 ± 0.54 mm at 1.5-mm implants, the difference was statistically significant (difference = 0.15 mm; 95% CI: 0.00 to 0.30; *P* [paired *t* test] = 0.046; Table 3b).

The comparison between the six centres is presented in Table 4. Three years post-loading there were no statistically significant differences between the centres for crown and implant failures (*P* [chi-square test] = 0.418), complications (*P* [chi-square test] = 0.130), PES score (for the 0.5-mm group, *P* [ANOVA] = 0.305; for the 1.5-mm group, *P* [ANOVA] = 0.501), peri-implant bone level changes (for the 0.5-mm group, *P* [ANOVA] = 0.745; for the 1.5-mm group, *P* [ANOVA] = 0.748) and patient preference (*P* [chi-square test] = 0.440) (Table 4).

Discussion

This trial was designed to evaluate whether it could be more advantageous to place implants 0.5 mm or 1.5 mm subcrestally. Only one statistically significant difference was noticed up to 3 years after loading: increased peri-implant marginal bone loss of 0.15 mm at implants placed 0.5 mm below the crest. This difference may not be considered clinically relevant and suggests that it is irrelevant to sink dental implants subcrestally

Table 4 Comparison of clinical outcomes between the six centres at 3 years after loading

Ouctome	Salina	Gualini	Rigotti	Mazzarini	Longhin	Grigoletto	*P* value
Drop-out	0/10	0/10	0/10	0/10	1/10	0/10	0.406
Crown failures	0/10	0/10	0/10	1/10	0/9	0/10	0.418
Implant failures	0/10	0/10	0/10	1/10	0/9	0/10	0.418
Complications	4/10	3/10	2/10	2/10	0/9	0/10	0.130
PES score at 3 y, 0.5-mm group, mean ± SD	11.70 ± 2.16	12.20 ± 2.66	13.00 ± 0.82	12.33 ± 1.41	11.78 ± 1.72	11.00 ± 2.11	0.305
PES score at 3 y, 1.5-mm group, mean ± SD	12.20 ± 1.23	12.10 ± 2.69	13.10 ± 0.74	12.30 ± 1.22	11.89 ± 2.37	11.50 ± 1.72	0.501
Peri-implant bone loss at 3 y, 0.5-mm group (mm), mean ± SD	0.61 ± 1.29	0.39 ± 1.23	0.32 ± 0.77	0.17 ± 0.35	0.52 ± 0.81	0.06 ± 0.19	0.745
Peri-implant bone loss at 3 y, 1.5-mm group (mm), mean ± SD	0.33 ± 0.55	0.32 ± 0.94	0.21 ± 0.46	0.10 ± 0.30	0.18 ± 0.53	0.00 ± 0.00	0.748
Patients with no preference	10/10	10/10	10/10	9/9	9/9	9/10	0.440

at least at the depths evaluated in the present trial; therefore, clinicians could choose to place implants at the depths (0.5 or 1.5 mm) they prefer. One purely logical consideration ought to be made: it might be sensible to place implants at a depth of 0.5 mm in order to be able to fully use 1 mm more of bone support, especially for those situations of limited bone heights. Ideally, in the same trial, the placement of identical implants at crestal level or even slightly supracrestally should have also been tested to have a complete ~~vision about~~ view of the relationships between implant positioning depth and aesthetic outcome as well other clinically relevant parameters. Nevertheless, it cannot be excluded that the difference in bone loss could increase overtime, so longer follow-up of the same cohorts of patients are necessary to test this hypothesis.

The present findings are in agreement with those of other similar RCTs[2-4] testing the same hypothesis, even though implants with different designs were used, such as transmucosal implants[2]. However, when implants were crestally placed, some statistically significant differences for bone loss were reported. For instance one RCT[4], evaluating platform-switched implants with a morse taper connection, placed at crestal level and 1 mm and 2 mm subcrestally, reported 0.27 mm more bone loss for implants positioned at crestal level 1 year after loading. Another RCT[5] comparing platform-switched implants at crestal level or 1 mm below showed 0.65 mm more bone loss at crestally placed implants 3 years after loading. However, there is no evidence that such small differences in bone loss affected aesthetics or any other clinical parameter. In simple words, the subcrestal positioning of implants at 0.5 or 1.5 mm in healed sites bears no clinically appreciable consequences for the patients.

In the present trial, no statistically significant differences or trends were observed for aesthetics evaluated using the PES scores up to 3 years after loading between implants positioned 0.5 mm or 1.5 mm subcrestally. This could be interpreted as both procedures achieving a similar aesthetic outcome. It is interesting to observe that aesthetics slightly improved between month 2 and month 12 post-loading, especially for mesial and distal papillas, suggesting that some sort of creeping attachment phenomena occurred after the delivery of the definitive crowns, meaning that the peri-implant soft tissues gradually grew around the crowns.

While comparing clinical outcomes amongst different centres, there were no statistically significant differences for implant failures, complications and peri-implant marginal bone level changes, although the sample was too small to detect possible differences between operators.

Since in the present investigation both procedures were tested in real clinical conditions and patient inclusion criteria were broad, results can be generalised with confidence to a wider population with similar characteristics.

Conclusions

No clinically appreciable differences were noticed when placing implants 0.5 mm or 1.5 mm subcrestally, therefore clinicians can do as they prefer.

Acknowledgements

The authors thank the following local outcome assessors for their help with this study: Dr Roberto Ringoli, Dr Piero Gualini, Dr Mandy Pen Shui, Dr Martina Furlanetto, Dr Celon and Dr Giulia Piccirilli.

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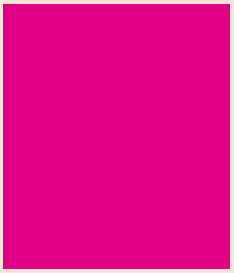

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