KEY WORDS
dental implant, crestal placement, subcrestal placement, aesthetics, bone levels, screw-retained, cement-retained

Randomised controlled trial

CRESTAL OR 1.5 MM SUBCRESTAL POSITIONING OF TRANSMUCOSAL DENTAL IMPLANTS WITH CEMENTED OR SCREW-RETAINED CROWNS IN POSTERIOR JAWS: 4-MONTH DATA FROM A SINGLE-CENTRE RANDOMISED CONTROLLED TRIAL

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OBJECTIVES. To compare crestal *versus* 1.5 mm subcrestal positioning of single transmucosal dental implants and screw-retained *versus* cemented crowns.

MATERIALS AND METHODS. One hundred and sixty partially edentulous patients requiring one single implant-supported crown in the premolar/molar area were randomly allocated to four arms: crestal positioning and screw-retained crown (Group 1, 40 patients); crestal positioning and cement-retained crown (Group 2, 40 patients); 1.5 mm subcrestal positioning and screw-retained crown (Group 3, 40 patients); or 1.5 mm subcrestal positioning and cement-retained crown (Group 4, 40 patients) by a single operator. After an unloaded healing period of 3 months, definitive metal-ceramic crowns were delivered, and patients were followed up to 4 months 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 satisfaction, all recorded, when possible, by blinded assessors.

RESULTS. At four months post-loading, four patients dropped out (two from Group 1 and one each from Groups 2 and 3, respectively). Two implants each failed in Groups 2 and 4, but there were no statistically significant differences between groups (P = 1.000). Complications affected four patients from Group 1, one from Group 2, two from Group 3 and six from Group 4, but between-group differences were not statistically significant (P = 0.207). The mean pink aesthetic scores were 10.30 ± 2.13 (Group 1), 10.22 ± 2.76 (Group 2), 10.47 ± 2.96 (Group 3), and 10.51 ± 2.24 (Group 4), respectively, with no statistically significant differences between groups (P = 0.9541). Likewise, there were no statistically significant differences in peri-implant marginal bone loss at 4 months after loading between groups (P = 0.9011: -0.21 mm ± 0.28 for Group 1, -0.25 mm ± 0.27 for Group 2, -0.28 mm ± 0.57 for Group 3 and -0.24 mm ± 0.26 for Group 4). Furthermore, there were no differences in patient satisfaction in terms of either function (P = 0.400) or aesthetics (P = 1.000), and all patients would undergo the same intervention again.

CONCLUSIONS. No appreciable statistical or clinical differences were found between crestal or 1.5 mm subcrestal placement of transmucosal implants in posterior jaws or between rehabilitation with screw-retained or cement-retained crowns. However, longer follow-ups are required in order to formulate reliable clinical recommendations.

CONFLICT OF INTEREST STATEMENT. GlobalD (Brignais, France), the manufacturer of the implants used in this investigation, partially funded this trial and donated the implants and the prosthetic components. However, all data belongs to the authors and the sponsor by no means interfered with the conduct of the trial or the publication of its results.

INTRODUCTION

Among the debates in implant dentistry there is the belief that aesthetics could be improved by placing implants in a subcrestal position. The origins of this idea are difficult to trace, but some authors attribute it 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](2), and found no statistically significant differences in peri-implant marginal bone levels or other secondary parameters 1 year after loading. This notwithstanding, the authors concluded 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 crestal bone and soft tissue outcomes in immediate post-extraction implants. Patients were randomly assigned to have their implant placed at the palatal crest or 1 mm subcrestally, and were followed up to 12 months post-surgery (8 months post-loading). No statistically significant differences were observed at 8 months post-loading, and the authors concluded that "the level of placement did not influence horizontal and vertical bone and soft tissue changes".

Another RCT[4] assessed platform-switched implants with a Morse taper connection placed crestally, or 1 or 2 mm subcrestally. One year after loading, there was a statistically significant difference of 0.27 mm more bone loss at implants positioned crestally than at those positioned 1 and 2 mm below, but no difference between those placed 1 or 2 mm subcrestally. However, contrasting results were reported in another RCT[5], in which platform-switched implants were placed at the crestal level or 1 mm below the crest. Three years after loading, significantly more bone loss (0.65 mm) was observed at implants placed 1 mm subcrestally as compared to implants placed crestally, but there were no difference in any of the remaining parameters evaluated. Another RCT[6] found no significant differences in bone levels or other parameters for two different implant types placed crestally *versus* 1.5-2 mm subcrestally. However, follow-up in this case was only 3 months, and implants were not loaded, meaning that no realistic conclusions can be drawn. Finally, in a split-mouth multicentre RCT[7] including 60 patients with a 3-year post-loading follow-up that compared implants placed 0.5 or 1.5 mm subcrestally, a statistically significant difference of 0.15 mm in bone loss favouring the 1.5 mm group was observed. Nonetheless, this difference was not considered clinically significant.

It would be interesting to know whether better aesthetic outcomes could be achieved by placing transmucosal implants crestally or 1.5 mm subcrestally, and at the same time to investigate whether it would be preferable to use screw-retained or cement-retained single metal-ceramic crowns. Indeed, another debate in implant dentistry that has been ongoing for over half a century is whether it is better to use screw-retained or cemented prostheses. Whilst the majority of RCTs have shown no differences for single crowns and cross-arch prostheses[8-12], one trial yielded results in favour of partial fixed cement-retained restorations[13], although this was poorly reported.

The aim of this single-centre RCT was to evaluate whether there are any clinical benefits to placing single transmucosal dental implants at either the crestal level or 1.5 mm subcrestally in healed posterior bone crests, and at the same time to evaluate the relative advantages and disadvantages of screw-retained *versus* cement-retained single crowns. At four months, this is the first report in a series planned in the protocol stage to present data up to 7 years post-loading. The present article is reported according to the CONSORT statement (http://www.consort-statement.org/) for improving the quality of reports from randomised controlled trials.

MATERIALS AND METHODS

Trial design

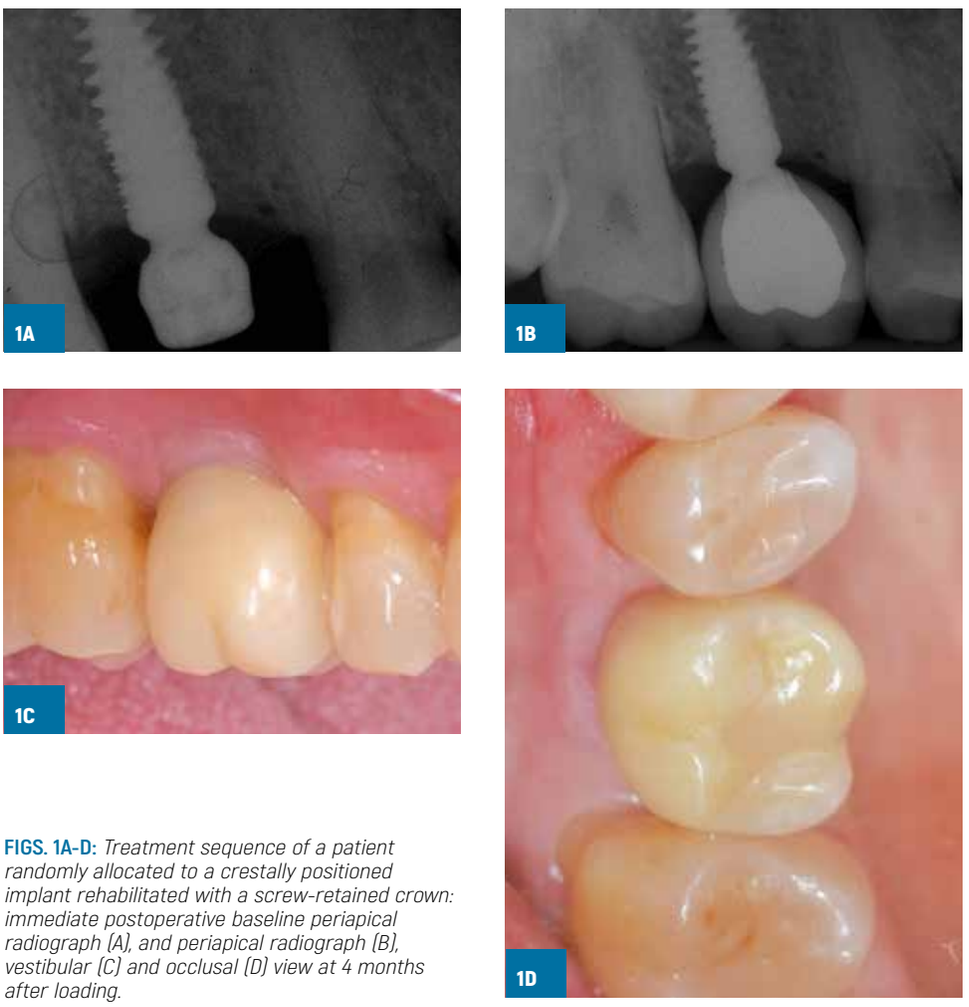
This was a single-centre randomised controlled trial (RCT) with four arms and blind assessment whenever possible. Patients were randomly allocated in equal numbers to four arms: crestal positioning and screw-retained crown (Group 1; **FIGS. 1A-D**); crestal positioning and cement-retained crown (Group 2; **FIGS. 2A-D**); 1.5 mm subcrestal positioning and screw-retained crown (Group 3; **FIGS. 3A-D**); or 1.5 mm subcrestal positioning and cement-retained crown (Group 4; **FIGS. 4A-D**).

Patient selection

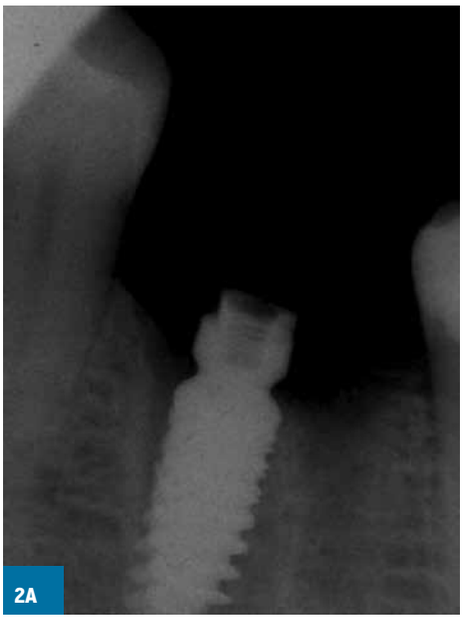
Any patient requiring one single implant-supported crown in the premolar or molar areas of either jaw, being at least 18 years old and able to understand and sign an informed consent form, was eligible for inclusion. The implant site had to allow for at least 2 mm of bone thickness around the implant body.

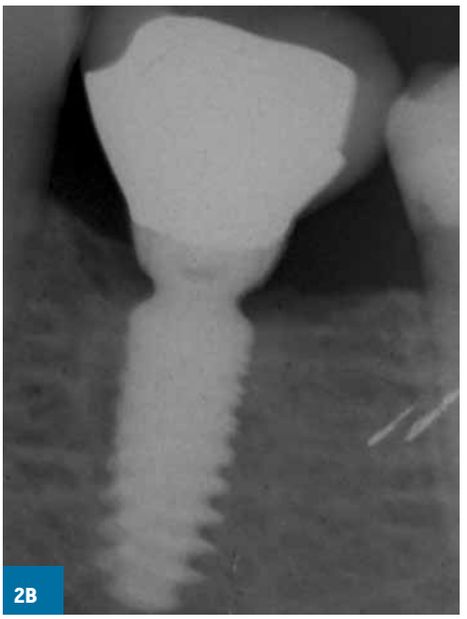
Exclusion criteria were:

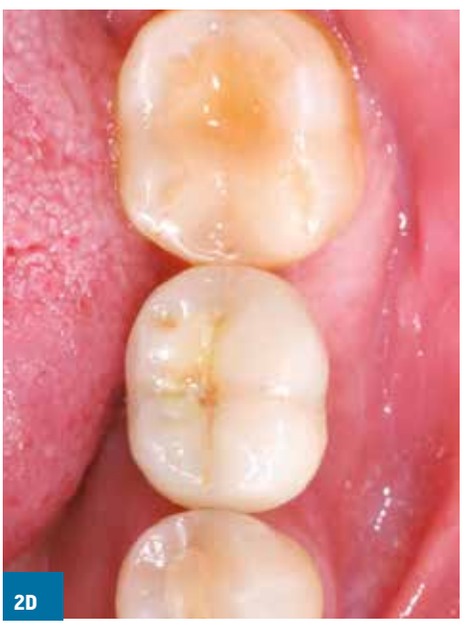
- General contraindications to implant surgery;
- Immunosuppressed or immunocompromised status;



FIGS. 1A-D: *Treatment sequence of a patient randomly allocated to a crestally positioned implant rehabilitated with a screw-retained crown: immediate postoperative baseline periapical radiograph (A), and periapical radiograph (B), vestibular (C) and occlusal (D) view at 4 months after loading.*

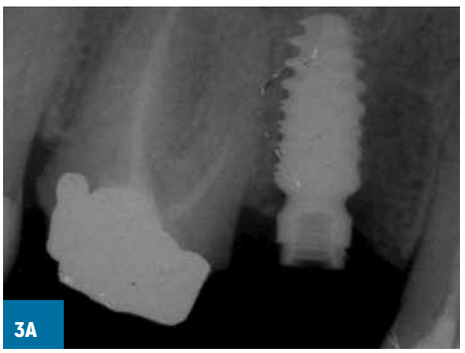


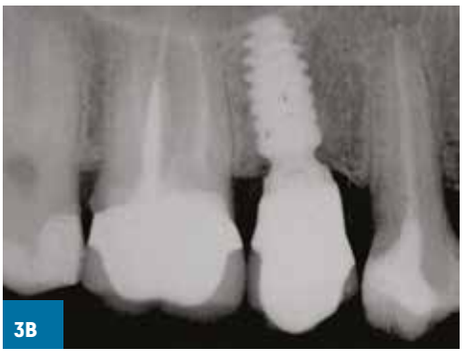


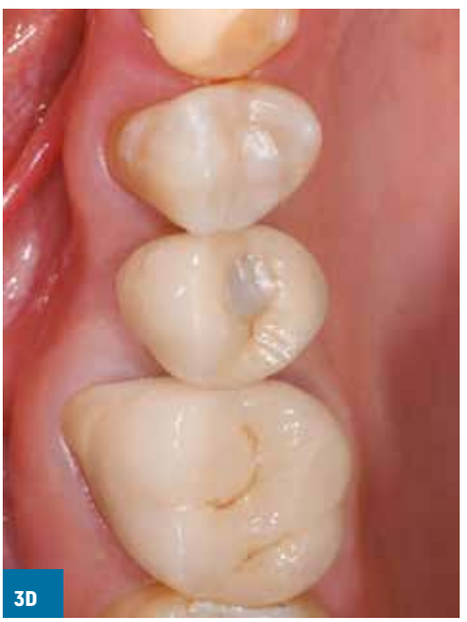


FIGS. 2A-D: *Treatment sequence of a patient randomly allocated to a crestally positioned implant rehabilitated with a cement-retained crown: immediate postoperative baseline periapical radiograph (A), and periapical radiograph (B), vestibular (C) and occlusal (D) view at 4 months after loading.*

- Irradiation to the head and/or neck area;
- Uncontrolled diabetes;
- Pregnancy or lactation;
- Poor oral hygiene and motivation;
- Untreated periodontitis;
- Substance abuse;
- Psychiatric disorders;
- Unrealistic expectations;
- Acute infection at the site intended for implant placement;





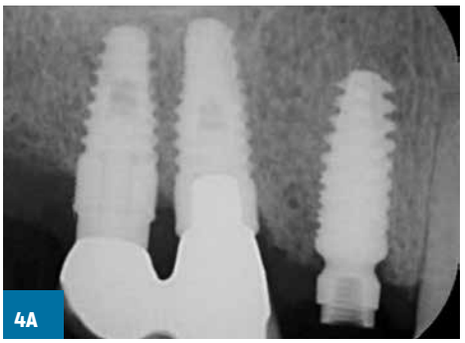


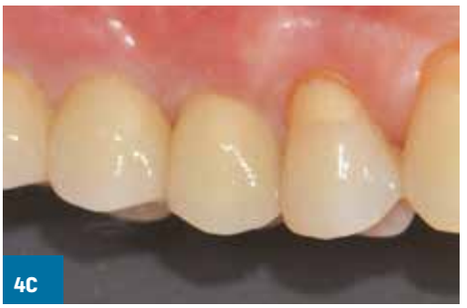
FIGS. 3A-D: *Treatment sequence of a patient randomly allocated to a subcrestally positioned implant rehabilitated with a screw-retained crown: immediate postoperative baseline periapical radiograph (A), and periapical radiograph (B), vestibular (C) and occlusal (D) view at 4 months after loading.*

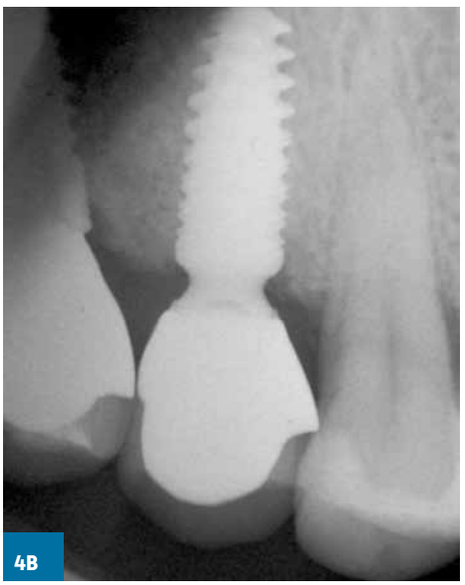
- The need for any type of bone augmentation at implant placement;
- Inability to commit to 7-year post-loading follow-up;
- Post-extraction sites (implants could be inserted after a healing period of 3 months);
- Current or previous treatment with intravenous aminobisphosphonates;
- Referral for implant placement alone (impossibility of follow-up at the treatment centre);
- Participation in other clinical studies precluding adhesion to the present protocol.

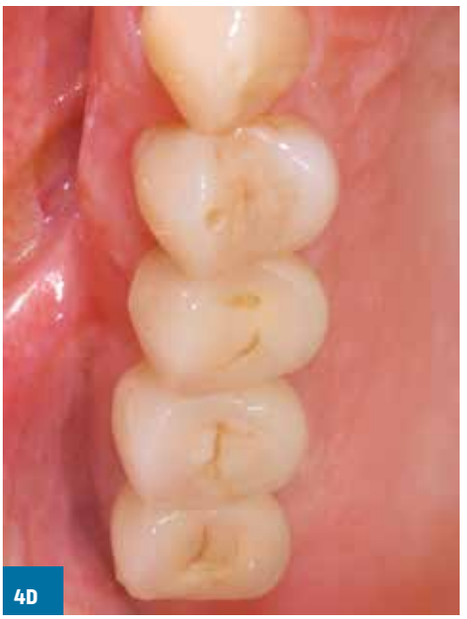
Patients were divided into three groups based on the number of cigarettes they declared smoking per day: i) non-smokers, ii) moderate smokers (up to 10 cigarettes per day) and iii) heavy smokers (more than 10 cigarettes per day).

All patients were treated both surgically and prosthetically by a single operator (Dr. Colombelli) in two private practices located in Lombardy, Italy. Prior to enrolment, all patients were asked to read and sign an informed consent form declaring that they understood the scope of the study (including procedures, follow-up assessments and any potential risks involved); they were given the opportunity 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.









FIGS. 4A-D: *Treatment sequence of a patient randomly allocated to a subcrestally positioned implant rehabilitated with a cement-retained crown: immediate postoperative baseline periapical radiograph (A), and periapical radiograph (B), vestibular (C) and occlusal (D) view at 4 months after loading.*

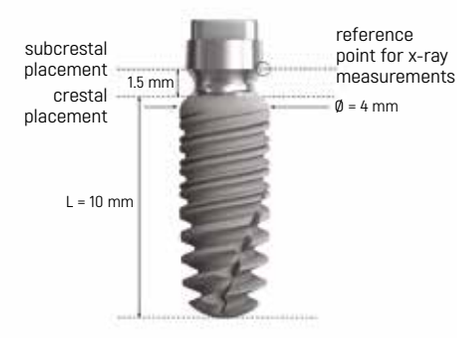


FIG. 5: *Schematic illustration of how implants were positioned (crestally or 1.5 mm subcrestally); please note the implant reference point used for the radiographic evaluation.*

Clinical procedures

Preoperative radiographs were taken using the method most appropriate to the individual clinical case, i.e. periapical, panoramic or cone-beam computed tomography (CBCT). All patients underwent at least one oral hygiene session in the week prior to implant placement. Patients received a single dose of prophylactic antibiotic 1 hour prior to the intervention (either 2 g of amoxicillin or 600 mg of clindamycin if allergic to penicillin), and rinsed with chlorhexidine mouthwash 0.2% for 1 minute prior to the intervention. Patients were treated under local anaesthesia using articaine with epinephrine 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 the operator was informed at which depth to prepare the implant site for crestal or subcrestal positioning (**FIG. 5**) and whether a screw-retained or a cement-retained crown was to be fitted. Implant sites were prepared as suggested by the implant manufacturer, using drills with increasing diameters and different lengths, according to the random allocation. TwinKon Universal SA2 (GlobalD, Brignais, France) tapered transmucosal threaded implants made of titanium alloy Ti4V6Al (grade 5) and having an external connection were used. The implant surface was roughened using sandblasting and double etching. The operator was free to choose implant lengths (6.0, 8.5, 10.0 or 11.5 mm long) but only the 4 mm diameter was used. According to the random allocation, the

neck of the implant was placed crestally or sunk 1.5 mm subcrestally using as a reference point the most apical peak of the surrounding bone. Healing screws were placed, and flaps were sutured around the implants, which were left to heal transmucosally unloaded for 3 months. A periapical radiograph was taken, which was repeated if the peri-implant marginal bone levels were difficult to assess. Ibuprofen 400 mg was prescribed to be taken 2 to 4 times a day with meals for as long as required. In the event of stomach problems or allergy to non-steroidal anti-inflammatory drugs, 1g of paracetamol was recommended instead. Patients were instructed to use 0.2% chlorhexidine mouthwash for one minute twice a day for 2 weeks, and to avoid brushing and possible trauma to the surgical sites. A soft diet for 2 weeks was recommended. After 10 days, patients were checked and sutures were removed.

After the 3-month unloaded healing period, the stability of individual implants was assessed using reverse torque at 20 Ncm; polyether (Impregum, 3M Espe, St. Paul, MN, USA) impressions were then taken at implant level with pick-up copings. According to the randomisation procedure, either definitive screw-retained or cement-retained metal-composite crowns on identical screw-retained titanium abutments were to be fitted within one week. Crowns were cemented with a radio-opaque provisional cement (TempBond, Kerr Corporation, Orange, CA, USA). A periapical radiograph was taken, and repeated if the peri-implant marginal bone levels were difficult to assess. Oral hygiene instructions were delivered.

Patients are to be recalled every 6 months for maintenance for the entire duration of the study. Dental occlusion will be assessed at each visit.

Outcome measures

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

Outcome measures were the following.

- Crown failure: impossibility of crown fitting due to implant failure or secondary to implant failure, or replacement of a definitive crown for any reason.
- Implant failures: 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 manually with 20 Ncm reverse torque at abutment connection, and thereafter (in this report 4 months after loading) by rocking the crown using the handles of two metal instruments.
- Any biological or biomechanical complications, i.e. fistula or peri-implantitis, and abutment screw loosening or fracture, respectively.
- Peri-implant marginal bone level changes: evaluated on digital periapical radiographs taken with the paralleling technique at implant placement, initial loading and 4 months after loading. A second radiograph was taken if the first was unreadable. Radiographs were saved in TIFF format with 600-dpi resolution and stored on a personal computer. Peri-implant marginal bone levels were measured using OsiriX (Pixmeo Sarl, Bernex, Switzerland) software. The software was calibrated for each individual image using the known implant length or, in the case of periapical radiographs not containing the full implant length, the height of the implant collar. 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 apical margin of the implant collar (**FIG. 5**) and the most coronal point of visible bone-to-implant contact. Measurements taken 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. Barausse).

- Aesthetic evaluation on the vestibular and occlusal images taken at delivery of the definitive crowns (4 months after initial loading), including one adjacent tooth per side[14]: performed on a computer screen by a blinded dentist (Dr. Barausse) using the pink aesthetic score (PES). 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 satisfaction: at 4 months after loading the patients were asked the following questions by the local blind assessor:
  - 1) "Are you satisfied with the function of your implant-supported tooth?" Possible answers were: "yes, totally", "yes, partially", "not sure", "not really", or "absolutely not". Patients were asked to provide reasons if they responded "not sure", "not really" or "absolutely not";
  - 2) "Are you satisfied with the aesthetic outcome of your implant-supported tooth?" Possible answers were: "yes, totally", "yes, partially", "not sure", "not really", or "absolutely not". Patients were asked to provide reasons if they responded "not sure", "not really" or "absolutely not";
  - 3) "Would you undergo the same treatment again?" Possible answers were "yes" or "no". Patients who responded "no" were to be asked to provide a reason.

A local blind outcome assessor (Dr. Berti) assessed implant stability and recorded patient satisfaction, and another blinded dentist (Dr. Barausse), not involved in the treatment of the patients, evaluated both aesthetic and marginal bone levels; neither assessor had knowledge of group allocation. Complications were handled and reported directly by the treating dentist (Dr. Colombelli), who was not blind.

Statistical analysis

No sample size calculation was performed, but it was agreed that 160 patients would be randomly allocated in equal numbers to each of the four arms under investigation. One computer-generated restricted randomisation list was 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 randomisation list, which was stored on a password-protected laptop. The random codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. The envelope corresponding to each patient's recruitment number was opened after flap elevation, and implants were accordingly placed crestally or subcrestally. Therefore, treatment allocation was 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 dentist (Dr. Buti) with expertise in statistics, who analysed the data without knowledge of the group codes. A comparison of the baseline characteristics between groups is presented. Descriptive statistics were performed employing means and standard deviations for quantitative data and frequencies and percentages for qualitative data. The statistical unit of the analysis was the patient. The primary outcome measure was the aesthetics score.

Differences in continuous outcomes (mean marginal bone level changes and aesthetics as assessed by a dentist) were compared using ANOVA followed by Tukey's HSD post-hoc test to detect between-group differences. Comparisons between the various follow-up endpoints and baseline measurements were made using paired t-tests to detect any changes in mean marginal bone level for each study group.

Differences in crown/implant failures and complications (dichotomous outcomes) were compared between groups using the chi-squared or Fisher's exact test (or Freeman-Halton extension of Fisher's exact test) depending on the count per cell (small cell sizes with values less than 5). The latter tests were also applied to estimate differences between groups in terms of patient satisfaction with aesthetics and function, as there were only two responses recorded (fully vs. partially satisfied) out of the five possible answers, and in terms of responses to the question "would you undergo the same treatment again?". All statistical comparisons were conducted at a 0.05 significance level.

RESULTS

One hundred and sixty-seven patients were screened, and 160 patients were consecutively enrolled in the trial; seven patients were not included because they wanted to receive the best treatment, and, this being the reason for conducting the trial, we were unable to state which it was. All patients were treated according to the allocated interventions.

At the 4-month follow-up, four patients had dropped out for the following reasons.

- Crestally placed implants with screw-retained crowns (Group 1):
  - Patient 23 did not return after suture removal due to financial problems, but reported being fine,
  - Patient 36 could not attend the 4-month follow-up due to orthopaedic surgery. By phone she responded to the satisfaction questionnaire and reported having no issues with her crown.
- Crestally placed implants with cement-retained crowns (Group 2):
  - Patient 155 could not attend the 4-month follow-up because she moved to another town. By phone she reported having no problems with her crown.
- 1.5 mm subcrestally placed implants with screw-retained crowns (Group 3):
  - Patient 29 did not return after suture removal due to financial problems but reported being fine.
- 1.5 mm subcrestally placed implants with cement-retained crowns (Group 4):
  - None

Missing data

- Crestally placed implants with screw-retained crowns (Group 1):
  - Patient 95's images were not taken at 4-month follow-up.
- Crestally placed implants with cement-retained crowns (Group 2):
  - Patient 47's periapical radiograph and images were not taken at 4-month follow-up,
  - Patient 115's periapical radiograph and images were not taken at 4-month follow-up.
- 1.5 mm subcrestally placed implants with screw-retained crowns (Group 3):
  - Patient 136's periapical radiograph and images were not taken at 4-month follow-up.
- 1.5 mm subcrestally placed implants with cement-retained crowns (Group 4):
  - Patient 105's images were not taken at 4-month follow-up,
  - Patient 144's periapical radiograph and images were not taken at 4-month follow-up.

Data from all remaining patients were evaluated in the statistical analyses.

The main deviations from the protocol were the following.

- Patients were supposed to receive metal-composite crowns but the great majority received metal-ceramic crowns instead. Exceptions were the following patients, who receive metal-composite crowns as per the protocol: Group 1 (Patients 2, 31, 35 and 138), Group 2

(Patients 14 and 21), Group 3 (Patient 43) and Group 4 (Patients 52, 68 and 76). Patient 9 (Group 1) received a full resin crown for financial reasons.

- Crestally placed implants with screw-retained crowns (Group 1):
  - Patient 41's crown was fitted 7 months after implant placement due to financial reasons,
  - Patient 99's crown was fitted 8 months after implant placement due to financial reasons,
  - Patient 106 did not show up for the 4-month post-loading appointment, but instead came 8 months after loading,
  - Patient 137 did not show up for the 4-month post-loading appointment, but instead came 7 months after loading.
- Crestally placed implants with cement-retained crowns (Group 2):
  - Patient 33's crown was fitted 6 months after implant placement due to financial reasons,
  - Patient 50 went abroad for work and the crown was fitted 7 months after implant placement.
- 1.5 mm subcrestally placed implants with screw-retained crowns (Group 3):
  - Patient 14's crown was fitted 6 months after implant placement due to financial reasons.
- 1.5 mm subcrestally placed implants with cement-retained crowns (Group 4):
  - Patient 132 did not show up for the 4-month post-loading appointment, but instead came 6 months after loading.

Patients were recruited and received the implants from September 2016 to June 2019. The follow-up of all patients remaining in the study was to 4 months after implant loading.

TABLE 1 PATIENT AND INTERVENTION CHARACTERISTICS

	Group 1 n = 40	Group 2 n = 40	Group 3 n = 40	Group 4 n = 40
Females	19 (48%)	18 (45%)	21 (53%)	21 (53%)
Mean age (range)	55.8 (32 to 75)	56.2 (37 to 75)	55.0 (38 to 77)	56.6 (35 to 79)
No smokers	32 (80%)	32 (80%)	34 (85%)	32 (80%)
Smoking up to 10 cigs./day	5 (12.5%)	6 (15%)	3 (7.5%)	6 (15%)
Smoking more than 10 cigs./day	3 (7.5%)	2 (5%)	3 (7.5%)	2 (5%)
Implants in first upper premolar position	3 (7.5%)	4 (10%)	2 (5%)	6 (15%)
Implants in second upper premolar position	5 (12.5%)	6 (15%)	7 (17.5%)	8 (20%)
Implants in first upper molar position	7 (17.5%)	4 (10%)	6 (15%)	5 (12.5%)
Implants in second upper molar position	2 (5%)	1 (2.5%)	1 (2.5%)	0 (0%)
Implants in first lower premolar position	2 (5%)	4 (10%)	1 (2.5%)	2 (5%)
Implants in second lower premolar position	2 (5%)	3 (7.5%)	2 (5%)	2 (5%)
Implants in first lower molar position	17 (42.5%)	13 (32.5%)	17 (42.5%)	14 (35%)
Implants in second lower molar position	2 (5%)	5 (12.5%)	4 (10%)	3 (7.5%)
Implants 6.0 mm in length	2 (5%)	3 (7.5%)	1 (2.5%)	4 (10%)
Implants 8.5 mm in length	27 (67.5%)	17 (42.5%)	27 (67.5%)	21 (52.5%)
Implants 10.0 mm in length	8 (20%)	19 (47.5%)	10 (25%)	12 (30%)
Implants 11.5 mm in length	3 (7.5%)	1 (2.5%)	2 (5%)	3 (7.5%)

Group 1: crestal + screw-retained; Group 2: crestal + cement-retained; Group 3: 1.5 mm subcrestal + screw-retained; Group 4: 1.5 mm subcrestal + cement-retained

Patient and implant characteristics are described by study arm in **TABLE 1**. There were no apparent significant baseline imbalances between the four groups.

- Crown and implant failures (**TABLE 2**): two implants failed, one from Group 2 and one from Group 4. The differences in proportions of implant failures between groups was not statistically significant (P = 1.000). Both failed implants were successfully replaced and loaded with similar implants, but data regarding the replacement implants was not recorded, being beyond the scope of the present study.
- Complications (**TABLE 2**): four patients from Group 1, one from Group 2, two from Group 3, and six from Group 4 were affected by complications, but differences between groups were not statistically significant (P = 0.207).

TABLE 2 DESCRIPTION OF FAILURES AND COMPLICATIONS IN CHRONOLOGICAL ORDER AND BY STUDY GROUP

Pat. #, position*, timing	Description	Outcome
Failures of implants positioned crestally with cement-retained crowns (Group 2)		
#28, 15, 3m p-i	Discomfort & implant mobility at abutment connection	Successfully replaced
Failures of implants positioned 1.5 mm subcrestally with cement-retained crowns (Group 4)		
#28, 26, 3m p-l	Discomfort, implant mobility & peri-implant radiolucency	Successfully replaced
Complications at implants positioned crestally with screw-retained crowns (Group 1)		
#138, 16, 3m p-l	Crown unscrewed and loss of composite at the access screw hole	Crown retightened at 20 Ncm and closure of the screw access hole with composite
#31, 36, 4m p-l	Crown unscrewed	Crown retightened at 20 Ncm
#35, 36, 4m p-l	Crown unscrewed	Crown retightened at 20 Ncm
#96, 16, 4m p-l	Loss of composite at the access screw hole	Closure of the screw access hole with composite
Complications at implants positioned crestally with cement-retained crowns (Group 2)		
#28, 15, 3m p-i	Discomfort & implant mobility at abutment connection	Successfully replaced
Complications at implants positioned 1.5 mm subcrestally with screw-retained crowns (Group 3)		
#43, 26, p-o	Bleeding	Patient compressed the area with gauzes soaked with tranexamic acid
#14, 46, 2m p-i	Healing screw loosened	Retightened
Complications at implants positioned 1.5 mm subcrestally with cement-retained crowns (Group 4)		
#5, 15, 10 days p-i	Buccal recession of 2 mm at tooth #14	Recession remained
#68, 44, 2m p-i #68, 44, 1m p-l	Lost healing screw and implant spontaneously submerged Discomfort at the gingival margin showing redness	Implant left submerged until abutment connection Supragingival scaling, crown cleaned and reshaped, 1% chlorhexidine gel twice a day for 2 weeks. Total resolution
#76, 45, 3m p-l	Peri-implant mucositis	Supragingival scaling, crown and abutment cleaned, 1% chlorhexidine gel twice a day for 2 weeks. Total resolution
#28, 26, 3m p-l	Discomfort, implant mobility & peri-implant radiolucency	Successfully replaced
#100, 46, 4m p-l	Crown decemented	Recemented
#116, 16, 4m p-l	Crown decemented	Recemented

**implant position; m p-i = months post-implantation; m p-l = months post-loading; p-o = post-operatively*

TABLE 3 PES SCORES AT 4 MONTHS AFTER LOADING BY GROUP AND BY DIFFERENT AESTHETIC DOMAIN (SD IN PARENTHESIS)

	Mesial papilla	Distal papilla	Soft tissue level	Soft tissue contour	Alveolar process deficiencies	Soft tissue colour	Soft tissue texture	Total PES score
Group 1 N = 37	1.54 (0.51)	1.51 (0.56)	1.70 (0.46)	1.57 (0.50)	1.19 (0.52)	1.46 (0.51)	1.32 (0.47)	10.30 (2.13)
Group 2 N = 36	1.56 (0.56)	1.50 (0.61)	1.72 (0.51)	1.53 (0.56)	1.19 (0.62)	1.39 (0.64)	1.33 (0.59)	10.22 (2.76)
Group 3 N = 38	1.58 (0.64)	1.53 (0.65)	1.74 (0.45)	1.58 (0.50)	1.16 (0.55)	1.50 (0.73)	1.39 (0.64)	10.47 (2.96)
Group 4 N = 37	1.57 (0.50)	1.54 (0.56)	1.73 (0.51)	1.59 (0.50)	1.16 (0.55)	1.54 (0.51)	1.38 (0.49)	10.51 (2.24)
P-value	0.9920	0.9926	0.9913	0.9532	0.9891	0.7395	0.9342	0.9541

Group 1: crestal + screw-retained; Group 2: crestal + cement-retained; Group 3: 1.5 mm subcrestal + screw-retained; Group 4: 1.5 mm subcrestal + cement-retained

- Aesthetics (**TABLE 3**): four months after loading, the average total PES scores, assessed by a blind assessor, were 10.30 ± 2.13 (Group 1), 10.22 ± 2.76 (Group 2), 10.47 ± 2.96 (Group 3), and 10.51 ± 2.24 (Group 4), respectively, the difference not being statistically significantly different (P = 0.9541). Likewise, there was no statistically significant difference between the four groups when assessing the individual aesthetic domains.
- Peri-implant marginal bone levels (**TABLE 4A**): bone levels at implant insertion (baseline) were 1.37 mm ± 0.15 for Group 1, 1.39 mm ± 0.14 for Group 2, 0.05 mm ± 0.06 for Group 3, and 0.07 mm ± 0.18 for Group 4, with implants in both subcrestally placed groups being in a statistically significantly deeper position than crestally placed implants (P = <0.0001*). At initial loading, peri-implant marginal bone loss was -0.10 ± 0.15 for Group 1, -0.10 ± 0.15 for Group 2, -0.11 ± 0.21 for Group 3, and -0.11 ± 0.12 for Group 4, the differences between groups not being statistically significant (P = 0.9848; **TABLE 4B**). At 4-month post-loading, peri-implant marginal bone loss was -0.21 ± 0.28 for Group 1, -0.25 ± 0.27 for Group 2, -0.28 ± 0.57 for Group 3, and -0.24 ± 0.26 for Group 4, the differences between the four groups not being statistically significant (P = 0.9011; **TABLE 4B**).

TABLE 4A MEAN RADIOGRAPHIC PERI-IMPLANT MARGINAL BONE LEVELS BETWEEN GROUPS AND TIME PERIODS UP TO 4 MONTHS AFTER LOADING

	Implant placement				Loading				4-month post loading			
	N	Mean	(SD)	[95% CI]	N	Mean	(SD)	[95% CI]	N	Mean	(SD)	[95% CI]
Group 1	40	1.37	(0.15)	[1.32 to 1.42] A	39	1.47	(0.21)	[1.40 to 1.54] A	38	1.58	(0.31)	[1.48 to 1.68] A
Group 2	40	1.39	(0.14)	[1.34 to 1.43] A	39	1.50	(0.20)	[1.44 to 1.57] A	36	1.64	(0.29)	[1.54 to 1.74] A
Group 3	40	0.05	(0.06)	[0.03 to 0.06] B	39	0.15	(0.23)	[0.08 to 0.23] B	38	0.32	(0.59)	[0.13 to 0.52] B
Group 4	40	0.07	(0.18)	[0.01 to 0.13] B	40	0.18	(0.23)	[0.11 to 0.26] B	38	0.31	(0.32)	[0.20 to 0.41] B
P-value	<0.0001*				<0.0001*				<0.0001*			

**Statistically significant difference; levels not connected by the same letter are statistically significantly different*

TABLE 4B MEAN RADIOGRAPHIC PERI-IMPLANT MARGINAL BONE LEVEL CHANGES BETWEEN GROUPS AND TIME PERIODS UP TO 4 MONTHS AFTER LOADING.

	Baseline to loading				Baseline to 4 months post-loading			
	N	Mean	(SD)	[95% CI]	N	Mean	(SD)	[95% CI]
Group 1	39	-0.10	(0.15)	[-0.15 to -0.05]	38	-0.21	(0.28)	[-0.30 to -0.12]
Group 2	39	-0.10	(0.15)	[-0.15 to -0.06]	36	-0.25	(0.27)	[-0.34 to -0.16]
Group 3	39	-0.11	(0.21)	[-0.18 to -0.04]	38	-0.28	(0.57)	[-0.46 to -0.09]
Group 4	40	-0.11	(0.12)	[-0.15 to -0.08]	38	-0.24	(0.26)	[-0.33 to -0.16]
P-value	0.9848				0.9011			

*All statistically different changes from baseline (P < 0.05). *Statistically significant difference*

- Patient satisfaction with function and aesthetics at 4 months after initial loading: These criteria were not assessed in patients who experienced an implant failure. All remaining patients were fully satisfied with both function and aesthetics, with the exceptions of seven patients who were only partially satisfied. In particular one patient from Group 1 was only partially satisfied with both function and aesthetics, one patient from Group 3 and three patients from Group 4 were only partially satisfied with function, and one patient from Group 3 and one from Group 4 were only partially satisfied with aesthetics. Nevertheless, there were no statistically significant differences between groups in patient satisfaction with either function (P = 0.400) or aesthetics (P = 1.000), and all patients stated that they would undergo the same intervention again.

DISCUSSION

This trial was designed to evaluate whether it would be more advantageous to place transmucosal implants in posterior jaws crestally or 1.5 mm subcrestally. At the same time it was tested whether it would be preferable to use screw-retained or cement-retained crowns.

No statistically significant differences or trends in this regard were noted up to 4 months after loading. Having said this, no firm conclusions can yet be drawn due to the brief duration of the follow-up period in this preliminary report. While awaiting subsequent findings from this trial, which is scheduled to last 7 years, there are no clinical contraindications for subcrestal implantation, at least at the depths evaluated in the present trial, and the decision whether to use screw-retained or cemented-retained crowns is at the discretion of the clinician. That being said, in the case of severely atrophic bone, it might be sensible to place implants crestally in order to exploit the full bone support for the time being, even though it cannot be excluded that a difference in bone loss could become evident over time; longer follow-ups with the same patient cohorts will be necessary to test this hypothesis.

With respect to crestal or 1.5 mm subcrestal positioning, our early findings are in general agreement with those of other similar RCTs[2-5,7], even though implants with different designs or for different indications were used in such cases. However, it should be noted that when implants were crestally placed, some statistically significant differences in bone loss have been reported. For instance one RCT[4], evaluating crestal and subcrestal (1 and 2 mm) placement of platform-switched implants with a Morse-taper connection, reported 0.27 mm greater bone loss for implants positioned at the crestal level 1 year after loading. In contrast, in a split-mouth multicentre RCT[7] with a 3-year post-loading follow-up that compared implants placed

0.5 or 1.5 mm subcrestally in 60 patients, a statistically significant difference of 0.15 mm in bone loss in favour of the 1.5 mm group was observed. However, this difference was not considered clinically significant. Another RCT[5], which compared platform-switched implants placed crestally or 1 mm subcrestally showed 0.65 mm more bone loss at subcrestally placed implants 3 years after loading. However, there is no evidence that such differences in bone loss affected either aesthetics or any other clinical parameter.

Similarly, most of the trials comparing screw-retained *versus* cement-retained restorations showed not clinically relevant differences between the two prosthetic options[8-12], and these results are in perfect agreement with the present finding. There was only one exception, a poorly-reported trial favouring partial fixed cement-retained restorations over screw-retained ones[13].

Put simply, neither crestal or 1.5 mm subcrestal positioning of implants in healed sites nor the use of screw- or cement-retained crowns appear to have any clinically appreciable consequences for patients in the very short term. However, aside from the brevity of the follow-up reported here, the main limitation of this trial is the relatively low number of patients included. Nonetheless, to the best of our knowledge, this is the trial with the largest sample size ever published, and we plan to follow these patients up to 7 years after loading.

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

CONCLUSIONS

No appreciable clinical differences were noted when placing transmucosal implants in posterior jaws crestally or 1.5 mm subcrestally, or between rehabilitation with screw-retained or cement-retained crowns. However, a longer follow-up is needed in order to formulate reliable clinical recommendations.

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