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TO SPLINT OR NOT TO SPLIT SHORT DENTAL IMPLANTS UNDER THE SAME PARTIAL FIXED PROSTHESIS: FIVE-YEAR RESULTS FROM A MULTICENTRE RANDOMIZED CONTROLLED TRIAL

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PURPOSE. To compare the clinical outcomes of two adjacent 6-mm-long dental implants splinted under the same prosthesis (control/splinted group) *versus* two identical implants supporting single crowns (test/unsplinted group).

MATERIALS AND METHODS. Forty-seven patients with edentulous posterior (premolars and/or molars) jaws received two adjacent 6-mm-long dental implants, which were submerged. Four months after, at impression taking, patients were randomized to receive either splinted or unsplinted cemented metal-ceramic definitive prostheses. Unfortunately, four patients died before randomization and three patients lost five implants, so only 40 patients were randomized, according to a parallel group design, to have both implants splinted under the same partial fixed prosthesis (19 patients) or to have them rehabilitated with two single crowns (21 patients, the unsplinted group). Outcome measures were: prosthesis and implant failures, complications, peri-implant marginal bone level changes and patient satisfaction. Patients were followed up to five years after loading.

RESULTS. After randomization, four patients dropped out from the splinted group and seven from the unsplinted one. One patient in each group had prosthesis/implant failures (Fisher's exact test P = 1.000; difference in proportions = 0.01; 95% CI -0.21, 0.23). Seven complications occurred in four patients with splinted implants *versus* five complications in three patients from the unsplinted group, the difference not being statistically different (Fisher's exact test P = 1.000; difference in proportions = -0.04; 95% CI -0.32, 0.27). At 5-year post-loading, patients with splinted implants lost -0.27 ± 0.53 mm of peri-implant marginal bone, as compared to -0.14 ± 0.26 mm in patients with unsplinted implants, the difference between groups not being statistically significant (P = 0.457; mean difference 0.13 mm; 95% CI -0.23 to 0.50).
There were no statistically significant differences between groups in terms of function, aesthetics or willingness to undergo the same intervention again (difference in proportions = -0.07; 95% CI -0.31, 0.19, Fisher's exact test P = 1.000).

CONCLUSIONS. This data seems to suggest that, up to five years after loading, the prognosis of short implants, mostly placed in mandibles characterised by dense bone quality, may not be influenced by splinting them or not under the same fixed prostheses. However, these preliminary results need to be confirmed by larger trials with follow-ups of at least five years.

CONFLICT OF INTEREST STATEMENT
Micerium (Avegno, Italy) partially supported this trial and donated the implants and prosthetic components used in the present investigation; however, the data belonged to the authors and Micerium by no means interfered in the conduct of the trial or the publication of its results.

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INTRODUCTION

Short dental implants (4 to 8 mm long)[1] have been shown to be an interesting and less invasive alternative to bone augmentation procedures to place longer implants, showing similar results up to 11 years after loading[2-12]. However, it is not yet clear whether or not it is better to join two or more short implants under the same prosthesis to decrease the potential risks of failure or mechanical complications such as screw loosening. Theoretically, it would be logical to think that joining short implants under the same fixed prosthesis could provide a more favourable load distribution. Unfortunately, however, only opinion-based recommendations are given as there have been no randomized controlled trials (RCTs) to test this hypothesis.

The aim of this randomized controlled trial (RCT) of parallel-group design was therefore to compare the clinical outcomes of two adjacent 6-mm-long dental implants splinted under the same prosthesis (control/splinted group) *versus* two identical implants supporting single crowns (test/unsplinted group). The test hypothesis was that there would be no differences between the two procedures, against the alternative hypothesis of a difference. This report presents the findings 5 years after loading. One-year data have previously been published[13]. This article is reported according to the CONSORT statement for improving the quality of reports of parallel-group randomized trials (http://www.consort-statement.org/).

MATERIALS AND METHODS

Study design

This trial was designed as a multicentre randomized controlled trial of parallel-group design with independent assessment, with the exception of complications and related failures, which were recorded by the treating dentists.

Inclusion/exclusion criteria

Any patient of 18 years of age with partially edentulous posterior jaw (premolars and/or molars) requiring at least two adjacent dental implants of length 6 mm and diameter 5 mm and able to understand and sign informed consent was eligible for inclusion in this trial.

Patients were not enrolled in the study if any of the following exclusion criteria applied:

- general contraindications to implant surgery;
- previous irradiation of the head and neck area;
- immunosuppression or immunocompromise;
- previous or ongoing treatment with intravenous aminobisphosphonates;
- untreated periodontitis;
- poor oral hygiene and motivation;
- uncontrolled diabetes;
- pregnancy or lactation;
- substance abuse;
- psychiatric problems or unrealistic expectations;
- lack of opposing occluding dentition/prosthesis in the area intended for implant placement;
- acute/chronic infection/inflammation in the area intended for implant placement;
- participation in other trials precluding proper adherence to the study protocol;
- referral for implant placement alone and inability to follow up at the treating centre;
- extraction sites with less than 3 months of healing;
- inability to follow up for 5 years.

Patients were categorised into three groups according their declarations: non-smokers, moderate smokers (up to 10 cigarettes per day), and heavy smokers (more than 10 cigarettes per day).

Patients were recruited and treated at eight different Italian private practices using a similar procedure, and each centre was supposed to treat 10 patients. The centres were the following: Rome (Dr. Marco Tallarico), Parabiago (Dr. Fulvio Gatti), Arzachena (Dr. Mario Silvio Meloni), Siena (Dr. Leonardo Muzzi), Florence (Dr. Nicola Baldini), Bari (Dr. Armando Minciarelli), Terme Vigliatore (Dr. Gaetano Iannello), and Montevarchi (Dr. Mauro Billi).

Patients were assessed to establish their eligibility for the study. A preoperative cone-beam computed tomography (CBCT) scan was obtained for every potentially eligible patient to quantify bone volumes at the planned implant sites. Patients having sufficient bone volumes to receive two 6-mm-long, 5-mm-wide implants at two adjacent sites were invited to join and informed of the nature of the study. Only after they fully understood what it entailed were they asked to sign informed written consent.

Clinical procedures

About 10 days prior to implant placement, all patients were subjected to professionally delivered oral hygiene, including debridement as required.

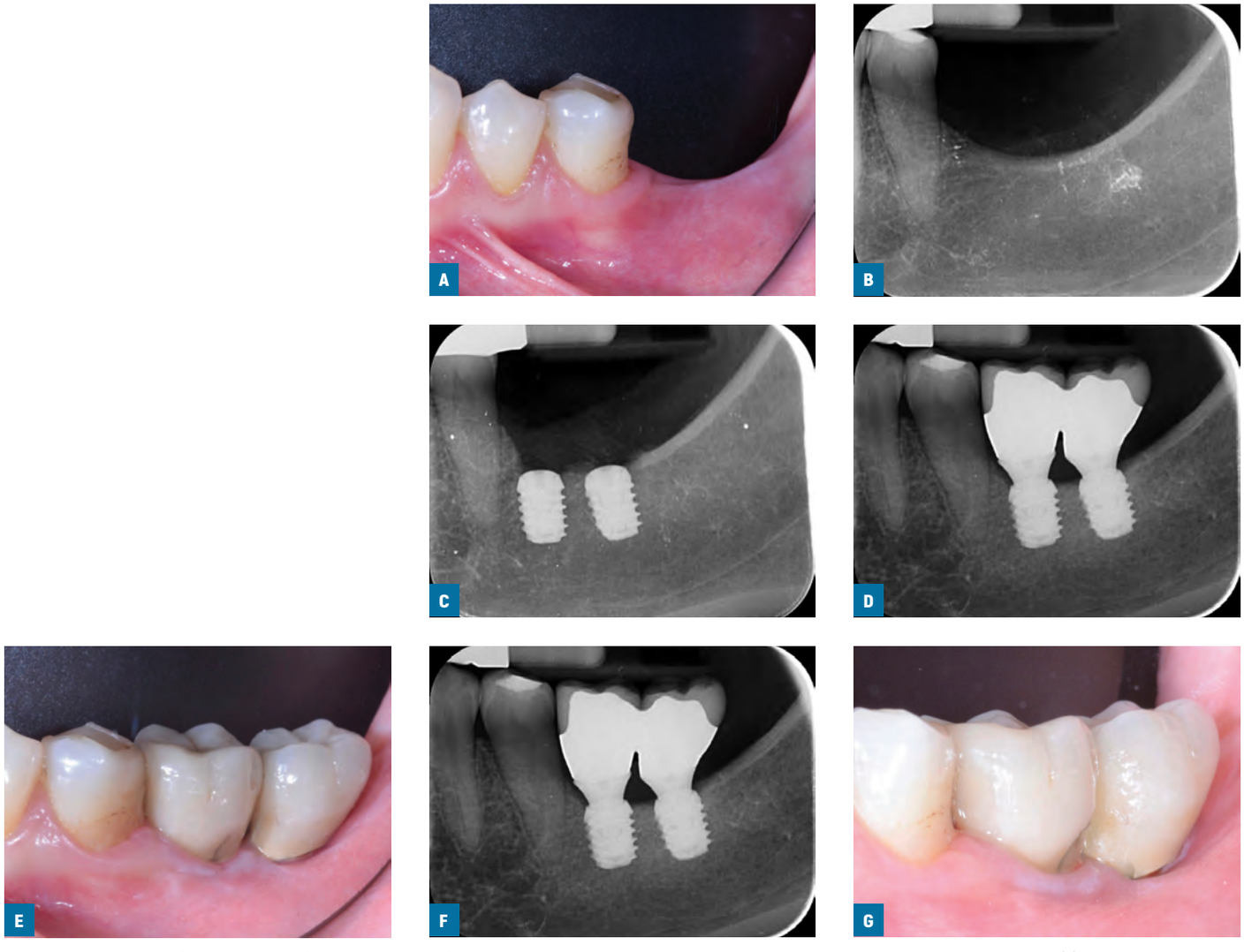
All patients received prophylactic antibiotic therapy: 2 g of amoxicillin one hour prior to the intervention. Patients allergic to penicillin were given clindamycin 600 mg one hour before implant placement. All patients rinsed with 0.2% chlorhexidine mouthwash for one minute prior to any surgical procedure and were treated under local anaesthesia using articaine with adrenaline 1:100,000. After crestal incision and full-thickness flap elevation, the two adjacent implant sites were prepared under prosthetic guidance using a surgical template. The standard placement procedure was adopted, as recommended by the manufacturer. Drills of increasing diameters were used to prepare the implant sites. Bone quality was subjectively reported as hard, medium or soft. The motor was set with a torque of 25 Ncm during implant insertion. The implants used were OSSTEM IMPLANT TSIII SA (Seoul, South Korea). These are tapered self-tapping implants with internal connection, diameter 5 mm and length 6 mm, with a 1-mm bevel (TS3S5005S). They are made of grade 4 titanium and 5 mm of their surface is sandblasted and acid-etched (SA) while the 1-mm bevel surface is only acid-etched (RA 0.3~0.5μm). Implants were to be placed at crestal level with their coronal portion flush to the surrounding bone. Cover screws were placed, implants were submerged, and flaps closed with Vicryl 4.0 sutures.

Baseline periapical radiographs of the study implants were taken using the paralleling technique. If the peri-implant marginal bone levels were unreadable or difficult to measure, a new radiograph was to be taken. Ibuprofen 400 mg was prescribed to be taken two to four times a day during meals, as long as required. In the event of allergy or gastric issues, 1 g paracetamol was prescribed instead. Patients were instructed to use 0.2% chlorhexidine mouthwash for one minute twice a day for two weeks, to eat a soft diet for one week, and to avoid brushing and trauma to the surgical sites. No removable denture that could load the study implants was allowed for one month. Sutures were removed after seven to ten days.

After 4 months of submerged healing, the implants were exposed and manually tested for stability using a torque of 30 Ncm. Healing abutments were placed, and impressions were taken about two weeks after; screw-retained pick-up impression copings were taken at implant level using a polyether material (ImpregumTM, 3M ESPE, Seefeld, Germany) and customised open impression trays. Once the healing abutments had been placed, patients were randomized according to a parallel-group design to receive either a fixed partial prosthesis

rigidly connecting the two adjacent implants (splinted group; **FIGS. 1A-G**) or two single crowns (unsplinted group; **FIGS. 2A-G**), by opening the sequentially numbered envelope corresponding to the patient recruitment number.

Within one month, after having tested the stability of the individual implants, either definitive cement-retained metal-ceramic crowns or a fixed partial prosthesis rigidly joining the two implants were cemented with provisional cement (ImplaCem Automix, Dentalica, Milan, Italy) on Osstem transfer abutments for cement-retained restorations according to the random allocation. Abutments were customised in the lab when necessary. The occlusal surfaces were in light contact with the opposing dentition. Periapical radiographs and clinical pictures of the study implants were taken. If the peri-implant marginal bone levels were unreadable, a new radiograph was taken. Oral hygiene instructions were delivered.

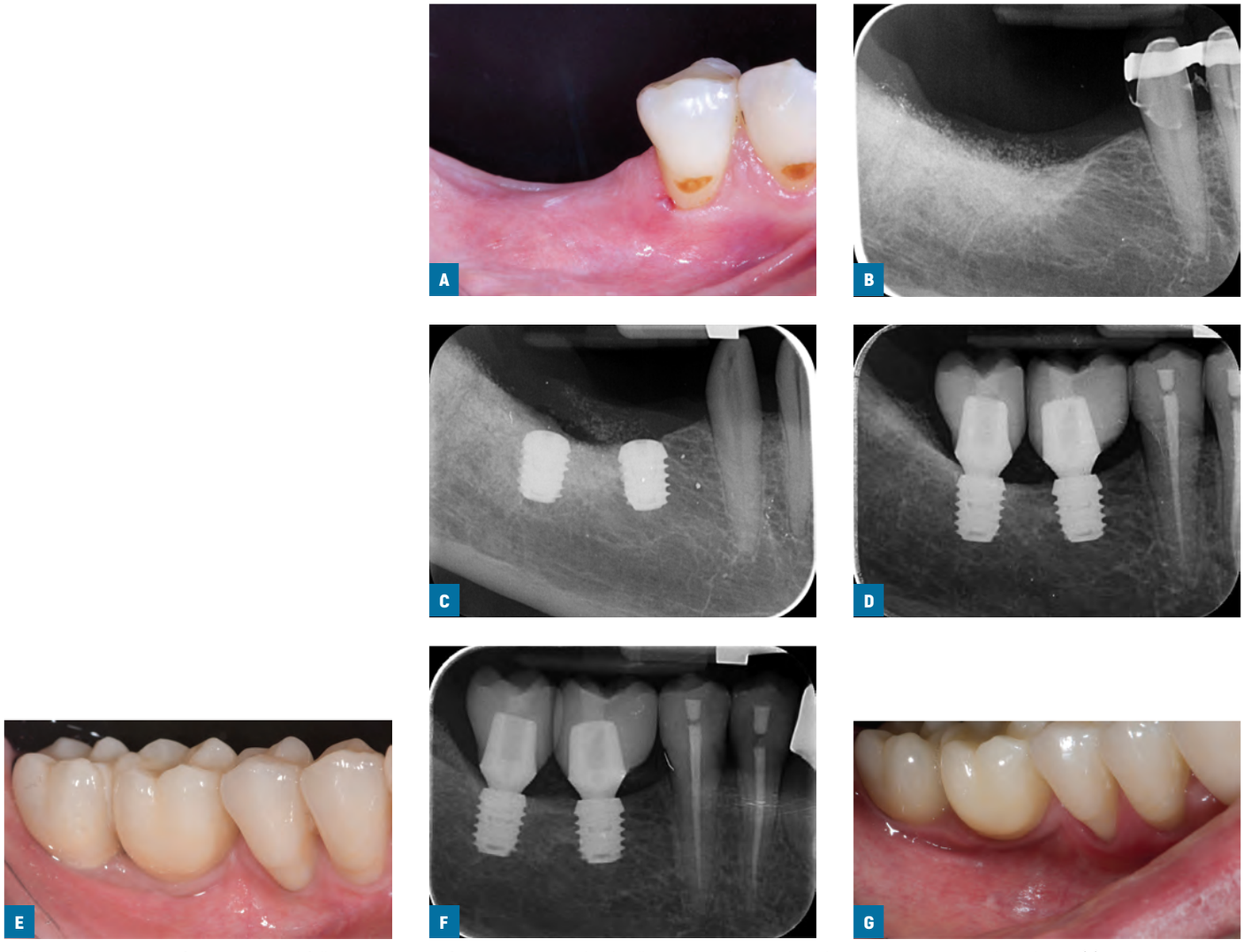


FIGS. 1A-G: *Sequence of treatment and follow-ups in one of the patients randomly allocated to the splinted group: preoperative clinical view (A) and periapical radiograph (B); baseline periapical radiograph (C); periapical radiograph (D) and clinical view at initial loading (E); periapical radiograph (F) and clinical view at five years after implant loading (G).*

One month after, patients were recalled for a check-up and to evaluate their satisfaction. Patients were enrolled in an oral hygiene programme with recall visits at least every six months for the entire duration of the study. Dental occlusion was assessed at each follow-up visit. Follow-ups were conducted by local independent outcome assessors together with the surgical operators.

Outcome measures

This study tested the null hypothesis that there would be no differences between the two procedures, against the alternative hypothesis of a difference.
Outcome measures were the following.



FIGS. 2A-G: *Sequence of treatment and follow-ups in one of the patients randomly allocated to the unsplinted group: preoperative clinical view (A) and periapical radiograph (B); baseline periapical radiograph (C); periapical radiograph (D) and clinical view at initial loading (E); periapical radiograph (F) and clinical view at five years after implant loading (G).*

- Prosthesis failures: loss of the prosthesis secondary to implant failure(s), or replacement of the prosthesis for any reasons.
- Implant failures: implant mobility, removal of stable implants dictated by progressive marginal bone loss or infection, or any mechanical failure rendering the implant unusable, such as implant fracture or deformation of the implant–abutment connection. Stability of individual implants was measured by local independent assessors, who were not informed of the nature of the study, manually tightening the screws with a torque of 30 Ncm at abutment fitting (four months after implant placement), initial loading (one month after delivery of the provisional prostheses). Partial fixed prostheses should have been removed at one and five years after loading to evaluate the stability of individual implants, whereas the stability of single implants was assessed by rocking the crown with the metal handles of two dental instruments.
- Any biological or prosthetic complications were reported.
- Peri-implant marginal bone level changes: these were evaluated on digital intraoral radiographs taken with the paralleling technique at implant placement, initial loading and five years after loading. In the event of not properly readable radiographs, new radiographs were taken. A central outcome assessor (Dr. Erta Xhanari) measured peri-implant marginal bone levels using Scion Image (Scion Corporation, Frederick, MD, USA) software. The software was calibrated for every single image using the known distance between the first two consecutive coronal threads. 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 to be the coronal margin of the implant collar; however, the actual reference point used was the interface between the threads (SA surface) and the implant bevel (**FIG. 3**), and the most coronal point of bone-to-implant contact. Implants with bone up to the coronal margin of the implant collar were assigned a value of zero. Measurements mesial and distal to each implant were averaged, and means were calculated at patient level and then at group level.
- Patient satisfaction: at one and five years after loading, the independent outcome assessor at each centre asked the patients the following questions: 'Are you satisfied with the function of your implant-supported prosthesis?' and 'Are you satisfied with the aesthetic outcome of your implant-supported prosthesis?'. Possible answers were: 'Yes, absolutely', 'Yes, partially', 'Not sure', 'Not really', and 'Absolutely not'. Patients were also asked 'Would you undergo the same treatment again?' Possible answers were: 'Yes' or 'No'.

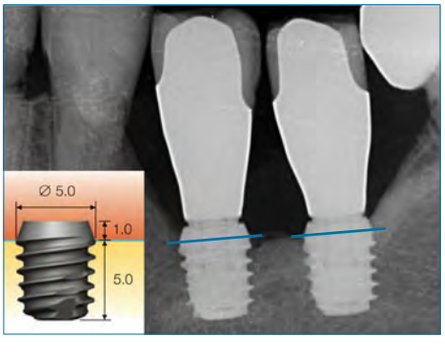


FIG. 3: *The actual reference points used in the present investigation (blue line). This is a protocol deviation, since at protocol stage it was decided to use the coronal margin of the implant collar.*

One independent assessor at each centre, blind to the interventions, took all measurements, with the exception of complications and some failures, which were managed and reported directly by the treating dentist. One single central outcome assessor (Dr. Erta Xhanari), not involved in the treatment of the patients, measured all peri-implant marginal bone levels, without knowing group allocation. However, it was possible to discriminate between single crowns and partial fixed prostheses on the radiographs.

Sample size

The sample size was calculated for the primary outcome measure (implant failure): a two-group continuity corrected chi-squared test with a 0.050 two-sided significance level will have 80% power to detect the difference between a proportion of 0.100 and a proportion of 0.300 for patients experiencing at least one implant failure (odds ratio of 3.857) when the sample size in each group is 72. However, it was decided to include only 40 patients in each group, since that was our realistic recruitment capacity over a 2-year recruitment period.

Randomization and allocation concealment

Eight restricted randomization lists were computer-generated. Only one of the investigators (Dr. Marco Esposito), not involved in the selection and treatment of the patients, was aware of the randomization sequence and could have access to the randomization lists, stored on his password-protected laptop computer. The randomized codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially after impression-taking, thereby concealing treatment allocation to the investigators in charge of enrolling and treating the patients.

Statistical analyses

All data analysis was carried out according to a pre-established analysis plan. The patient was the statistical unit of the analyses. A dentist with expertise in statistics (Dr. Jacopo Buti) analysed the data without knowing group allocation. Differences in the proportions of patients with prosthesis failures, implant failures and complications (dichotomous outcomes) were compared between groups using Fisher's exact probability test, and between centres using the Freeman–Halton extension of Fisher's exact test (when cell count <5). Paired t-tests were used to compare the mean radiographic measurement at implant placement, initial loading, and at 1 and 5 years after loading. Unpaired t-tests were used to compare the mean radiographic marginal bone level changes between groups. Comparisons of satisfaction with function and aesthetics between groups and between centres were made via Fisher's exact probability test and the Freeman-Halton extension of Fisher's Exact test (when cell count <5), respectively, as outcomes reported fell only into two (fully vs. partially satisfied) out of the five categories (with the exception of one patient who was 'not sure' and was grouped together with the 'not fully satisfied' group). Fisher's exact probability test was used to compare the groups' willingness to undergo the same intervention again. All statistical comparisons were conducted at the 0.05 level of significance. A modified intention-to-treat analysis was applied.

RESULTS

Forty-seven patients were considered eligible and were consecutively enrolled in the trial. Each centre was supposed to enrol 10 patients, who were to be randomized into two equal groups of five patients each; however, only one centre (Rome) recruited 10 patients. The remaining centres recruited nine patients (Parabiago and Arzachena), seven patients (Florence), six patients (Siena), four patients (Bari) or one patient (Montevarchi and Terme Vigliatore). One patient at the Florence centre was actually treated twice and originally presented as two different patients; while the actual number of patients was six, we included the data as if they were from two different patients. Five additional patients were screened for eligibility at three centres, but were not interested in participating in the trial. Unfortunately, four patients died or became comatose, while three other patients lost five implants after implant placement but before randomization and loading.

Due to this under-recruitment, premature patient death or coma (four patients) and implant failures before loading (three patients), rather than the forty patients that should have been allocated to each group, only 19 patients were randomized to the splinted group, and 21 patients to the unsplinted group. Patients were recruited and treated from November 2016 to January 2018. The main baseline patient characteristics of the randomized patients are presented in **TABLE 1**. There were no apparent significant baseline imbalances between the two groups.

TABLE 1 PATIENT AND INTERVENTION CHARACTERISTICS AT RANDOMIZATION

	Splinted (n = 19)	Unsplinted (n = 21*)
Females	12 (63%)	14 (67%)
Mean age at implant insertion (range)	58.8 (44-74)	56.5 (39-80)
Smoking up to 10 cigarettes per day	4 (21%)	2 (10%)
Smoking more than 10 cigarettes per day	1 (5%)	1 (5%)
Total number of implants inserted	38	42
Total number of implants inserted in maxillae	10 (53%)	10 (48%)
Implants in premolar sites	5 (13%)	5 (12%)
Implants in molar sites	33 (87%)	37 (88%)
Implants in soft bone	0 (0%)	0 (0%)
Implants in medium bone	12 (32%)	5 (12%)
Implants in hard bone	26 (68%)	37 (88%)
Implants placed with less than 25 Ncm torque	6 (3 patients)	2 (1 patient)

**One patient was treated twice in the same group and counted as two patients (protocol deviation). The patient dropped out after the 1-year follow-up.*

Protocol deviations

The following protocol deviations were recorded.

- All centres used metal-ceramic prostheses instead of the metal-composite prostheses required by the research protocol.
- The partial fixed prostheses should have been removed at 1 and 5 years after loading to test the stability of individual implants but this was not done.
- The radiographic reference mark (the coronal margin of the implant collar) for measuring bone loss agreed at protocol stage was not used, but instead a lower positioned reference mark was chosen (**FIG. 3**).
- One patient from the Rome centre included in this analysis was not part of the previously published one-year analysis, having been excluded by mistake from the data analysis sheet.

Unsplinted group

- One patient from the Florence centre was actually included and randomized twice to the same treatment procedure and was counted as two patients. Since the patient dropped out after the first year after loading, it was decided not to modify the original number of patients enrolled in the study.
- Two patients received screw-retained disilicate crowns instead of metal-composite ones.
- All the periapical radiographs were not taken in one patient.
- In one patient, a panoramic radiograph was taken instead of a periapical radiograph at baseline, and a periapical radiograph was not taken at loading.
- In one patient, a panoramic radiograph was taken instead of a periapical radiograph at baseline and loading.
- In one patient, a panoramic radiograph was taken instead of a periapical radiograph at loading and one year after loading.

Splinted group

- All the periapical radiographs were not taken in two patients.
- Baseline, loading and 1 year follow-up radiographs were not taken in one patient.
- In one patient, a panoramic radiograph was taken instead of a periapical radiograph at 1 year after loading.

Drop-outs

Before randomization, seven enrolled participants were lost to the study due to death, coma or implant failure.

Details of death/coma were the following

- 1 patient died before impression-taking and delivery of final restoration due to stroke;
- 1 patient died before impression-taking due to cardiac ischaemia;
- 1 patient dropped out before impression-taking due to coma after a car accident;
- 1 patient died before impression-taking from septicaemia following lung infection developed during hospitalization due to cardiac ischaemia.

Details of implant failures before randomization

Before randomization, five implants failed in three patients.

- One failed implant was in position 36 and the patient had pain and swelling with purulent discharge. The implant was removed 3 weeks after placement. The patient refused to have the implant replaced, and a partial fixed prosthesis supported by the remaining short implant and a previously inserted implant was fitted.
- Two implants in positions 36 and 37 in one patient were removed 4 weeks after their placement due to infection.
- Two other implants, in positions 25 and 26, from the same patient were found not to be osseointegrated at abutment connection.

Following randomization, a total of 11 patients dropped out: four patients from the splinted and seven from the unsplinted group.

Splinted group

- One patient dropped out up before the first year after loading for personal reasons: her daughter was getting married and she declared that she was too busy to attend the one-year check-up.
- One patient was last seen at one year after loading, being unwilling to attend later follow-up.
- One patient moved to another town and become unreachable at two years post-loading.
- One patient stopped attending check-ups four years post-loading due to health problems.

Unsplinted group

- One patient moved to another town after the first year after loading.
- Two patients were last seen one year and 18 months after loading, being unwilling to attend later follow-up.
- Two patients (nominally, actually this was the same patient treated twice in the study) dropped out two years after loading: last seen 16 months after loading and unwilling to attend further after a COVID infection.
- The data from two patients were lost, since their respective centres, which originally enrolled only one patient each, did not reply to the request for 5-year data.

The follow-up of all remaining patients was to five years after implant loading. The data from all remaining patients was evaluated in the statistical analyses.

Prosthesis failures: after randomization, one splinted prosthesis (out of 15 patients) failed because of implant failures (peri-implantitis at 35 and 37) *versus* one unsplinted crown (out 14 patients) that failed, together with its implant, in position 37. There was no statistically significant difference in prosthesis failures between the two procedures (Fisher's exact test P = 1.000; difference in proportions = 0.01; 95% CI -0.21, 0.23).
Implant failures: after randomization, two splinted implants in the same patient failed versus one unsplinted implant. There was no statistically significant difference in implant failures between the two procedures (Fisher's exact test P = 1.000; difference in proportions = 0.01; 95% CI -0.21, 0.23). More specifically, the splinted group implants in positions 35 and 36 were removed at four years post-loading, whereas the unsplinted implant in position 37 was removed at five years after loading. All the failed implants were affected by peri-implantitis.
Complications: One complication occurred before loading in one patient, who was then randomly allocated to the unsplinted group; the patient reported persistent post-operative pain at implants in position 36 and 37 that spontaneously ceased after four weeks.
After loading, seven complications occurred in four patients out of the 15 with splinted implants *versus* five complications in three patients out of the 15 in the unsplinted group, the difference not being statistically significant (Fisher's exact test P = 1.000; difference in proportions = -0.04; 95% CI -0.32, 0.27).
Complications in the splinted group were the following.

- Peri-implantitis at both implants in positions 35 and 36 after the first year, treated with non-surgical therapy. Both implants failed at the fourth year after loading.
- Major marginal bone loss after the first year in function; this affected both implants in positions 26 and 27 without no inflammatory signs, and stabilized without any intervention.
- Prosthesis screw loosening twice on distal implant in position 46. After the second loosening the screw was replaced.
- Abutment screw loosening 18 months after loading; the abutment was successfully tightened on the implants in positions 36 and 37

Complications in the unsplinted group were the following.

- Chipping of the ceramic veneer of the crown in position 15 at one year after loading; this was resolved chairside.
- Peri-implantitis affecting both implants in positions 36 and 37 at three years after loading; this was treated with open flap surgery using airflow and dedicated curettes. However, at year five the implant in position 37 was removed.
- Severe peri-implantitis at both implants, in positions 35 and 36, which were supported by less than 1 mm of bone. The patient refused treatment and intends to wait for the implants to become mobile.

Peri-implant marginal bone level changes could be measured at all implant surfaces on the periapical radiographs. No measurements were performed on panoramic radiographs. There were no statistically significant differences in bone levels between the two groups at either implant placement, loading, or at one and five years after loading (**TABLE 2**). Both groups gradually lost marginal peri-implant bone, and this was statistically significant at one year after placement (P <0.05) but not at five years (**TABLE 2**). At five years post-loading, patients with unsplinted implants lost -0.14 ± 0.26 mm compared with -0.27 ± 0.53 mm for splinted implants, the difference between groups not being statistically significant (P = 0.457; mean difference 0.13 mm; 95% CI -0.23 to 0.50; **TABLE 2**).

TABLE 2 COMPARISON OF MEAN MARGINAL BONE LEVELS (SD) IN MM AT IMPLANT PLACEMENT, LOADING, AND ONE AND FIVE YEARS AFTER LOADING BETWEEN THE TWO GROUPS, AND CHANGES FROM BASELINE (LOADING) WITHIN EACH GROUP

	Splinted	Unsplinted	Mean difference	95% CI of the difference	P-value from unpaired sample T-test
	N MEAN (SD)	N MEAN (SD)			
At implant placement	17 0.02 (0.06)	17 0 (0.01)	-0.02	-0.05; 0.02	0.279
At loading	17 0.21 (0.37)	16 0.06 (0.19)	-0.15	-0.36; 0.05	0.138
1-year post-loading	16 0.36 (0.45)	18 0.16 (0.30)	-0.19	-0.47; 0.08	0.159
Mean changes from loading to 1 year	16 -0.14 (0.31)	16 -0.12 (0.20)	0.02	-0.17; 0.21	0.836
P-value from paired t-test from loading to 1 year	0.049*	0.039*			
95% CI of the difference (1-year)	-0.30; 0.03	-0.22; -0.01			
5-year post-loading	12 0.45 (0.72)	14 0.44 (1.03)	-0.01	-0.72; 0.71	0.981
Mean changes from loading to 5 years	12 -0.27 (0.53)	11 -0.14 (0.26)	0.13	-0.23; 0.50	0.457
P-value from paired t-test from loading to 5 years	0.109	0.111			
95% CI of the difference (5-year)	-0.60; 0.07	-0.31; 0.04			

**Statistically significant difference*

TABLE 3 COMPARISON AMONG DIFFERENT CENTRES AT FIVE YEARS AFTER LOADING ONLY FOR THOSE PATIENTS WHO WERE ACTUALLY RANDOMIZED

	Rome	Parabiago	Arzachena	Siena	Florence	Bari	P-value
Drop-out	3/10	2/7	1/6	0/6	2/6	1/3	0.759
Patients with implant failures	0/7	2/5	0/5	0/6	0/4	0/2	0.136
Patients with complications	1/7	2/5	0/5	1/6	1/4	1/2	0.579
Peri-implant bone loss	-0.3 ± 0.47	-0.24 ± 0.38	-0.13 ± 0.29	-0.61 ± 0.90	0	0	0.746
Patients not fully satisfied for function	1/7	1/4	1/5	0/6	0/4	0/2	0.833
Patients not fully satisfied for aesthetics	1/7	1/4	1/5	0/6	0/4	0/2	0.833
Patients not willing to redo intervention	1/7	1/4	1/5	0/6	0/4	0/2	0.833

Patient satisfaction: at five years after loading, all patients declared to the independent outcome assessors that they were highly satisfied with both the function and aesthetics of their implant-supported prostheses, with the exception of three patients from the splinted group, who were partially satisfied with function, partially satisfied with aesthetics or not really satisfied with either function or aesthetics, respectively. Of the latter patients, one experienced peri-implantitis at both implants (one failed) and another one episode of abutment loosening. One patient from the unsplinted group declared that he were not sure about the function or whether he would undergo the same treatment procedure again. This patient lost one implant. Two patients from the splinted group (one having had an abutment loosening) were not willing to undergo the same treatment again. There were no statistically significant differences between groups in terms of either satisfaction with function and aesthetics or

willingness to undergo the same intervention again (difference in proportions = -0.07; 95% CI -0.31, 0.19, Fisher's exact test P = 1.000).

Comparison among different centres: There were no differences among the six centres in any of the outcome measures (**TABLE 3**).

DISCUSSION

This trial was designed to provide preliminary data on whether it would be more advisable to join two adjacent short implants under the same prosthesis or to restore them with single crowns. The general opinion is that it would be preferable to join implants under the same prosthesis to decrease the risk of possible biomechanical complications. However, our preliminary results, albeit based on a small study population, suggest both prosthetic alternatives yield very similar clinical outcomes. Obviously, our results need to be confirmed by RCTs with larger sample sizes and longer follow-ups (more than ten years).

It is difficult to compare our results with those from other, similar trials since there no other trials have yet tested the same hypothesis. However, an interesting observation in this study was that the majority of implants from both groups were inserted into bone subjectively judged by the clinicians at drilling as hard bone, meaning that it was felt to be composed mainly of cortical bone. This could be tentatively explained by two factors: 1) the majority of the implants were placed in posterior mandibles, and bone in mandibles tends to be denser than in maxillae; 2) jaws were quite atrophic, which makes the presence of areas characterised by dense cortical bone more common. This observation could also partly explain the positive outcomes of single unsplinted implants in the present study. To have a more complete representation of actual situation, trials focusing only on short implants splinted or not in the posterior maxilla should be conducted. The most pressing issue now is to evaluate the long-term outcomes of these two prosthetics options, and only larger trials with longer follow-ups can definitively resolve this issue.

The main limitations of the present trial are the small sample size and the protocol deviations (especially the missing radiographs and panoramic radiographs taken instead of periapical radiographs), which further reduced the sample size for the radiographic evaluation. Unfortunately, the planned sample size was not achieved since most of the centres did not recruit the number of patients agreed a priori, which would have been statistically insufficient anyway. In addition, some patients died or had implant failures after implant placement but before being randomized. Nevertheless, when data from other RCTs become available, it should be possible to combine the present findings with those from similar trials in meta-analyses, thereby obtaining larger samples sizes to yield a more precise estimate of possible differences, if any.

Furthermore, the use of a different radiographic reference point, approximately 1 mm more apical to the one decided upon at the protocol stage, could have affected the exact quantification of bone loss since, when placing the implant flush to the surrounding bony crest as agreed for the present study, the first bone to implant contact was actually about 1 mm more coronal. Having said this, while the calculation of the actual bone loss could have been somewhat over-optimistic, the comparison between the two groups, which was the objective of the study, remains valid.

In addition, both procedures were tested under real clinical conditions and patient inclusion criteria were rather broad; therefore the results of the present investigation can be generalised with confidence to a wider population with similar characteristics, bearing in mind that the great majority of implants were placed in dense mandibular bone.

CONCLUSIONS

The present data seems to suggest that up to five years after loading the prognosis of short implants, mostly placed in mandibles characterised by dense bone quality, may not be influenced by splinting them or not under the same fixed prostheses. However, these results need to be confirmed by larger trials with follow-ups of at least five years.

REFERENCES

1. Renouard F, Nisand D. Impact of implant length and diameter on survival rates. Clinic Oral Implan Res 2006;17 Suppl 2:35-51.
2. Felice P, Barausse C, Pistilli R, Ippolito DR, Esposito M. Five-year results from a randomized controlled trial comparing prostheses supported by 5 mm long implants or by longer implants in augmented bone in posterior atrophic edentulous jaws. Int J Oral Implantol 2019;12:25-37.
3. Felice P, Pistilli R, Barausse C, Piattelli M, Buti J, Esposito M. Posterior atrophic jaws rehabilitated with prostheses supported by 6 mm long 4 mm wide implants or by longer implants in augmented bone. Five-year post-loading results from a randomized controlled trial. International J Oral Implantol 2019;12:57-62.
4. Bolle C, Felice P, Barausse C, Pistilli R, Trullenque-Eriksson A, Esposito M. Four mm-long *versus* longer implants in augmented bone in posterior atrophic jaws: one year post-loading results from a multicentre randomized controlled trial. Europ J Oral Implantol 2018;10:31-47.
5. Gastaldi G, Felice P, Pistilli R, Barausse C, Trullenque-Eriksson A, Esposito M. Short implants as an alternative to crestal sinus lift: a 3-year multicentre randomized controlled trial. Europ J Oral Implantol 2018;11:391-400.
6. Cannizzaro G, Felice P, Minciarelli AF, Leone M, Viola P, Esposito M. Early implant loading in the atrophic posterior maxilla: 1-stage lateral *versus* crestal sinus lift and 8 mm hydroxyapatite-coated implants. A 5-year randomized controlled trial. Europ J Oral Implantol 2013;6:13-25.
7. Esposito M, Buti J, Barausse C, Gasparro R, Sammartino G, Felice P. Short implants *versus* longer implants in vertically augmented atrophic mandibles: a systematic review of randomized controlled trials with a 5-year post-loading follow-up. Int J Oral Implantol 2019;12:267-280.
8. Esposito M, Barausse C, Pistilli R, Piattelli M, Di Simone S et al. Posterior atrophic jaws rehabilitated wih prostheses supported by 5x5 mm implants with a nanostructured calcium-incorporated titanium surface or by longer implants in augmented bone. Five-year results from a randomized controlled trial. Int J Oral Implantol 2019;12:39-54.
9. Guljé FL, Raghoebar GM, Vissink A, Meijer HJA. Single crowns in the resorbed posterior maxilla supported by either 11-mm implants combined with sinus floor elevation surgery or by 6-mm implants: a 5-year randomized controlled trial. Int J Oral Implantol 2019;12:315-326.
10. Thoma DS, Haas R, Sporniak-Tutak K, Garcia A, Taylor TD, Hammerle CHF. Randomized controlled multicentre study comparing short dental implants (6 mm) *versus* longer dental implants (11-15 mm) in combination with sinus floor elevation procedures: 5-year data. J Clinical Periodontol 2018;45:1465-74.
11. Felice P, Barausse C, Pistilli R, Buti J, Gessaroli M, Esposito M. Short implants *versus* bone augmentation for placing longer implants in atrophic maxillae. Five-year post-loading results of a randomized controlled trial. Clinical Trials in Dentistry 2020;2:35-48.
12. Felice P, Barausse C, Pistilli R, Kalemaj Z, Esposito M. Four-mm-long *versus* longer implants in augmented bone in posterior atrophic jaws: three-year post-loading results from a multicentre randomized controlled trial. Clinical Trials in Dentistry 2020;2:5-26.
13. Tallarico M, Gatti F, Meloni SM, Muzzi L, Baldini N et al. To splint or not to split short dental implants under the same partial fixed prosthesis? One-year post-loading data from a multicentre randomized controlled trial. Clinical Trials in Dentistry 2020;1:47-58.