KEY WORDS
Machine abutment, Cast abutment, Bacterial leakage, Peri-implant marginal bone loss

Randomised controlled trial

RANDOMIZED MACHINED *VERSUS* CAST ABUTMENTS FOR SINGLE DENTAL IMPLANTS: A 3-YEAR WITHIN-PATIENT MULTICENTRE RANDOMIZED CONTROLLED TRIAL

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PURPOSE. To compare clinical outcomes of machined titanium abutments (machined group) *versus* cast cobalt-chrome abutments (cast group).

MATERIALS AND METHODS. Thirty-one partially edentulous subjects received two single non-adjacent implant-supported crowns each at three centres. Three and a half months after implant placement, implants were randomized at impression taking to receive one machined and one cast abutment according to a within-patient study design. Four patients dropped out and one patient lost one implant before randomization, so only 26 patients had their implants randomized. Outcome measures were: prosthesis and implant failures, any complications, and radiographic peri-implant marginal bone level changes. Patients were followed up for 3 years after loading.

RESULTS. After randomization, three patients dropped out. One implant failed and two crowns on cast abutments were lost, but differences in implant and prosthesis failures were not statistically different (McNemar test P = 1.000; difference in proportions = 0.04 and P = 0.500; difference in proportions = 0.08, respectively). Two minor complications occurred in the cast group *versus* one in the machined group, the difference not being statistically different (McNemar test P = 1.000; difference in proportions = 0.04; 95% CI 0.18 to 22.06). Both groups presented statistically significant peri-implant marginal bone loss from implant placement to 3 years after loading, respectively -0.72 ± 0.90 mm (P = 0.001) for machined and -0.60 ± 0.61 mm (P <0.001) for cast abutments, with no statistically significant differences between the two groups (mean difference -0.12 mm; 95% CI -0.57 to 0.34; P = 0.624).
Both groups gradually lost marginal peri-implant bone from loading (baseline) to 3 years after loading, but this was not statistically significant; machined lost -0.05 ± 0.12 mm while cast lost -0.14 ± 0.11 mm, a difference that was not statistically significant (mean difference 0.06 mm; 95% CI -0.24 to 0.35; P = 0.708).

CONCLUSIONS. The present clinical data suggest that implant prognosis up to 3 years after loading is not affected by the choice of machined or cast abutments.

CONFLICT OF INTEREST STATEMENT
Ticare (Mozo-Grau, Valladolid, Spain) partially supported this trial, and donated the implants and prosthetic components used in the present investigation. However, all data remained the property of the authors, and Ticare by no means interfered with either the conduct of the trial or the publication of its results.

INTRODUCTION

A much debated issue in implant dentistry is the potential influence of marginal bacterial leakage from the implant-abutment junction on the occurrence of peri-implant inflammation, marginal bone loss and peri-implantitis. Theoretically, it would be logical to assume that any procedure able to minimise this leakage could improve the long-term prognosis of implant supported prostheses. Several potential solutions have been proposed to this end, such as the use of different connection types (internal *versus* external). Unfortunately, recent results from a long-term RCT showed that this had no significant effect[1]. An alternative approach to the problem could be to maximise the abutment-implant fit, using more precise pre-machined (milled) abutments instead of fully cast abutments, which are believed to be less precise. However, this hypothesis must be tested first *in vitro*, to see whether the difference in fit actually exists and is quantifiable, and then in long-term RCTs to evaluate whether a higher degree of fit could improve the long-term prognosis of dental implants.

One *in vitro* study[2] on external hexagon connections showed no difference in vertical misfit but a greater degree of horizontal misfit – about 66 µm – at machined titanium with respect to cast cobalt-chromium abutments. Nonetheless, two *in vitro* studies by the same group[3,4] on external hexagon connections revealed no difference in bacterial leakage between machined and fully cast cobalt-chromium abutments. Similar results have been reported for other *in vitro* studies[5,6].

Despite the fact that none of the abovementioned *in vitro* studies showed any difference in fit between machined *versus* fully cast abutments on implants with the same type of external connection, it might be of interest to study implants with an internal connection both *in vitro* and under real clinical conditions. Thus far, there have been neither *in vitro* studies nor RCTs comparing machined *versus* fully cast abutments on implants with an internal connection. Hence, both *in vitro* studies and long-term RCTs are needed to shed light on the issue. With this in mind, the study presented here originally had two main aims:

1. to compare the implant-abutment fit at machined titanium abutments (machined group) *versus* fully cast cobalt-chrome abutments (cast group) *in vitro*;
2. to compare, in a randomized controlled trial (RCT) of within-patient design, the clinical outcomes of machined titanium abutments (machined group) *versus* fully cast cobalt-chrome abutments (cast group).

The data pertaining to the former aim has previously been published[7], and revealed no difference in tight fit/gaps between the two abutment types. As for the latter aim, the 1 year clinical data[7] was published together with the *in vitro* data. However, at the protocol stage, it was planned to follow the patients up to 10 years after loading, and this report presents the clinical results up to 3 years after loading.

The test hypothesis was that there would be no difference in clinical outcomes between machined and fully cast abutments, against the alternative hypothesis of a difference.

This article is reported according to the CONSORT statement (http://www.consort-statement.org/) for improving the quality of reports of within-person randomized controlled trials and its extension checklist for reporting within-person randomized trials (http://www.consort-statement.org/extensions/overview/withinperson).

MATERIALS AND METHODS

Study design

This trial was designed as a multicentre RCT of within-patient design with blind radiographic assessment. Complications and failures were reported by the treating dentists in an unblin-

ded fashion. Each patient received two non-adjacent implants, each randomly allocated to machined or cast abutment, respectively. Random allocation was made at the time of impression taking, three and a half months after implant placement.

Inclusion/exclusion criteria

Any partially edentulous patient of at least 18 years of age requiring at least two non-adjacent single-implant-supported crowns and able to understand and sign an informed consent form was screened for eligibility. Broad inclusion criteria were used, including any type of bone, any location, smokers, etc. Bone volumes allowed placement of two implants at least 8 mm long and 3.75 mm wide. Implants could also be placed in previous post-extraction sockets or in augmented bone, if at least 3 months had passed from the extraction and 6 months from the augmentation procedure.

Patients were not admitted to the study if any of the following exclusion criteria applied:

- general contraindications to implant surgery;
- irradiation to the head and neck area;
- immunosuppression or immunocompromise;
- previous or ongoing treatment with intravenous amino-bisphosphonates;
- untreated periodontitis;
- poor oral hygiene and motivation;
- uncontrolled diabetes;
- pregnancy or lactation;
- substance abuse;
- psychiatric problems;
- unrealistic expectations;
- acute/chronic infection/inflammation in the area intended for implant placement;
- any form of tissue augmentation needed at implant placement;
- participation in other trials if the present protocol could not be properly adhered to;
- referral for implant placement alone and unavailable for follow-up at treatment centre;
- extraction sites with less than 3 months of healing;
- unable to commit to 10-year post-loading follow-up.

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

Patients were to be recruited and treated in four different centres using similar procedures, and each centre was supposed to recruit and treat 15 patients. However, one centre failed to recruit any patient. The three remaining centres were all private practices, two located in Italy (belonging to Dr. Marco Tallarico in Rome and Dr. Silvio Mario Meloni in Arzachena) and one in Albania (Dr. Etha Xhanari in Tirana).

Patients were assessed to establish their eligibility for the study. Specifically, preoperative radiographs were obtained for every potentially eligible patient to quantify bone volumes at the planned implant sites. Patients having sufficient bone volumes to receive two non-adjacent single implants were invited to join the study and informed what it entailed. Only after they fully understood the nature of the study were they asked to join and provide informed written consent. For patients with more than two suitable implant sites, operators were free to choose those sites with the most similar characteristics at the screening appointment. The selected study implant sites were then coded as number 1 and number 2.

Clinical procedures

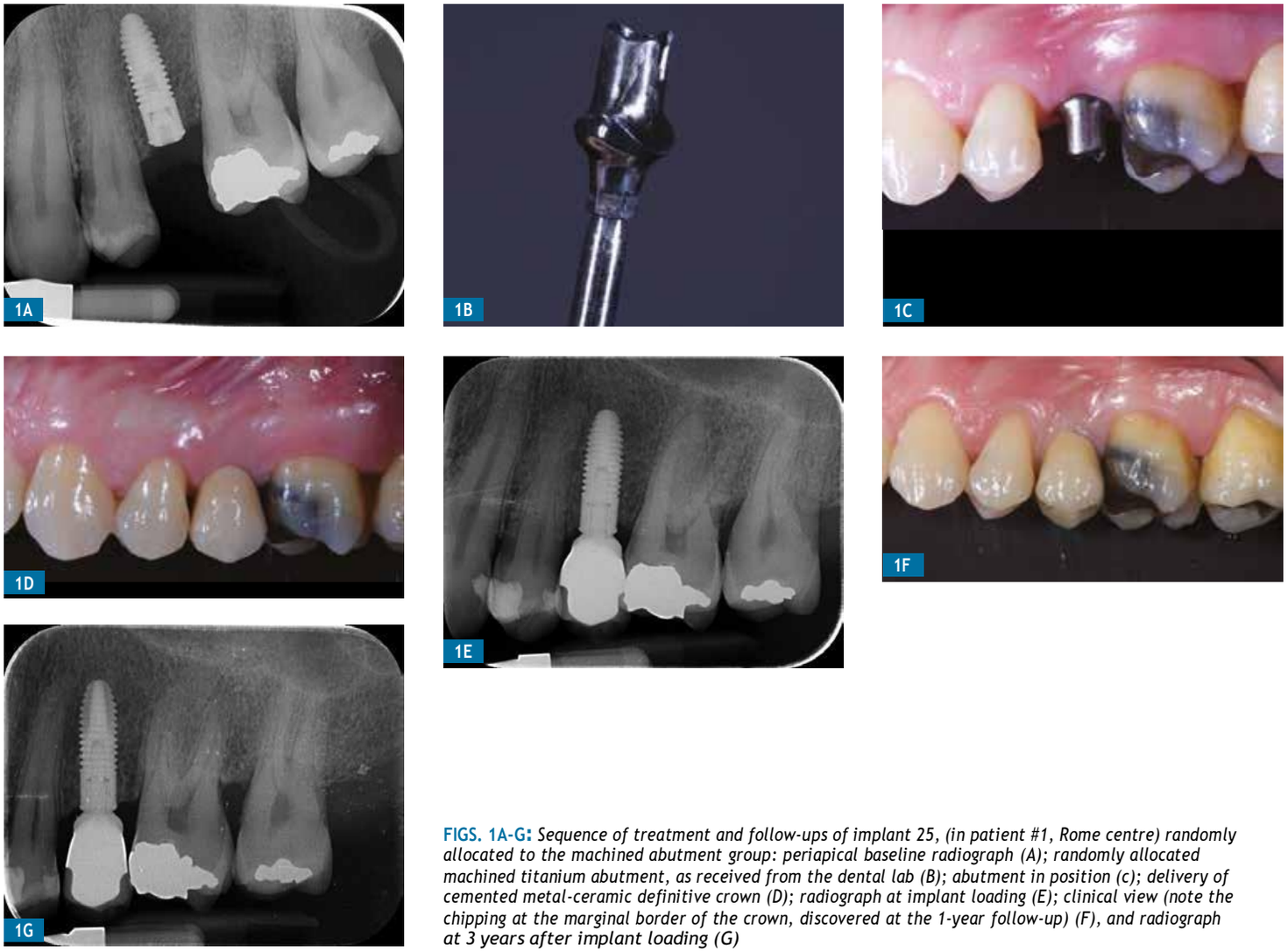
About 10 days prior to implant placement, all patients were subjected to professionally delivered oral hygiene procedures, including debridement if required. On the day of the intervention, all patients received prophylactic antibiotic therapy: 2 g of amoxicillin (or 600 mg clindamycin if allergic to penicillin) 1 hour prior. All patients rinsed with 0.2% chlorhexidine mouthwash for 1 minute prior to any surgical procedure, and were treated under local anaesthesia using articaine with adrenaline 1:100,000. After crestal or slightly palatal incisions and raising of full-thickness flaps, the two non-adjacent implant sites were prepared under prosthetic guidance using a surgical template.

Both implants were placed in the same surgical session. The standard implant placement procedure, as recommended by the manufacturer, was adopted. Drills with increasing diameters were used to prepare the implant sites at a speed of 800 to 1000 revolutions per minute under copious saline irrigation. The following drilling sequence was used for 3.75 mm implants: locator drill, 2 mm drill, 3 mm drill, 3.3 mm drill and profile drill. In hard bone, the 3.5 mm drill was also used, followed, if necessary, by the 3.75 mm bone-tapping. For the 4.25 mm implants, the same procedure was followed, adding the 3.8 mm drill and the profile drill for 4.25 diameter implants, and then, in the presence of hard bone only, by the 4.1 mm and, if necessary, the 4.25 mm bone-tapping. Bone quality was subjectively reported as hard, medium or soft, and implant lengths and diameters were recorded.

The implants used were self-tapping Ticare Inhex implants (Mozo-Grau, Valladolid, Spain) with 11° internal conical connection and a RBM (Resorbable Blast Media) titanium surface and implant mount. Operators were free to choose implant lengths (8, 10, 11.5, 13 or 15 mm) and diameters (3.75 or 4.25 mm), according to the clinical indications and their preferences. Implants were placed at crestal bone level, with their coronal portion flush to the surrounding bone, ideally with a torque of 35 to 45 Ncm. 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 not readable or difficult to estimate, a new radiograph was taken. Ibuprofen 600 mg was prescribed to be taken two to four times a day during meals, for as long as required. In the event of allergy or stomach problems, 1 g paracetamol was prescribed instead. Patients were instructed to rinse with 0.12% chlorhexidine mouthwash for one minute twice a day for 2 weeks, to have a soft diet for one week, and to avoid brushing or trauma to the surgical sites. Sutures were removed after seven to 10 days.

After three months of submerged healing, implants were exposed, manually tested for stability at a torque of 10 Ncm, and standard Ticare-Inhex healing abutments (Mozo-Grau, Valladolid, Spain) wereplaced. Sutures were placed if needed.

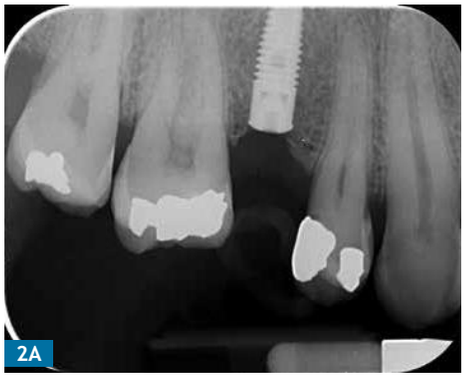
Two weeks afterwards, impressions at implant level were taken using standard screw-retained Ticare-Inhex impression copings (Mozo-Grau, Valladolid, Spain), a polyether impression material (Impregu- mTM, 3M ESPE, Seefeld, Germany), and customised open impression trays. Healing abutmentswere placed, and implants were randomized to receive either a premachined titanium Stan- dard Ticare-Inhex hex titanium preparable abutment (Mozo-Grau, Valladolid, Spain) with a neck of height 3 mm (machined group; **FIGS. 1A-G**) or an identical cast chromium-cobalt abutment from the fully castable hex UCLA abutment (Mozo-Grau, Valladolid, Spain) (cast group; **FIGS. 2A-G**), according to a within-pa-tient study design. The implant to be placed was revealed by opening the sequentially num- bered envelope corresponding to the patient recruitment number. All fully cast abutmentswere cast in a single Spanish laboratory (Laboratorio Viloria, Valladolid, Spain) using an in- duction casting machine (Ally Digital, Manfredi Reddish Stone, Pinerolo, Italy). Operators then had the abutments prepared at their own laboratory. Either 4- or 5-mm diameter abutments were used, according to the clinical indications and operator preference.

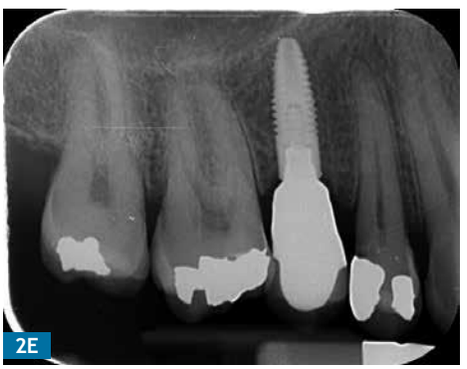


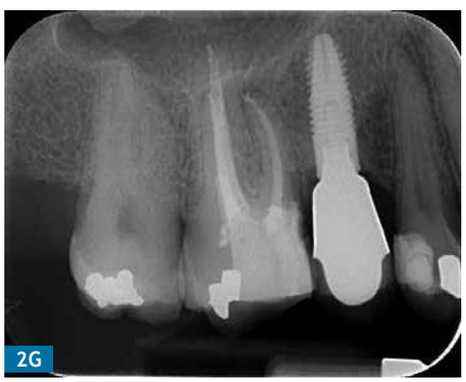
FIGS. 1A-G: *Sequence of treatment and follow-ups of implant 25, (in patient #1, Rome centre) randomly allocated to the machined abutment group: periapical baseline radiograph (A); randomly allocated machined titanium abutment, as received from the dental lab (B); abutment in position (c); delivery of cemented metal-ceramic definitive crown (D); radiograph at implant loading (E); clinical view (note the chipping at the marginal border of the crown, discovered at the 1-year follow-up) (F), and radiograph at 3 years after implant loading (G)*

Within one month, after having tested the stability of the individual implants, the prepared abutments were screwed into the study implants with 30 Ncm torque according to the random allocation, and definitive cement-retained metal-ceramic crowns were cemented onto the study abutments with radiopaque provisional cement (ImplaCem Automix, Dentalica, Milan, Italy). The occlusal surfaces were in slight contact with the opposing dentition. Periapical radiographs of the study implants were taken. If the peri-implant marginal bone levels were not readable, a new radiograph was taken. Oral hygiene instructions were delivered. One week after initial loading, occlusion was checked and oral hygiene instruction reinforced, if necessary.

Patients were enrolled in an oral hygiene programme with recall visits at least every 6 months for the entire duration of the study. Dental occlusion was evaluated at each follow-up visit. Follow-ups were conducted by local blind outcome assessors together with the main operators.







FIGS. 2A-G: *Sequence of treatment and follow-ups of implant 15 (in patient #1, Rome centre), randomly allocated to the cast abutment group: periapical baseline radiograph (A); randomly allocated cast cobalt-chromium abutment, as received from the dental lab (B); abutment in position (C); delivery of cemented metal-ceramic definitive crown (D); radiograph at implant loading (E); clinical view (F), and radiograph at 3 years after implant loading (G)*

Outcome measures

Outcome measures were the following.

- *Crown failures*: loss of the crown secondary to implant failure, or replacement of the crown for any reason.
- *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, by manually tightening the screws with 10 Ncm torque at abutment connection (3 months after implant placement), and 30 Ncm torque at initial loading (fitting of definitive crowns). At 1 and 3 years after loading, the stability of each crown was assessed by rocking the crown with the metal handles of two dental instruments.

- *Any biological or prosthetic complication* was reported.
- *Peri-implant marginal bone level changes*: evaluated on digital intraoral radiographs taken with the paralleling technique at implant placement, initial loading (baseline), and one and three years after loading. In the event radiographs were not properly readable, new radiographs were to be taken. A centralised trained outcome assessor (Dr. Caroline Bolle) measured peri-implant marginal bone levels using Image J (National Institutes of Health, Bethesda, Maryland, USA) software. The software was calibrated for each image using the known implant length, unless the full implant length was not represented in the radiograph, in which case the diameter at the implant neck was used for calibration. Measurements of the mesial and distal bone crest levels 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 estimated most coronal point of bone-to-implant contact. Implants with bone up to the coronal margin of the implant collar were given a value of zero. Mesial and distal measurements of each implant were averaged, and means were calculated at group level.

One independent assessor at each centre, blind to the interventions, assessed implant stability. Complications were managed and reported directly by the treating dentist. One single centralised outcome assessor (Dr. Caroline Bolle), not involved in the treatment of the patients nor aware of the scope of the study, measured all peri-implant marginal bone levels, blindly. Although one of the clinicians noticed cast cobalt-chrome abutments appeared slightly more radiopaque than machined titanium abutments on radiographs, the outcome assessor did not notice that possible difference.

No sample size was calculated since there have been no previous trials evaluating this matter. However, it was decided to include only 60 patients (15 patients per centre), since that was our realistic recruitment capacity over a 2-year recruitment period. Four computer-generated restricted randomization lists were created. Only one of the investigators (Dr. Marco Esposito), not involved in the selection and treatment of patients, was aware of the randomization sequence and had access to the randomization lists, which were stored on his password-protected laptop computer. The randomization codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes, which were opened sequentially after impression taking, thereby concealing treatment allocation from the investigators in charge of enrolling and treating the patients.

Statistical analysis

All data analyses were carried out according to a pre-established analysis plan. The abutment was the statistical unit of the analyses. A dentist with expertise in statistics (Dr. Jacopo Buti) analysed the data without knowing group allocation. A comparison between groups of the characteristics at implant placement is presented. Differences in proportion between the groups were compared for dichotomous outcomes (crown/implant failures and complications) using McNemar's chi-squared test. For continuous outcomes (mean marginal bone level changes), differences between groups were compared using a paired t-test.

Comparisons between the various follow-up endpoints and implant placement and loading (baseline) measurements were made by paired t-tests, to detect any changes in mean marginal bone level for each study group. A mixed-effects model, using treatment group and centre as fixed effects, baseline (loading) radiographic bone levels as covariate and patient as random effect, was created to compare between groups and centres changes in marginal bone levels between implant loading (baseline), and 1- and 3-year follow-ups. Differences

among centres in dichotomous outcomes were calculated using the chi-squared test or the Freeman-Halton extension of Fisher Exact test (when cell count <5). All statistical comparisons were conducted at the 0.05 level of significance. A modified intention-to-treat analysis was applied.

RESULTS

Sixty-five patients were screened for eligibility, but only 31 patients were consecutively enrolled in the trial by the three participating centres. Reasons for not including 34 patients were: unable to commit to 10-year follow-up (12 patients), need for bone augmentation at implant placement (nine patients); needed two adjacent implants (eight patients); requested immediate loading (three patients); refused to participate in the trial (two patients).

Each centre was supposed to enrol 15 patients; however not a single centre managed to achieve this goal; specifically: Dr. Tallarico recruited 13 patients, Dr. Meloni five patients and Dr. Xhanari 13 patients.

Unfortunately, five patients dropped out after implant placement but before randomization and loading for the following reasons:

- patient #2 (Rome centre) died of a heart attack 6 weeks after implant placement;
- patient #3 (Rome centre) refused to continue with the treatment due to family issues and then COVID-19;
- patient #5 (Roma centre) was diagnosed with breast cancer 2 months after implant placement; she stopped dental treatment, first for cancer treatment and then for fear of COVID-19;
- patient #11 (Rome centre) lost implant #26 one week after the second stage surgery but before random allocation at impression taking. Unfortunately, the patient eventually opted for a partial fixed prosthesis on natural teeth (#25 to #27) to avoid a new implant;
- patient #3 (Arzachena centre) moved to Panama 3 months after implant placement.

Three drop-outs occurred after randomization and before 3-year follow-up:

- patient #6 (Rome centre) moved to another country after the 1-year follow-up;
- patient # 4 (Tirana centre) moved to another country after the 2-year follow-up;
- patient #9 (Tirana centre) moved to another country before the 1-year follow-up.

Patients #10 and #12, did not attend the 1-year follow-up but did attend the 3-year follow-up, so are no longer considered drop-outs.

The following protocol deviations were recorded:

- dentists delivered 600 mg ibuprofen post-operatively instead of the 400 mg dictated by the protocol;
- patients #4, #7, #9 and #12 (Rome centre) received two adjacent implants, while the protocol dictated they should not have;
- patient #6's (Rome centre) periapical radiographs at implant placement of both implants were lost;
- patient #2's (Arzachena centre) study implant (45, cast group) was connected under the same prosthesis to an implant in position 46, which was not in the study;
- patient #8's (Tirana centre) periapical radiographs at implant placement of both implants were lost;
- in patient #3 (Tirana centre), a crown was remade as screw-retained, instead of cemented, following mucositis caused by cement retention.

Patients were recruited and treated from April 2017 to January 2019. The follow-up of all remaining patients was up to 3 years after implant loading.

The main patient characteristics of the 26 patients with randomly allocated implants were: 15 females and 11 males of mean age 45 years (range from 21 to 83); 22 were non-smokers and four smoked up to 10 cigarettes per day.

The main baseline characteristics of the implants which were actually randomized are presented in **TABLE 1**. There were no apparent significant baseline imbalances between the two groups, with the possible exception of more 10 mm-long implants in the machined group and more 8 mm-long implants in the cast group.

Prosthesis failures

Two crowns from the cast group failed *versus* none from the machined group. The difference was not statistically significant (McNemar test P = 0.500; difference in proportions = 0.08; 95% CI not estimated). One cemented crown on a cast abutment (#46) in patient #3 (Tirana) was replaced by a screw-retained crown because the implant was affected by peri-implant mucositis due to cement retention 1 month after loading. 17 months after loading, patient #5 (Arzachena) presented to the clinic holding in his hand the implant which had been placed in position #15 with its crown.

Implant failures

One implant from the cast group (patient #5 from Arzachena centre, see above) failed *versus* none from the machined group. The difference was not statistically different (McNemar test P = 1.000; difference in proportions = 0.04; 95% CI not estimated).

In addition, two implants failed before randomization:

- patient #7 (Tirana): during surgery implant #24 was placed too near the adjacent tooth. It was immediately removed and replaced after 2 months. The patient remained in the trial;

TABLE 1 CHARACTERISTICS OF THE RANDOMIZED IMPLANTS ALONE

	Machined (n = 26)	Cast (n = 26)
Number of maxillary implants	13	12
Implants in incisor sites	1	0
Implants in canine sites	2	0
Implants in premolar sites	12	13
Implants in molar sites	11	13
Implants in soft bone	3	2
Implants in medium bone	17	16
Implants in hard bone	6	8
11.5 mm-long implants	4	4
10 mm-long implants	19	5
8 mm-long implants	3	17
4.25 mm diameter implants	18	22
3.75 mm diameter implants	8	4

— patient #11 (Roma): implant #26 failed 1 week after second stage surgery. The patient preferred a traditional fixed tooth borne prostheses on natural teeth, avoiding a new implant, and therefore exited the trial.

Complications

Two minor complications occurred in the cast group *versus* one in the machined group, the difference not being statistically different (McNemar test P = 1.000; difference in proportions = 0.04; 95% CI 0.18 to 22.06). Complications in the cast group were one case of peri-implant mucositis (patient #3, Tirana) affecting implant #46 1 month after loading, caused by cement retention; this was resolved by changing the crown from cemented to screw-retained. The other complication (patient #12, Rome) was a minor chip at the ceramic crown margin, noticed at 3-year follow-up and treated via polishing. The complication in the machined group (patient #1, Rome) was a minor chip at the ceramic crown margin, noticed at the 1-year follow-up, which required no treatment (**FIG. 2F**).

Peri-implant marginal bone level changes could be measured on the periapical radiographs at all implant surfaces. There were no statistically significant differences in bone levels between the two groups either at loading (baseline), or at one and three years thereafter (**TABLE 2**). Both groups gradually lost a statistically significant amount of marginal peri-implant bone from implant placement (P = 0.001 for machined abutments and <0.001 for cast abutments), but not from implant loading (baseline): P = 0.699 for machined abutments and P = 0.226 for cast abutments (**TABLE 2**). At three years post-loading, patients with machined abutments had lost -0.72 ± 0.90 mm, as compared to -0.60 ± 0.61 mm at cast abutments, from implant placement, with no statistically significant differences between the two groups (mean difference -0.12 mm; 95% CI -0.57 to 0.34; P = 0.624). Whereas three years from implant loading (baseline), patients with machined abutments had lost -0.05 ± 0.12 mm, those with

TABLE 2 COMPARISON OF MEAN MARGINAL BONE LEVELS (SD) IN MM AT IMPLANT PLACEMENT, LOADING, AND AT 1 AND 3 YEARS AFTER LOADING BETWEEN THE TWO GROUPS, AND CHANGES FROM BASELINE WITHIN EACH GROUP

	Machined	Cast	Mean difference	95% CI of the difference	P-value (paired sample t-test)
	N mean (SD)	N mean (SD)			
At implant placement	24 0.13 (0.24)	24 0.10 (0.24)	0.03		
At loading (baseline)	26 0.78 (0.78)	26 0.60 (0.69)	0.18	-0.09 to 0.44	0.181
1-year post-loading	22 0.89 (1.00)	22 0.76 (0.79)	0.13	-0.16 to 0.42	0.357
Mean changes at 1 year	22 -0.06 (0.56)	22 -0.10 (0.29)	0.07*	-0.12 to 0.16*	0.739*
P-value (paired t-test) from loading to 1 year	0.620	0.104			
95% CI of the difference (1 year)	-0.31 to 0.19	-0.23 to 0.02			
3-year post-loading	23 0.83 (0.93)	22 0.70 (0.59)	0.02	-0.27 to 0.30	0.904
Mean changes at 3 years	23 -0.05 (0.12)	22 -0.14 (0.11)	0.06*	-0.24 to 0.35	0.708*
P-value (paired t-test) from loading to 3 years	0.699	0.226			
95% CI of the difference (3 years)	-0.30 to 0.20	-0.37 to 0.09			

**Mixed effects model*

cast abutments had lost -0.14 ± 0.11 mm, a difference that was not statistically significant (mixed-effects model; P = 0.708; mean difference 0.06 mm; 95% CI -0.24 to 0.35; **TABLE 2**).

Comparison between centres

There were no differences among the three centres in any of the outcome measures (**TABLE 3**).

DISCUSSION

This trial was designed to provide some preliminary data on whether it would be more advisable to use machined or cast abutments with the aim of reducing possible bacterial leakage at the implant-abutment junction characterised by an internal connection, in order to minimise bone loss and the risk of peri-implantitis. Our preliminary results, based on a small study population, suggest very similar clinical short-term results for both types of abutments. Naturally, our preliminary results will require confirmation over longer follow-ups (at least of 10 years in function) and by further studies with larger sample sizes.

Indeed, the main limitation of the present trial was the small sample size. Unfortunately, the planned sampled size was not achieved since one centre did not provide any data, and the three remaining centres did not recruit the number of patients agreed upon a priori. In addition, some patients died or had implant failures after implant placement but before being randomized. The study was also affected by lost radiographs, which further reduced the sample size for radiographic evaluation. Furthermore, travel restrictions imposed during the COVID-19 pandemic also reduced the number of patients being able to attend the 1-year follow-up, though two patients reappeared for the 3-year follow-up.

A further limitation was the short duration of this trial. However, it is hoped that all centres will continue to monitor their patient cohorts up to 10-year follow-up, since, if some differences between the two abutment types exist, they might appear only after several years in function. Finally, one of the treating clinicians claimed to be able to distinguish between the different abutments on radiographs; however, the outcome assessor, not only was unaware of the aim of the study, but also noticed no differences in abutment radiopacity, since she was fully focussed on measuring bone levels.

All that being said, both abutments were evaluated under real clinical conditions, and patient inclusion criteria were rather broad; therefore the results of this investigation can be generalized with confidence to a wider population with similar characteristics.

It is difficult to compare the current results with those of other similar RCTs, since no other trials have tested this hypothesis. If data from other RCTs do become available, it should be possible to combine the data presented here with those from similar trials. Such meta-analy-

TABLE 3 COMPARISON AMONG CENTRES AT OF 3-YEAR POST-LOADING OUTCOMES IN RANDOMIZED PATIENTS

	Rome	Arzachena	Tirana	P-value	Total
Drop-outs	1/9	0/4	2/13	1.000	3/26
Crown failures	0/8	1/4	1/11	0.435	2/23
Implant failures	0/8	1/4	0/11	0.174	1/23
Complications	2/8	0/4	1/11	0.553	1/23
Bone loss from loading to 3 years	-0.08 ± 0.11	-0.24 ± 0.20	-0.05 ± 0.13	0.655*	-0.09 ± 0.08

**Mixed effects model*

ses will provide larger sample sizes and enable more precise estimation of possible differences between the two types of abutments, if any. Meanwhile, the previously published *in vitro* data from this study[7] revealed no differences in the fit of the cast and machined abutments. These results were in good agreement with findings from previous *in vitro* studies[2-6], and support the clinical observations from the present study.

CONCLUSIONS

The clinical data presented here suggest that implant prognosis up to three years after loading is not affected by the use of machined *versus* cast abutments. Based on this data, dentists can choose whichever they prefer, pending confirmation of these preliminary results by larger trials with follow-ups of at least 10 years.

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