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MACHINED *VERSUS* CAST ABUTMENTS FOR DENTAL IMPLANTS: A 1-YEAR WITHIN-PATIENT MULTICENTRE RANDOMIZED CONTROLLED TRIAL ASSESSING MARGINAL SEAL CAPACITY AND OUTCOMES

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PURPOSE To compare clinical outcomes of machined titanium abutments (machined group) *versus* cast cobalt-chrome abutments (cast group) and to evaluate *in vitro* their implant fit.

MATERIALS AND METHODS This study comprised two parts. In the *in vitro* part, the implant–abutment fit of 5 cast abutments and 5 machined abutments screwed on with a torque of 30 Ncm was qualitatively and quantitatively evaluated using micro-computed tomography (μ-CT) and $AgNO_3$ to reveal connection gaps. In the clinical part, 31 partially edentulous subjects received two single non-adjacent implant-supported crowns at three centres. At impression taking, three and a half months after implant placement, implants were randomized to receive a machined or cast abutment according to a within-patient study design. Unfortunately, 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 to 1 year after loading.

RESULTS The fit of the implant–abutment connection was assessed *in vitro* using μ-CT scans. No gaps were revealed at any of the machined or cast abutments tested.
In the clinical part, after randomization, three patients dropped out, no implant failed, but one crown on a cast abutment was replaced. The between-group difference in prosthesis failure was not statistically different (McNemar chi-square test P = 1.0; difference in proportions = 0.039). One complication occurred in each group, the difference not being statistically different (McNemar test P = 1.000; difference in proportions = 0; 95% CI 0.06 to 15.99). Both groups presented statistically significant peri-implant marginal bone loss from implant placement to 1 year after loading, respectively -0.76 ± 1.01 mm for machined and -0.69 ± 0.82 mm for cast abutments, with no statistically significant differences between the two groups (mean difference 0.07 mm; 95% CI -0.54 to 0.67; P = 0.828). Both groups gradually lost marginal peri-implant bone from loading to 1 year after loading but this was not significantly different, respectively -0.06 ± 0.56 mm for machined and -0.10 ± 0.29 mm for cast abutments, with no statistically significant differences between the two groups (P = 0.739; mean difference 0.07 mm; 95% CI -0.12 to 0.16; P = 0.739).

CONCLUSIONS Our clinical data suggests that implant prognosis up to 1 year after loading is not affected by using machined or cast abutments. In support of these findings, *in vitro* analysis proved that both types of abutments allow a tight fit with no gaps. Therefore, for the time being dentists should feel free to choose whichever type they prefer. However, these preliminary results need to be confirmed by larger trials with at least 10 years of follow-up.

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INTRODUCTION

One of the issues often discussed in implant dentistry is marginal bacterial leakage from the implant-abutment junction, which could potential cause peri-implant inflammation, marginal bone loss, and peri-implantitis. Theoretically, it would be logical to think that any procedure able to minimize this leakage could improve the long-term prognosis of implant-supported prostheses. Several options have been proposed to tackle this problem, such as the use of different connection types. Unfortunately, however, recent results from a long-term RCT refuted this proposed solution[1]. An alternative approach to the problem could be to maximize the abutment-implant fit by using more precise pre-machined (milled) abutments instead of fully cast abutments, which are believed to be less precise.

To test this hypothesis, the fit must first be evaluated *in vitro* to see if there is actually a quantifiable difference, and then long-term RCTs must be conducted to evaluate whether a better fit may improve the long-term prognosis of dental implants. To this end, one *in vitro* study[2] evaluating external hexagon connections showed no difference in vertical misfit, but a greater degree of horizontal misfit—of the order of about 66 μm-at machined titanium abutments with respect to cast cobalt-chromium. However, two other *in vitro* studies of external hexagon connections by the same group[3,4] showed no difference in bacterial leakage between machined or fully cast cobalt-chromium abutments. Similar results have also been reported in other *in vitro* studies[5,6].

All the abovementioned *in vitro* studies concluded no difference in fit between machined *versus* fully cast abutments on implants with the same type of external connection. Nevertheless, it could be of interest to evaluate the fit of implants with an internal connection, both *in vitro* and under real clinical conditions. Thus far, however, there have been no *in vitro* studies or RCTs evaluating machined *versus* fully cast abutments on implants with an internal connection.

Hence, we set out to shed light on the issue by designing this study, which had the following two objectives:

1. To compare the implant–abutment fit of 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 outcome of machined titanium abutments (machined group) *versus* fully cast cobalt-chrome abutments (cast group). The hypothesis tested was that there would be no difference in clinical outcomes between machined and fully cast abutments, against the alternative hypothesis of a difference.

This report presents the *in vitro* data and initial clinical outcomes up to 1 year after loading. At protocol stage, it was planned to follow the patients up to 10 years after loading. The present article is reported according to the CONSORT statement (http://www.consort-statement.org/) and its extension checklist for improving the quality of reporting of within-person randomized trials (http://www.consort-statement.org/extensions/overview/withinperson).

MATERIALS AND METHODS
In vitro component

The implant-abutment fit of 5 fully cast abutments and 5 machined abutments was qualitatively and quantitatively evaluated using micro-computed tomography (μ-CT). The implant sample comprised ten self-tapping Ticare-Inhex implants (Ticare, Valladolid, Spain) with internal connection and RBM (Resorbable Blast Media) titanium surface of 13 mm in length and 3.75 mm in diameter. Abutments were five machined Ticare-Inhex hex titanium preparable abutments with neck of height 3 mm and diameter 5 mm, and 5 identical fully cast chromium-cobalt abutments. No power analysis was used to calculate the sample size because this was the first time that this type of measurement had been made. However, we initially chose 5 implants, and then found high reproducibility in the outcome, so we considered the sample size to be robust enough to draw sound conclusions.

The abutments were given a different number from 1 to 10 in a random sequence (https://www.random.org/). To secure each implant in a vertical position, their apical portion was embedded in a cylindrical acrylic Dentsply orthodontic resin (Dentsply Sirona, Bensheim, Germany) holder. Abutments were screwed in numerical order according to the randomization number, from #1 to #10, to the implants by a single operator using 30 Ncm torque.

μ-CT scanning was performed before and after infiltration of the implant/abutment fit with a revealing silver nitrate solution, which would increase the visual contrast of the gaps between the implant and abutment in the event of imperfect marginal seal. Silver nitrate is a heavy metal salt with a notably higher X-ray absorption coefficient than titanium and cobalt-chrome alloy, and can flow through nanometer-sized gaps. A 50 wt% ammoniacal silver nitrate solution was prepared by dissolving 25 g of $AgNO_3$ crystals (Mallinckrodt Chemical Works, St. Louis, USA) in 25 ml of 28 wt% aqueous ammonium hydroxide (NH_4OH; Sigma-Aldrich, St. Louis, USA) in the presence of ambient laboratory light. This produced a black solution. Additional 28% NH_4OH was used to titrate the black solution slowly until it became clear. The resulting solution was diluted to 50 ml with distilled water to achieve a 50 wt% solution (pH 9.5). The abutment/implant structure was immersed upside down in the $AgNO_3 \cdot NH_4OH$ solution and placed in a desiccator in the dark overnight. The implants were left to dry for ~3 h before being scanned.

μ-CT scanning was performed using a XT H 225 (Nikon, Tokyo, Japan) scanner equipped with a 1.0 mm aluminium filter. X-rays were produced using 150kV and 34 μA tube voltage and current, respectively. 720 projections and four frames per projection were taken to perform a 3D reconstruction of the implant–abutment structure using CT Pro 3D (Nikon Metrology, Brighton, MI, USA), and the reconstructed files were visualized via VG Studio Max 3.0 (Volume Graphics GmbH, Heidelberg, Germany).

If a gap was detected, i.e., silver nitrate solution was visible along the implant–abutment connection line, discrete quantification of the level of fit/leakage was determined from previously reported standards[7].

The statistical plan was to assess normality of the variable first via the Kolmogorov test, and then the t-test, if a parametric test could be applied, or the Wilcoxon test otherwise.

Clinical component
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 unblinded fashion. Each patient provided two non-adjacent implants which received a randomly

allocated machined or cast abutment, respectively. Random allocation was performed at the time of impression taking.

Inclusion/exclusion criteria

Any partially edentulous patient requiring at least two non-adjacent single implant-supported crowns, being at least 18 years old and able to understand and sign informed consent, was screened for eligibility. Broad inclusion criteria included any type of bone, any location, smokers, etc. Bone volumes were to allow placement of two implants of length and width at least 8 mm and 3.75 mm, respectively. Implants could also be placed in 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 of the head and neck area;
— immunosuppression or immunocompromised;
— previous or ongoing treatment with intravenous aminobisphosphonates;
— 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 required at implant placement;
— participation in other trials, if the present protocol could not be properly adhered to;
— referred for implant placement alone, and unavailable for follow-up at the treating 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 their declaration: 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 (Dr. Marco Tallarico's in Rome and Dr. Mario Silvio Meloni's in Arzachena) and one in Albania (Dr. Etha Xhanari's in Tirana).

Patients were assessed to establish their eligibility for the study. 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 were informed of its nature. Only after they fully understood the nature of the study were they asked to join and sign 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 visit. 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 given professional oral hygiene, including debridement as required. All patients received prophylactic antibiotic therapy: 2 g of amoxicillin 1 hour prior to the intervention, or clindamycin 600 mg 1 hour before implant placement if allergic to penicillin. All patients rinsed with chlorhexidine mouthwash 0.2% 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 full-thickness flap elevation, 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 was adopted, as recommended by the manufacturer, with the coronal limit of the neck of the implant placed flush to the bone crest. 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: locator drill, 2-mm drill, 3-mm drill, 3.3-drill and profile drill for 3.75 mm implants. In cases of hard bone, the 3.5-mm drill was used, followed, if necessary, by the 3.75-mm bone-tapping drill. The same procedure was used for the 4.25-mm implants, adding the 3.8-mm drill and the profile drill for 4.25-diameter implants, followed, in the presence of hard bone only, by the 4.1-mm and, if necessary, by 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, a prosthetic indexation in their apical part, and an RBM (Resorbable Blast Media) titanium surface. Operators were free to choose implant lengths (8, 10, 11.5, 13 or 15 mm) and diameters (3.75 and 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 unreadable 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 patients with allergy or stomach problems, 1 g paracetamol was prescribed instead. Patients were instructed to use 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 and trauma to the surgical sites. Sutures were removed after seven to 10 days.

After 3 months of submerged healing, implants were exposed, manually tested for stability by delivering a torque of 10 Ncm, and standard Ticare-Inhex healing abutments were placed. Sutures were applied if needed.

Two weeks afterwards, impressions were taken at implant level using standard screw-retained Ticare-Inhex impression copings, a polyether impression material (ImpregumTM, 3M ESPE, Seefeld, Germany), and customized open impression trays. Healing abutments were placed, and implants were randomized according to a within-patient study design to receive either a pre-machined titanium Standard Ticare-Inhex hex titanium preparable abutments with a neck height of 3 mm (machined group; **FIGS. 1A-G**) or an identical cast chromium-cobalt abutment, derived from the fully castable hex UCLA abutment (cast group; **FIGS. 2A-G**), by opening the sequentially numbered envelope corresponding to the patient recruitment number. All fully cast abutments were cast at a single Spanish laboratory (Laboratorio Viloria, Valladolid, Spain) using an induction casting machine (Ally Digital, Manfredi Reddish Stone, Pinerolo, Italy). Operators had then the abutments prepared at their own laboratory. Either

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); fitting of definitive cemented metal-ceramic crown (D); radiograph at implant loading (E); clinical view (note the chip at the marginal border of the crown, discovered at 1-year follow-up) (F), and radiograph at 1 year after implant loading (G).*

4- or 5-mm diameter abutments were used according to clinical indications and operator preference.

Within one month, after having tested the stability of the individual implants, the prepared abutments were screwed into the study implants, according to random allocation, using 30 Ncm torque, 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 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 appointment. Follow-ups were conducted by local blind outcome assessors together with 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); fitting of definitive cemented metal-ceramic crown (D); radiograph at implant loading (E); clinical view (F) and radiograph at 1 year 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. The stability of individual implants was tested by local independent assessors, who were not informed about the nature of the study and manually tightened the screws with 10 Ncm torque at abutment connection (3 months after implant placement) and with 30 Ncm torque at initial loading (delivery of definitive crowns). At 1 year after loading, the stability of individual crowns was assessed by rocking the crown with the handles of two metal dental instruments.
- *Any biological or prosthetic complications* were reported.

— *Peri-implant marginal bone level changes* were evaluated on digital intraoral radiographs taken with the paralleling technique at implant placement, initial loading (baseline) and one year after loading. In the event of unclear radiographs, new radiographs were to be taken. A trained centralized 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 every single image using the known implant length. If the full implant length was not displayed in the radiograph, the diameter at the implant neck was used for calibration. Measurements of the mesial and distal bone crest level adjacent to each implant was made to the nearest 0.01 mm. Reference points for the linear measurements were the coronal margin of the implant collar and the most coronal point of 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 for each group.

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

No sample size was calculated since there have been no previous trials evaluating this issue. 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 or treatment of patients, was aware of the randomization sequence and had access to the randomization lists, stored on his password-protected laptop computer. The randomization codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially after impression-taking, and treatment allocation was concealed to the investigators charged with enrolling and treating the patients.

Statistical analysis

All data analysis was 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 the proportion for dichotomous outcomes (crown/implant failures and complications) were compared between groups using McNemar's chi-squared test. Differences between groups in continuous outcomes (mean marginal bone level changes) were compared using a paired t-test. Comparisons between the various follow-up endpoint and implant loading (baseline) measurements were made using paired t-tests to detect any changes in mean marginal bone level changes in each study group. A mixed-effects model using treatment group, centre and baseline (loading) radiographic bone levels as fixed effects and patient as the random effect was created to compare changes in marginal bone levels between implant loading (baseline) and 1-year follow-up between groups and centres. Differences in dichotomous outcomes among centres were calculated using the chi-squared test or the Freeman-Halton extension of Fisher's Exact test (when cell count <5). All statistical comparisons were conducted at the 0.05 level of significance. An intention-to-treat analysis was applied.

RESULTS

In vitro component

FIG. 3 shows a representative μ-CT scan of one cast and one machined abutment on titanium implants before and after immersion in the gap-revealing silver nitrate solution. Fit was sound in all samples of the two abutments tested, and not a single gap was revealed. After exposure to silver nitrate, the μ-CT images displayed some bright remnants of the dried silver nitrate solution on the external surfaces of the implants (see machined Ti after $AgNO_3$ in **FIG. 3** as an example), but no bright silver nitrate signal was evident at the abutment–implant connection line. As a consequence, both implant–abutment groups tested had an equal leakage score of zero.

Clinical component

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

Each centre was supposed to enrol 15 patients, but no single centre managed to achieve this goal. In particular, Dr. Tallarico (Rome) recruited 13 patients, Dr. Meloni (Arzachena) five patients, and Dr. Xhanari (Tirana) 13 patients.

Unfortunately, five patients dropped out after implant placement but before randomization and loading due to the following reasons:
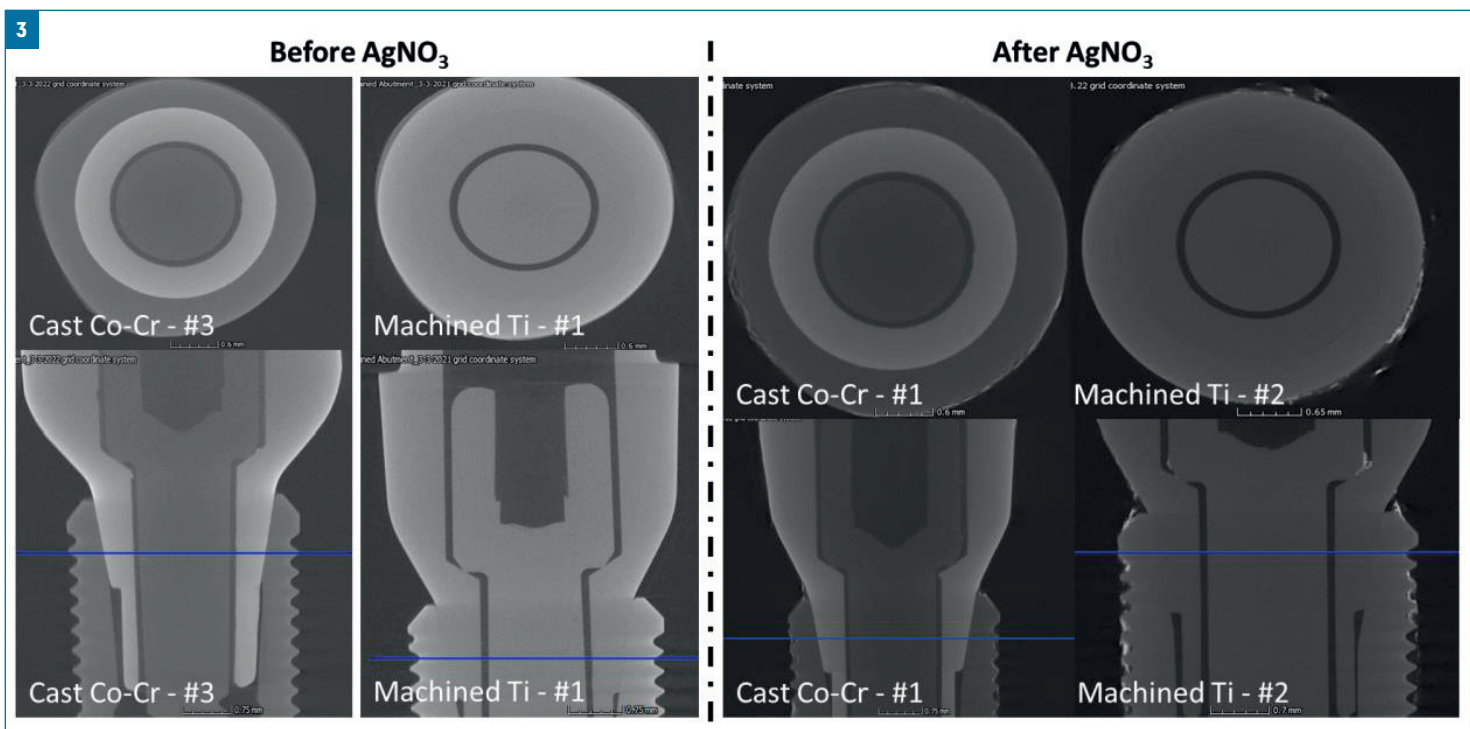
FIG. 3: *Representative images for cast and machined abutments screwed on implants using 30 Ncm torque. Left images: abutment-implant connection before immersion in silver nitrate solution. Right images: abutment-implant connection after immersion in silver nitrate solution. Bottom row: representative longitudinal cross-section. Top row: transversal cross-section at the level of the blue line shown in the corresponding bottom row image.*

- 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 initially to family problems and then to COVID-19;
- patient #5 (Rome centre) was diagnosed with breast cancer 2 months after implant placement and suspended dental treatment, initially due to cancer treatment and then to fear of COVID-19;
- patient #11 (Rome centre) lost implant #26 one week after second-stage surgery but before random allocation at impression-taking. Unfortunately, the patient preferred his treatment to be finished with a partial fixed prosthesis on natural teeth (#25 to #27), rather than a new implant;
- patient #3 (Arzachena centre) moved to Panama 3 months after implant placement.

After randomization three drop-outs occurred:
- patients # 9, 10 and 12 (Tirana centre) were living abroad, and could not fly back to Tirana due to COVID-19 restrictions.

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, #12 (Rome centre) received two adjacent implants, while the protocol dictated that they should not;
- patient #6 (Rome centre); periapical radiographs at implant placement of both implants were lost;
- patient #8 (Tirana centre); periapical radiographs at implant placement of both implants were lost;
- patient #3 (Tirana centre) the crown was remade as screw-retained, instead of cemented, after mucositis caused by retention cement.

Patients were recruited and treated from April 2017 to January 2019. The follow-up of all remaining patients was 1 year after implant loading.

The main patient characteristics of the 26 patients having their implants randomly allocated were: 15 females and 11 males, mean age 45 years (range from 21 to 83), 22 non-smokers and four smoking 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

One month after loading, one cemented crown on cast abutment (#46) in patient #3 (Tirana) was replaced by a screw-retained crown because the implant was affected by peri-implant mucositis caused by retention cement. The difference was not statistically different (McNemar test $P = 1.000$; difference in proportions = 0.039; 95% CI not estimated).

Implant failures

No implants failed after randomization. However, 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 ONLY

	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 opted for a traditional fixed tooth-borne prosthesis on natural teeth rather than a new implant, and therefore left the trial.

Complications

One complication occurred in each group, the difference being not statistically significant (McNemar test P = 1.000; difference in proportions = 0; 95% CI 0.06 to 15.99). The complication in the cast group (patient #3, Tirana) consisted of peri-implant mucositis affecting #46, 1 month after loading, caused by retention cement. It was resolved by replacing the cemented crown with a screw-retained. The only complication in the machined group (patient #1 Rome) was a minor chip at the margin of the ceramic crown, noticed at 1-year follow-up, which required no treatment (**FIG. 2F**).

Peri-implant marginal bone level

Peri-implant marginal bone level changes could be measured at all implant surfaces on periapical radiographs. There were no statistically significant differences in bone levels between the two groups either at loading (baseline) or 1 year after loading (**TABLE 2**). Both groups gradually lost a statistically significant amount of marginal peri-implant bone (P = 0.003 for machined abutments and 0.001 for cast abutments) from implant placement, but not from implant loading (baseline): P = 0.620 for machined abutments and P = 0.104 for cast abutments (**TABLE 2**). At 1-year post-loading, patients with machined abutments had lost -0.76 ± 1.01 mm from implant placement, as compared to -0.69 ± 0.82 mm for cast abutments. At 1 year post-loading, patients with machined abutments had lost -0.06 ± 0.56 mm from implant loading (baseline), as compared to -0.10 ± 0.29 mm for cast abutments, the difference between groups being not statistically significant (mixed-effects model; P = 0.739; mean difference 0.07 mm; 95% CI -0.12 to 0.16; **TABLE 2**)

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

	Machined			Cast			Mean difference	95% CI of the difference	P-value from 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 from 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					

Mixed-effects model

TABLE 3 COMPARISON BETWEEN DIFFERENT CENTRES AT 1 YEAR AFTER LOADING, ONLY FOR THOSE PATIENTS WHO WERE ACTUALLY RANDOMIZED

	Rome	Arzachena	Tirana	P-value	Total
Drop-outs	0/9	0/4	3/13	0.250	3/26
Crown failures	0/9	0/4	1/10	1.000	1/23
Implant failures	0/9	0/4	0/10	1.000	0/23
Complications	1/9	0/4	1/10	1.000	1/23
Bone loss from loading to 1 year	-0.14 ± 0.31	-0.23 ± 0.61	0.04 ± 0.45	0.319*	-0.08 ± 0.44

Mixed-effects model

Comparison among centres

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

DISCUSSION

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

The main limitations of this trial were the small sample size, the lost radiographs – which further reduced the sample size for radiographic evaluation – and the limited duration. 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 agreed number of patients. In addition, some patients died or had implant failures after implant placement but before being randomized, and, finally, travel restrictions imposed by the COVID-19 pandemic also affected the number of patients able to attend the 1-year follow-up. That being said, it is hoped that all centres will continue to

monitor these patient cohorts up to the 10-year follow-up, since, if some differences between the two abutment types exist, they might appear only after several years in function.

It has also been suggested that it was possible for one of the assessing clinicians to discern the different abutment types on the radiographs - another potential limitation of this trial. However, the outcome assessor in question not only had no idea of the aim of the study, but also failed to notice any differences in abutment radiopacity, since she was entirely focused on evaluating bone levels. It is difficult to compare our results with those of other RCTs, since no other trials have attempted to test this hypothesis. Nevertheless, when data from other RCTs becomes available, it should be possible to combine it with ours in a meta-analysis; this would provide a larger sample size, and therefore a more accurate estimate of any differences between the two types of abutment.

Meanwhile, the *in vitro* data obtained in this study appear to support the similarity of the two abutments tested, revealing no differences in the fit of the cast and machined abutments. These results are in line with those found in previous *in vitro* studies by others[2-6] and with the clinical outcome of the present study. However, the main limitation of the *in vitro* tests we performed was that the implants were not mechanically and/or biologically challenged, as would be the case in the clinical scenario. That being said, both abutments were evaluated under real clinical conditions, and patient inclusion criteria were rather broad; therefore, the results of this investigation may be generalized with confidence to a wider population with similar characteristics.

CONCLUSIONS

Our clinical data suggests that up to 1 year after loading implant prognosis is not affected by the choice of machined or cast abutments. In support of these findings, our *in vitro* analysis proved that a tight fit with no gaps is formed by the two types of abutments. Therefore, pending confirmation of these preliminary results by larger trials with follow-ups of at least 10 years, dentists should feel free to choose whichever they prefer.

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