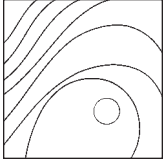


Esthetic Outcomes of Single-Tooth Implant-Supported Restorations Using Metal-Ceramic Restorations with Zirconia or Titanium Abutments: A Randomized Controlled Clinical Study



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The aim of this study was to test whether zirconia abutments exhibit the same clinical and esthetic outcomes as titanium abutments in single-tooth implant restorations in the esthetic area. The 24 treated patients were randomly assigned to a test (zirconia abutment) or control (titanium abutment) group. Objective evaluations were carried out using the Implant Crown Aesthetic Index (ICAI) and the Papilla Index (PI) at the 1-month and 12-month follow-up examinations after crown cementation. No significant differences, either in ICAI or in other periodontal or radiographic measurements, were observed. At 1 year, zirconia and titanium abutments exhibited the same esthetic outcomes. Int J Periodontics Restorative Dent 2016;36:e59–e66. doi: 10.11607/prd.2599

The use of dental implants to replace missing teeth in esthetic zones is a well-documented therapy, showing high survival and success rates.¹ One of the most challenging tasks is to fulfill the esthetic expectation of the patient by creating an esthetic restoration that is stable over time and indistinguishable from adjacent natural teeth.^{2,3} Patient satisfaction must be considered a key factor of treatment success during the final evaluation of the implant restorations.⁴ For this reason, a considerable number of objective indices for esthetic assessment have been proposed to quantify esthetic results.^{5–7} Although much emphasis is placed on aspects of the prosthesis, gingival parameters such as soft tissue color, texture, and biotype and papillae form should be considered to enhance implant esthetics. Many authors have found that blending in peri-implant soft tissue with the surrounding gingiva and mucosa is essential for an optimal esthetic outcome.⁵

It has been demonstrated that the critical soft tissue dimension on the buccal aspect of the dental implant appears to be 2 mm.⁸ In patients with less than 2 mm of buccal soft tissue volume, the choice of reconstruction material can significantly influence the esthetic outcome at implant sites.⁸ Although various authors have proposed the use of all-

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ceramic abutments for single-tooth implants in the esthetic zone,^{9,10} the clinical benefit with regard to soft tissue appearance has rarely been investigated and more clinical investigations are warranted.¹¹ The 3-year results from a randomized controlled clinical trial demonstrated that zirconia and titanium abutments exhibited the same survival, technical, biologic, and esthetic outcomes.¹² A recent study¹³ found no difference in mucosal discoloration between zirconia and titanium abutments, contradicting an earlier study.¹

The aim of this study was to assess the esthetic result of single-tooth implant restorations using different abutment materials (zirconia versus titanium) in association with metal-ceramic crowns with an esthetic composite index combined with patient perception feedback. A secondary aim was to evaluate the stability of both hard and soft peri-implant tissues using clinical and radiographic outcome variables.

Materials and methods

Subjects for the study were recruited from the pool of patients in need of single implant-supported restoration at the Department of Periodontology at the University of Siena. Approval of the original study protocol was obtained from the Ethical Committee of the "Azienda Ospedaliera-Universitaria Senese" Ospedale "Le Scotte" Siena, Italy, and was performed in accordance with the Helsinki Declaration. All the characteristics of the protocol were explained to the patients before they

signed an informed consent form in agreement. The trial was registered on clinicaltrials.gov with the registration number NCT02315794.

A total of 24 patients were enrolled in this trial beginning in January 2009, and all finished the 12-month examination in January 2013. Patients were recruited for the study if they fulfilled the following inclusion criteria: noncompromised systemic health; periodontal health or healthy periodontum after periodontal therapy; monoedentulism in the esthetic zone of either the maxilla or mandible; in the cases of recently extracted teeth a conventional healing protocol was used (at least a 4-month healing period was required prior to implant placement); and a minimum of 2 mm of keratinized gingiva at the edentulous site. No bone regenerative techniques were considered in association with the implant surgery.

All subjects received a session of prophylaxis including instruction on proper oral hygiene measures and scaling. Surgical treatment was not scheduled until the patient could demonstrate an adequate standard of supragingival plaque control.

All patients were randomly assigned to the test or control group using a computer-permuted block randomization system with an allocation ratio of 1:1. The randomization was performed by means of sealed envelopes containing a code by the dentist responsible for the prosthetic restoration. Both patients and analyzing statisticians were blinded.

Prior to surgery, patients were asked to rinse with a 0.2% chlorhexi-

dine solution for 1 minute. Following local anesthesia, a horizontal incision was made with a scalpel to create an envelope flap. A full-thickness flap was elevated at the top of the edentulous crest. Drilling of the implant bed was performed according to the manufacturer's protocol (Thommen). Rough surface (sandblasted, thermal acid-etched microrough surface) implants with a polished collar and internal hexagonal connection (SPI Element, Thommen) were inserted. The implant was positioned by placing the 0.5-mm polished collar subcrestally, thus avoiding possible interference during the prosthetic stage (Figs 1 and 2). Buccal bone thickness was measured using a periodontal probe. Measurements were taken as the horizontal distance from the buccal wall to the implant shoulder. Healing abutments were then connected, and flap closure was achieved with single interrupted sutures. The patients were instructed to cool down the operation site with a cold pack during the first 6 hours following surgery and to rinse with a 0.2% chlorhexidine solution twice a day for 2 weeks. Systemic antibiotics were prescribed for 7 days post-surgery.

After a 3-month healing period, all patients were randomly assigned to the test or control group. The abutment used in the test group was an yttrium oxide-stabilized zirconia abutment (SPIART, Thommen), while the one used in the control group was an unalloyed commercially pure titanium grade 4 (CPTi Gr 4) abutment (SPIEASY, Thommen). Both abutments were machined and designed for ce-

mented implant restorations. No provisional restoration was delivered. A porcelain-fused-to-metal crown was cemented. Figures 3 to 8 show examples of final restorations for each treatment group. All patients were included in a structured maintenance program.

The primary outcome of this study was the assessment and comparison of patient and clinician satisfaction relative to esthetic results using the Implant Crown Aesthetic Index (ICAI).⁵ Secondary outcomes were the clinical evaluation of the peri-implant soft tissues, radiographic evaluation of the crestal bone, and recording of patient-related outcomes by means of the Visual Analog Scale (VAS), recommended as a subjective measure of implant esthetics.¹⁴

The ICAI index is based on nine variables including crown- and peri-implant soft tissue-related features. When comparing the prosthetic restoration to the adjacent teeth, penalty points are assigned when the different items do not achieve the requisite effect (0 penalty points = excellent; 1 or 2 points = satisfactory; 3 or 4 points = moderate; 5 or more points = poor). The nine selected items are explained in Fig 9.

This esthetic assessment was performed 1 month and 12 months, respectively, after crown placement. A subanalysis of the crown and soft tissue esthetic index was also performed. Each single-tooth implant was photographed with a digital camera (D80 with 105-mm macro lens, Nikon; EM-140 annular flash, Sigma). Technical complications were classified as major (requiring



Fig 1 The implant was positioned leaving the 0.5-mm polished collar subcrestal.



Fig 2 Healing abutments were placed at the end of the surgical procedure.



Fig 3a Clinical image showing the final restoration in place (test group).



Fig 3b Radiographic control of the final restoration in place (test group).



Fig 4 Clinical image of the final restoration in place (test group).



Fig 5 Clinical image of the final restoration in place (test group).



Fig 6a Clinical image of the final restoration in place (control group).



Fig 6b Radiographic control of the final restoration in place (control group).

replacement of the restoration), medium, or minor (to be corrected with small efforts).¹⁵

At baseline (prior to surgery), after crown placement, and at the 12-month follow up, the following



Fig 7 Clinical image of the final restoration in place (control group).



Fig 8 Clinical image of the final restoration in place (control group).

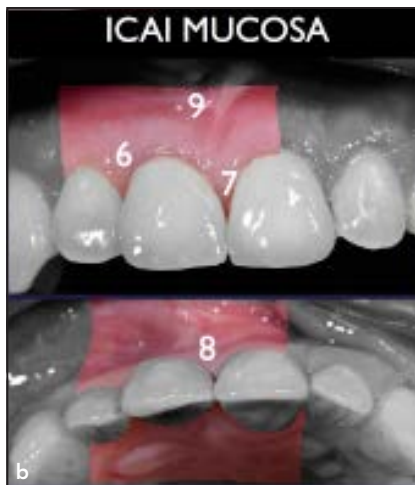
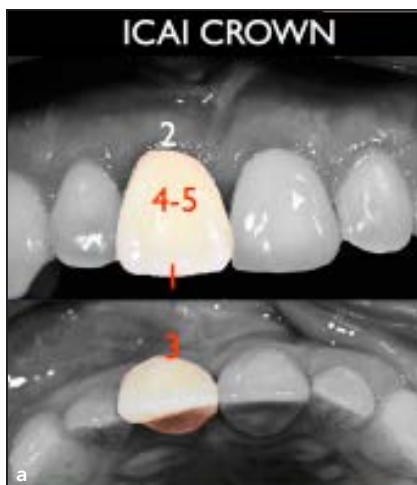


Fig 9 ICAI index. (a) Crown: (1) mesiodistal dimension; (2) position of the incisal edge; (3) labial convexity; (4) color and translucency; and (5) surface. (b) Mucosa: (6) position of the labial margin; (7) position of interdental papilla; (8) contour of the labial surface; and (9) color and surface.

periodontal parameters were recorded at the implant site and at the distal and mesial adjacent teeth: probing pocket depth (PPD), gingival/mucosal recession, probing attachment levels (PAL), full-mouth plaque score, and full-mouth bleeding score. The measurements were recorded using a CPC-15 manual periodontal probe (Hu-Friedy) to the nearest millimeter, at six sites per tooth and implant.

The following periodontal parameters were recorded to assess the peri-implant soft tissue: mucosa

thickness (assessed with a calibrated endodontic file 2 mm apical to the gingival margin), position of the gingival/mucosal margin (measured with a periodontal probe from the incisal edge to the margin at the mesial, zenith, and distal sites) to the nearest millimeter, amount of keratinized mucosa measured in the midbuccal site, and position of the interdental soft tissues by means of the Papilla Index (PI).¹⁶

Intraoral periapical radiographs were taken after implant surgery (baseline) and after the 12-month

follow up using a long-cone parallelizing technique and an individualized positioner (Rinn system, Dentsply) using an autopolymerizing silicone key registering the adjacent teeth. The crestal bone levels were measured by means of an image analysis software (NIS-Elements, Nikon), which scanned and calibrated the radiographs using the implant diameter as a fixed point of reference.

The following radiographic measurements were recorded: vertical distance (parallel to the implant long axis) from the contact point to the bone crest on the mesial and distal sides, vertical distance from the implant shoulder (placed 1 mm supracrestally) to the most coronal bone in contact with the implant on the mesial and distal sides, and horizontal distance from the implant shoulder to the adjacent teeth on the mesial and distal sides (HITD).

Patient satisfaction was assessed using the VAS. All patients were asked to complete a satisfaction questionnaire concerning items such as the esthetic-related variables (eg, harmony of gingival margin, overall esthetic satisfaction) and lifestyle-related variables (eg, confidence when smiling, phonic ability, comfort when chewing or biting).¹⁷

Two clinicians not involved in patient treatment were calibrated prior to the beginning of the study to record all outcome measurements. They were blinded in regard to treatment group assignment: one of the two examiners (A.C.) performed the esthetic analysis, and the second examiner (C.D.) recorded all secondary outcome parameters.

Table 1 Demographic and clinical characteristics at baseline

	Mean age (y)	Sex (Male/Female)	Mean FMPS (%)	Mean FMBS (%)	Facial mucosa thickness (mean \pm SD) (mm)	Buccal bone thickness (mean \pm SD) (mm)
Test (n = 10)	54.1	4/8	27	17	2 \pm 1	1.66 \pm 0.44
Control (n = 12)	57.7	3/9	33	18	2 \pm 1	1.59 \pm 0.8
<i>P</i>	.73	.99	.23	.81	.42	.77

Data analysis

A subject-level analysis was performed for each study outcome. Chi-square and Fisher tests were applied to evaluate the intra- and intergroup differences of qualitative data. Mann-Whitney test was applied for quantitative data. A significance level of $P = .05$ was used in all statistical tests. Statistical analysis was completed using SPSS version 21.0 for Windows (IBM).

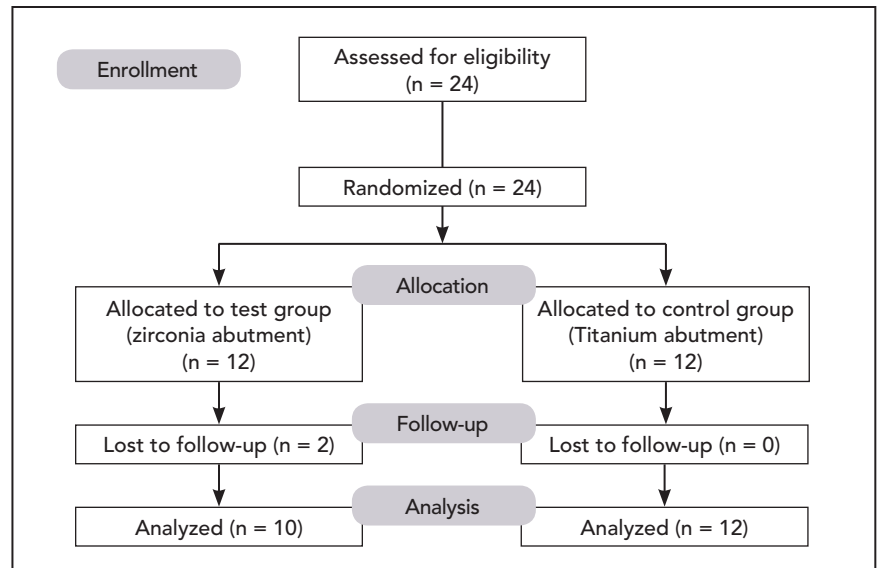


Fig 10 CONSORT flow diagram.

Results

Figure 10 shows the flow diagram for this study population. At baseline, there were no statistically significant differences between the control and test groups for any of the demographic and clinical characteristics studied (Table 1).

The overall ICAI scores at 1 month and 12 months after crown placement were 15 and 14, respectively, for the test group, whereas the corresponding values for the control group were 13 and 9, respectively. When considering ICAI items only belonging to the prosthetic crown, scores for the test group were 8 and 9 for 1 and 12 months, respectively, compared with 5 and 4 for the control group.

When considering ICAI items belonging only to the mucosa, scores were 7 and 5, respectively, for the test group and 8 and 5, respectively, for the control group, after 1 month and 12 months. Differences between the test and control groups were not statistically significant at either evaluation period. Intragroup analysis showed significant differences in the control group for ICAI items regarding mucosa ($P = .01$) (Table 2).

The detailed analysis of the four items regarding the mucosa evaluated in the ICAI at 1 month resulted in statistically significant differences between the test and control groups favoring the test

group for color and surface of labial mucosa ($P = .010$). In the test group, 8 patients presented excellent color and surface of the labial mucosa (zero penalty points), and 4 patients presented a satisfactory result (one penalty point), while in the control group only 1 patient presented an excellent result, 10 patients presented satisfactory results, and 1 patient had a poor esthetic outcome. At 12 months, the differences were not significant.

Intragroup analysis showed significant differences in the control group between 1 month and 12 months regarding papillae ($P = .016$). No intragroup differences were seen in the test group (Table 2).

	Test (n = 10)				Control (n = 12)			
	1 mo	12 mo	<i>P</i> ^a	<i>P</i> ^b	1 mo	12 mo	<i>P</i> ^a	<i>P</i> ^b
ICAI crown (median)	8	9	.99	.11	5	4	.07	.07
ICAI mucosa (median)	7	5	.07	.37	8	5	.01*	.74
ICAI total (median)	15	14	.85	.57	13	9	.09	.22
Labial margin position (median)	1	1	.32	.37	1	1	.60	.85
Mucosa in interproximal embrasures (median)	3	1	.1	.70	5	1	.02*	.31
Labial surface contour (median)	1	1	.16	.13	1	1	.16	.43
Labial mucosa color and surface (median)	0	0	.99	.01*	1	0	.12	.82
Mesial Papilla Index (median)	1	1	.01*	.06	0	2	.01*	.07
Distal Papilla Index (median)	1	1	.01*	.06	0	2	.01*	.07

^aIntragroup difference between 1 mo and 12 mo.

^bDifference between test and control groups.

*Statistically significant.

An improvement in the PI was observed after 12 months in both groups, with significant intragroup differences (for the test group, $P = .008$; for the control group, $P = .001$) (Table 2).

All surgical procedures healed uneventfully, and all implants osseointegrated successfully. No biologic or technical complications were noted during the 12 months of follow-up.

Both the questionnaire and the VAS demonstrated a good acceptance of the treatment received. The VAS score was 8.5 in the test group and 9 in the control group.

The results of all the clinical and radiographic variables are reported in Table 3. In regard to PPD, recession, and bleeding on probing, no significant differences were found between the treatment groups or between the baseline and 12-month follow-up within the groups. The

thickness of the buccal oral mucosa did not undergo significant changes during the study.

The marginal bone level 1 month after crown placement was located 1.54 mm (SD 1.27) apical to the reference point in the test group implants, whereas the corresponding value in the group B implants was 1.41 mm (SD 0.96). The mean peri-implant bone level change that occurred during the 1-year period was not significant for the test group implants, but it was significant for the mesial aspect of the control group implants ($P = .01$). Intergroup differences were observed for mesial bone loss at 12 months ($P = .02$).

Discussion

The aim of this study was to evaluate the esthetic results of zirconia versus titanium used as abutments

for single-tooth implant-supported crowns in the anterior maxilla and mandible. More specifically, the aim was to evaluate the chromatic influence of the two materials in the connective tissue tract from bone to crown margin.

In this investigation, the recommendations of the European Workshop in Periodontology were followed.¹⁸ During this clinical trial, no surgical or prosthetic complication was reported. This result was in agreement with a recent paper by Zembic et al,¹² although a shorter follow-up was considered in the present protocol.

The amount of keratinized tissue (2 mm), which was one of the inclusion criteria for this work, could explain the lack of differences when evaluating the esthetic outcome. The thickness of such tissue can be sufficient to mask the grayish appearance of the titanium abutment in the peri-implant mucosa.

It may be argued that from a functional standpoint, zirconia abutments performed as well as titanium abutments. However, it must be noted that metal-ceramic crowns were placed on all the abutments. Nevertheless, 12 months may not be sufficient to determine relevant differences between the two groups. Long-term follow-up should be considered to evaluate hard and soft tissue stability and to record the incidence of possible adverse events.

Other limitations affected this study and may have an influence on its conclusions. First, a small sample size, further reduced by two dropout patients in the test group, may be partially responsible for the lack

Table 3 Clinical and radiographic outcomes

	Mean PPD (mm)			Mean recession (mm)			Median BoP			Mean facial mucosa thickness (mm)			Mean mesial bone loss (mm)			Mean distal bone loss (mm)		
	1 mo	12 mo	P	1 mo	12 mo	P	1 mo	12 mo	P	1 mo	12 mo	P	1 mo	12 mo	P	1 mo	12 mo	P
	Test (n = 10)	2.69 ± 0.7	2.68 ± 0.4	0.8	0.11 ± 0.3	0.15 ± 0.3	.3	0	0	.6	2 ± 1	2 ± 1	.8	1.54 ± 1.27	1.11 ± 0.8	.20	1.55 ± 1.43	1.16 ± 0.89
Control (n = 12)	2.56 ± 0.3	2.69 ± 0.9	0.7	0.06 ± 0.1	0.15 ± 0.2	.11	0	0	.33	2 ± 1	2 ± 0	.32	1.41 ± 0.96	1.98 ± 0.6	.01*	1.43 ± 0.9	1.74 ± 0.7	.42
P	.8	.8		.10	.8		.6	.6		.4	.23		.20	.02*		.45	.32	

PPD = pocket probing depth; BoP = bleeding on probing.

*Statistically significant.

of statistically significant results. Cases were considered dropouts when it was impossible to collect the 12-month data.

Second, more than half of the patients were periodontally treated in a supportive periodontal program. In these cases, healthy gingival tissues associated with a reduction of periodontal attachment were present. This can explain the poor overall esthetic result in both treatment groups, especially where the papillae outcome was concerned.

The ICAI indicated a worse, though not significant, result in the test group. The same difference in penalty points between the two groups was found for the total ICAI outcome.

Focusing on mucosal ICAI, better esthetic results for mucosal color and contour were reported by the test group at the 1-month follow up. These results were not confirmed after 12 months. Nevertheless, an increase in buccal peri-implant thickness was not demonstrated in this study. The PI demonstrated a significant improvement between the 1-month and 12-month peri-

ods independent of the treatment group, confirming the results of previous studies.^{19–21}

Clinical and radiographic outcomes reported a stable result during the follow-up. Patient feedback was positive in both test and control groups: the final opinion on esthetic outcomes demonstrated a degree of general satisfaction. This result confirmed data reported by several studies wherein single implant crowns were evaluated and patient-centered outcomes were considered.^{22,23}

Conclusions

Within the limitations of this study, it can be concluded that no significant differences were found in terms of esthetic results between zirconia and titanium abutments in single implants covered by metal-ceramic crowns. Patient opinion of the treatment was satisfactory in both groups, and clinical and radiographic outcomes were stable during the follow-up period.

Acknowledgments

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