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Complete List of Authors:	Gallucci, German; Harvard School of Dental Medicine, Restorative Dentistry Guetter, Linda; University Of Geneva, Fixed Prosthodontic Nedir, Rabah; University Of Geneva, Stomatolgy and Oral Surgery Bischof, Mark; University Of Geneva, Stomatolgy and Oral Surgery Belser, Urs; University Of Geneva, Fixed Prosthodontic
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Esthetic Outcomes with PFM and All-ceramic Single-Implant Crowns: a Randomized Clinical Trial

German O. GALLUCCI*

Linda GRÜTTER**

Rabah NEDIR***

Mark BISCHOF***

Urs C. BELSER**

* Department of Restorative Dentistry and Biomaterials Sciences
Harvard School of Dental Medicine, Harvard University
Boston, United States

** Department of Fixed Prosthodontics and Occlusion
School of Dental Medicine, University of Geneva
Geneva, Switzerland

*** Department of Stomatology and Oral Surgery
School of Dental Medicine, University of Geneva
Geneva, Switzerland

Address for correspondence:

German O. GALLUCCI

188, Longwood Avenue
02115 - Boston, MA, USA
german_gallucci@hsdm.harvard.edu

HARVARD UNIVERSITY
Harvard School of Dental Medicine
Department of Restorative Dentistry
and Biomaterials Sciences

Abstract

Objectives: The aim of this randomized controlled clinical trial is to compare the objective and subjective esthetic outcomes of two types of screwed-retained single-implant crowns. **Materials and Methods:** Participants were randomly assigned to the test (all-Ceramic) and control (PFM) groups and were seen under investigation at Baseline (B), Crown Insertion (CI), 1-year follow-up (1-Y), and 2-year follow-up (2-Y). Objective parameters were assessed by an intra-oral digital photograph (1:1 ratio), a study cast, a standardized radiograph, periodontal/peri-implant measurements, and questionnaires were obtained for the subjective parameters. In addition, a Pink Esthetic Score (PES) and White Esthetic Score (WES) were calculated for both groups. For the subjective evaluation, a Visual Analogue Scale (VAS) questionnaire was used to assess the level of patient satisfaction regarding the esthetic outcome. Then, 9 expert clinicians visually inspect assessed the subjective evaluation at the professional level. Statistical analysis was used to compare between groups and investigational appointments.

Results: 20 patients were included in the study, 10 allocated to the all-Ceramic group and 10 to the PFM group. No statistically significant differences were observed for the objective measurements comparing the test and control groups. Minor chipping of the ceramic veneering material was observed in the 2 patients of control group. The mean difference for all groups comparing objective parameters revealed an increase of papilla height between time points. A slight recession (0.26mm) of the peri-implant mucosal margin at the implant site was observed between 1Y and 2Y. Mean values for PES and WES were 13.9 and 13.1 for the PFM group and for the all-ceramic group respectively. These values were not statistically significant. Implant crown volume, outline, translucency and characterization showed major discrepancies with the contra-lateral natural teeth. As for subjective parameters, Visual Analogue Scale (VAS) patients' responses regarding their perceptions of the esthetic outcome showed no statistical differences betwen groups and clinicians' accuracy scores were 50% and 47% for PFM and all-Ceramic crowns respectively.

Conclusion: PFM and all-ceramic single-implant restorations may be indistinguishable from each other regarding the objective/subjective assessment of esthetic integration. The material chosen for fabricating an implant crown *per se* does not ensure an optimal esthetic outcome if other esthetic parameters are not present.

Introduction

The dental literature proposes several methods for identifying esthetic parameters related to the anterior maxilla (Preston, 1993, Snow, 1999, Sterrett et al., 1999, Magne and Belser, 2002, Magne et al., 2003, Gallucci et al., 2007). These esthetic parameters are taken into consideration when mimicking the anatomy of natural dentition in prosthodontic, periodontal and restorative procedures.

When it comes to implant prosthetic rehabilitations in the anterior maxilla, (Jemt, 1997) described an index to assess the size of the inter-proximal papillae adjacent to single-tooth implant restorations. Similarly, (Chang et al., 1999a, Chang et al., 1999b) compared crown and soft tissue dimensions between implant-supported single-tooth replacements and the contra-lateral natural tooth using crown form, soft tissue dimensions, and soft tissue conditions as variables. In addition, the patients' overall satisfaction with the esthetic outcomes was scored using a Visual Analogue Scale (VAS). Comparing patients' and clinicians' judgments of the esthetic outcome of implant-supported single-tooth replacements, the authors concluded that esthetic outcomes were appreciated more by the patients than by prosthodontists. Patient overall satisfaction regarding treatment outcome with maxillary anterior implants was also assessed by self-administered mailed questionnaire (Levi et al., 2003). The authors concluded that the implant position, restoration shape, overall appearance, effect on speech, and chewing capacity were critical for the patient's overall acceptance of a dental implant treatment.

Additional methods to assess the esthetic outcome of single-tooth implant rehabilitations in the anterior maxilla have been proposed (Belser et al., 2009, Furhauser et al., 2005, Meijer et al., 2005). Furhauser et al. (2005) evaluated the reproducibility of a newly proposed Pink Esthetic Score (PES) by comparing seven variables to a natural reference tooth. Meijer et al. 2005 proposed an index for rating esthetics of single-implant crowns and adjacent soft tissues.

Belser et al. 2009 presented a simplified scoring system in order to assess the White Esthetic Score (WES) and the Pink Esthetic Score (PES). In this cross-sectional retrospective study, 45 patients were assessed for the objective esthetic outcome of anterior single-implants restorations. The authors confirmed the suitability of PES/WES index for the objective outcome assessment of the esthetic dimension of anterior single-tooth implants.

Scientific evidence about the objective and subjective assessment of esthetic parameters of single-implant anterior rehabilitations is mainly based on retrospectives studies. When it comes

to the prosthodontic/esthetic consideration, good level of evidence is presented for the abutment portion of the implant-prosthetic complex (Andersson et al., 2003, Jung et al., 2008, Sailer et al., 2009). However, only limited evidence is available based on a prospective and controlled comparison of the esthetic outcomes of different implant crown types/materials.

The aim of this randomized controlled clinical trial is to compare the objective and subjective esthetic outcomes of two types of screwed-retained single-implant crowns. The hypothesis of this investigation is that Porcelain-Fused-to-Ceramic (PFM) and all-ceramic implant restorations are indistinguishable when it comes to the objective/subjective comparison of esthetic integration. The null hypothesis will be defined as follows: all-ceramic implant restorations achieve a different esthetic integration when compared with PFM implant restorations.

Materials and Methods

Study Design

This study was approved by the Ethical Committee of School of Dental Medicine - University of Geneva. Twenty patients were invited to participate in this study. All patients were informed about the characteristic of the study and granted a signed consent form. This study and its implementation adhered to the principles outlined in the declaration of Helsinki on experimentation involving human subjects.

The fulfillment of the inclusion criteria was verified by the investigators at the patients' screening session, including:

General inclusion criteria:

1. Age > 21 years.
2. Absence of relevant medical conditions.
3. Absence of periodontal disease.
4. Availability for 24 months follow-up.

General exclusion criteria:

1. Heavy smokers (more than 10 cigarettes/day).

Specific inclusion criteria:

1. One missing tooth in the anterior maxilla (First bicuspid to first bicuspid).
2. Presence of two intact adjacent teeth.
3. Adequate native bone to achieve implant primary stability.
4. Facial keratinized mucosa width of at least 2mm.
5. Full Mouth Plaque Scores (FMPS) and Full Mouth Bleeding Scores (FMBS) < 25 %

Specific exclusion criteria:

1. Adjacent implants
2. Presence of periapical radilucency at the adjacent teeth.
3. Missing adjacent teeth.

All participants were randomly assigned to one of the two treatment options. A random permuted block system was generated by a collaborator (S.S.) who was not involved in the study. Six permuted blocks containing three test and three control subjects were generated and included in 24 sealed envelopes. A copy of the randomization sequence was preserved for accuracy assessment at the end of the study. Upon patient's enrollment, a sealed envelope was assigned by order of inclusion in the study. The permuted block randomization system ensured the uniformity of the patient allocation during the clinical trial by randomly distributing 3 participants to the test and 3 participants to the control group every 6 treated patients. In order to avoid bias during the prosthodontic treatment, the individually assigned sealed envelopes were only opened after final impression taking and were subsequently sent to the dental laboratory for fabrication of the implant crowns.

The patients were seen under investigation at the following time points:

Baseline (B) – defined as two months after implant placement and before any soft-tissue conditioning or prosthodontic treatment was rendered to the participants.

Crown Insertion (CI) – defined as two weeks after the delivery of the crown but no later than one month.

1-year follow-up (1Y) – defined as within the 12th month after crown insertion.

2-year follow-up (2Y) – defined as within the 24th month after crown insertion.

At each investigational appointment, objective and subjective evaluations were performed. For the objective assessment at baseline, the study design was double blinded since neither the investigators nor the patients were aware of the assigned group. For the objective measurements at CI, 1Y and 2Y the study design was single-blinded being only the participants unaware of the group they were allocated.

For the subjective evaluation, the trial design was double blinded. Neither the patients nor external expert clinicians were informed about the results of the randomization.

Prosthodontic procedures

All patients received single-implants in the anterior maxilla (Standard Plus, Straumann Co, Basel, Switzerland). During the healing phase, all patients wore a removable interim prosthesis. After a minimum 2-month healing period, peri-implant soft-tissue conditioning with a fixed screw-retained provisional and subsequent prosthodontic treatment began. Final impressions were taken at the implant level and subsequently sent to the lab for fabrication of screwed-retained single-implant crowns. For the test group, a screwed-retained all-ceramic crown was fabricated using an in In-Ceram block composed of 90% alumina + glass infiltration (synOcta®-In-Ceram-blank, Ø 9mm, height 15mm and synOcta® abutment, height 2.5mm, Straumann Co. Basel Switzerland). The ceramic block was reduced to the desired shape and dimension. In average, a 1.5mm space was left for the ceramic veneering. Then the all-ceramic framework was glass-infiltrated to reach its optimal mechanical strength. For the ceramic veneering, alumina ceramic was applied in a stratified fashion to mimic the volumetric composition of the natural tooth (figure 1a).

For the control group, a screwed-retained PFM crown was fabricated using a cast-on gold coping (synOcta®-gold coping crown, height 4.5mm, ceramicor and synOcta® abutment, height 2.5mm, Straumann Co. Basel Switzerland). The desired framework shape and dimensions were waxed-up onto the cast-on gold coping and invested in a casting mold. Then, the framework was casted using a high gold content alloy for PFM restorations (ISO 9693 standard). The stratified ceramic veneering was performed in an average thickness of 1.5mm with feldspathic ceramic (figure 1b).

Objective and Subjective Measurements

At each investigational appointment, an intra-oral digital photograph (1:1 ratio), a study cast, a standardized radiograph, periodontal/peri-implant measurements, and a questionnaire were obtained for the assessment of parameters presented in Table 1. Figure 2 represents the objective measurements taken at the implant site and adjacent teeth for each investigational appointment.

In addition, a Pink Esthetic Score (PES) and White Esthetic Score (WES) (Belser et al., 2009) was calculated for both groups by three independent observers at the end of the study. The PES included the following parameters: mesial and distal papilla, curvature of the facial mucosa, level of the facial mucosa, root convexity, soft tissue color, and texture. The WES included: tooth form, tooth volume/outline, color, translucency, and characterization. Both scores were recorded for each group and subsequently compared between groups.

For the subjective evaluation, a Visual Analogue Scale (VAS) questionnaire was used to assess the level of patient satisfaction regarding the esthetic outcome. In a 100 mm straight line where the left end read: “not satisfied at all” and the right end: “fully satisfied”, patients were asked to answer by marking a cross line representing their level of satisfaction. Then all answers were measured form left to right to obtain a numeric value for the patients’ blinded answer.

Nine expert clinicians who were not involved either in the treatment or the investigation accepted to participate in the subjective evaluation at the professional level. They were asked to visually inspect the standardized intraoral photographs and choose one of the following three possible answers when assessing each case, 1: “PFM Implant crown”, 2: “all-Ceramic Implant crown”, 3: “I can’t tell”. Responses obtained from expert clinicians were recorded and statically analyzed.

Statistical Analysis

A non-parametric statistical analysis (Mann-Whitney U-test) was used to compare the objective and subjective parameters between the groups at B, CI, 1Y, and 2Y time point. In addition, objective and subjective parameter (all groups) was analyzed to compare the difference between each study time point. Statistically significant differences were indicated at a P-value ≤ 0.05. For the “within groups” comparison of the PES and WES, a descriptive analysis was

used to calculate the mean value followed of the standard deviation. A Paired T-test was used for the comparison between test and control group with a P-value 0.05 indicating the statistical difference.

For the assessment of expert clinicians' responses, a Receiver Operating Characteristic (ROC) curve was used. The accuracy measurements were statistically calculated using the True Positive (TP) and True negatives (TN) rates over the total number of responses. The p-values correspond to whether these accuracy rates are statistically significantly different from what would be expected from a random guessing.

Results

Twenty patients were included in the study, 10 allocated to the all-Ceramic group and 10 to the PFM group (fig. 3). Three drops-out were recorded. Two patients moved abroad before receiving the final crowns and one patient was unreachable after completing the 1-Year follow-up. The randomization sequence generated by an external collaborator (SS) matched 100% the patient allocation at the end of the study. No implant or abutment failures were recorded during the whole length of the study. A minor chipping was observed in two patients of the ceramic group, and this was corrected by mechanical polishing.

Objective measurements comparing the test and control groups are presented in Table 2. No statistically significant differences were observed for PH, CLt, Cli, KMi, KMt, FMPS, FMBS and FBIC at any of the time points, with the only exception of FMPS at 2Y.

The mean difference for all groups comparing objective parameters between B to CI, CI to 1Y, 2Y are presented in Table 3. The mean PH between B and CI increased by 0.40mm (P- value 0.01) at the mesial site and by 0.49mm (P- value 0.004) at the distal site. The same pattern was observed for PH between CI and 1Y where the mean value for the mesial papilla increased by 0.23mm (P- value 0.05) and 0.17mm (P- value 0.03) for the distal site respectively. Between 1Y and 2Y the increase in papilla height of 0.36mm (P- value 0.008) was only observed for the mesial site. The clinical Crown Length (CL) of teeth adjacent to the implant site remained unchanged throughout the length of the study. The CL at the implant site showed no statistical differences between CI and 1Y. However, between 1Y and 2Y the peri-implant mucosal margin receded by 0.26mm (P- value 0.005).

Differences for the mean values of KM, FMPS, and FMBS were not statistical significant among all compared time points. FBIC was statically significant comparing B to CI and 1Y to 2Y; no changes were observed between CI and 1Y (figure 4).

PES and WES results are presented in Table 4. Out of a maximum score of 20, the PFM group scored mean value of 13.89 and 13.12 for the all-ceramic group. These values were not statistically significant. PES was higher than WES in both groups. Tooth volume/outline, and translucency/characterization values scored the lowest for both groups and were not statistically significant between test and control groups.

As for subjective parameters, Visual Analogue Scale (VAS) patients' responses regarding their perceptions of the esthetic outcome are presented in Figure 5. Out of a maximum 100, in the control group patients scored 84.79 (±13.44) and 87.71 (±8.38) in the test group at CI, 85.67 (±11.51) for the control and 81.02 (±18.26) for the test group at 1Y, and at 2Y the scores were of 91.81 (± 5.94) and 91.78 (± 10.04) for the control and test groups respectively. All this comparisons showed no statistical differences (P-values: 0.72 at CI, 0.82 at 1Y, and 0.98 at 2Y).

For the subjective evaluation at the professional level, ROC curve assessing expert clinicians' ability to correctly determine the crown type for both groups was not statistically significantly different from the value that would be expected from random guessing (figure 6). Clinicians' accuracy scores were 50% and 47% for PFM and all-Ceramic crowns respectively.

Discussion

The long-term survival rate of single-implant crowns in the anterior maxilla has been well documented (Bragger et al., 2005). During the length of this study, no implant or abutment failure was observed. In only two test group patients a minor chipping of the veneering ceramic was observed. This was resolved by an intra-oral mechanical polishing.

No statistical differences were observed when the objective esthetic parameters were compared between the two groups. However the relatively small sample size remains one of the limitations of this investigation.

In order to accurately assess the esthetic outcome of single-implant restorations, comprehensive specific criteria should ideally be taken in consideration. In a cross-sectional study, (Belser et al., 2009) proposed a novel comprehensive index, comprising Pink Esthetic Score and white esthetic score (PES/WES; being 20 the highest possible combined score). When the same index was used in this randomized clinical study to test the esthetic outcome of

PFM and all-ceramic implant rehabilitations, no differences could be confirmed between the test and control group. Both types of single-implant restorations seemed to be suitable for achieving esthetic integration. Although PFM and all-Ceramic single-implant crowns present different characteristics, the fabrication technique calls for anatomically correct design of the framework supporting the veneering material. The framework design should not play a role in the esthetic outcome when an optimal opaque layer and a uniform thickness (1.5 to 2mm) of ceramic veneering are achieved (Stein and Kuwata, 1977). This prosthetic volume is often abundant in anterior implant crowns when the implants are in a correct three-dimensional position. It seems appropriate that a natural looking esthetic integration would be achieved with an anatomically correct reproduction of the missing tooth structures. Several Certified Dental Technicians were involved in the fabrication of all test and control implant crowns. In general, they have achieved most of the esthetic parameters, with either crown type. When the WES score was analyzed in terms of tooth form, tooth volume/outline, color, translucency, and characterization, the same pattern could be observed for both groups. Tooth form, color (hue and value) and surface texture scored similar to the contra-lateral tooth whereas the tooth volume, outline, translucency, and characterization scored the lowest and no differences were observed between test and control groups. This could be explained by the fact that the selection of the implant crown material represents just one of the variables needed to achieve the desired esthetic outcome. In addition to the crown material selection, other parameters such as tooth morphology, translucency and light reflection, surface texture, level of cervical margin, presence of inter-proximal papilla, and resemblance to the contra-lateral tooth need to be considered in achieving a balanced esthetic integration. It can be concluded that, without the other specific esthetic parameters, the implant crown material alone would not be sufficient to ensure the optimal esthetic outcome. When objective parameters for all groups were compared between the time points (B, CI, 1Y and 2Y), an increase of the papilla height and bone remodeling around the implant was observed (table 2). This could be explained by the implant crown insertion, where its cervical diameter would displace the peri-implant mucosa into the inter-proximal embrasures (Gallucci et al., 2007). The papilla height value at the mesial and distal site increased with statistically significant difference from B to CI, form CI to 1Y, 1y to 2Y (only mesial site). The influence of prosthesis rehabilitations on peri-implant soft tissues has been previously analyzed in different clinical situations.(Gallucci et al., 2007, Kinsel et al., 2000, Belser et al., 2009, Furhauser et al., 2005, Jemt, 1997, Meijer et al., 2005, Chang et al., 1999b). Similarly to the results obtained in this clinical trial, (Jemt, 1997) concluded that the soft

tissue contour adjacent to single-implant restorations changed in a systematic manner during the time period between insertion of the crowns and follow-up examinations 1 to 3 years later.

When the PES was compared between the two groups, no differences were observed. The selection of the implant crown material could not be associated with PES morphology related parameters such us PH, curvature of the facial mucosa, and level of the facial mucosa since these related to the overall implant-prosthetic morphology. However, the peri-implant soft tissue color and texture are directly related to the crown morphology as well as to the prosthetic material. In a randomized clinical trial (Jung et al., 2008) measured the color-change of all-ceramic restorations compared with PFM restorations on the marginal peri-implant soft tissue. The authors concluded that, although the all-ceramic crowns presented a better match with the contra-lateral tooth, there were no statistical significance between all-ceramic and PFM single-implant crowns. Similar to PES presented in this study, the peri-implant soft tissue color and texture failed to show any differences when comparing test and control groups. In this context, the influence of the underlying implant-crown material on the peri-implant soft tissue would be influenced to the mucosal thickness. The width of the keratinized mucosa and the implant site ranged from 4.31mm to 5.25mm. This data could explain why no differences were observed on the peri-implant mucosa color between test and control crowns. Of greater importance is the soft-tissue handling at the time of implant placement, where a substantial amount of keratinized mucosa should ideally be preserved at the facial aspect (Buser et al., 2004).

Clinical observation by (Chang et al., 1999b) concluded that, in comparison to the contra-lateral natural crown, the implant supported crown was longer and had a lower height of the distal papilla. In this randomized study, the implant mucosal margin receded by 0.26mm at the implant between CI and 1Y. However, this change had a minor impact on the overall esthetic outcome as indicated by the PES at the level of the facial mucosa.

When the patients judged their own satisfaction with the achieved esthetic outcome, no statistical differences could be demonstrated between test and control groups. The blinded and subjective evaluation by the participants revealed satisfactory scores ranging from 84 to 92 out of a 100 at CI, 1Y and 2Y. Although the WES revealed differences for both groups for the tooth outline, volume, translucency and characterization, in most patients this may not influence their level of satisfaction with the treatment rendered. Conversely, these esthetic variables were more evident to the independent reviewers (PES/WES), which indicates that differences in assessing an esthetic outcome exist between professionals and patients. This differentiation should be carefully taken into consideration by clinicians when delivering a final rehabilitation.

At this stage, both the professional and patient satisfaction with the esthetic outcome should ideally determine whether the implant-crown has achieved an esthetic integration.

The subjective evaluation by expert clinicians fails to show any clinical differences between the groups. While the accuracy in detecting the crown location was high, the expert clinician responses were below the line of no discrimination to what the ROC curve would consider a random guessing. It can be concluded that the clinical differentiation of the esthetic outcomes between PFM and all-ceramic implant crowns may be inconsistent when mayor esthetic parameters are in balance with the natural characteristics of the natural dentition.

Conclusions

1- The material chosen for the fabrication an implant crown *per se* does not ensure an optimal esthetic outcome if other esthetic parameters are not present.

2- The Crown Length at the implant site showed no statistical differences between CI and 1Y. However, between 1Y and 2Y the peri-implant mucosal margin receded by 0.26mm. This was not related to the minor chipping observed in two test implant crowns.

3- Papilla height increased at each study time point, with the distal papilla less marked that the mesial one.

4- Implant crown volume, outline, translucency and characterization showed major discrepancies with the contra-lateral natural teeth.

5- The hypothesis of this investigation that PFM and all-ceramic single-implant restorations are indistinguishable from each other regarding the objective/subjective assessment of esthetic integration was confirmed.

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Tables:

Table 1: Objective and subjective measurements at each investigational appointment.

Parameters	Baseline (B)	Crown Insertion (CI)	1-Year (1Y)	2-Year (2Y)
Objective Measurements				
Mesial and distal papilla height **(PH)** at the implant site.	-	•	•	•
Clinical Crown Length **(CLi)** at the Implant site.	-	•	•	•
Clinical Crown Length **(CLt)** at the adjacent teeth	•	•	•	•
Width of the buccal keratinized mucosa **(KM)** at the implant site and adjacent teeth.	•	•	•	•
Full-mouth plaque score **(FMPS)**	•	•	•	•
Full-mouth bleeding score **(FMPS)**	•	•	•	•
First bone-to-implant contact **(FBIC)**	-	•	•	•
Subjective				
Patient Visual Analogue Scale **(VAS)** questionnaire.	-	•	•	•
Experts clinicians evaluation **(CE)**	-	•	•	•

Table 2: Comparison of objective parameters between test and control group at B, CI, 1Y, 2Y.

	Baseline			Crown Insertion			1-Year			2-Year		
	PFM	All-Ceramic	*p*	PFM	All-Ceramic	*p*	PFM	All-Ceramic	*p*	PFM	All-Ceramic	*p*
Papilla Height - PH (mm)												
Mesial	**2.85** ± 1.30	**2.83** ± 0.96	*0.78*	**3.02** ± 0.88	**3.37** ± 0.88	*0.61*	**3.35** ± 0.92	**3.33** ± 1.11	*0.82*	**3.65** ± 0.48	**3.72** ± 1.10	*0.67*
Distal	**2.10** ± 1.23	**2.32** ± 0.72	*0.54*	**2.73** ± 0.89	**2.55** ± 0.69	*0.90*	**3.67** ± 1.17	**2.60** ± 0.56	*0.09*	**3.22** ± 0.72	**2.87** ± 0.49	*0.09*
Clinical Crown Length – CL (mm)												
Mesial Adjacent Tooth	**9.42** ± 0.80	**9.75** ± 0.97	*0.54*	**9.44** ± 0.92	**9.80** ± 1.14	*0.61*	**9.46** ± 1.06	**9.88** ± 1.40	*0.59*	**9,12** ± 0.94	**10.19** ± 1.49	*0.32*
Implant Crown	-	-	-	**9.49** ± 1.20	**9.04** ± 2.11	*0.96*	**9.67** ± 1.08	**9.48** ± 1.57	*1.00*	**9.01** ± 0.70	**9.26** ± 1.90	*0.79*
Distal Adjacent Tooth	**8.83** ± 1.17	**8.97** ± 1.76	*0.78*	**8.89** ± 1.11	**8.98** ± 1.78	*0.69*	**9.14** ± 1.09	**9.46** ± 1.28	*0.59*	**8.84** ± 1.29	**9.07** ± 1.07	*0.76*
Width Keratinized Mucosa – KM (mm)												
Mesial Adjacent Tooth	**4.22** ± 0.83	**4.50** ± 1.19	*0.66*	**3.62** ± 0.91	**4.75** ± 1.16	*0.19*	**3.57** ± 0.53	**4.42** ± 1.51	*0.26*	**4.66** ± 1.36	**4.50** ± 0.89	*0.16*
Implant Site	**5.25** ± 1.28	**4.52** ± 1.69	*0.91*	**4.31** ± 1.86	**4.50** ± 1.60	*0.94*	**4.57** ± 0.97	**4.43** ± 1.71	*0.85*	**4.83** ± 0.98	**4.67** ± 1.03	*0.74*
Distal Adjacent Tooth	**4.12** ± 1.64	**4.00** ± 0.92	*0.82*	**3.75** ± 1.48	**4.37** ± 0.91	*0.14*	**3.85** ± 1.06	**4.43** ± 1.27	*0.37*	**4.45** ± 1.41	**4.51** ± 1.22	*0.51*
Plaque Score – FMPS (%)												
Full-mouth	**16.0** ± 0.08	**18.1** ± 0.08	*0.71*	**14.2** ± 0.08	**10.5** ± 0.09	*0.28*	**12.7** ± 0.07	**10.5** ± 0.09	*0.84*	**6.2** ± 5.30	**13.1** ± 18.84	*0.001*
Bleeding Score – FMBS (%)												
Full-mouth	**5.9** ± 0.04	**9.8** ± 0.07	*0.17*	**6.3** ± 0.05	**5.2** ± 0.01	*0.65*	**14.0** ± 0.09	**12.1** ± 0.11	*0.45*	**8.3** ± 4.57	**9.7** ± 6.94	*0.73*
First bone-to-implant contact – FBIC (mm)												
Mesial	**2.11** ± 0.27	**2.12** ± 0.40	*0.80*	**1.66** ± 0.29	**1.90** ± 0.39	*0.13*	**1.64** ± 0.37	**1.61** ± 0.46	*0.94*	**2.25** ±0.86	**2.24** ±1.11	*0.97*
Distal	**2.26** ± 0.39	**2.18** ± 0.31	*0.88*	**1.79** ± 0.26	**2.02** ± 0.33	*0.19*	**1.75** ± 0.39	**1.84** ± 0.42	*0.70*	**2.47** ±0.55	**2.29** ±0.93	*0.69*
VAS	-	-	-	84.79 ± 13.44	87.71 ± 8.38	*0.72*	85.67 ± 11.51	81.02 ± 18.26	*0.82*	91.81 ± 5.94	91.78 ± 10.04	*0.98*

All data are presented as mean ± SD.
P-values= 0.05.
PFM: Porcelain-fused-to-metal
VAS: Visual Analogue Scale

Table 3: Mean Difference of Objective parameters (all groups) when compared form B to CI, CI to 1Y, and 1Y to 2Y.

	Baseline vs. Crown Insertion		Crown Insertion vs. 1-Year		1-Year vs. 2-Year	
Papilla Height - PH (mm + P-Value)						
Mesial	0.40	***0.01***	0.23	***0.05***	0.36	***0.008***
Distal	0.49	***0.004***	0.17	***0.03***	0.00	*0.92*
Clinical Crown Length – CL (mm + P-Value)						
Mesial Adjacent Tooth	0.03	*0.59*	0.14	*0.94*	-0.11	*0.37*
Implant Crown	-	-	0.43	*0.46*	-0.26	***0.005***
Distal Adjacent Tooth	0.02	*0.77*	0.29	*0.38*	-0.28	*0.32*
Width Keratinized Mucosa – KM (mm + P-Value)						
Mesial Adjacent Tooth	0.16	*0.73*	-0.01	*0.70*	0.13	0.85
Implant Site	-0.49	*0.30*	0.09	*0.61*	0.16	0.59
Distal Adjacent Tooth	0.01	*0.85*	0.52	*0.59*	0.17	*0.72*
Plaque Score – FMPS (P-Value)						
Full-mouth	*0.26*		*0.98*		*0.61*	
Bleeding Score – FMBS (P-Value)						
Full-mouth	*0.81*		*0.25*		*0.26*	
First bone-to-implant contact – FBIC (mm + P-Value)						
Mesial	0.276	**0.006**	-0.10	*0.56*	0.388	***0.05***
Distal	0.173	**0.05**	-0.01	*0.64*	0.262	***0.05***

All data are presented as mean difference and P-Value, except for FMPS and FMBS that are presented as P-value only. P-values = 0.05.

Table 4: Comparative results of PES and WES between test and control group (Belser et al., 2009).

PES						WES				
Mesial Papilla	Distal Papilla	Curvature of Facial Mucosa	Level of Facial Mucosa	Root Convexity, Soft Tissue Color and Texture	Tooth Form	Tooth volume/ outline	Color (Hue/Value)	Surface Texture	Transluce-cy and Characteri-zation	Total Score
PFM (Mean Score + SD)										
1.71 ± 0.48	**1.28** ± 0.18	**1.72** ± 0.48	**1.29** ± 0.48	**1.57** ± 0.43	**1.71** ± 0.54	**0.83** ± 0.40	**1.33** ± 0.51	**1.34** ± 0.51	**1.00** ± 0.63	**13.89** ± 2.11
All-Ceramic (Mean Score + SD)										
1.37 ± 0.74	**1.42** ± 0.20	**1.50** ± 0.53	**1.37** ± 0.52	**1.37** ± 0.51	**1.25** ± 0.70	**1.12** ± 0.64	**1.26** ± 0.71	**1.37** ± 0.52	**1.13** ± 0.35	**13.12** ± 2.69
PFM vs. all-Ceramic (P-Value)										
0.52	0.86	0.69	1.00	0.60	0.36	0.61	1.00	1.00	0.59	0.83

PES and WES: minimum value was 0 and the maximum was 2.
P-values = 0.05

Figures:

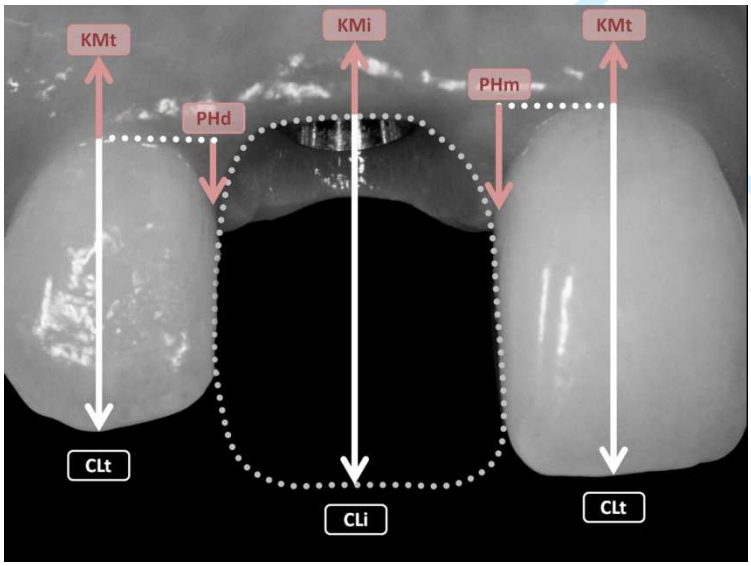
Figure 1

A: Test group, screwed-retained all-ceramic Implant crown.

B: Control group, screwed-retained PFM implant crown.

Figure 2

Graphic representation of objective measurements at the implant site and adjacent teeth.



PH: Distance between the mesial (m) and distal (d) papilla and the zenith of the mid-facial gingival margin of the adjacent teeth.
CLi: Distance between the mid-facial gingival margin and the incisal edge of implant crown.
CLt: Distance between the mid-facial gingival margin and the incisal edge of adjacent teeth.
KMi: Width of the buccal keratinized mucosa at the implant site.
KMt: Width of the buccal keratinized mucosa (Gingiva) at the adjacent teeth.

Figure 3: Standardized Intra-oral Digital Photographs (1:1 ratio) of the test and control group.

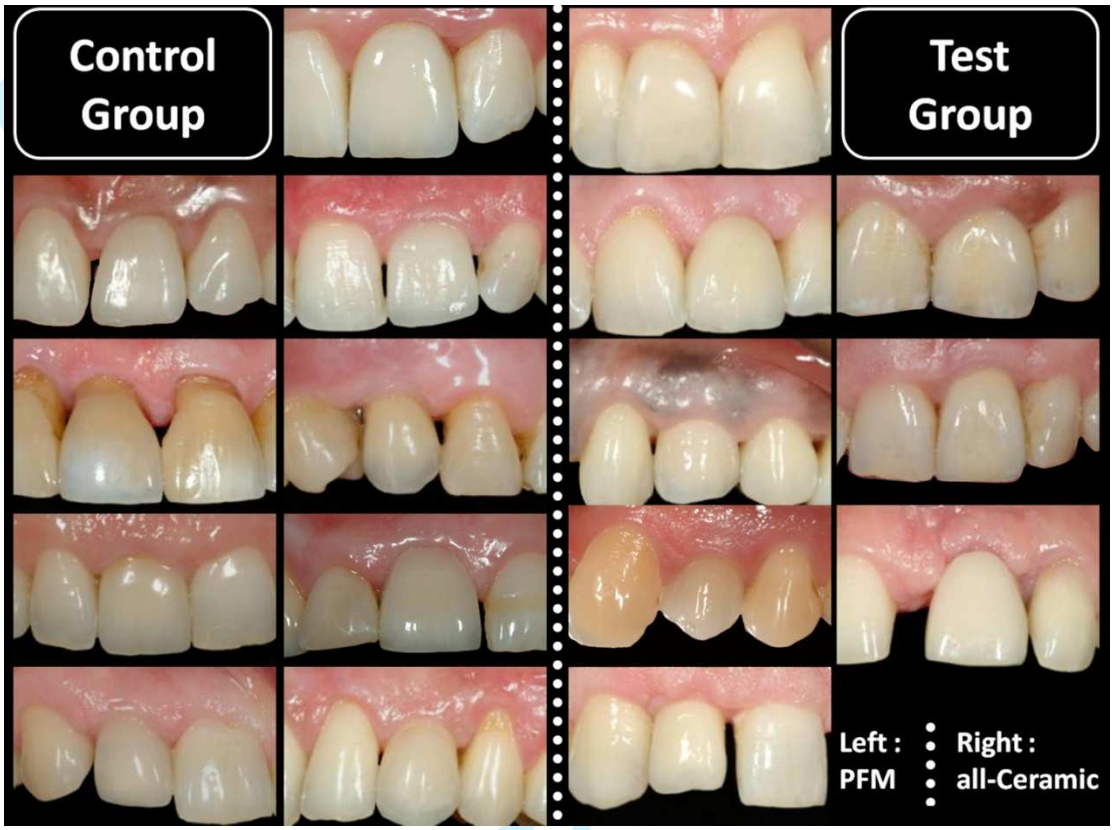


Figure 4: Standardized radiographs a B, CI, 1-Y, 2-Y. Top: PFM. Bottom: all-Ceramic

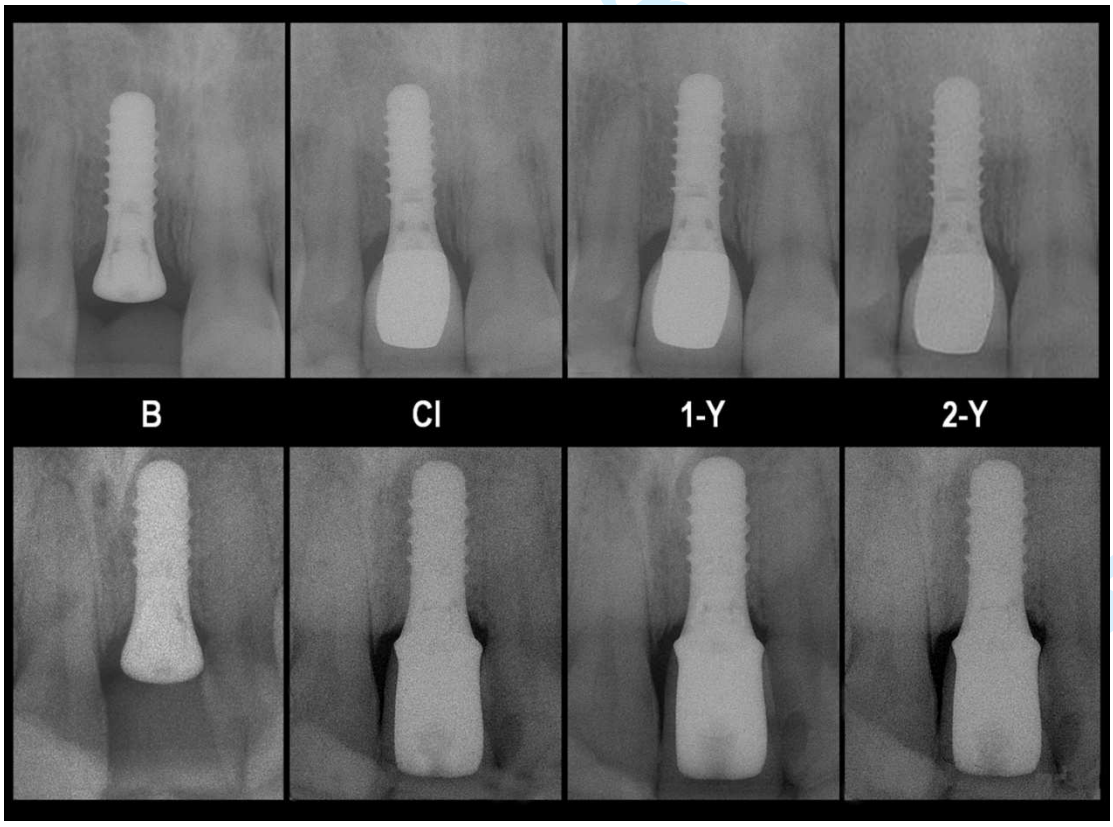


Figure 5: VAS results of patients' satisfaction regarding the esthetic outcome between test and control groups (in mm, 0 to 100 scale).

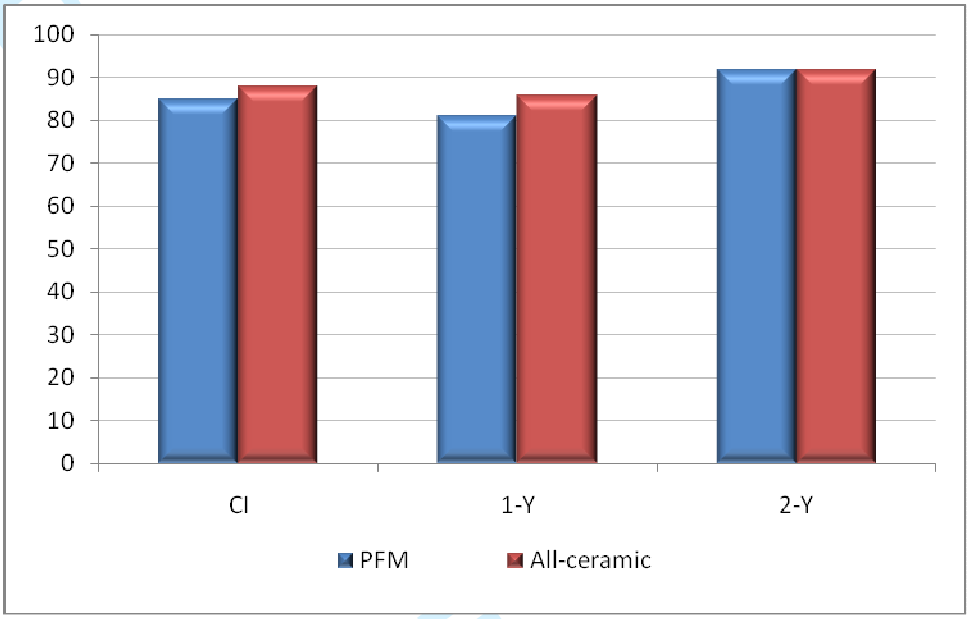
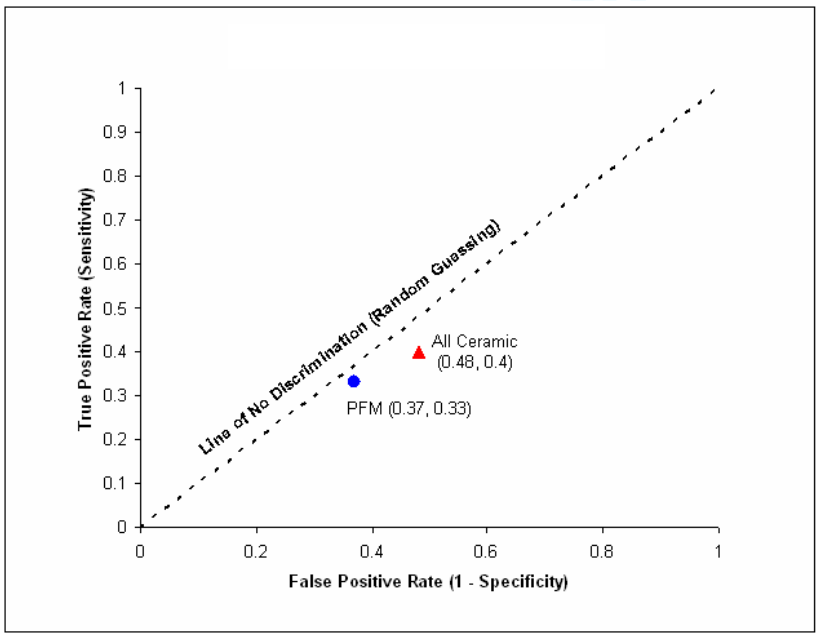


Figure 6: Receiver Operating Characteristic (ROC) for the clinicians' evaluation of crown type by visual inspection.



Receiver Operating Characteristic (ROC) curve including the line of no discrimination – These accuracy rates are not statistically significantly different than the value that would be expected from random guessing.

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CONSORT Statement 2001 Checklist

Items to include when reporting a randomized trial

PAPER SECTION And topic	Item	Descriptor	Reported on Page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned").	5
INTRODUCTION Background	2	Scientific background and explanation of rationale.	3
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	4
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	6
Objectives	5	Specific objectives and hypotheses.	4
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).	4
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	5
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)	5
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	6
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	5
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	6
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	7
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	8
Recruitment	14	Dates defining the periods of recruitment and follow-up.	5
Baseline data	15	Baseline demographic and clinical characteristics of each group.	8
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).	8
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval).	9
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	9
Adverse events	19	All important adverse events or side effects in each intervention group.	8
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	9-12
Generalizability	21	Generalizability (external validity) of the trial findings.	12
Overall evidence	22	General interpretation of the results in the context of current evidence.	9-12

From Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet 2001; 357(9263):1191-1194.

The CONSORT Statement 2001 checklist is intended to be accompanied with the explanatory document that facilitates its use. For more information, visit www.consort-statement.org.