ORIGINAL ARTICLE

A 5-year randomized controlled trial comparing zirconiabased versus metal-based implant-supported single-tooth restorations in the premolar region

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Abstract

Objective: To compare 5-year biological, technical, aesthetic, and patient-reported outcomes of single-tooth implant-supported all-ceramic versus metal-ceramic restorations.

Materials and methods: Thirty patients with 63 premolar agenesis participated in the 5-year follow-up. The prosthetic treatment on single-tooth implants was randomly assigned to all-ceramic crowns on zirconia abutments (AC = 31) or metal-ceramic crowns on metal abutments (MC = 32). All patients were recalled to clinical examinations at baseline, 1, 3, and 5 years after prosthetic treatments. Biological, technical, and aesthetic outcomes including complications were clinically and radiographically registered. The patient-reported outcomes were recorded using OHIP-49 questionnaire before treatment and at each follow-up examination.

Results: At the 5-year examination, the survival rate was 100% for implants and 100% for AC and 97% for MC crowns and abutments. The marginal bone loss after 5 years was minor and not significantly different (p = .056) between AC (mean: 0.3, *SD*: 1.1) and MC (mean: -0.1, *SD*: 0.4) restorations. The success rate of the implants based on marginal bone loss was 77.4% for AC- and 93.7% for MC restorations. The marginal adaptation was significantly better for MC than for AC restorations (p = .025). The aesthetic outcomes and patient-reported outcomes between AC and MC restorations were not significantly different.

Conclusions: The biological, aesthetic and patient-reported outcomes for implantsupported AC and MC restorations were successful and with no significant difference after 5-years. The marginal adaptation of the MC crowns cemented on titanium abutments showed a significantly better fit than restorations based on zirconia crowns cemented on zirconia abutments.

KEYWORDS

aesthetic outcome, biological outcome, cement-retained, implant prosthetic treatment, implant-supported single-tooth restorations, patient-reported outcome, technical outcome, titanium abutment, zirconia abutment

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Replacement of missing teeth with dental implants is an established treatment modality, which has become a routine option for many clinicians and patients (Morton et al., 2018). A promising long-term survival rate of single-tooth implants has led to the development of more aesthetic solutions using ceramic materials, especially zirconia, which make it possible to imitate the appearance of the natural tooth (Höland et al., 2008; Pjetursson et al., 2018). Zirconia is increasingly being used as an alternative for metal abutment and metal-ceramic crowns for implant-supported reconstructions. The use of zirconia as a material for biomedical devices is based on reliable mechanical properties achieved by the addition of Yttria (Y₂O₃) to zirconium dioxide (van Brakel et al., 2012). The biologic benefits of zirconia as an abutment material remain a matter of scientific debate because of different issues, among the other complex nature of the cell response to the abutment material, which is influenced by both the material and the surface topography (Nothdurft, 2019; Nothdurft et al., 2015). Different abutment materials may have a significant effect on the peri-implant inflammation (Sanz-Martín et al., 2018), but histological analysis of biopsies from patients with zirconia and titanium abutments revealed no distinct differences with respect to peri-implant soft tissue health, and it was concluded that the perceived differences in appearance of soft tissue overlaying the abutments could be due to optical properties rather than biological differences (van Brakel et al., 2012). Despite a different microbial profile and genome counts at the titanium and zirconia abutments, healthy clinical conditions at the peri-implant mucosa and marginal bone have been recorded at zirconia and titanium abutment materials (de Oliveira Silva et al., 2020) (Appendix S1).

From a technical point of view, zirconia abutments have shown a lower fracture resistance and lower flexural strength than titanium abutments (Atoui et al., 2013; Att et al., 2006; Kim et al., 2009), but both abutment materials have met the requirement for clinical application (Kim et al., 2009). In addition to the promising in vitro results evaluating fracture resistance of metalceramic crowns supported by titanium abutments and all-ceramic crowns supported by zirconia abutments (Hosseini et al., 2012; Sghaireen, 2015), the clinical performance of the conventional two-piece abutment-crown restorations based on zirconia and titanium abutments needs to be investigated in comparative long-term clinical studies. Only a few clinical studies with short observation period have reported on zirconia as an alternative material to titanium abutments (Baldini et al., 2016; Carrillo de Albornoz et al., 2014; Vechiato-Filho et al., 2016). Randomized clinical trials following restorations using zirconia compared with titanium abutments for 5 years or more are missing. One RCT reported on customized zirconia and titanium abutments 5 years after crown insertion, where the implant platform in the study was an external hexagon (Zembic et al., 2013), in which strength is claimed to be less superior to internal connections using zirconia abutment (Sailer et al., 2009). Another clinical study compared zirconia and titanium abutments after 5 years without randomization

(Lops et al., 2013), and the type of implant system was not reported. Thus, more knowledge on the clinical performance and survival rate of the zirconia abutment with internal connection to the implant and zirconia-supported crowns on single-tooth implants is required (Hu et al., 2019).

The purpose of this randomized clinical trial was to compare the 5-year biological, technical, aesthetic and patient-reported outcome of implant-supported all-ceramic crowns cemented on zirconia abutments with metal-ceramic crowns cemented on titanium abutments in patients with tooth agenesis in the premolar region.

2 | MATERIALS AND METHODS

In this RCT, the inclusion criteria were patients with tooth agenesis in the premolar region, having no contraindications for oral implant treatment as described in the 1-year follow-up paper (Hosseini et al., 2011). The participants were consecutively enrolled from January 2008 to December 2009 at the Department of Oral Rehabilitation according to the study protocol accepted by the Danish Regional Committee on Biomedical Research Ethics (H-1-2009-119). This study followed the recognized standards (Declaration of Helsinki) and guidelines (CONSORT: Consolidated Standards of Reporting Trials [Schulz et al., 2010]). For each participant, informed consent was provided prior to the inclusion in the study and the method was not changed after trial commencement. Briefly, 36 patients (18 men and 18 women, mean age: 28.1 years) were included. The missing premolars were replaced with 75 implants (Astra Tech Implant System®, Dentsply Sirona, Mölndal, Sweden) restored randomly with zirconia abutments and zirconia all-ceramic crowns (AC restorations) or metal abutments and metalceramic crowns (MC restorations). The prosthetic treatments were randomized using concealed envelopes at site level between AC (test group: n = 38) and MC (control group: n = 37) restorations. A stratification procedure was performed in patients with two or more premolar implants to ensure that these patients had both an all-ceramic and a metal-ceramic restoration. To conceal the random allocation as long as possible, a person independent of the treatments informed the treating prosthodontist about the type of restoration (AC or MC) after the impression was taken. For patients with several premolar restorations, the allocation of restoration material started with the most distal restoration in the first quadrant and continued to the second, third, and finally to the most distal restoration in the fourth quadrant (Hosseini et al., 2011). The sample size was determined by a power calculation based on peri-implant marginal bone loss of a comparable patient group provided from results of a published 3-year prospective study (Hosseini et al., 2013). The clinically relevant difference in mean marginal bone loss (δ) between two patient groups was set to 0.2 mm, standard deviation of marginal bone loss (σ) was set to 0.3 mm, and type 1 (α) and type 2 (β) errors were set to 5% and 20%, respectively. Thirty-five implantsupported single-tooth restorations should be used in the test and in the control group.

2.1 | Treatment procedure

All included implants were inserted by four experienced oral surgeons at the Department of Oral and Maxillofacial Surgery, Glostrup University Hospital (Copenhagen, Denmark), according to the standard surgical guidelines from the manufacturer. In 35 implant regions with atrophy of the buccolingual dimension, a local bone grafting procedure with a combination of autologous bone and a xenograft bone substitute and collagen membrane (Bio-Oss® and Bio-Gide® membranes, Geistlich Pharma AG) was accomplished. After a healing period of 4-6 months, the patients were referred to the Department of Oral Rehabilitation, School of Dentistry, Copenhagen, for prosthetic treatment and follow-up examinations. All zirconia abutments were ZirDesign[™] (Astra Tech Implant System®, Dentsply Sirona), whereas the metal abutments were 35 titanium abutments (TiDesign[™], Astra Tech Implant System[®], Dentsply Sirona), and 2 gold abutments (Cast-to[™], Astra Tech Implant System®, Dentsply Sirona).

The abutments were prepared with chamfer preparations and a finish line design located 1 to 1.5 mm submucosally in visible regions and <1 mm submucosally in non-visible regions.

The all-ceramic crown copings for AC restorations were manufactured from presintered zirconia blanks by computer-aided design/computer-aided manufacturing (CAD/CAM) technique. The metal-ceramic copings for MC restorations were fabricated using the conventional lost-wax casting technique. All crowns were buccally designed with an all-porcelain butt joint.

All abutments were screw-retained using a screw torque of 25 Ncm in accordance with the manufacturer's recommendations. All crowns were cement-retained: 71 ISSCs with phosphate cement (DeTrey® Zinc, Dentsply, Konstanz, Germany) and 4 (AC: n = 3, MC: n = 1) with resin cement (Panavia®, Kuraray, Okayama, Japan). All patients were instructed to optimal oral hygiene regime at the time of crown cementation and at each follow-up examination. Further supportive therapy was initiated by an oral hygienist if indicated.

2.2 | Follow-up examinations

All patients were recalled for baseline, and 1-, 3- and 5-year followup examinations, and the clinical trial ended after the last follow-up as the quality control of treatments was completed 5 years from the prosthetic treatment was performed. The clinical and radiographic assessments were blinded and performed by one observer, who was not involved in the treatment of the patients. Clinical photographs of the restorations, including the neighboring teeth and marginal peri-implant mucosa, were taken by using a digital camera (Canon EOS450D, Canon) with a macro lens flash (MACRO RING LITE MR-14 EX, Canon) at all follow-up examinations. Digital intraoral radiographs (Digora® Optime digital films, Soredex, Tuusula, Finland) were obtained by using long cone paralleling technique with Eggen's film holders at each follow-up examination, and were assessed using the Digora Optime system. Biological, technical and aesthetic variables were registered at all examinations. Trial outcome measures were not changed after the trial commenced.

2.3 | Biological outcome variables

Implant survival and success rates were recorded. Peri-implant health and oral hygiene were assessed by recording mobility of the implant, probing pocket depth (PPD), modified Plaque Index (mPII), and Sulcus Bleeding Index (mBI) at four aspects of each implant (Mombelli et al., 1987). The median values of four scores of mPII and mBI at each implant were used for statistical analyses. The marginal bone levels at the implants were assessed as the most coronal boneimplant contact mesially and distally. The peri-implant marginal bone loss was the mean value of the change in the mesial and the distal marginal bone level between baseline and follow-up examinations. The implant success rate was based on the criteria described by Albrektsson et al. (1986), that is, a marginal bone loss (MBL) less than 1.5 mm during the first year and less than 0.2 mm annually, that is, less than 0.8 mm between the 1-year and the 5-year examination.

Diagnosis of peri-implantitis was based on a combination of bleeding and/or suppuration by gentle probing, probing depth more than 5 mm, and a marginal bone level located at least 3 mm apical to the most coronal intra-osseous part of the implant after the first year of the loading (Berglundh et al., 2018). Additionally, diagnosis of peri-implant mucositis was based on the presence of suppuration/ bleeding by gentle probing and/or registration of fistula in the absence of bone loss after initial bone remodeling (Berglundh et al., 2018).

2.4 | Technical outcome variables

Clinical examinations included assessments of crown survival, technical complications such as abutment screw loosening, loss of retention or fracture of ceramics, and radiological recording of cement excess. The marginal fit of the crowns was recorded radiologically using a modified marginal adaptation score: Score 1 was excellent fit, score 2 was distinguishable misfit, score 3 was distinct misfit, and score 4 was unacceptable misfit (Dueled et al., 2009).

2.5 | Professional-reported aesthetic outcome variables

The professional-reported aesthetic outcome of the restorations was evaluated using the Copenhagen Index Score (CIS) (Dueled et al., 2009; Hosseini & Gotfredsen, 2012). According to this index, each score ranged from 1 for the best to 4 for the poorest aesthetic outcome. The following five variables from CIS were used in this study: crown morphology score, crown color match score, mucosal discoloration score, and papilla index score.

2.6 | Patient-reported outcome variables

A possible impact on oral health-related quality of life was evaluated by the patients using a Danish version of the Oral Health Impact Profile questionnaire (OHIP-49) before prosthetic treatment, at baseline and at 3- and 5-year examinations (Gjørup & Svensson, 2006). Each answer was scored with a Likert response scale from 0 (never experienced problem) to 4 (problem experienced very often). The summary of questions 3, 4, 20, 22, 31, and 38 was used to describe the patient-reported aesthetic outcome (Dueled et al., 2009), the masticatory function was expressed by the summary scores of questions 1, 28, 29, and 32 (Goshima et al., 2010), and the overall oral health impact on quality of life was described by a summary of the scores from all 49 OHIP questions. The analyses of patient-reported outcome variables included the comparison between patients treated with one premolar implant (AC or MC), or patients with at least two implants with both types of restorations.

2.7 | Statistics

The statistical analyses of outcome variables were performed with the SPSS version 27. Descriptive analyses of data were performed. To account for individual differences in response to the different type of restorations, models had to incorporate patients as a random subject. For the quantitative data (differences in bone level, bone loss, and CIS values), evaluation was performed using a linear mixed model analysis. For ordinal categorical data at implant level (differences in mPII, mBI, marginal adaptation score, and professional-reported aesthetic scores in the test and control groups), a generalized linear mixed model analysis was applied. The patients were the statistical unit for description of the patient-reported outcomes. Thus, the Mann-Whitney U test for difference in the total scores between groups of patients, the Wilcoxon signed-rank test for difference in the total scores between examinations, and the chi-squared test for difference in nominal data between different patient groups were used. The statistical significance level was set at p < .05.

3 | RESULTS

The mean follow-up time of patients from the prosthetic treatment to 5-year examination was 62.3 months. Thirty patients showed up at the five-year follow-up examination. The characteristics of these patients are listed in Table 1. The number of dropout patients was six. Four patients with nine implant-supported restorations (AC: n = 5, MC: n = 4) did not respond to several recalls, one patient (AC: n = 1) had moved to another city and refused to show up, and one (MC: n = 1) patient informed after 1 year that he did not wish to participate in the study any longer according to the informed ethical guidelines. TABLE 1 Characteristics of patients participating in the 5-year follow-up examination

Number of patients	30
Number of implants	63
Age of patients	Median: 23.6 years, range: 19.3–54.1
Gender	Female: <i>n</i> = 14, Male: <i>n</i> = 16
Number of agenesis for each patient	Median: 5, range: 1–12
Number of implants in premolar region	63
Implant type	Astra Tech®, Dentsply Sirona, Mölndal, Sweden
Implant width (mm)	3.5: <i>n</i> = 2, 4.0: <i>n</i> = 4, 4.5: <i>n</i> = 22, 5.0: <i>n</i> = 35
Implant region	Maxillary premolars: <i>n</i> = 33 Mandibular premolars: <i>n</i> = 30
Number of adjacent premolar implants	14 (seven patients)
Restoration type	AC: <i>n</i> = 31, MC: <i>n</i> = 32

Abbreviations: AC, all-ceramic restorations; MC, metal-ceramic restorations.

3.1 | Biological outcomes

Sixty-three implants placed in 30 patients were all followed for 5 years with an implant survival of 100%.

The major part of the patients maintained optimal oral hygiene with no or minimal plaque and Bleeding on Probing (Score 0 and 1; Table 2), and there were no significant differences in mPII and mBI scores between AC and MC restorations (p = .360 and .350, respectively) at the 5-year examination. Table 2 demonstrates slightly more frequent Bleeding on Probing at AC restorations than at MC restorations. The mean values of the probing pocket depth (AC: 2.8 mm, *SD* 0.9 mm; MC: 2.7 mm, *SD* 0.6 mm; p = .862) and the mean of the marginal bone loss (AC: 0.3 mm, *SD* 1.1; MC: -0.1 mm, *SD* 0.4; p = .056) were not significantly different between the test and the control group. However, the frequency of implants with marginal bone level more than 2 mm and marginal bone loss more than 0.8 mm was more in AC than in MC restorations. The change in the mean of marginal bone level mesially and distally in AC and MC restorations during the study is demonstrated in Figure 1.

The value of the PPD was less than 5 mm except for one implant site with AC restoration (PPD: mesial: 10 mm, distal: 8 mm). This implant site had a reduced marginal bone level already at the baseline registration. As the reduction of marginal bone level was increased, the patient received supra- and subgingival debridement combined with antibiotic regimen and chlorhexidine rinse and several recalls with supportive care after the 3-year examination. Nevertheless, the implant site demonstrated an excessive marginal bone loss at the 5-year observation period (MBL = 5.3 mm mesially, MBL = 4.5 mm distally, MBI: score 3) (Figure 2). Thus, the patient was referred to surgical treatment of the peri-implantitis after the 5-year examination, and the data from the 5-year examination were included in the analysis.

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TABLE 2 Descriptive analyses (frequency of valid/non-missing data) of the plaque (mPII) and bleeding (mBI) scores, biological complications, marginal bone level, and marginal bone loss in relation to restoration material (AC: all-ceramic, MC: metal-ceramic) at the 5-year examination

Biological outcomes	AC	МС
mPII		
Score 0	56.7% (n = 17)	58.1% (n = 18)
Score 1	16.7% (n = 5)	29.0% (n = 9)
Score 2	23.3% (n = 7)	12.9% (n = 4)
Score 3	3.3% (n = 1)	0%
mBI		
Score 0	51.7% (n = 15)	25.8% (n = 8)
Score 1	13.8% (n = 4)	51.6% (n = 16)
Score 2	31.0% (n = 9)	19.4% (n = 6)
Score 3	3.4% (n = 1)	3.2% (n = 1)
Marginal bone level	<2mm: 83.9% (n = 26)	0-2 mm: 100% (<i>n</i> = 32)
(measured from implant/	2-2.9 mm: 12.9% (n = 4)	2–2.9 mm: 0% (n = 0)
abutment connection)	≥3 mm: 3.2% (<i>n</i> = 1)	≥3 mm: 0% (<i>n</i> = 0)
Marginal bone loss (MBL) between 1- and 5-yea	r examinations
Implant level	<0.8 mm: 77.4% (n = 24)	<0.8 mm: 93.8% (n = 30)
	0.8–2 mm: 19.3% (<i>n</i> = 6)	0.8-2 mm: 6.3% (n = 2)
	>2 mm: 3.2% (<i>n</i> = 1)	$> 2 \mathrm{mm}: 0\% \ (n = 0)$
Subject level	≥0.8 mm 13.3% (<i>n</i> = 4) ^a	≥0.8 mm 6.7% $(n = 2)^{b}$

^aOne of the patients had marginal bone loss at two AC restorations. ^bTwo patients with marginal bone loss at two implants with both AC and MC restorations.

At the 5-year follow-up, nine implants (AC: n = 7, MC: n = 2) distributed at six patients did not meet the criteria for implant success, as the marginal bone loss (MBL) was more than 0.8 mm between the 1-year and the 5-year examination (Table 2). Thus, the test group (AC) had a 5-year biological success of 77.4%, whereas the control group (MC) had a 5-year success rate of 93.8%. However, all implant sites had a MBL less than 1.5 mm during the first year of loading, and only one implant demonstrated a MBL more than 2.3 mm (AC: n = 1) from baseline to 5-year examination.

The peri-implant mucositis was registered at 34.4% of AC restorations and at 22.6% of MC restorations after 5 years. At these sites, the mBI had score 2 or 3 including buccal marginal fistula at one implant site in the test group (Figure 3).

3.2 | Technical outcomes

The survival rates of AC and MC restorations were unchanged between the 1- and 5-year examination, that is, AC: 100% and MC: 97%.

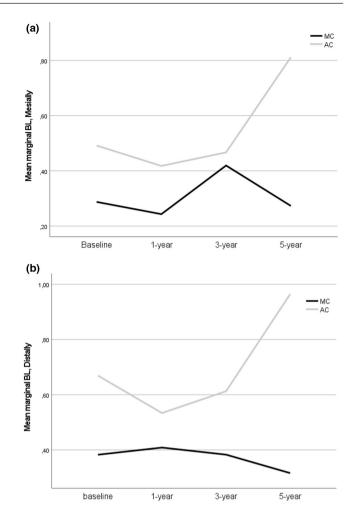


FIGURE 1 Mean of marginal bone level mesially (a) and distally (b) in the test (AC) and control (MC) group over the observation time

Technical complications at the 3-year examination were loss of retention of two MC crowns (6.2%, both recemented) and ceramic veneering fractures of one MC crown (3.1%, the same crown had chipping fracture at the 1-year examination).

The technical complication at the 5-year examination was one ceramic veneering fracture of one AC crown (3.2%) in the same patient with one ceramic fracture at the 3-year examination (Figure 4). No fractures or other complications related to the zirconia or titanium abutments were seen during the 5-year study period.

Thus, a total number of five technical complications (MC: n = 4, percentage: 12.5%; AC: n = 1, percentage: 3.2%) were registered 5 years after loading.

The radiologically evaluated marginal adaptation scores were significantly (p = .003) lower, that is, with better fit of the MC compared with the AC restorations at the 5-year examination (Figure 5). There was no significant correlation between the marginal adaptation scores and the marginal bone loss at the 5-year examination, and no cement excess was detected radiographically at the last examination.



FIGURE 2 Clinical photographs and radiographs of the worst case with implant region 45 with AC restoration and region 35 with MC restoration at the baseline, and 1-, 3-, and 5-year examination. The marginal bone level at the implant region 35 did not change during the follow-ups, while a severe progression of marginal bone loss (peri-implantitis) occurred at the implant region 45

FIGURE 3 Fistula of the marginal peri-implant mucosa registered buccally at the implant site with zirconia-based restoration at the 5-year examination



3.3 | Aesthetic outcomes

The six professional-reported aesthetic scores at the 5-year examination were not significantly different between the AC and MC restorations (Table 3).

Median mucosal discoloration scores in both groups (median = 1) were unchanged at all examination times. From the 1- to the 5-year examination, the mucosal discoloration score increased; that is, the

marginal mucosa covering the implant/abutment became darker at eight implant sites of the AC restorations and at 4 implant sites of the MC group.

The mesial papilla changed significantly from baseline to 1 year (p = .001) and from 3-year to 5-year examination (p = .011) as the papilla filled more of the mesial proximal space (papilla index scores, mesially reduced). The mesial papilla showed no significant changes between the 1- and 3-year examinations (p = .736).

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FIGURE 4 Fracture of veneering ceramics in the same patient. One chip-off fracture of MC-crown region 15 at the 3-year examination, and one fracture of veneering ceramic of AC restoration region 14 at the 5-year examination

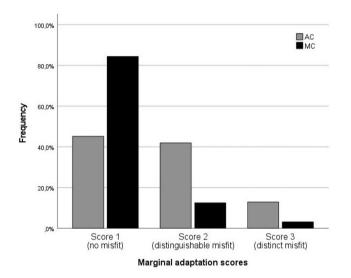


FIGURE 5 Bar chart demonstrating the difference in the frequency of the marginal adaptation scores between the AC and MC restorations at the 5-year examination

Distal papilla index scores did not change significantly between the examinations.

The papilla index score and the marginal bone level were not significantly correlated after 3 and 5 years.

3.4 | Patient-reported outcomes

The total mean (*SD*) summary of OHIP-49 scores, and the aesthetic and masticatory OHIP scores at different examination times are listed in Table 4. A significant difference was seen between scores before prosthetic treatment and baseline, and 1-, 3- and 5-year follow-up examinations.

Among all OHIP questions, OHIP-7 was a question about food impaction, having the highest mean values of scores for all participants compared with other OHIP-49 questions before and after the prosthetic treatment (Figure 6). The mean of this score was significantly higher in patients with two adjacent implants compared to patients with only one implant-supported restoration at the baseline examination (single implant: mean 1.67, SD 1.18; adjacent implants: mean 3.0, SD 0.89; p = .018).

4 | DISCUSSION

In the present study, the 5-year survival rate of the implants was 100% in both the test and the control group. The survival rate of zirconia-based restorations was 100% and 97% of the metal-based restorations. Although minor complications were registered more often in the AC than in the MC group, only the marginal adaptation score was significantly worse for AC reconstructions.

Another randomized clinical study with 5-year follow-up (Zembic et al., 2013) reported slightly lower survival rates of the implants (AC: 88.9% and MC: 90%) compared with our study, but with a similar survival rate for all-ceramic and metal-ceramic restorations (100%).

In the present study, the 5-year biological success rate of the implants based on marginal bone loss between the 1- and 5-year examination (Albrektsson et al., 1986) was lower for implants supporting the zirconia abutments than for implants supporting metal abutments. After five years, more mean marginal bone loss after five years was registered for implants supporting zirconia compared with implants supporting titanium abutments. This is in accordance with a review study (Vechiato-Filho et al., 2016), based on 11 clinical studies of single-tooth implants with one to 5 years of follow-up, reported more marginal bone loss around implants supporting zirconia abutments (0.38 ± 0.87) compared with the implants supporting titanium abutments (0.2 ± 0.13).

The biological outcome of zirconia versus titanium abutments in our clinical study was monitored using probing pocket depth, bleeding or suppuration on probing, and radiological evaluation of marginal bone loss. In general, our results indicated less favorable biological conditions associated with implants in the AC compared with implants in MC restorations at the 5-year follow-up examination. Thus, more peri-implant mucositis was demonstrated with zirconia than with metallic abutment. It is uncertain whether this is related to the abutment or the crown material, but could be explained with a more apically placed marginal bone level and less optimal fitting of the AC crowns/zirconia abutments compared to the MC crowns with the

TABLE 3 Percentage of the aesthetic scores at the 5-year follow- up examination in the test and control group and the statistical analyses of the difference with <i>p</i> -values and 95% confidence interval for Exp (coefficient)	Aesthetic variables	Score 1 (%)	Score 2 (%)	Score 3 (%)	Score 4 (%)	p-value (95% CI)
	Harmony and symmetry					
	AC	26.7	66.7	6.6	0	.891 (0.23–5.35)
	MC	28.1	59.4	12.5	0	
	Crown morphology					
	AC	35.5	45.2	19.3	0	.544 (0.28–1.98)
	MC	34.4	59.4	6.2	0	
	Crown colour match					
	AC	41.9	54.9	3.2	0	.426 (0.51-4.72)
	MC	34.4	62.5	3.1	0	
	Mucosal discoloration					
	AC	64.5	22.5	6.5	6.5	.125 (0.12–1.30)
	MC	81.2	12.5	6.3	0	
	Papilla, mesially					
	AC	48.4	35.5	9.7	6.4	.858 (0.39-3.10)
	MC	48.4	38.7	9.7	3.2	
	Papilla, distally					

32.3

25.8

Abbreviations: AC, all-ceramic crown based on zirconia and zirconia abutments (test group); MC, metal-ceramic crown and titanium abutments (control group).

41.9

58.1

22.6

9.7

3.2

6.4

.814 (0.41-3.13)

TABLE 4 Means and standard deviations (SDs) of the summary scores of overall oral health impact profile on quality of life (OHIP-49 scores), summary scores of aesthetic OHIP-questions (OHIP 3, 4, 20, 22, 31, and 38), and summary scores of masticatory function OHIP questions (OHIP 1, 28, 29, and 32). The p-values demonstrate the significant level of the differences between the outcomes before treatment and after treatment at each follow-up examination

AC

MC

Summary of OHIP scores	Before prosthetic treatment	Baseline	1 year	3 years	5 years
OHIP-49	24.93 (26.67)	10.47 (11.10)	9.47 (11.97)	9.93 (12.70)	9.27 (12.96)
p-values ^a	-	.003	.000	.004	.004
Aesthetic	5.10 (5.72)	0.97 (1.66)	1.36 (2.86)	1.25 (2.26)	0.90 (2.01)
p-values ^a	-	.000	.000	.006	.001
Masticatory function	2.28 (2.91)	0.91 (1.40)	0.61 (1.20)	0.61 (1.20)	0.50 (1.04)
p-values ^a	-	.011	.003	.029	.006

^aBefore vs. follow-ups.

metallic abutments. Another 5-year RCT of zirconia versus titanium abutments on single-tooth implants reported on slightly more marginal bone loss around implants with zirconia abutments between baseline and the 5-year follow-up than observed at implants with titanium abutments, where almost no change was registered (Zembic et al., 2013). The number of included patients and the differences were, however, so small that it is doubtful to interpret clinical implications of these findings. This was supported by another clinical study, demonstrating almost the same mean marginal bone loss at the zirconia and at the titanium abutments after the 5-year examination (Lops et al., 2013). This is also in accordance with several other studies, demonstrating no significant differences in the clinical

evaluation of plaque, Bleeding on Probing, or PPD between different restoration materials (Lops et al., 2013; Vechiao-Filho et al., 2016; Zembic et al., 2013).

A study by Welander et al. (2008) indicated high biocompatibility of the zirconia material since the proportion of leukocytes at the barrier epithelium was lower at zirconia than at titanium abutments. The reason for differences in the biological outcomes around zirconia and titanium abutments might also be other factors such as cement excess, misfit between crown and abutment, and irregularities promoting plaque accumulation rather than material properties as such (Vechiato-Filho et al., 2016). The presence of cement excess has been mentioned as a biological disadvantage of implant-supported

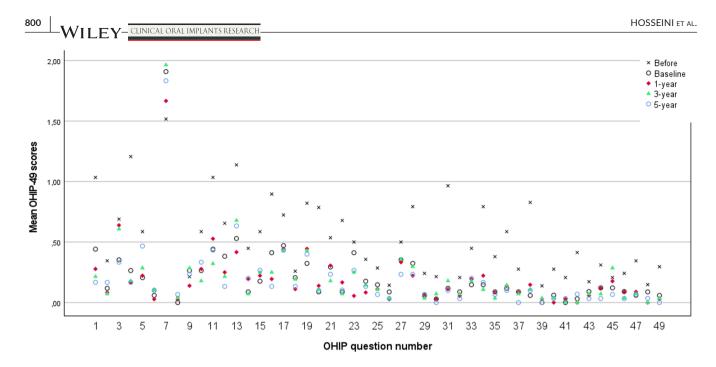


FIGURE 6 Mean of the OHIP scores at different examination times

restorations (Bonde et al., 2010; Zembic et al., 2013). In our study, all implant-supported restorations were cement-retained crowns, but no detectable cement excess was registered at the 3- and 5-year examination. The registration was, however, based on 2D X-rays without the possibility to detect any cement excess in the buccolingual dimension. The effect of cement-retained versus screw-retained reconstructions on the peri-implant tissue has been investigated in several clinical studies, indicating no significant difference in the biological outcomes (Cacaci et al., 2017: Heierle et al., 2019: Kraus et al., 2019). However, in the study by Kraus et al. (2019), two patients lost their implants in the cemented group due to biological complications. And in a histological study by Thoma et al., (2018), more inflammatory cells were associated with cemented compared to screw-retained all-ceramic crowns. In our study, primarily using phosphate cement, no cement excess was detected and only minor inflammatory reactions were observed. The increased peri-implant inflammation at the zirconia crowns with all-ceramic crown seen in our study could be a result of less optimal marginal adaptation of the all-ceramic compared with the metal-ceramic restorations.

Only a few clinical studies have reported on marginal adaptation of crowns and abutments. An in vivo study of 270 crowns of different materials demonstrated a significant larger marginal gap at zirconia and glass-ceramic crowns compared with the metal-ceramic crowns (Huang et al., 2015).

Despite the higher risk of fracture reported for zirconia abutments compared with titanium abutments (Foong et al., 2013; Hosseini et al., 2012), no abutment fractures were found in our study. The frequency of ceramic fractures was lower in the AC than in the MC group, but veneering fractures of AC crowns were more extended with exposure of the zirconia core materials (adhesive fracture) in contrast to chipping of ceramic veneering (cohesive fracture) of the MC crowns. These results are in accordance with an in vitro study of dynamic loading of AC and MC restorations on single-tooth implants (Hosseini et al., 2012). A clinical study of metal-ceramic and all-ceramic single crowns with a follow-up time of up to 12.8 years reported an even greater incidence of veneering fracture of zirconia than of metal-ceramic crowns; therefore, it has been proposed to avoid full-coverage veneers on implant-supported zirconia crowns to avoid veneering fractures (Rammelsberg et al., 2020).

The aesthetic evaluation of the restorations in our study demonstrated no significant differences between the AC and MC group. This is in contrast with our previous publication of the 1-year results, which revealed a significantly better color match of the zirconia-based crowns compared with the metal-ceramic crowns (Hosseini et al., 2011). These contrasting results could be a result of the change in the color of the natural neighboring teeth (Baratieri et al., 2007), the limited number of included patients in this study, the 6 dropout patients with 12 implant-supported single crowns, or a result of minor changes in the subjective evaluations. No difference in the discoloration of the marginal peri-implant mucosa between zirconia and titanium abutments has also been reported in other randomized clinical studies (Bösch et al., 2018; Carrillo de Albornoz et al., 2014; Linkevicius & Vaitelis, 2015). However, a prospective multicenter study indicated more mucosal discoloration adjacent to titanium compared with zirconia abutments (Bressan et al., 2011). These conflicting outcomes may be due to the heterogeneity of studies with regard to implant region, evaluation method, or different follow-up times (Hu et al., 2019). It is also interesting to note that regardless of restoration material or thickness of the soft tissue, a difference between the gingival color around natural teeth and the peri-implant soft tissue has been reported (Bittner et al., 2020; Bösch et al., 2018; Bressan et al., 2011; Cosgarea et al., 2015). Although results have been ambiguous, the overall results of different studies indicate more

favorable peri-implant mucosal color for all-ceramic compared with metal abutments (Pitta et al., 2020). In our study with implants in the premolar regions, the main part of the restorations had no marginal discoloration of the peri-implant mucosa and the dental papilla filled the entire or more than half of the proximal space for most reconstructions. Thus, the change in the interdental papilla was not statistically significant over time and the overall aesthetic outcome was close to optimal.

The patients were also satisfied with both the aesthetic and functional results of the implant-supported single-tooth restorations of both materials. The prosthetic rehabilitation had a significant effect on the patient-reported aesthetic and functional outcome. Most unsatisfied were patients with food impaction, especially when two adjacent implants were inserted, but more clinical studies are needed to discover the reason for this patient-reported complication.

Analysis of the aesthetic satisfaction with single-tooth implant indicated no significant difference between restorations based on zirconia or metal abutments, which is in consistent with the other studies (Carrillo de Albornoz et al., 2014; Hosseini et al., 2013). However, a drawback of the present study was using OHIP questionnaires, as the majority of the participants had several restorations of different materials, but similar to 1-year results of this study using VAS for each restoration, no differences in the patient's aesthetic satisfaction with different materials were recorded (Hosseini et al., 2011). This agrees with a proposal previously described that most patients are less critical about the aesthetic outcome than the dentists (Fava et al., 2015; Hosseini & Gotfredsen, 2012).

5 | CONCLUSION

The overall 5-year outcome of cement-retained, implant-supported single-tooth restorations demonstrated high survival and success of zirconia-based and metal-based, implant-supported restorations in the premolar region.

A superior marginal adaptation was found at the metal-ceramic crowns with titanium abutments compared to zirconia crowns with zirconia abutments. There were no other significant differences in the biological, technical, aesthetic, or patient-reported outcome between the AC versus MC restorations.

CLINICAL APPLICABILITY

Based on the results of this study, metal-ceramic crowns at titanium abutment and zirconia-based crowns at zirconia abutments could be used in the clinic in the premolar region as the risk of complications is low.

AUTHOR CONTRIBUTIONS

Mandana Hosseini: Data curation (lead); formal analysis (lead); funding acquisition (lead); investigation (lead); methodology (lead); project administration (lead); writing – original draft (lead). Nils Worsaae: Supervision (supporting); validation (supporting); writing – review and editing (supporting). Klaus Gotfredsen: Conceptualization (lead); supervision (lead); writing – review and editing (lead).

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

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