Randomized Controlled Clinical Trial of Zirconia-Ceramic and Metal-Ceramic Posterior Fixed Dental Prostheses: A 3-year Follow-up

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> Purpose: The aim of this study was to test whether posterior fixed dental prostheses (FDPs) with zirconia frameworks exhibit similar survival rates and technical and biologic outcomes as those with metal frameworks. Materials and Methods: Fifty-nine patients in need of 76 FDPs replacing one to three posterior teeth (molars and premolars) were included in the study. The three- to five-unit FDPs were randomly assigned to 38 zirconia-ceramic and 38 metal-ceramic FDPs. At baseline, 6 months, and 1 to 3 years after cementation, the technical outcome of the reconstructions was examined using the United States Public Health Service (USPHS) criteria. The biologic outcome was analyzed at test (abutment) and control (contralateral) teeth by assessing: probing pocket depth (PPD), probing attachment level (PAL), plague control record (PCR), bleeding on probing (BOP), and tooth vitality. Radiographs of the FDPs were made. Statistical analysis was performed by applying Kaplan-Meier, Pearson chi-square, Fisher exact, and Mann-Whitney U tests. Results: Fifty-three patients with 67 FDPs (36 zirconia-ceramic, 31 metal-ceramic) were examined after a mean observation period of 40.3 ± 2.8 months. Six patients with 9 FDPs were lost to follow-up. The survival of both kinds of FDPs was 100%. No significant differences regarding the technical and biologic outcomes were found. Minor chipping of the veneering ceramic was found in 25% of the zirconia-ceramic and 19.4% of the metal-ceramic FDPs. Extended fracturing of the veneering ceramic occurred solely in zirconia-ceramic FDPs (C: 8.6%, D: 2.8% [USPHS criteria]). Few biologic complications were found. Both types of FDPs rendered the same mean values for the biologic parameters (mean PPD, PCR, and BOP for zirconiaceramic FDPs = 2.4 ± 0.3 , 0.1 ± 0.1 , and 0.3 ± 0.2 , respectively; mean PPD, PCR, and BOP for metal-ceramic FDPs = 2.4 ± 0.3 , 0.1 ± 0.1 , and 0.3 ± 0.2 , respectively). Conclusion: Zirconia-ceramic FDPs exhibited a similar survival rate to metal-ceramic FDPs at 3 years of function. Int J Prosthodont 2009;22:553-560.

Recently, increased use of all-ceramic materials for the fabrication of crowns and fixed dental prostheses (FDPs) has been reported.¹⁻³ Advantages of allceramic materials over traditional metal-ceramics include their tooth-resembling color and enamel-like translucency.¹ The main shortcoming is their inferior load-bearing capacity compared to metals. As a consequence, they have traditionally been applied in areas of lower loading forces. Nowadays, various kinds ceramics are available for use in reconstructive dentistry. Besides the conventional glass-ceramics, new high-strength ceramics including alumina or zirconia have been introduced. Glass-ceramics exhibit good optical but low physical properties. In contrast, alumina and zirconia ceramics offer superior stability but low translucency. Therefore, these materials may be successfully used as core materials for crowns and FDPs in areas exhibiting loading forces under which traditional ceramics would fail.^{2,3}

Systematic reviews of the literature regarding allceramic and metal-ceramic reconstructions revealed that crowns made of ceramics with increased stability

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exhibited survival rates similar to those of traditional metal-ceramic crowns.⁴ The survival of all-ceramic FDPs, however, was significantly lower than that of metal-ceramic FDPs.⁵ It is interesting to note that the low survival rates of the all-ceramic FDPs were mainly caused by reconstructions made of glass-ceramics or glass-infiltrated ceramics. These FDPs frequently exhibited fractures occurring in the connector area. After 5 years of clinical follow-up, 10%⁶ to 12%⁷ of framework fractures were reported in two studies with posterior FDPs made out of glass-infiltrated ceramic. In contrast, two meta-analyses reported much lower failure rates for metal-ceramic FDPs.^{8,9} After an observation period of 10 years, failure rates for metal-ceramic FDPs amounted to 8%⁹ and 10%,⁸ respectively. Consequently, based on these data, metal frameworks veneered with tooth-colored ceramics still represent the standard material choice for FDPs.

High-strength ceramic zirconia has the potential to be applied as an alternative material to metal for the fabrication of frameworks for posterior FDPs.^{10,11} Zirconia exhibits fracture strength and toughness superior to those of all other ceramics.^{12,13} Several clinical studies showed promising results for FDPs with zirconia frameworks after observation periods of 3 to 5 years.^{14–17} In these investigations, low fracture rates of zirconia frameworks, ranging from 0% to 2.2%, were reported.^{14–17} The reasons for failure of FDPs were primarily biologic complications such as secondary caries or technical complications such as fracture of the veneering ceramic. Interestingly, these are the same types of complications leading to the loss of metal-ceramic FDPs.^{5,18}

It may be hypothesized that reconstructions with zirconia frameworks will lead to clinical outcomes similar to those with a metal framework. If so, metalceramic reconstructions might be replaced by zirconiaceramic reconstructions in the future. For proof of this change of material choice, clinical studies are needed comparing zirconia-ceramic and metalceramic reconstructions in various indications. A comparison of the two types of reconstructions in the same patient cohort, however, has yet to be published.

The aim of this randomized controlled clinical trial was to test whether posterior FDPs with zirconia frameworks would exhibit the same survival rates and technical and biologic outcomes as those with metal frameworks.

Materials and Methods

Patients and Reconstructions

Fifty-nine patients (27 women, 32 men) in need of at least one FDP in the posterior region of the maxilla or mandible were included in this study. The requirements

of the Helsinki Declaration were fulfilled and the patients provided informed consent.

Only patients in good general health were included in this study. Furthermore, the included patients had to be periodontally healthy with no obvious signs of bruxism. In accordance with the requirements for conventional metal-ceramic reconstructions, the prospective abutment teeth had to fulfill the following clinical criteria: proper positioning in the dental arch (ie, tooth axes adequate for an FDP), sufficient amount of dentin for the retention of the FDP (in case of a lack of abutment height, core buildups were fabricated), and vital or endodontically treated to a clinically sound state.

Seventy-six three- to five-unit posterior FDP sites were included and randomly assigned to either zirconiaceramic or metal-ceramic restorations by means of a randomization list. Thirty-eight zirconia-ceramic and 38 metal-ceramic FDPs were inserted. The FDPs were replacing premolars and molars. Sixty-eight FDPs were three-unit, 6 were four-unit, and 2 were five-unit.

Prosthodontic Procedures

All treatments were performed by clinicians who were experienced with zirconia-based reconstructions. The preprosthetic as well as the prosthetic treatments for both types of FDPs were performed according to the techniques normally applied for metal-ceramic reconstructions. The preparation of the abutment teeth was adapted to the previously described requirements for the computerized framework production of the zirconia frameworks.¹⁹ In short, the abutment teeth were prepared with a circumferentially rounded shoulder (1.0 mm in width), an axial reduction of 1.5 mm, and an occlusal reduction of 1.5 to 2.0 mm. The tapering angle was 6 degrees to 10 degrees, as recommended by the manufacturer of the computer-assisted manufacture (CAM) system. In order to control the tooth substance reduction, a diagnostic wax-up of the planned reconstruction was made for each patient. A silicone key of this wax-up was made and used for the checking of the preparation depth during tooth preparation.

After preparation, full-arch impressions were taken using a polyether material (Permadyne, 3M ESPE). Provisional restorations were fabricated (Protemp Garant, 3M ESPE) and cemented with eugenol-free temporary cement (Freegenol Temporary Cement, GC Europe). Master casts were made of super hard rock (GC Fujirock EP, GC Europe). All dies were hardened with plaster hardener (Margidur, Benzer). Thereafter, die spacer was applied starting 1 mm above the preparation margin. For zirconia frameworks, two layers of spacer (REF 6590 0001, DeguDent) were applied as recommended by the manufacturer; one layer was applied for the metal frameworks (Silverspacer no. 3,

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	Alfa (A)	Bravo (B)	Charlie (C)	Delta (D)
Framework fracture	No fracture of framework			Fracture of framework
Veneering fracture	No fracture	Chipping, but polishing possible	Chipping down to the framework	New reconstruction is needed
Occlusal wear	No occlusal wear on reconstruction or on opposite teeth	Occlusal wear on reconstruction or on opposite teeth < 2 mm	Occlusal wear on reconstruction or on opposite teeth > 2 mm	New reconstruction is needed
Marginal adaptation	No probe catch	Slight probe catch, but no gap	Gap with some dentin or cement exposure	New reconstruction is needed
Anatomical form	Ideal anatomical shape, good proximal contact	Slightly over- or under- contoured, weak proximal contact	Highly over- or under- contoured, open proximal contact	New reconstruction is needed

Table 1USPHS Criteria

Benzer). All frameworks were manually made out of modeling wax (ZTM Thiel, Erkodent). The frameworks were designed according to the individual anatomical situation of the respective patient to supply sufficient support for the veneering material. Care was taken not to fall below the minimally required material dimensions as recommended by the manufacturer for proper framework stability.

The zirconia frameworks were fabricated by means of a CAM system (Cercon, DeguDent). The details of the fabrication procedure in its prototype stage were published elsewhere.^{12,13} In short, a wax cast of the framework was made according to the anatomical situation of the respective patients providing space for an even thickness of the veneering ceramic. The morphology of the framework's wax cast was captured optically and the data obtained were digitized and enlarged using specialized computer software (Cercon brain, DeguDent). This was done to compensate for the sintering shrinkage of approximately 28%. The frameworks were machined out of presintered zirconia blanks (Cercon base 30 or 38) using hard metal mills in the milling machine. Subsequently, they were sintered to full density (Cercon heat, DeguDent), thus shrinking to the dimensions of the wax original. The metal frameworks were fabricated by means of the traditional lostwax technique.²⁰ According to the fabrication procedure described above, wax casts were made following the patient's anatomical needs. The wax casts were then fabricated out of a gold alloy (Degudent U, DeguDent).

Both ceramic and metal frameworks were manufactured by one experienced technician. The veneering of the two kinds of frameworks was performed by means of the corresponding veneering ceramics using conventional veneering techniques. Two specifically designed veneering ceramics were used to veneer the two different frameworks (zirconia: Cercon Ceram S, Ceramco; metal: Duceram Plus, DeguDent).

The interior surface of all FDPs was gently grit-blasted (granule size: 110 μ m, pressure: 2 bars for 10 seconds) and cleaned with alcohol. Thereafter, both zirconia-

ceramic and metal-ceramic FDPs were cemented using the same resin cement (Panavia 21 TC, Kuraray). Prior to cementation, the abutment teeth were preconditioned according to the manufacturer's instructions. After cementation, occlusion was adjusted as needed and any reshaped surfaces were meticulously polished with ceramic polishers (Komet nos. 9425, 9426, and 9547, Brasseler).

Baseline Examination

Immediately following cementation of the reconstructions, probing pocket depths (PPD) of the restored teeth were assessed at four sites, radiographs of the abutment teeth were obtained, clinical photographs of the reconstructions were taken, and pulpal vitality of the abutment teeth was tested using carbon dioxide (CO₂).

Follow-up Examination

At 6 months and 1, 2, and 3 years following incorporation, the reconstructions were examined for technical and biologic failures or complications. For the evaluation of the technical performance of the FDPs, the United States Public Health Service (USPHS) criteria were used (Table 1). In order to do so, the entire FDP was evaluated and the worst finding per FDP was used for the rating.

An outcome was rated Alfa (A) when no problem occurred, Bravo (B) when small but clinically acceptable defects were found, Charlie (C) when the defects reached a level that was no longer clinically acceptable, and Delta (D) when the FDP had to be replaced due to the defect (Table 1).

All patients were informed about the clinical status of their FDPs. In the event of complications, attempts were made to preserve the reconstructions. In case of deficient marginal adaptation rated C or D according to the USPHS criteria, the respective areas were repaired using a composite resin. The FDPs remained in the study for further observation.

		Zirconia-ceramic			Metal-ceramic		
	Three-unit	Four-unit	Five-unit	Three-unit	Four-unit	Five-unit	
Maxilla	11	4	1	13	1		
Mandible	18	2		16		1	
Pontic	10 PM, 19 M	$4 \times 1 \text{ PM} + 1 \text{ M}$ $2 \times 2 \text{ PM}$	2 PM + 1 M	10 PM, 19 M	2 PM	2 PM + 1 M	

PM = premolar; M = molar.

In case of chipping or fracture of the veneering ceramic (B, C, or D), the FDPs were thoroughly cleaned with alcohol and impressions of the FDP surface were made with a low viscous A-silicone impression material (President, Coltène Whaledent). After taking the impression, the damaged areas were thoroughly polished and the FDPs remained in situ for further follow-up. Subsequently, the impressions were cast with epoxy resin (EpoFix, Struers). A fractographic analysis of the epoxy replicas was performed to determine the origin and direction of the crack propagation.²¹

The biologic outcome was assessed applying the following periodontal parameters at abutment (test) and control teeth (analogous, contralateral, not crowned teeth): PPD, probing attachment level (PAL), absence or presence of plaque by means of the plaque control record (PCR),²² and bleeding on probing (BOP).

Furthermore, pulpal vitality was tested at both abutment and control teeth with CO_2 . Occlusal and functional relationships between FDPs and opposing arches were recorded.

Finally, radiographs of the abutment teeth and clinical photographs of the reconstructions were taken. Alginate impressions for study casts were made of both maxillae and mandibles.

Statistical Analysis

Descriptive statistics were applied to the data. Analysis of the 3-year survival rate of zirconia-ceramic and metal-ceramic FDPs was performed by means of Kaplan-Meier survival statistics followed by a log-rank test.²³ Patients or FDPs lost to follow-up were censored.

The USPHS evaluation of the two types of FDPs was compared using the Pearson chi-square test. The correlation of the ratings for chipping of the veneering ceramic and occlusal wear was done by Fisher exact tests.²³

For the comparison of PPD, PAL, PCR, and BOP between test and control teeth and between the two groups, Mann-Whitney *U* and *t* tests were used.²³ The level of significance was set at P < .05.

Results

Fifty-three patients (25 women, 28 men) with 67 FDPs were examined after a mean observation period of 40.3 ± 2.8 months. The mean age of the patients was 54.4 ± 12.7 years. Thirty-six FDPs were zirconia-ceramic and 31 were metal-ceramic. Detailed information on the FDPs is given in Table 2. Six patients with 9 three-unit FDPs (2 zirconia-ceramic and 7 metal-ceramic) were lost to follow-up. Two of these patients had passed away, leading to the loss of 2 metal-ceramic FDPs. The other 7 patients could no longer be located. Of those, 2 patients with 2 metal-ceramic FDPs were lost after baseline. The remaining could not be recruited for the 3-year follow-up.

No fracture of a zirconia or metal framework was observed. Both types of FDPs showed a 100% survival rate. The Kaplan-Meier survival times (STs) of the two types of FDPs were statistically similar (mean $ST_{zirconia-}$ $_{\text{ceramic}} = 36.9 \text{ months}, 95\% \text{ confidence interval (CI)} =$ 32.0–41.8 months; mean $ST_{metal-ceramic} = 40.6$ months, 95% CI = 38.3-43 months). The technical evaluation by means of the USPHS criteria revealed no statistically significant differences between the two types of reconstructions (Table 3). In case of the worst-case scenario (ie, failure of all FDPs that could not be followed-up for the entire observation period), a decrease of the survival rates to 94.7% for zirconia-ceramic and to 81.6% for metal-ceramic FDPs would be found. Besides these very good survival rates for the zirconia-ceramic FDPs, clinically relevant differences were seen between the two types.

More technical problems occurred in zirconiaceramic FDPs, yet these were not statistically significant. The marginal adaptation was judged clinically unacceptable (C) in 16.7% of the zirconia-ceramic and in 6.5% of the metal-ceramic FDPs (Fig 1). Whereas minor chipping (B) occurred with similar frequency at both types of FDPs ($B_{zirconia-ceramic} = 25\%$, $B_{metal-ceramic} =$ 19.4%), clinically unacceptable fractures of the veneering ceramic ($C_{zirconia-ceramic} = 5.6\%$, $D_{zirconia-ceramic} =$ 2.8%) solely occurred in zirconia-ceramic FDPs

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Table 3	USPHS Rating	of Zirconia-C	Ceramic and	Metal-Ceramic FDPs
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		USPHS			
	Type of FPD	Alfa (A)	Bravo (B)	Charlie (C)	Delta (D)
Framework fracture	ZC MC	100% (n = 36) 100% (n = 31)			
Veneering fracture	ZC MC	66.6% (n = 24) 80.6% (n = 25)	25% (n = 9) 19.4% (n = 6)	5.6% (n = 2)	2.8% (n = 1)
Occlusal wear	ZC MC	33.3% (n = 12) 38.7% (n = 12)	63.9% (n = 23) 58.1% (n = 18)	2.8% (n = 1) 3.2% (n = 1)	
Marginal adaptation	ZC MC	19.4% (n = 7) 29% (n = 9)	63.9% (n = 23) 64.5% (n = 20)	16.7% (n = 6) 6.5% (n = 2)	
Anatomical form	ZC MC	94.4% (n = 34) 80.6% (n = 25)	5.6% (n = 2) 19.4% (n = 6)		

ZC = zirconia-ceramic; MC = metal-ceramic.



Fig 1 Kaplan-Meier graph of the marginal adaptation (MA) of the FDPs in relation to time. Marginal gaps (USPHS: C) were categorized as events, whereas slight probe catch (USPHS: B) was not and is marked on the line with respect to the time of the observation.



Fig 2 Kaplan-Meier graph of chipping or fracture of the veneering ceramic (FV) of the FDPs in relation to time. Fractures (USPHS: C, D) were categorized as events, whereas minor chips (USPHS: B) were not and are marked on the line with respect to the time of their occurrence.

(Figs 2 to 5). The fractographic examination revealed that the chipping and fractures of the veneering ceramic had originated from its occlusal roughnesses (Figs 3b and 4c). However, no statistical correlation was found between the amount of occlusal wear of the veneering ceramic and the incidence of chipping.

Generally, only a few biologic complications occurred during the follow-up period. In one patient, secondary caries was found at the margin of a metalceramic FDP after 33.2 months. The caries was removed and the marginal regions were repaired. Loss of vitality of an abutment tooth was found in one patient with a metal-ceramic FDP after 0.5 months and one patient with a zirconia-ceramic FDP after 16.9 months. In both cases, root-canal treatment of the abutment teeth was successfully performed through an access cavity in the reconstructions. No difference in PPDs, PALs, PCRs, and BOP of the test and control teeth was found at both types of FDPs (Table 4). Furthermore, no difference in radiographic outcome of the abutment teeth was found.

Discussion

In the present study, no statistically significant difference in the clinical outcome of zirconia-ceramic and metal-ceramic posterior FDPs was found at 3 years of function. No fractures of ceramic or metal frameworks occurred. Hence, the survival rate was 100% for both types of FDPs. Furthermore, no statistical difference was found with respect to technical or biologic complications between the two types of FDPs. Technical problems, such as unacceptable marginal accuracy and extended fracture of the veneering ceramic, however, tended to occur more frequently in zirconiaceramic FDPs.

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Figs 5a to 5c A clinically inacceptable fracture of the veneering ceramic on a maxillary five-unit zirconia-ceramic FDP. Fractographic analysis revealed that the cracks had initiated from the mesial and distal connectors and propagated to the center of the palatal cusp.



C 14X

Palatal

The present results are very promising and definitely surpass the results reported for FDP frameworks fabricated from other ceramics. After similar observation periods of 3 to 5 years, high failure rates were reported for FDPs fabricated from glass or glass-infiltrated ceramics.^{6,7,24-27} Framework fractures were found in 7%

Table 4 Mean Values and Standard Deviations of the Biologic Parameters at Abutment Teeth (Test) and Analogous Contralateral Untreated Teeth (Control) of Both Types of FDPs

	Zirconia-ceramic		Metal-	Metal-ceramic		
	Test	Control	Test	Control		
PPD PAL PCR BOP	$\begin{array}{c} 2.4 \pm 0.3 \\ 2.5 \pm 0.2 \\ 0.1 \pm 0.1 \\ 0.3 \pm 0.2 \end{array}$	$\begin{array}{c} 2.3 \pm 0.3 \\ 2.0 \pm 0.4 \\ 0.2 \pm 0.2 \\ 0.2 \pm 0.2 \end{array}$	$\begin{array}{c} 2.4 \pm 0.3 \\ 2.3 \pm 0.2 \\ 0.1 \pm 0.1 \\ 0.3 \pm 0.2 \end{array}$	$\begin{array}{c} 2.4 \pm 0.4 \\ 2.6 \pm 0.6 \\ 0.3 \pm 0.3 \\ 0.2 \pm 0.2 \end{array}$		

PPD = probing pocket depth; PAL = probing attachment level; PCR = plaque control record; BOP = bleeding on probing

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to 13% of glass-ceramic FDPs^{24,25} and 0% to 12% of glass-infiltrated ceramic FDPs.^{6,7,26,27} In all of these studies, catastrophic fractures of the reconstructions were the main reason for failure.^{6,7,24-27}

In previous clinical studies, apart from excellent framework survival, zirconia-ceramic reconstructions were frequently subject to technical or biologic problems.¹⁴⁻¹⁷ The most frequently occurring technical complication was chipping or fracture of the zirconia veneering ceramic, ranging from 8% to 25% of the FDPs.^{14–16} In contrast, metal-ceramic FDPs have shown very low rates of chipping of the metal veneering ceramic.¹⁸ The present investigation showed no statistically significant differences between the outcome of the zirconia and the metal veneering ceramics. Still, the observations differed on a clinically relevant level. While acceptable, a similar number of minor chips (B) were found at both types of reconstructions (B_{zirconia-ceramic} = 25%, B_{metal-ceramic} = 19.4%). However, clinically unacceptable major fractures of the veneering ceramic (C and D) were found solely in zirconia-ceramic FDPs for 5.6% and 2.8% of the reconstructions, respectively.

The reason for the problems with zirconia veneering ceramics still remains to be clarified. Several factors have been investigated in recent laboratory studies, which may possibly affect the rate of veneering fractures. Among the factors analyzed were the thermal compatibility of the veneering ceramics and the zirconia frameworks,^{28,29} different surface treatments of the frameworks,³⁰ the flexural strength of the veneering ceramics,³¹ and the bond strength between veneering ceramics and zirconia frameworks.³²⁻³⁴ As an example, the application of a veneering ceramic with a thermal expansion coefficient (TEC) not matching zirconia led to extended fractures of the veneering ceramic.²⁸ In more recent in vitro studies, the TEC seemed to play a major role while the strength of the veneering ceramic itself and the bond between the veneering ceramic and the framework were of minor importance.^{29,30} Additionally, a correlation of clinical factors and the occurrence of chipping were observed in the present study. It appeared that roughness of the veneering ceramic resulting from occlusal contacts or grinding was associated with chipping. The analysis of the crack propagation direction revealed that the chipping in almost all FDPs had originated from a roughness of the ceramic at the occlusal region of the cusp.

Another clinical factor to consider with regard to risk for chipping of the veneering ceramic is the design of the framework, which ideally provides space for an even thickness of the veneering ceramic. In the present study, a CAM technique was used for the fabrication of the ceramic frameworks. Hence, for both types of FDPs the frameworks were manually modeled out of wax, respecting the anatomical situation of the patients. The support for the veneering ceramics was similar at both framework materials and cannot be considered a crucial factor for the greater extension of chipping in the zirconia-ceramic group.

The marginal accuracy of the two types of FDPs exhibited no differences from a statistical point of view. However, clinically unacceptable marginal gaps were found at only two metal-ceramic FDPs, but occurred at six zirconia-ceramic FDPs. This difference might be associated with the different fabrication procedures and the fact that the study was conducted with the first available version of the CAM procedure.³⁵ Further development of computer-aided system software may lead to an improvement in accuracy.³⁶

Finally, the biologic parameters in the two groups were similar in the present study. No difference in periodontal parameters or radiographic appearance was found at abutment or control teeth and associated with both types of reconstructions. The favorable biologic integration of zirconia-ceramic FDPs is in agreement with the results of other studies.^{15,16}

Conclusion

Within the limitations of the observational period, the excellent survival rate of zirconia frameworks in this randomized controlled clinical trial indicates this type of ceramic to be a valid alternative to metal frameworks. Higher rates of clinical complications were, however, found at zirconia-ceramic FDPs compared to metal-ceramic FDPs. It is clear that a longer observation period is required to validate these medium-term results.

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