Prospective Evaluation of Zirconia Posterior Fixed Partial Dentures: 7-Year Clinical Results

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> Purpose: The clinical performance of three- and four-unit fixed partial dentures (FPDs) with frameworks made of yttria partially stabilized zirconia was determined after a mean observational period of 84 months. Materials and Methods: Seventy-five patients were treated with 99 posterior FPDs. Fifty-one specimens were veneered with an experimental ceramic suitable for titanium and zirconia frameworks; 48 restorations were veneered with a commercially available low-fusing ceramic optimized for zirconia frameworks. All restorations were luted with zinc-phosphate cement. Statistical analysis was performed according to Kaplan-Meier; potential risk factors were analyzed using the Cox regression analysis. Results: Nineteen restorations failed completely: 12 due to technical complications, 6 due to biologic complications, and 1 for unknown reasons. The overall survival rate after 84 months was 83.4%. Thirty-two events required clinical intervention for restoration maintenance, resulting in a time-dependent success rate of 57.9% after 84 months. Nineteen dropouts occurred during the follow-up time. None of the evaluated factors showed an association with survival or success of the restorations. **Conclusions:** After a mean observational period of 7 years, the survival and success rates of zirconia-based posterior FPDs were inferior to those published for metalceramic FPDs. The majority of failures were caused by technical complications (material fractures). The main reasons for clinical intervention to maintain function were fractures of the veneering ceramic and decementations. Int J Prosthodont 2013;26:164-171. doi: 10.11607/ijp.3229

Advances in computer-aided design/computerassisted manufacturing (CAD/CAM) technology allow the use of zirconia in dentistry.^{1,2} The application of yttria partially stabilized crystalline tetragonal zirconia (Y-TZP) significantly improves the flexural strength and fracture toughness of all-ceramic restorations. In terms of fracture resistance, zirconiabased fixed partial dentures (FPDs) have the potential to withstand physiologic occlusal forces applied in the posterior region. Therefore, they provide interesting alternatives to metal-ceramic restorations.²⁻⁴

The early results of clinical studies for zirconia FPDs demonstrated high survival rates ranging

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from 92% to 100% for observational periods of 1 to 5 years.⁵⁻⁷ Fractures of zirconia frameworks were found to be rare. Moreover, zirconia-based and metal-ceramic FPDs demonstrated comparable survival rates, at least for mean observational periods of up to 3 years.⁷⁻⁹ The most common technical complication in zirconia-based restorations was fracture of the veneering ceramic with or without exposing the zirconia framework.⁸⁻¹² The incidence of chippings ranged from 0% after 2 years to 54% after just 1 year.⁶⁻⁹ Although only major chippings that could not be polished or repaired required a replacement of the restoration, this phenomenon was considered a serious problem.^{6,7,13-15}

For an adequate comparison of zirconia-based FPDs with metal-ceramic restorations, which are considered the standard of care in fixed prosthodontics, long-term studies with mean observational periods of more than 5 years are necessary.¹⁶⁻²¹ At the moment, long-term data with observational periods of more than 5 years for validating the clinical potential of zirconia are rare.^{1.2,6,12} Presently, data with observational periods of 10 years are only available for zirconia FPDs fabricated from a prototype system²² and demonstrate increased failure and complication rates

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with an overall survival rate of 67%, a fracture rate of the veneering ceramics of 32%, and secondary caries in 27% of restorations. Further in vivo studies with larger sample sizes and longer follow-up periods are required to investigate possible influencing factors for technical failures, such as veneering material, location in the mouth, span, and cementation mode. The aim of this prospective university-based study was to evaluate the clinical performance of conventionally cemented zirconia-based posterior three- and four-unit FPDs fabricated with a market-introduced CAM system (Cercon Smart ceramics, DeguDent) after a mean observational period of 7 years. Fouryear results of this study population have already been published.²³ Time-dependent overall survival and success rates, as well as possible influencing factors (type of veneering ceramic, location in the mouth, and span), were assessed. The null hypothesis was that the 7-year clinical performance of posterior zirconia-based FPDs is comparable with the survival and success rates documented in the literature for metal-ceramic FPDs.

Materials and Methods

Patient Selection

A total of 75 patients (36 women, 39 men) participated in this study. All subjects were recruited in the Prosthetic Department at the University of Goettingen, Goettingen, Germany, from 2001 to 2005. The age of the subjects ranged from 26 to 76 years (mean age, 49.4 ± 12.4 years). Inclusion criteria were a signed consent form, antagonistic teeth in the area of the restoration, vital abutments or abutments with sufficient endodontic treatment, and a maximum of two missing teeth in the posterior area. Patients with one or more of the following diagnoses were excluded from participation: bruxism, severe periodontal disease, pulpitis, horizontal abutment tooth mobility \geq 1 mm, and pregnancy/lactation. The patients were informed about the purpose of the investigation, clinical procedures, and advantages/risks of the applied material. The Ethics Committee of the University of Goettingen, approved the study (application no. 19/9/00), and all subjects gave informed consent.

Clinical Approach

The clinical procedures were similar to those for metal-ceramic restorations and were performed by experienced dentists (full-time faculty members), except for two FPDs, which were carried out by students under the supervision of a dental clinician. A detailed

initial instruction and clinical training were performed to ensure calibration of the clinicians who treated the patients. All patients received oral hygiene instruction and professional tooth cleaning prior to prosthetic treatment. The patients received up to four FPDs. A total of 99 restorations (81 three unit, 18 four unit) were inserted (39 FPDs in the maxilla, 60 in the mandible). For the majority of abutment teeth, composite resin was used for the core buildup. However, the preparation design was modified in accordance with guidelines for zirconia-based restorations. A chamfer design with at least 0.8 mm of circular reduction was used. The occlusal reduction was 1.5 to 2 mm, and the taper angle ranged from 6 to 8 degrees (according to the manufacturer's instructions). Impressions were made with a polyether material (Impregum, 3M ESPE). The restorations were luted with zincphosphate cement (Harvard, Richter & Hoffmann Harvard Dental). The preferred occlusal concepts were a canine-protected articulation or a group function on canines and premolars.

Laboratory Techniques

All frameworks were produced by a CAM system that was introduced to the German market in 2001. For the frameworks, manually fabricated wax patterns were digitized and enlarged by approximately 30% to compensate for shrinkage during sintering. Subsequently, the frameworks were milled from presintered zirconia blanks (Cercon base, DeguDent). All specimens were produced with the same machine (Cercon brain, DeguDent) and then sintered to full density for 6 hours at 1,350°C (Cercon heat, DeguDent). The calibration of the milling unit was performed every 6 months according to the manufacturer's instructions. The bur calibration was done via individual barcodes that were loaded by the scanner of the milling machine. To increase safety, the burs were changed every 50 units (manufacturer's instructions preset a change after 100 units).

Ninety-seven restorations were fabricated from noncolored blanks. The remaining two restorations were milled from a dentin-colored presintered material (Cercon base-colored, DeguDent). The minimum framework thickness was 0.4 mm and, for optimizing the periodontal area around the abutment teeth, the minimum connector dimension was 9 mm². The frameworks manufactured in 2001 (51 units) were veneered with an experimental veneering ceramic. This material was designed for the veneering of titanium and zirconia frameworks and therefore had an intermediate thermal expansion coefficient (TEC) of 8.5 µm/m*K. Since the beginning of 2002, a ready-to-market veneering material (Cercon Ceram-S, DeguDent) with a TEC optimized for the veneering of zirconia frameworks (9.5 μ m/m*K) was used for the remaining 48 specimens. Internal parts of the reconstructions were sandblasted with aluminum oxide (110 μ m, 2.0 bar) before the FPDs were cemented. After final adjustment of the occlusion, the surface was meticulously polished.

Evaluation Procedures

The examinations started at the point of final cementation (baseline). To determine the points of potential complications as precisely as possible, the FPDs were continuously reevaluated in 6-month follow-up intervals. Clinicians who placed the restorations did not perform the recalls. The following parameters were assessed: decementation (mobility), loss of vitality of the abutment teeth (cold spray test), need for endodontic treatment, marginal integrity, secondary caries, fracture of the framework, and chipping of the ceramic veneer. All patients were asked to visit the Department of Prosthodontics exclusively in the event of problems.

Statistical Analysis

For statistical evaluation, information on the survival and success rates of the reconstructions was used. Survival was defined as the reconstruction remaining in situ at the follow-up examination without presenting an absolute failure (in-situ criterion).^{17,23} Absolute failure was defined as a clinically unacceptable fracture of the ceramic or a biologic event (caries, tooth fracture, periodontal reason), which required replacement of the entire restoration or the extraction of the tooth. Success was defined as a reconstruction that remained unchanged and did not require any intervention to maintain function during the entire observational period.^{17,23} Necessary interventions to maintain function were divided into technical complications (minor chipping of the ceramic, recementation of an intact restoration) and biologic complications (caries, endodontic treatments, periodontal interventions). The survival time of a restoration was defined as the period between the day of cementation and the last follow-up appointment or, in cases of failure, the appointment scheduled to address the failure as documented in the patient's file. Data were excluded if patients were lost to followup or declined further participation in the study. The time-dependent survival rates (in-situ criterion) and the success rates (intervention free) were calculated according to Kaplan-Meier.

Different observations in one and the same patient (several FPDs per patient) were dependent. This dependence was allowed for by adjusted variance estimation in the Cox regression model. Thus, for the analysis of the data, a marginal model was applied.²⁴ Multivariate Cox regression was performed for each influence factor. A level of significance of < 5% was accepted to determine a statistically significant influence. Statistical analysis was performed using a computer program (Software R, version 2.8, www.r-project.org).

Results

Thirty-nine FPDs were placed in the maxilla and 60 in the mandible. Within the 7-year period, there were 19 complete failures (replacement of the restoration) (Table 1) and 32 partial failures (clinical intervention to maintain function, ie, recementation, polishing of a slight chipping, endodontic treatment). Nineteen FPDs were lost to follow-up (dropout rate, 19.2%; 12 in the experimental group, 6 in the Ceram-S group, 18 three-unit FPDs, and 1 four-unit FPD). Their data were excluded from further statistical evaluation. Sixty-one FPDs remained in function: 41 FPDs were observed in situ without any clinical posttreatment (Fig 1) (Table 2); 20 of the remaining restorations required clinical intervention to maintain their function.

The overall survival rate (in situ criterion) according to Kaplan-Meier was 83.4% (Fig 2) after 84 months.

Twelve restorations failed due to technical reasons: four framework fractures led to replacement of the restoration (Fig 3). The overall framework survival rate was 93.8%. Four additional total failures due to loss of retention could not be recemented because of progressed secondary caries, and another four had to be replaced due to extensive fractures of the ceramic veneer (one with the experimental ceramic, three with Cercon Ceram-S). Another six total failures were caused by biologic complications: one longitudinal root fracture of an endodontically treated premolar, two abutment losses due to severe periodontal lesions, and three abutment losses to progressed marginal caries lesions.

Apart from the four cases where loss of retention led to total failure, seven restorations showed loss of retention that was managed by recementation of the FPD. The loss of retention mainly occurred in the mandible (relation of maxilla to mandible, 9:1) and was observed between month 11 and month 55 after cementation (mean, 29.2 \pm 14.8 months).

Marginal caries lesions were observed in four cases. One was treated with a composite resin filling. Four losses of vitality occurred.

Table 1Reasons for Complete Failures of the FPDs

Reason for failing	No. of restorations ($n = 99$)
Technical complications	12
Core fracture	4
Extensive ceramic veneer fracture	4
Retention loss/resultant caries	4
Biologic complications	6
Marginal secondary caries	3
Periodontal lesion	2
Root fracture	1
Unknown	1
Total	19

Table 2Complication and Corresponding ClinicalIntervention to Maintain the Restorations In Situ

Complication	No. of restorations (n = 99)	Management
Slight core fracture	1	Sealing with composite
Chipping of ceramic veneer	19	Polishing
Decementation	7	Adhesive recementation
Secondary caries	1	Sealing with composite
Loss of vitality	4	Endodontic treatment
Total	32	

Fig 3 Fracture of the framework of an FPD retainer after removal of the fragment (after 55 months). Insert: view of mesial fractured wall.

During the 7-year observation period, chipping (cohesive failure of the veneering ceramic) was observed for 23 FPDs (13 with the experimental ceramic and 10 with the Cercon Ceram-S material) (Figs 4a and 4b). Four of these chippings were major chippings resulting in the need to replace the FPD.



Fig 1 Three-unit FPD that remained intact after 81 months of clinical service.

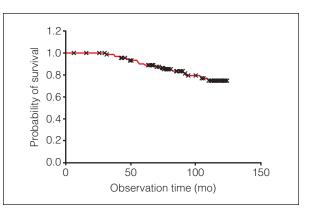


Fig 2 Survival probability of 83.4% for Cercon FPDs after an observation period of 84 months, according to Kaplan-Meier.

The overall success rate (no clinical intervention) according to Kaplan-Meier was 57.9% after 84 months (Fig 5).

Cox regression was used to identify risk factors for failure or a complication. Tested factors were span, location (arch), and type of veneering ceramic. None of these factors showed a significant impact on survival (Table 3) or success (Table 4) of the zirconia FPDs.



Fig 4a Minor chipping of the ceramic veneer at the palatal side of a pontic after 109 months of clinical function.

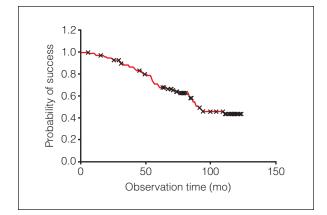


Table 4	Results of the Multivariate Analysis of
Potential	Risk Factors for a Complication*

Factor	Coefficient	SE	Hazard (exp) coef	Р
Span	-0.121 0.394 0.886		0.394 0.886	
Arch position	-0.331	0.317	0.718	.300
Veneering material	0.093	0.303	1.098	.770
SE = standard error.				

*Cox regression model.

Discussion

The present study revealed that after a mean observational time of 7 years, CAM-fabricated zirconiabased FPDs in the posterior region have a survival rate of 83.4%, while the success rate (interventionfree restoration) was 57.9%.

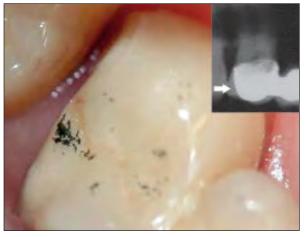


Fig 4b Fracture of the ceramic veneer at the distal side of a maxillary molar after 55 months. Insert: *arrow* shows insufficient framework support of the veneering material.

Fig 5 (left) Success probability of 57.9% for Cercon FPDs after an observational period of 84 months, according to Kaplan-Meier.

Table 3	Results of the Multivariate Analysis of
Potential	Risk Factors for a Complete Failure*

Factor	Coefficient	SE	Hazard (exp) coef	Р
Span	-0.482	0.635	0.617	.390
Arch position	-1.093	0.572	0.335	.055
Veneering material	-0.239	0.497	0.787	.640

SE = standard error.

*Cox regression model.

The majority of total failures (12 of 19) were caused by technical complications: four fractures each of the framework and the veneering ceramic and another four to retention loss causing secondary caries.

During the complete observational period, five frameworks (6.25%) fractured (Table 5), whereas one fracture in the form of a slight marginal defect, which could be sealed with a composite resin filling, remained in function and therefore was rated as a complication. Compared to the 4-year results where only one framework fracture was detected, this marks a substantial increase within 3 years.²³ Framework fractures were reported to be a rare event in shortto midterm clinical reports on posterior soft-milled zirconia FPDs, with fracture rates of up to 8%.^{1,6,7,12} This is in accordance with the findings of the present study. A recent review concluded that there is a possible advantage for hard-milled hot isostatic pressed (HIP) zirconia regarding framework toughness because absolutely no fractures were reported for restorations supported by HIP zirconia.⁶

	Th	Three-unit FPDs ($n = 81$)		Four-unit FPDs ($n = 18$)	
Failure/complication	Cases	Cases Relation to units under risk		Relation to units under risk	
Chipping of ceramic veneer	19	23.5%	4	22.2%	
Decementation	11	13.6%	0	0%	
Marginal secondary caries	3	3.7%	1	5.6%	
Fracture of core ceramic	5	6.2%	0	0%	
Loss of vitality	3	3.7%	1	5.6%	
Periodontal lesion	1	1.2%	1	5.6%	
Root fracture	1	1.2%	0	0%	
Total	43	53.1%	7	39.0%	

Table 5 Complications and Failures According to the No. of Units

Additional clinical studies are required to determine whether the fracture rate of the present study is related to the specific brand tested or if this incidence has to be expected generally when using soft-milled zirconia FPDs in the posterior area.

Most notable is the change in the survival and success rates from the earlier reported 4-year results to the presently reported 7-year results. The survival rate decreased from 94% to 83.4%, resulting in an increase of the annual failure rate of 1.5% within 1 to 4 years to 3.3% within 5 to 7 years. This finding is very important for the interpretation of the available data on zirconia FPDs.

Comparative prospective clinical trials with observational periods of up to 3 years did not reveal any difference in the survival probability of metal-ceramic and zirconia posterior FPDs.⁸⁻¹⁰ Systematic reviews comparing the clinical performance of metal-ceramic and all-ceramic restorations have used these data to estimate 5-year survival rates by assuming constant annual failure.4,17,21 With this assumption, events occurred evenly during the observational period. The calculated 5-year estimated survival is likely to favor overestimation of all-ceramic FPDs.²¹ These reviews have estimated a 5-year survival rate of 88.6% for allceramic FPDs made from different materials and a significantly higher overall survival rate for metal-ceramic FPDs (94.4%).^{4,17,21} It was proposed that the improved mechanical properties of zirconia have a positive effect on survival rates.⁴ This is not supported by the findings of the present study, as the 7-year survival rate of 83.4% marks no clear difference from the survival rates calculated for FPDs made with different ceramic materials. Therefore, the results of the present study, with an increase in the annual failure rates, indicate that longer observational periods are required to evaluate the reliability of all-ceramic FPDs more precisely.

The overall survival rates reported in systematic reviews for metal-ceramic FPDs range from 94.4% after 5 years to 89.2% after 10 years.^{4,17,19,21} Retrospective studies on the clinical performance of metal-ceramic restorations reported a survival rate of 78% after 18 years.²⁰

Therefore, the survival rates for zirconia-based FPDs are inferior to those published for metal-ceramic restorations.

Several studies found a higher incidence of technical complications for zirconia compared to metalceramic restorations.⁶⁻¹⁰ This is consistent with the results of the present study, as the 7-year data demonstrate that chipping is the major problem for this type of restoration. In 23 of the FPDs (28%), a chipping occurred, causing 19 (of 32) complications and 4 (of 19) total failures. It is important to consider that the majority of the veneer fractures reported were undetected by the patients and were incidental findings during review appointments. In other studies, the chipping rate for FPDs after different observational times (2 to 5 years) ranged from 0% to 54%.^{1,2,6,8-10} Thus, the results of the present study are within this range and underline the necessity of a profound solution for this problem. Meanwhile, some recommendations for optimizing the fabrication process of zirconia-based FPDs were published, eg, modification of the firing protocol.¹³⁻¹⁵ This might reduce the chipping rate and could therefore be recommended; however, in the present study, these modifications were not used. In summary, the results demonstrate that chipping is a major problem in these restorations and has a determining influence on the complication rate.

The most frequent biologic complication leading to failure was marginal secondary caries (3 of 6 cases). A loss of vitality leading to the need for root canal treatment was detected in 4 of 200 abutment teeth.

Recent reviews have found that 6% to 8% of abutments of conventional FPDs suffer from a loss of vitality within the first 5 years.^{17,21} The results of the present study are therefore not exceptional.

After a mean observational period of 7 years, 57.9% of the zirconia restorations remained event free and were rated successful. For metal-ceramic restorations, success rates of up to 71% after 18 years are reported.^{17,19,20} Therefore, the success rates for the zirconia FPDs evaluated in the present study are inferior to those published for metal-ceramic FPDs.

When interpreting the results of the present study, it has to be considered that the study was started in 2001 with an early-stage CAM system. Meanwhile, various improvements in scanning and milling technology have been introduced to improve fitting accuracy. At least two types of failures (loss of retention and secondary caries) can be influenced by the development stage of the CAM system used. Earlier studies with a prototype system revealed high secondary caries rates of 20% after 5 years and 32% after 10 years, indicating reduced fitting accuracy in this phase.^{5,22} In the present study, the secondary caries rate was reduced to 5%, which can be attributed to the improvements already incorporated into the ready-to-market system. To verify the positive effect of innovative CAD/CAM systems on clinical performance, studies with updated CAD/CAM systems are needed.

Besides the time-dependent survival and success rates according to Kaplan-Meier, a Cox regression analysis was performed to identify possible risk factors for complications and failures such as span (three or four unit), location (arch), and type of veneering ceramic.

Consistent with the 4-year results, no significant association of the type of veneering material and failure or complication rates could be determined. This leads to the assumption that the difference in the TECs of the two ceramics (experimental, 8.5 μ m/m*K; Cercon Ceram-S, 9.5 μ m/m*K) has no effect on fracture susceptibility of the veneering ceramics. Meanwhile, it is assumed that other factors such as pronounced anatomical design of the framework or an extended cooling period during the firing process are more relevant to the long-term stability of the veneering ceramics.¹³⁻¹⁵

Moreover, the span (three or four unit) of the FPDs seemed to have no impact on the survival and success rates within a 7-year observational period. However, Sax et al found a significant difference (4.9-times higher risk) of chipping incidence for four- and five-unit zirconia-based FPDs when compared to three-unit FPDs after 10 years of clinical service.²² A similar

effect could be detected in a long-term evaluation of metal-ceramic FPDs.¹⁸ Interestingly, these differences were detected in a comparison of three-unit FPDs and restorations with four and more units. Maybe the missing inclusion of restorations with more than four units in the present study explains the missing difference between the groups. Moreover, it has to be taken into account that only 18 four-unit restorations were included in the study population. Based on the findings of the Cox regression analysis, FPDs in the maxilla showed a tendency for higher survival compared to restorations in the mandible (hazard ratio, 0.335). Nevertheless, this trend does not reach the level of significance (P = .055). The increased number of decementations that occurred in the mandible can explain this effect. A total of 11 decementations occurred during the full observational period. A possible explanation for this comparatively high rate of retention loss may be the reduced internal fit of the frameworks that were achieved with the early-stage CAM system used in the present study, as well as the use of a conventional zinc-phosphate cement.²³ Accounting for the high decementation rate, the use of zinc-phosphate cements for conventional luting of zirconia FPDs should be reconsidered.

To interpret the results of the present study, it has to be considered that it was conducted in a university setting by experienced dentists. This can bias the outcome measurements; therefore, more data generated under typical conditions of a private practice are needed to more comprehensively determine the clinical performance. Additionally, it has to be kept in mind that 16 subjects (19 FPDs) did not attend the 7-year recall and could therefore not be reassessed, resulting in a dropout rate of 19%.

In summary, the results of the present study demonstrate reduced survival and success rates of earlystage CAM-fabricated zirconia FPDs compared with results published for metal-ceramic FPDs. Therefore, the null hypothesis has to be rejected. Further clinical investigations with updated CAD/CAM systems are needed for the meticulous evaluation of zirconiabased FPDs.

Conclusion

Considering the mean observational time of 84 months, the following conclusions can be drawn:

 The 7-year survival and success rates of conventionally luted zirconia-based FPDs in the posterior region fabricated by an early-stage CAM system are inferior to the survival rates published for metal-ceramic FPDs.

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- Technical complications and failures are mainly caused by chipping of the veneering porcelain, fractures of the framework, or loss of retention.
- The use of zinc-phosphate cement led to an increased rate of loss of retention. Therefore, the use of this type of luting agent for zirconia-based FPDs appears to be a critical factor.
- The failure and complication rates increased substantially between years 4 and 7, indicating that at least midterm clinical observations are needed for the meticulous evaluation of all-ceramic materials.
- Complication and failure rates were not associated with the arch position, span, or type of veneering ceramic.

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