Prospective Evaluation of Posterior Fixed Zirconia Dental Prostheses: 10-Year Clinical Results

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**Purpose:** To investigate the clinical survival and success rates of conventionally luted three- and four-unit fixed dental prostheses (FDPs) with zirconia frameworks (Cercon Smart Ceramics, DeguDent) after a mean observation period of 119 ± 36 months. **Materials and Methods:** A total of 75 patients were treated in the Department of Prosthodontics at the University of Goettingen, Germany, and a total of 99 posterior FDPs were inserted and luted with zinc phosphate cement. Time-dependent survival and success rates were calculated using Kaplan-Meier curves, and their relationships with the type of veneer (ceramic), location (maxilla vs mandible), and span length (three-unit vs four-unit) were analyzed with a Cox regression model (P < .05). **Results:** Of the 99 inserted FDPs, 24 were lost to follow-up, 51 remained functional and passed the 10-year examination (overall survival rate: 75.0%; 95% confidence interval [CI]: 0.64, 0.85), and 13 were absolute failures caused by technical events (technical survival rate: 84%; 95% CI: 0.64, 0.85). In 50 FDPs, relative failure required a clinical intervention to maintain function (overall success rate: 40%; 95% CI: 0.29, 0.52). For 35 of these FDPs, the relative failure was caused by technical events (technical success rate: 61%; 95% CI: 0.48, 0.73). None of the evaluated factors showed an association with overall or technical survival or success. **Conclusion:** Zirconia-based posterior FDPs produced with a first-generation computer-assisted manufacturing (CAM) system revealed high rates of absolute and relative failure, mainly due to technical events, after a mean observational period of 10 years. Further clinical studies with updated computer-assisted design (CAD)/CAM systems are needed to determine the long-term performance of zirconia-based FDPs. Int J Prosthodont 2018;31:35–42. doi: 10.11607/ipj.5283

In previous decades, zirconia (ie, yttrium-containing tetragonal zirconia polycrystalline [Y-TZP]) has been well established in the field of fixed prosthodontics. This process was promoted by advanced requirements regarding esthetics and biocompatibility in dental therapies and was stimulated by the excellent mechanical properties of zirconia. There have been several clinical investigations evaluating the performance of zirconia-based fixed dental prostheses (FDPs). Nevertheless, studies documenting long-term results with mean observation times of more than 5 years are still rare. Some studies with more extended follow-up periods were recently published that showed survival rates for zirconia-reinforced, glass-infiltrated alumina ceramic FDPs ranging from 83.4% after 7 years to 94.7% after 6.9 years and to 84.6% after 9.7 years. One study published in 2011 that used a prototype computer-assisted manufacturing (CAM) system (a precursor of the system used in the present study) reported high complication and failure rates after an observation time of 10.7 years, with a 10-year overall survival rate of only 67% and a significantly higher ceramic veneer fracture (CVF) rate for four- and five-unit FDPs than for three-unit FDPs. In general, the most common technical complication associated with zirconia-based restorations was CVFs, with a 5-year incidence of up to 30%. These fractures led to significantly inferior stability of the ceramic veneer in relation to porcelain-fused-to-metal (PFM) restorations. Other crucial factors in the survival and success rates of zirconia-based FDPs have been reported in long-term clinical studies and systematic reviews, including the minimum diameter of the connectors, maximum span length, marginal and internal precision, and secondary caries and loss of retention.
In addition, the processing technique for zirconia cores might be an influential factor on the frequency of core fractures. Zirconia can be milled in a presintered state and subsequently sintered to final density. Another fabrication process is based on the milling of the restoration directly from hot isostatic pressed (HIP) zirconia, which results in a higher fracture force resistance. This process might be important for the prevention of framework fractures; however, it is more time consuming than milling from a presintered material.\textsuperscript{8–14} Conventional luting for zirconia FDPs has been reported to be a possible risk factor for retention loss and secondary caries.\textsuperscript{3,15} Moreover, retention loss occurred more frequently in FDPs luted with zinc phosphate or glass-ionomer cements than in restorations fixed with resin cements.\textsuperscript{11}

The aim of the current investigation was to determine the time-dependent (10-year) overall and technical survival and success rates using Kaplan-Meier curves for CAM-fabricated, conventionally luted posterior zirconia FDPs. The 4- and 7-year results of this study population have already been published.\textsuperscript{3,15} Furthermore, possible risk factors for clinical absolute and relative failures, such as span length (three-unit/four-unit), position (maxilla/mandible), and type of ceramic veneer (experimental/Cercon Ceram S), were evaluated with a multivariate Cox regression model. The null hypothesis was that the 10-year clinical performance of posterior zirconia-based FDPs is comparable to the overall survival and success rates documented in the literature for fully veneered metal-ceramic FDPs.\textsuperscript{10,11}

### Materials and Methods

#### Patient Selection

In this study, 75 patients (36 female, 39 male) were recruited from 2001 to 2005 in the Department of Prosthodontics at the University Medical Center of Goettingen, Germany. The subjects’ ages ranged from 26 to 76 years (mean age: 49.4 ± 12.4 years). Inclusion criteria included a signed consent form, antagonistic teeth in the area of the FDP, vital abutments or abutments with sufficient endodontic treatment, and a maximum of two missing neighboring teeth in the posterior area. Patients with one or more of the following diagnoses were excluded from participation: bruxism, severe periodontal disease, pulpitis, a horizontal abutment tooth mobility of ≥ 1 mm, or pregnancy/lactation. The patients were informed of the purpose of the investigation, clinical procedures, and advantages/risk of the applied material. The Ethics Committee of the University of Goettingen approved the study (application no. 19/9/00). All subjects provided written informed consent.

#### Clinical Approach

The clinical procedures were similar to those used with metal-ceramic restorations. With the exception of two FDPs inserted by students under the supervision of a dental clinician, the procedures were performed by experienced dentists (full-time faculty members). Detailed initial instructions and clinical training were performed to ensure calibration of the clinicians who treated the patients. All patients received oral hygiene instructions and professional prophylaxis prior to prosthetic treatment. Patients received up to four FDPs. A total of 99 tooth-supported, single-span FDPs supported by terminal abutments (81 three-unit and 18 four-unit/two neighboring pontics) were inserted (39 in the maxilla, 60 in the mandible). A composite was used for the core build-up for the majority of abutment teeth; however, the preparation design was modified in accordance with the guidelines for zirconia-based restorations. Specifically, a chamfer design with a circular reduction of at least 0.8 mm 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 FDPs were finally luted with zinc phosphate 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 using a CAM system (Cercon smart ceramics, DeguDent) introduced to the German market in 2001. For the frameworks, manually fabricated wax patterns were digitized and enlarged by about 30% to compensate for shrinkage during sintering. Frameworks were milled from presintered zirconia blanks (Cercon base, DeguDent). All FDPs were produced with the same device (Cercon brain, DeguDent) and then sintered to full density for 6 hours at 1,350°C (Cercon heat, DeguDent). The milling unit was calibrated every 6 months according to the manufacturer’s instructions. The burs were calibrated with individual barcodes that were read by the scanner of the milling device and were changed every 50 units. A total of 97 FDPs were fabricated from noncolored blanks, and the remaining 2 were milled from a dentin-colored presintered material (Cercon base-colored, DeguDent). The minimum framework thickness was 0.4 mm. To optimize the periodontal area around the abutment teeth, the minimum connector dimension was 9 mm\textsuperscript{2}. The frameworks manufactured in 2001 (51 units) were veneered with an experimental
cementation. Necessary interventions to maintain function due to relative failure were divided into technical events (eg, ceramic fracture, loss of retention) and biologic events (eg, caries, endodontic treatments, periodontal interventions). The survival time of an FDP was defined as the period between the day of cementation and the last follow-up appointment or, in the case of a failure/event, the appointment scheduled to address the failure/event as documented in the patient’s file. Data were classified as censored observations if patients were lost to follow-up or declined further participation in the study.

Time-dependent technical survival and success rates of FDPs were calculated for span length (three-unit vs four-unit), position (maxilla vs mandible), and ceramic veneer (experimental ceramic vs Cercon Ceram-S) using Kaplan-Meier survival analysis. The influences of span length, position, and ceramic veneer on technical survival and success rates were examined using a multivariate Cox regression model. Different observations from the same patient were considered to be dependent on the adjusted variance estimation in the Cox regression model.

The significance level was set at $\alpha = 5\%$ for all statistical tests. All analyses were performed using R statistical software (version 3.0.2, www.r-project.org) with the R-package ‘prodlim’ for the survival analyses.

### Results

Of the 99 FDPs, 51 passed the 10-year examination. The mean observation time was $119 \pm 36$ months (minimum = 100, maximum = 165). A total of 24 FDPs had to be coded as dropouts (recall rate of 75.8%), and their data were censored. Another 24 FDPs were considered absolute failures following replacement of the FDP: 13 were caused by technical events and 10 by biologic events. Moreover, one FDP was lost in alio loco for unknown reasons (Table 1). Therefore, the overall 10-year survival rate was 75.0% (95% confidence interval [CI]: 0.64, 0.85) according to the Kaplan-Meier analysis (Fig 1). The corresponding 10-year technical
The survival rate (free of absolute failure caused by technical events) was 84% (CI: 0.75, 0.94) (Fig 2). Of the 13 absolute failures caused by technical events, 4 were related to core fractures (Fig 3). Additionally, four FDPs failed due to extensive CVFs, and five failures were related to loss of retention (recementation not possible) (Table 1).

Only 24 of the 99 FDPs remained functional without any clinical intervention; thus, the overall success rate (free of any events) after a mean observation time of 10 years was 40.0% (CI: 0.29, 0.52) (Fig 4). Relative failures occurred in 50 FDPs. Eleven biologic events required a clinical intervention to maintain function: Six FDPs with secondary caries required marginal composite filling, and endodontic treatment of an abutment tooth was needed for five (Table 2). A total of 39 relative failures were caused by technical events (1 marginal core fracture/31 CVFs/7 loss of retention) (Table 2). Thus, the technical success rate (free of technical events) after an observation period of 10 years was 57% (CI: 0.45, 0.69) (Fig 5).

For 35 FDPs, relative or absolute failure of the ceramic veneer was recorded. In four FDPs, extended fractures led to replacement of the FDP. The functions of all other FDPs could be maintained by polishing (Fig 4). The 10-year ceramic veneer success rate based on Kaplan-Meier analysis was 61% (CI: 0.49, 0.73).

A Cox regression model was used to identify risk factors for absolute and relative failures in the zirconia FDPs. Factors considered were span length (three-unit/four-unit), position (maxilla/mandible), and type of ceramic veneer (experimental/Cercon Ceram S). None of these factors had significant effects on overall or technical survival and success rates (Table 3). However, the overall survival rate showed a tendency for a possible association with FDP position (Hazard Ratio [HR]: 0.46/P = .0686). The survival probability for FDPs in the mandible was 69% (CI: 0.56, 0.82); for those in the maxilla, it was 83% (CI: 0.7, 0.95) (Table 3).

**Discussion**

This study revealed that, after a mean observation time of 10 years, CAM-fabricated, zirconia-based FDPs in the posterior region had an overall survival rate of 75.0% (CI: 0.64, 0.85) and an overall success rate (free of any intervention) of 40% (CI: 0.29, 0.52). The overall survival rates reported in systematic reviews for metal-ceramic FDPs range from 94.4% after 5 years to 89.2% after 10 years.7,8,11
In the present study, an annual overall failure rate of 2.5% was calculated. This rate is in the range of the annual failure rates calculated for FDPs made from densely sintered zirconia in a systematic review (2.02%) based on studies published between 1998 and 2013.\(^{10}\) In the same review, based on 15 studies published between 1989 and 2013, the annual failure rate for metal-ceramic FDPs was estimated at 1.15%.\(^ {10}\)

The date of publication is highly relevant for the comparison of the overall survival rates between zirconia and metal-ceramic FDPs. To reduce potential sources of bias, all restorations should be fully veneered using the same type of material in the occlusal area. This precondition is fulfilled in the above-mentioned systematic review\(^ {10}\) because only recently published studies for metal-ceramic FDPs were included. This eliminates potential bias introduced by partially veneered or gold-acrylic restorations included in earlier published reviews.\(^ {10}\) Therefore, it must be stated that the overall survival rates for zirconia-based FDPs fabricated with an early-stage CAM system are inferior to those of metal-ceramic FDPs fabricated with various framework materials (eg, titanium, gold alloys, or cobalt-chromium).

### Table 2  Relative Failures and Corresponding Clinical Intervention to Maintain Function

<table>
<thead>
<tr>
<th>Type of relative failure</th>
<th>No. of restorations (N = 99)</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marginal core fracture</td>
<td>1</td>
<td>Sealing with composite</td>
</tr>
<tr>
<td>Ceramic veneer fracture</td>
<td>31</td>
<td>Polishing</td>
</tr>
<tr>
<td>Loss of retention</td>
<td>7</td>
<td>Adhesive recementation</td>
</tr>
<tr>
<td>Secondary caries</td>
<td>6</td>
<td>Sealing with composite</td>
</tr>
<tr>
<td>Loss of vitality</td>
<td>5</td>
<td>Endodontic treatment</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td></td>
</tr>
</tbody>
</table>

### Table 3  Multivariate Cox Regression Results Reflecting Model Coefficient, Hazard Ratio (HR), and 95% Confidence Interval (CI) and Significance of Span Length, Position, and Ceramic Veneer on Overall and Technical Survival and Success Rates

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Coefficient</th>
<th>HR</th>
<th>HR 95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall survival</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Span length</td>
<td>-0.23</td>
<td>0.8</td>
<td>0.35, 1.8</td>
<td>.5866</td>
</tr>
<tr>
<td>Position</td>
<td>-0.77</td>
<td>0.46</td>
<td>0.2, 1.04</td>
<td>.0636</td>
</tr>
<tr>
<td>Ceramic veneer</td>
<td>-0.43</td>
<td>0.65</td>
<td>0.26, 1.63</td>
<td>.358</td>
</tr>
<tr>
<td>Overall success</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Span length</td>
<td>0.05</td>
<td>1.05</td>
<td>0.59, 1.88</td>
<td>.8570</td>
</tr>
<tr>
<td>Position</td>
<td>-0.39</td>
<td>0.68</td>
<td>0.37, 1.22</td>
<td>.1906</td>
</tr>
<tr>
<td>Ceramic veneer</td>
<td>0.25</td>
<td>1.29</td>
<td>0.70, 2.39</td>
<td>.4197</td>
</tr>
<tr>
<td>Technical survival</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Span length</td>
<td>-0.57</td>
<td>0.57</td>
<td>0.15, 2.17</td>
<td>.4071</td>
</tr>
<tr>
<td>Position</td>
<td>-0.38</td>
<td>0.68</td>
<td>0.25, 1.84</td>
<td>.4529</td>
</tr>
<tr>
<td>Ceramic veneer</td>
<td>-0.36</td>
<td>0.7</td>
<td>0.18, 2.68</td>
<td>.6001</td>
</tr>
<tr>
<td>Technical success</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Span length</td>
<td>0.18</td>
<td>1.2</td>
<td>0.52, 2.77</td>
<td>.677</td>
</tr>
<tr>
<td>Position</td>
<td>-0.01</td>
<td>0.99</td>
<td>0.48, 1.99</td>
<td>.9743</td>
</tr>
<tr>
<td>Ceramic veneer</td>
<td>0.53</td>
<td>1.7</td>
<td>0.83, 3.48</td>
<td>.1464</td>
</tr>
</tbody>
</table>
In the present study, an overall complication rate (both biologic and technical events) of 60% after a mean observation period of 10 years was calculated. This finding supports the findings of a systematic review reporting a 5-year overall complication rate of 27.6% for zirconia FDPs. The majority of complications in the present study were caused by technical events, and the most common technical complications were CVFs and loss of retention. This finding is also in agreement with the findings of two more recently published systematic reviews that reported the incidence of CVFs and loss of retention were significantly higher for zirconia FDPs than for metal-ceramic FDPs. The most frequent biologic complication was secondary caries. This finding supports the findings of a systematic review that reported a significantly higher rate of secondary caries with zirconia FDPs than with metal-ceramic FDPs.

When interpreting the results of the present study, the fact that the study was started in 2001 with an early-stage CAM system must be considered. The present results led to the suggestion that the increased event rates for secondary caries and loss of retention are directly related to semi-optimal fit of the FDPs fabricated at this stage of development. The effect of the fabrication technique on clinical performance can be demonstrated in the results of the present study, which used a first-generation CAM system (Cercon Smart Ceramics, DeguDent) rather than its precursor prototype CAM system (DCM-system, University of Zurich). The 10-year overall survival rate for the FDPs fabricated with the CAM prototype system was 67% (present study: 75%), the framework fracture rates were 8.5% for the prototype system (6.2% in the present study), and the complication rates caused by secondary caries were 27% for the prototype system (8% in the present study). This effect might be attributed to an improved quality of fit for the restoration due to improved scanning technology and new milling strategies. Nevertheless, for the first-generation CAM system used in the present study, reduced internal fit accuracy compared with that of metal-ceramic crowns has been demonstrated. This reduced internal fit quality might explain the increased risk for loss of retention, especially if conventional cementation methods are used. Since the starting point of the present study, various improvements in scanning and milling technology have been introduced to improve fit accuracy, thus reducing at least two types of failures observed in the present study: loss of retention and secondary caries.

Moreover, technical improvements, such as prolonged cooling periods during the veneering firing process and a pronounced anatomical design of the zirconia cores, offer reduced chipping rates and are not included in the present study.

Furthermore, it must be considered that the present study was conducted in a university setting. Additionally, the FDPs were fabricated by experienced dentists. This issue can bias the outcome measurements; therefore, more data generated under typical conditions in a private practice are needed to determine the clinical performance more comprehensively. Additionally, it must be noted that 21 subjects (24 FDPs) did not attend the 10-year follow-up examination. Consequently, they could not be reassessed, resulting in a dropout rate of 24%.

Even given the limitations of the present study, the findings make a valuable contribution to the literature on the clinical performance of all-ceramic FDPs, as they provide 10-year data from a prospective clinical study, which is still rare for this type of restoration. There is only one study with a mean observation time of more than 10 years that evaluated a prototype CAM system for zirconia-based FDPs. Further studies with at least 10-year results only exist for other all-ceramic materials—such as glass-infiltrated alumina ceramic and lithium disilicate—or for implant-based FDPs and glass-infiltrated alumina FDPs.

In the present study, 4 out of 24 absolute failures were caused by framework fractures. This finding supports observations from other clinical investigations demonstrating an improved framework stability of three- and four-unit posterior zirconia FDPs compared with veneered reinforced glass-ceramic FDPs and glass-infiltrated alumina FDPs.

Apart from material selection, the core fracture rate is influenced by the framework design. In vitro and in vivo results support the hypothesis that core fractures of all-ceramic FDPs are more dependent on connector size than on the material itself. A promising approach to further reduce the risks of technical failures and complications might be the use of monolithic zirconia FDPs. As these FDPs are fabricated without any ceramic veneer, the risk of CVF is eliminated. Furthermore, the lack of ceramic veneer offers more space for enlarged connector areas and increased material thickness, thus improving fracture...
stability. Although monolithic zirconia restorations could potentially yield better long-term stability, clinical data on this type of restoration are still rare and limited by short observational periods and low numbers of included restorations and patients.25,26

Another attempted avoidance of long-term failures of zirconia cores is the use of HIP zirconia27,28; however, at this time, clinical data on long-term performance are scant.7–12 Thus, the clinical advantages of this material remain unclear.

In the present study, the factors of ceramic veneer, span length, and location were evaluated for their potential impact on overall and technical survival and success rates. In accordance with the equivalent analysis during the 7-year evaluation of this study, neither ceramic veneer nor span length had a statistically significant influence.3 Only location showed a tendency for a correlation with the overall survival rate of FDPs, with those in the mandible having a lower survival rate than those in the maxilla (HR = 0.46/P = .0636). In the maxilla, a 10-year survival rate of 83% (95% CI: 0.7, 0.97) was measured. In contrast to that finding, FDPs in the mandible showed a survival rate of 69% (95% CI: 0.56, 0.82). The HR of 0.46 indicates a 2.1-fold higher risk for an absolute failure of FDPs placed in the mandible compared to FDPs placed in the maxilla. An obvious explanation for this difference could be that decementation causing loss of the restoration occurred more frequently in the mandible than in the maxilla.

A possible explanation for an increased risk for loss of retention can be seen in the cementation method used in the present study (conventional luting with zinc phosphate cement). Based on the findings of a systematic review including 27 studies, zinc phosphate and glass-ionomer cements were over-represented in cases of retention loss, whereas only a few incidents of retention loss have been reported in restorations using resin-based luting agents.10 Therefore, the recommendation to critically reconsider conventional luting of zirconia FDPs was supported by the findings of the present study.3,10,11

Based on the findings of the present study, overall and technical survival and success rates for zirconia-based FDPs are still inferior to those of metal-ceramic FDPs with different framework materials, particularly in terms of technical events (eg, CVF, framework fracture, loss of retention).7,11,29–32

The null hypothesis of the present study must be rejected. Based on the available clinical data, metal-ceramic FDPs should be considered the gold standard for veneered FDPs in the posterior region.

Conclusions

Considering the limitations of the present study, after a mean observation time of 10 years, the following conclusions can be drawn:

- The 10-year overall and technical survival and success rates of conventionally luted zirconia-based FDPs in the posterior region fabricated using an early-stage CAM system confirmed their inferiority to the published survival rates of metal-ceramic FDPs.
- Most absolute and relative failures were caused by technical events (eg, framework fractures and extensive CVFs).
- Conventional luting led to a significantly increased rate of decementation, particularly in the mandible; therefore, the use of this type of luting in the mandible should be critically considered.
- Span length, type of ceramic veneer, and position of the FDP had no significant impacts on overall or technical survival and success rates.

Acknowledgments

The authors would like to thank Stephan Kerl and Ulrich Wenzel for their technical assistance and DeguDent for its financial support of the study. The authors report no conflicts of interest.

References


**Literature Abstract**

**Engineering a Highly Elastic Human Protein-Based Sealant for Surgical Applications**

Surgical sealants have been used for sealing or reconnecting ruptured tissues, but often have low adhesion, inappropriate mechanical strength, cytotoxicity concerns, and poor performance in biologic environments. To address these challenges, the authors engineered a biocompatible and highly elastic hydrogel sealant with tunable adhesion properties by photocrosslinking the recombinant human protein tropoelastin. The subcutaneous implantation of the methacryloyl-substituted tropoelastin (MeTro) sealant in rodents demonstrated low toxicity and controlled degradation. All animals survived surgical procedures with adequate blood circulation by using MeTro in an incisional model of artery sealing in rats, and animals showed normal breathing and lung function in a model of surgically induced rat lung leakage. In vivo experiments in a porcine model demonstrated complete sealing of severely leaking lung tissue in the absence of sutures or staples, with no clinical or sonographic signs of pneumothorax during 14 days of follow-up. The engineered MeTro sealant has high potential for clinical applications because of its superior adhesion and mechanical properties compared to commercially available sealants, as well as the opportunity for further optimization of the degradation rate to fit desired surgical applications on different tissues.


—David Ojcius, USA