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Fifteen-year outcome of three-unit fixed dental prostheses made from monolithic lithium disilicate ceramic

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ABSTRACT

Objectives: The purpose of this prospective study was to evaluate the clinical long-term outcome over 15 or more years of crown-retained fixed dental prostheses (FDPs) made from a lithium disilicate ceramic (IPS e.max Press, Ivoclar Vivadent AG).

Methods: Thirty-six three-unit FDPs replacing anterior (16%) and posterior (84%) teeth were inserted in 28 patients. Abutment teeth were prepared following a standardized protocol. The size of the proximal connector of the FDPs was 12 mm^2 (anterior) or 16 mm^2 (posterior). FDPs were cemented either conventionally with glass-ionomer cement (n = 19) or adhesively with composite resin (n = 17). The following parameters were evaluated at baseline, 6 months after cementation and then annually (at abutment and contralateral teeth): probing pocket depth, plaque index, bleeding on probing, and tooth vitality.

Results: Three FDPs were defined as drop-outs. The mean observation period of the remaining 33 FDPs was 167 months (range: 79–225 months). The survival rate (survival being defined as FDPs remaining in place either with or without complications) according to Kaplan-Meier was 48.6% after 15 years. The success rate (success being defined as free of complications and remaining unchanged) was 30.9% after 15 years.

Conclusions: Fatigue and crack propagation caused by clinical aging in monolithic lithium disilicate ceramics seem to take considerable time, as shown by the presented survival and success rates after 15 years. Further long-term studies are necessary to evaluate the reliability of FDPs made from other all-ceramic materials over a period of 15 or more years.

1. Introduction

A general aim of prosthodontics is to restore a reduced dentition with permanent restorations that might serve the patient life-long. However, long-term data over 15 or more years are important but rare in fixed prosthodontics. For the “gold standard” in fixed prosthodontics, i.e. metal-ceramic fixed dental prostheses (FDPs), a few studies covering 15 or more years are available [1], but most studies report only clinical outcome of 10 or less years [1]. Therefore, recent meta-analyses focused on the survival after 10 or even 5 years only [2–7]. However, to focus on the outcome after 10 or 5 years and to calculate linear annual failure rates might possibly mislead clinicians about the “true” longevity of restorations. Longer-term studies on metal-ceramic FDPs revealed repeatedly, that in the first years after insertion usually only a few failures occur, but within medium term (5–10 years) the failure rate starts to increase and after 10 years the failure rate often showed a sharp further increase [1,8–10]. An exception from this failure pattern was only reported for minimally invasive anterior resin-bonded FDPs (RBFDPs) fabricated from alumina ceramic reporting a 15-year survival rate of 95.4% that dropped to 81.8% after 18 years [11].

For all-ceramic FDPs recently various clinical studies have been published presenting 10-year survival rates ranging from 93.6% to only 67% [12–17]. These studies have shown that chipping of the veneering material is one of the frequently occurring complications with FDPs made from veneered zirconia. Chaar et al. reported a cumulative chipping rate of 37.7% after 10 years [14] for zirconia reinforced alumina ceramic; comparable results were reported for veneered zirconia [16]. Rinke et al. also described for veneered zirconia FDPs that the majority of failures were caused by technical events. They reported a technical success rate of 57% after 10 years [15]. Sax et al. showed a significant correlation between bridge span and chipping rate for veneered zirconia [12].

In a recent long-term study a superior cumulative 10-year survival rate of 96.5% was reported for 1410 complete coverage single tooth

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restorations made from monolithic lithium disilicate ceramic [18]. For FDPs made from monolithic lithium disilicate ceramic a lower but still promising 10-year survival rate of 87.9% has been reported [13], which compares well to the outcome of metal-ceramic FDPs after 10 years [1,8–10]. So monolithic lithium disilicate FDPs showed promising results after 10 years, but no data yet are available after 15 or more years of clinical observation.

Therefore, the purpose of the present study report is to present first long-term data on the clinical outcome of three-unit lithium disilicate ceramic FDPs after a service period of at least 15 up to 18 years.

2. Materials and methods

Patients referred to the Department of Prosthodontics of the University at Kiel, Germany, with the indication for three-unit FDPs were selected for the study. Informed consent was obtained from all study participants on a written form approved by the Ethical Committee of the Medical Faculty of the University at Kiel updated in 2019.

Detailed description of patient selection, study design, prosthodontic procedures has previously been published [13,19,20].

In short, a total of 36 monolithic lithium disilicate ceramic FDPs (IPS e.max Press, Ivoclar Vivadent AG, Schaan, Liechtenstein) were inserted between 2000 and 2001. Thirty fixed FDPs replaced posterior teeth, while 6 FDPs replaced anterior teeth. Of the 30 posterior FDPs, 9 premolars (8 in the maxilla and 1 in the mandible) and 21 molars (11 in the maxilla and 10 in the mandible) were replaced. Twenty patients received one restoration. Eight patients received two restorations. The cause of tooth loss was not documented. The mean (standard deviation) age was 47.5 (11.6) years (17 women, 11 men). Only patients with missing single teeth and space equal or smaller than the width of a molar were included. As described previously, the abutment teeth had to be vital, without any active periodontal disease, the bone level had to correspond to at least two-thirds of the root length and a maximum tooth mobility of Grade 1 according to the scale of Nyman and Lindhe was accepted. Periodontal health, among others, was also documented as a baseline on the contralateral teeth due to the overriding inclusion criteria. Patients with known bruxism were excluded.

Of the cemented 36 FDPs, 30 were integrated in the posterior region of the maxilla and mandible, and 6 replaced anterior teeth in the maxilla.

All restorations were constructed as three-unit end-to-end FDPs. No cantilever FDPs were provided. The indication and fabrication of the restorations was carried out according to the study protocol (among other criteria: proximal connector dimensions at least 4 x 3 mm for anterior FDPs and 4 x 4 mm for posterior FDPs as recommended by the manufacturer, minimum occlusal thickness was 1.5 mm). The dental technicians were trained to observe the required thicknesses of the restorations. Connector heights and widths were measured for each FDP using a precision gauge. All thicknesses of the restorations were cross checked by faculty dentists and the data were documented accordingly. In addition, all restorations were inspected at once before cementation by two supervisors with a specialization in Prosthodontics (approved by the German Society for Prosthetic Dentistry and Biomaterials [DGPro]). The restorations were cemented either with glass-ionomer cement (n = 19, Ketac-Cem, 3 M ESPE, St. Paul, Minn.) or composite resin (n = 17, Variolink II, Ivoclar Vivadent AG). In both cases the ceramic luting surfaces were etched with 5% hydrofluoric acid for 20 s (IPS Ceramic Etching Gel, Ivoclar Vivadent AG) before cementation. In the case of adhesive cementation, additional silane was applied to the ceramic luting surface (Monobond S, Ivoclar Vivadent AG).

After insertion initial follow-up recalls were performed after six and twelve months and then annually. Kaplan-Meier survival curves [21] were used to demonstrate cumulative survival rates and cumulative success rates.

Life Tables analysis according to Kaplan-Meier were performed using SPSS Software v16.0 (SPSS Inc., Chicago, USA). Within the analysis a distinction was made between biological and technical complications. For survival rates, technical failures such as catastrophic fractures of the restoration or severe biological complications such as abutment fractures were considered a failure. For the success rate calculation, a distinction was made between ceramic-related technical complications (ceramic fractures and chipping) and other biological complications (e.g. loss of retention or endodontic therapy).

The data from the date of cementation to either the end of the last follow-up examination (August 2018) or the last date of known status for patients who had passed away or who had left the study at their own request were taken into account.

The log-rank test was performed for statistical comparison of cementation groups at a 95 percent confidence level.

3. Results

All patients were asked to undergo an annual follow-up examination. Of the 28 patients at baseline, two had passed away within the first 2 years after cementation of the restorations. The 3 FDPs of these patients did not show any complications until death, they were assessed as "drop out" of the study. Some patients withdrew from the study at their own request. The 5-year recall was performed for 33 FDPs, the 8-year recall for 30 FDPs, 10-year recall for 29 FDPs and 15-year recall was evaluated for 12 FDPs. Between the follow-up after 10 years and after 15 years 4 patients (6 FDPs) left the study at their own request and 11 FDPs failed. Data of deceased and otherwise dropped-out patients were censored at the date of the last available information.

Figs. 1 and 2 show the survival and success rates according to the Kaplan-Meier analysis.

The survival rate after 10 years amounted to 87.9% (95% confidence interval [CI]: 77%–99%, 3 losses due to catastrophic ceramic fractures) and dropped to 48.6% after 15 years of observation (95% CI: 30%–67%, in total 6 catastrophic ceramic fractures and 6 biological failures). All FDP losses (both technical and biological complications) were considered as failures. The attached clinical photos of the restorations show exemplary FDPs without failure and with different failure modes (Figs. 5–7). Six FDPs (3 patients) could not be re-examined after 15 years because they had left the study for personal reasons (evaluation as success until the last follow-up appointment). Nine FDPs (25%) failed within the observation period of 120–180 months.

Considering only ceramic failures due to catastrophic fractures and ceramic complications such as chipping which had no effect on the clinical function of the restoration, the success rate reached 84.7% (95% CI: 72%–92%) after 10 years and 59.1% (95% CI: 39%–79%) after 15 years. Looking at all technical and biological complications and losses, the success rate of FDPs after 10 years was 69.7% (95% CI: 54%–85%) and dropped to 30.9% (95% CI: 14%–48%) after 15 years. In addition, the outcome of the patients who received 2 FDPs seemed not to indicate a clustering effect with regard to the total outcome.

In order to obtain a clear statement regarding the long-term reliability of pure posterior FDPs, the survival and success rates of pure posterior FDPs were also analyzed and graphically presented in Fig. 3. It can be seen that the survival rate after 10 years amounts to 88.9% (95% CI: 77%–100%) and decreased to 48.1% (95% CI: 27%–69%) after 15 years of observation. With regard to the complications that occurred, the success rate was 74.1% (95% CI: 58%–91%) after 10 years and 29.8% (95% CI: 11%–49%) after 15 years. The cementation method had no statistically significant influence for any comparison. Fig. 4 shows the type of cementation in relation to the survival of the restorations.

4. Discussion

The present study showed a dramatic drop of the monolithic lithium disilicate ceramic FDPs survival and success rates after 10 years to only

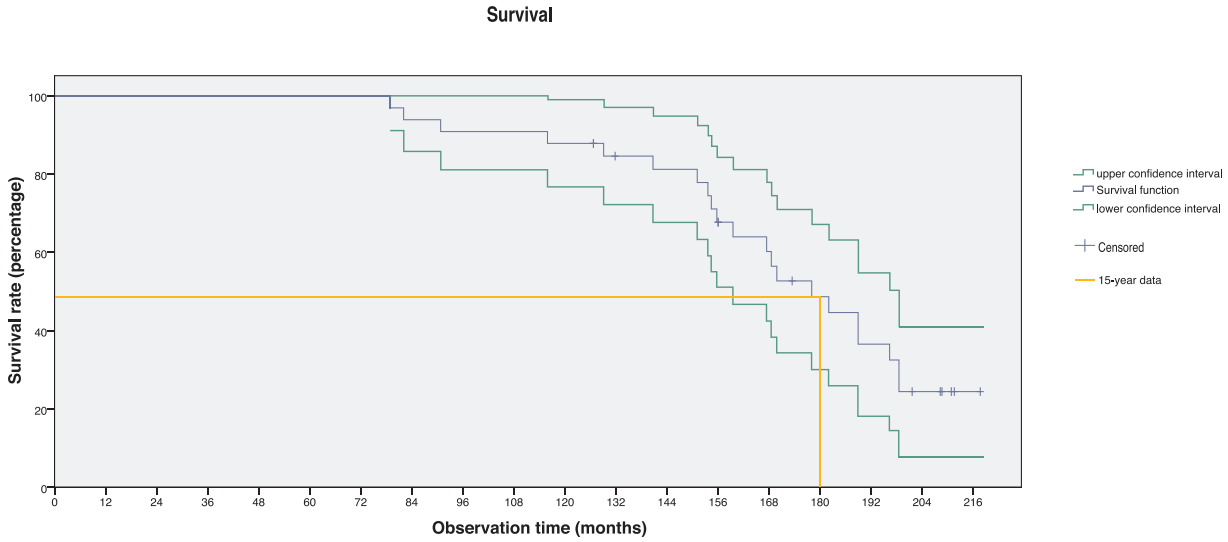

Fig. 1. Kaplan-Meier analysis shows the survival rate over all restorations including upper and lower 95% confidence interval. For the survival rate the event "catastrophic fracture of the FDP" or loss due to biological reasons was considered as a failure.

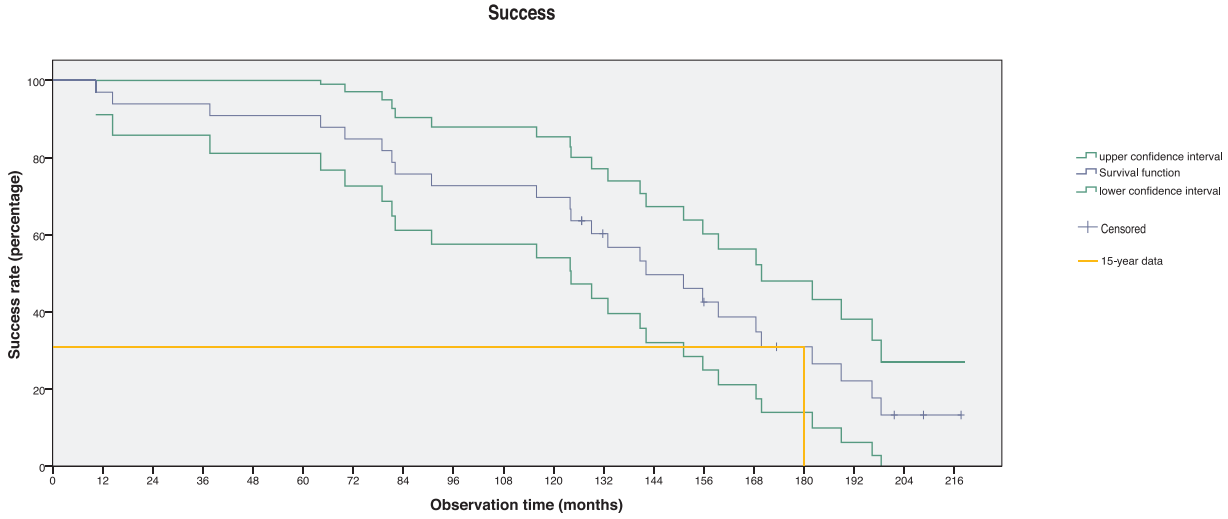

Fig. 2. Kaplan-Meier analysis shows the success rate over all restorations including upper and lower 95% confidence interval (all complications and failures).

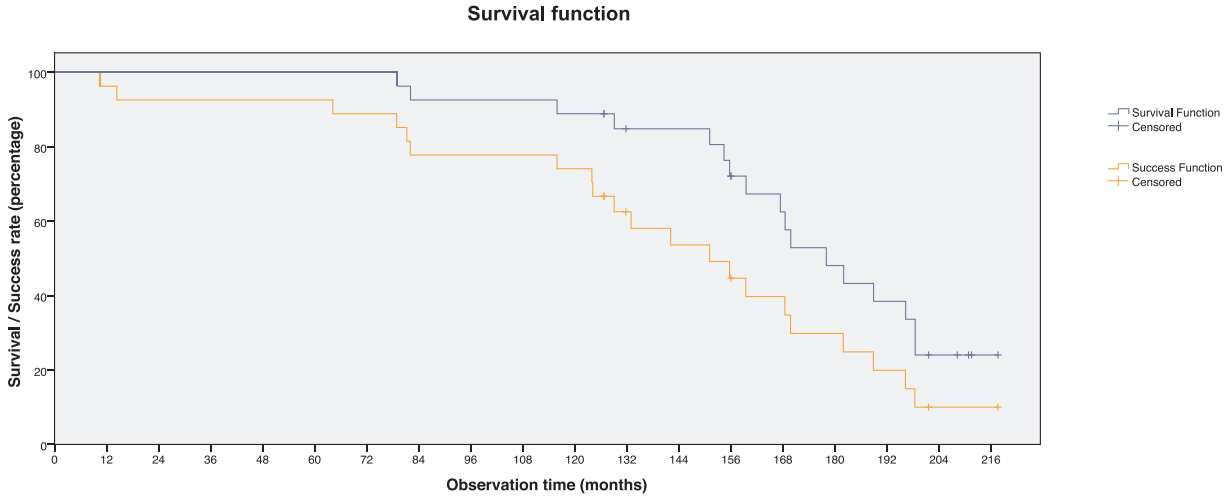

Fig. 3. Kaplan-Meier analysis shows the outcome in regard to survival and complication rates solely of the posterior FDPs.

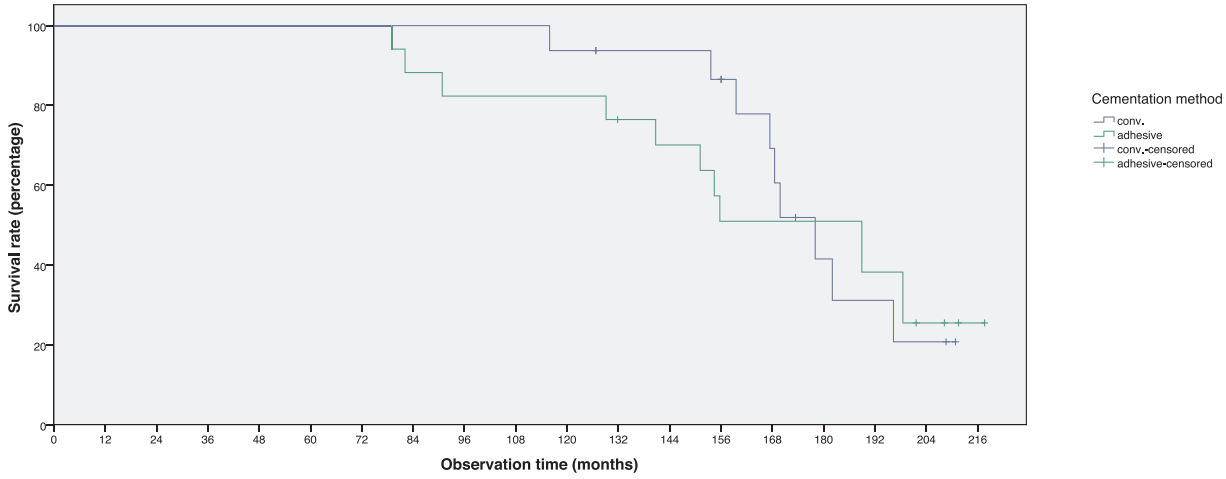

Fig. 4. Kaplan-Meier analysis shows the survival rate over all FDPs in relation to the cementation method.

Fig. 5. Example of a successful FDP after 18 years of surveillance.

Fig. 6. Example of a FDP that failed due to catastrophic fracture after 82 months in the occlusal and lateral view.

48.6% and 30.9% after 15 years, respectively. Unfortunately, in the currently available literature there are no other clinical studies on FDPs made from any other all-ceramic material (including zirconia) that cover 15 or more years clinical observation to which the current results could be compared. However, for monolithic lithium disilicate single crowns a 15-year survival rate of 81.9% has been reported, in which also the most common cause of failure was the fracture of the ceramic material [22]. Molar restorations were found to be more frequently affected by failures, whereas age and sex had less or no influence on the outcome [18,22]. The higher loading forces occurring in the posterior region might explain the inferior result for posterior crowns. The high failure rates caused by fracture of the ceramic material in the current study might be also related to the posterior position of most of the evaluated FDPs. The ceramic manufacturer indicated in the material's instructions that lithium disilicate should only be used for anterior FDPs up to the replacement of the first premolar but not for the replacement of more posterior teeth. This limited indication is supported by the results of the current study.

With the above mentioned exception, the specifications of the manufacturers, were strictly followed. Despite the fact that the study was carried out by university faculty dentists, it can be assumed that by complying with the manufacturer's recommendations regarding the required material thicknesses and the correct clinical treatment procedures, equivalent results can be expected in the area of general dentists.

The survival of the restorations was not influenced by the cementation method as depicted in Fig. 4 and no statistically significant difference was detected. Although the oral environment and the occurrence of leakage in the marginal area might influence the longevity of dental restorations, in the current study adhesive and conventional cementation resulted in a comparable clinical outcome.

Our results reveal that fatigue and crack propagations caused by the clinical aging and loading conditions might require substantial time: In the present study, no fractures occurred within the first six years, but after 7 years ceramic fractures started and the fracture rate increased substantially after 10 years. Compared to the still "gold standard", i.e. metal-ceramic FDPs, our results with all-ceramic FPDs are considerably inferior [1,8–10]. In a recent long-term study with metal-ceramic FDPs the 15-year survival rate was 61.6% and therefore considerable better than our results [10]. Interestingly, the 15-year survival rate of minimally-invasive metal-ceramic RBFDPs in this study was even better with 66.5%, although statistically not different from crown-retained metal-ceramic FDPs.

Fig. 7. Example of a FDP that failed due to debonding at the anterior abutment tooth. In addition, a crack formation is visible on the lateral view.

In an early meta-analysis on conventional metal-ceramic FDPs including 42 studies an overall survival rate of 74% was calculated after 15 years [23]. In contrast to completely fractured monolithic all-ceramic restorations in the current study, veneered metal-ceramic restorations with a stable metal framework seem to survive for a longer period of time and, if chippings occur, often can be maintained by intraoral repairs. Although the results showed acceptable survival rates after 10 years, ageing in the oral environment with associated crack progressions seems to lead to higher failures in monolithic restorations than in metal-supported constructions in the long-run. The results of the investigations on the mid-term survival of zirconia FDPs so far appear promising, but long-term data over 15 years are still needed, before it is known whether this zirconia really will withstand the test of time better than lithium disilicate when used for FDPs. In view of the presented results, further long-term studies are necessary to evaluate the reliability of FDPs made from other all-ceramic materials over a period of 15 and more years.

Ethical approval

All procedures performed in this study involving human participants were carried out with the consent of the Ethics Committee and in accordance with the provisions of the Helsinki Declaration of 2013.

Declaration of Competing Interest

None.

Acknowledgements

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