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Long-term clinical outcome of three-unit fixed-fixed posterior zirconia ceramic inlay-retained FDPs with a modified design

M. Sad Chaar^{a,*}, Nicole Passia^b, Merlind Becker^a, Matthias Kern^a

- a Department of Prosthodontics, Propaedeutics and Dental Materials, School of Dentistry, Christian-Albrechts University at Kiel, Arnold-Heller-Str. 16, Kiel 24105, Germany
- b Department of Prosthodontics, Faculty of Medicine and University Hospital Carl Gustav Carus, Technische Universität Dresden, Dresden, Germany

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ABSTRACT

Objectives: To assess the long-term clinical outcome of posterior inlay-retained fixed dental prostheses (IRFDPs) with a modified design made from zirconia ceramic.

Methods: In 30 patients thirty 3-unit IRFDPs were placed to replace 7 premolars (4 in the maxilla, 3 in the mandible), and 23 first molars (15 in the maxilla, 8 in the mandible). Preparations were accomplished in agreement with the general principles for ceramic inlay restorations and modified with a short retainer-wing bevel preparation within the enamel at the buccal and oral sides. The frameworks were milled from 3Y-TZP ceramic, and the pontics were veneered with feldspathic ceramic. All IRFDPs were bonded with a phosphate monomer containing luting resin after air-abrasion of the intaglio surfaces. The patients were recalled 6–12 months after placement, and then annually. Kaplan-Meier analysis was used to calculate the survival and complication rates of the IRFDPs.

Results: The mean observation time was 10.6 ± 1.5 years. The 10-year cumulative survival rate was 89% with 4 failures, two of them were due to deep secondary caries with loss of retention, one due to repeated debonding with enamel fractures, and one due to generalized progressive periodontitis. The most common complication was chipping of the veneering ceramic (20.1%). Eighteen IRFDPs were free of any type of complication up to 15.4 years, which corresponds to a 10-year cumulative success rate of 70.4%.

Conclusion: The long-term clinical performance of modified IRFDPs made of veneered zirconia ceramics was favorable after 10 years, therefore, they represent a treatment alternative to replace posterior single missing teeth.

Clinical significance: Zirconia-based IRFDPs fabricated in the modified design may represent a substancepreserving alternative to conventional posterior FDPs to replace posterior single missing teeth, particularly in cases where implants cannot be placed, and when the adjacent teeth already have small restorations or defects.

1. Introduction

Conventional metal-ceramic fixed dental prostheses (FDPs) as well as implant-supported single crowns have both been considered to be valid treatment options for the replacement of single missing posterior teeth [1,2]. However, both modalities still have several clinical drawbacks, particularly the invasive full crown preparation, which may present a risk for pulp injuries [3].

Resin-bonded FDPs (RBFDPs) provide a minimally invasive treatment option indicated for replacing missing teeth when the abutment teeth are intact, particularly for young patients, where implants are

contraindicated and conventional FDPs are extremely invasive [4]. Likewise, inlay-retained FDPs (IRFDPs) represent a minimally invasive treatment option that use box-shaped preparation forms as retainers, especially in cases with preexisting fillings or defects of the abutment teeth [5].

While some authors used noble metal alloy as the material of choice for the framework of IRFDPs [6], others chose lithium disilicate ceramic [7], fiber-reinforced composites [8], or zirconia [9]. A two-retainer design (end-to-end design) was chosen in all clinical trials [10]. The most common reported complications were secondary caries, chipping of the veneering material, debonding, and framework fractures [11–13].

E-mail address: schaar@proth.uni-kiel.de (M.S. Chaar).

^{*} Corresponding author.

Accordingly, different suggestions regarding the framework design have been proposed to overcome the problem of debonding. A fixedremovable design for posterior IRFDPs to act as stress breaker was suggested [14]. However, 33.7% of the restorations reported a history of debonding after 10 years. Instead, Wolfart and Kern considered in 2006 a new framework rigid design for zirconia-based IRFDPs using additional short retainer-wings at the buccal and oral sides of the abutment teeth aiming to improve stress distribution, minimize torsion forces at the inlay-retainers, and increase the adhesive surface to enamel [15]. The idea was to remedy the previously mentioned complications with the conventional inlay preparation design. Initial results indicated no clinical failures within the first two years [16]. Furthermore, mid-term results were very promising with a 5-year cumulative survival rate of 95.8% [17]. Additionally, 25 of the IRFDPs (83.3%) were free of any biological or technical complications. However, long-term clinical data with the modified design are still missing, but required before this new design could be recommended for clinical application.

Therefore, the aim of the current study was to assess the long-term clinical outcome of posterior zirconia-based IRFDPs manufactured with this new design after an observation period of 10 years.

2. Materials and methods

The ethic committee of the Christian-Albrechts University at Kiel approved the study protocol in 2006 (Approval No. D 119/06) as well as the 10-year follow-up in 2022 (Approval No. D 429/22) and all participants gave their informed written consent before inclusion. All recruited patients were enlightened in details about all treatment options (single implant-supported crown, conventional FDP, IRFDP, and resin-bonded FDP if the abutment teeth were sound), as well as about non-treatment. A detailed description on study design, patient selection, prosthodontic procedures, follow-up examination and the outcome over a mean observation time of 64.4 months has been published (17). Therefore, only a brief description of the study protocol and important procedures is provided in this paper.

Between 2007 and 2010 thirty IRFDPs were placed in 30 patients (18 females, 12 males, mean age 41.9 years). The IRFDPs replaced 7 second premolars (4 in the maxilla, 3 in the mandible) and 23 first molars (12 in the maxilla, 6 in the mandible). While 51 of the abutment teeth (22 premolars and 29 molars) were restored with preexisting fillings with an average of 1.7 involved surfaces per abutment tooth, only 9 abutments were sound (8 premolars and 1 molar).

Tooth preparations were performed with box-shaped defect-oriented inlay cavities (size 3 \times 3 mm, minimum thickness 1.2 mm), and modified with a retainer-wing bevel preparation within the enamel (thickness 0.2–0.5 mm) at both the buccal and oral sides (Fig. 1a, b). After final impressions and models fabrication, the frameworks were designed so that the minimum proximal connector dimensions were at least 3 \times 3 mm (height x width), the proximal wing-extensions were 3 mm in length and at least 0.6 mm thick. All restorations were milled out of 3Y-TZP

zirconia ceramic (Vita In-Ceram YZ, Vita Zahnfabrik, Bad Säckingen, Germany) using the CEREC inLab System (Sirona Dental GmbH, Bensheim, Germany). The green-frameworks were then sintered at $1530\,^{\circ}\mathrm{C}$ (VITA Zyrcomat, Vita Zahnfabrik) according to the manufacturer recommendation. Thereafter, all frameworks were veneered using the conventional layering technique with feldspathic porcelain (VITA VM 9, Vita Zahnfabrik).

Rubber dam was applied always during bonding procedures, which were performed using the total-etch technique with 37% phosphoric acid (Total Etch, Ivoclar-Vivadent, Schaan, Liechtenstein) and a dentine adhesive (Clearfil New Bond, Kuraray, Osaka, Japan). Moreover, the inner retention surfaces for all IRFDPs were airborne-particle abraded with 50 μ m alumina particles at a pressure of 2.5 bar followed by ultrasonically cleaning in 96% isopropyl alcohol, and then inserted adhesively with a phosphate monomer containing luting resin (Panavia 21 TC, Kuraray). Excess cement was removed gently, and margins were covered with oxygen-inhibiting gel (OXYGUARD II, Kuraray).

A baseline evaluation for all IRFDPs was conducted one to three weeks after insertion, followed by recall visits after 6 and 12 months and then annually (Fig. 2). In each recall visit technical complications in terms of framework fracture, chipping of the veneering ceramic, occlusal wear, degradation of marginal adaptation and loss of retention were recorded. Biological complications in terms of secondary caries, loss of vitality, endodontic complications as well as tooth fracture were estimated. Moreover, periodontal parameters including probing depth, bleeding on probing and tooth mobility were reported at four sites of the abutment teeth and their contra laterals. Success was defined as IRFDP, which still in function without any reported complication or intervention. Survival was defined as IRFDP, which still in function, but it underwent one or more of the aforementioned technical or biological complications that needed intervention or repair. Failure was defined as IRFDP, which was removed or remade regardless of the reason.

Statistical analysis was performed using descriptive statistics and Kaplan-Meier survival nonparametric analysis. The analytical software used in the current study was Statistix 10.0 (Analytical Software,



Fig. 2. Occlusal view of the same IRFDP after 12 years with a chipping at the lingual cusps.



Fig. 1. a, b. Occlusal view of the modified preparation for the zirconia-based IRFDP (left) and the inserted IRFDP with additional short retainer-wings at the buccal and oral sides of the abutment teeth (right).

Tallahassee, Florida, USA) with confidence intervals of 95%.

3. Results

Over a mean observation period of 10.6 years (SD = 1.5) years (min 1.3, max 15.4), five patients (16.7%) were regarded as dropout because they did not complete the 10-year follow-up. Another five patients, who were relocated and could not complete the 10-year follow-up visit, were contacted via telephone and confirmed their regular visits to their dentists. Their dentists were also contacted and they reported on the current status of the involved IRFDPs.

Four IRFDs failed during the observation period (equally distributed according to gender). Two of them replaced second premolars (one upper and one lower) and two replaced first upper molars. The first IRFDP failed because of repeated debondings, resulting in partial enamel fracture of one of the abutment teeth after 4 years of observation and could not be recemented again. The second failure was due to the loss of the distal molar abutment because of general severe periodontitis. In this case the patient lost simultaneously another three molars during the periodontal therapy. The other two failures were reported after 8.7 years and 15.4 years, both owing to secondary caries and the last one showed also debonding at the mesial retainer wing. Accordingly, the cumulative 10-year survival rate of the IRFDPs using the Kaplan–Meier analysis was 89% (95% CI: 72–96.2%) (Fig. 3).

The most common reported complication was chipping of the veneering ceramic at the pontic area (Fig. 2b). This was reported in 6 IRFDPs replacing first molars. Two of them required intraoral repair with composite resin because the zirconia core material was exposed and the antagonist contact was lost (major chipping). Accordingly, the 10-year cumulative chipping rate was 19.4%. Nevertheless, the latter complications had no impact on the clinical function of the affected IRFDPs.

Secondary caries affected 5 IRFDPs at the margins of the retainers, two of which resulted in loss of the restoration, while 3 IRFDPs were treated and their integrity could be restored. Consequently, the 10-year secondary caries rate was 8.1%, as only two events were reported within the 10-year follow-up.

Furthermore, debonding was reported in 4 IRFDPs, one of which as aforementioned was a repeated one and ended with a failure of the involved IRFDP. Another IRFDP, replacing a first premolar, reported a combination of debonding and deep secondary caries on both retainer wings, and therefore, had to be replaced with a conventional FDP after 15.4 years. The third debonded IRFDP was fully debonded while the patient was chewing on licorice after 7.1 year. It could be successfully rebonded again, and it was still in function up to the last recall visit after 10.4 years without reporting any kind of complications. The fourth

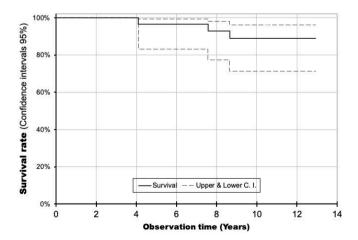


Fig. 3. Kaplan-Meier's curve demonstrating the 10-year cumulative survival rate of the IRFDPs of 89% (95% CI: 72–96.2%).

debonded IRFDP, was partially debonded at the mesial retainer after 12.4 years, hence, the involved IRFDP was separated at the middle of the pontic, and the mesial part was removed, cleaned, polished, conditioned as recommended in our study protocol, and it was rebonded again after reshaping the proximal surface with composite to achieve a proximal contact to the distal part, so that two cantilever IRFDPs had been developed. The mesial abutment premolar was cleaned carefully with CleanJet for enamel and polymer-based round bur for dentin. To check an appropriate removal of biofilm, SiroInspect (Dentsply Sirona, Sirona Dental Systems, Bensheim, Germany) was used. Accordingly, the 10-year reported cumulative debonding rate was 10.5%.

No framework fractured in this clinical investigation. Loss of vitality was not reported for any of the involved abutment teeth, and no significant changes of the periodontal parameters were stated except for one patient who suffered from general severe periodontitis. Moreover, 18 IRFDPs (60%) were free of any kind of complications, thus the 10-year cumulative success rate according to Kaplan-Meier analysis was 70.4%. The descriptive analysis of the complications that were reported for the 30 IRFDPs is shown in Table 1.

4. Discussion

The present clinical follow-up investigation was conducted to evaluate the long-term outcome of zirconia-based IRFDPs with a modified design, as little data on the long-term outcome of IRFDPs is available. The 10-year cumulative survival rate reported for IRFDPs in the current study was 89%, which fits well into the results reported for conventional FDPs as stated in a systematic review with meta-analysis (89.2%) [18], as well into the results of implant-supported single crowns according to a systematic review with meta-analysis (89.4%) [19], and much better than the results of a previous study on 101 fixed-removable metal ceramic RBFDPs with a 10-year survival rate of 62.4% [14]. However, these comparisons should be interpreted cautiously, as the design, indication, status of the abutment teeth, and many different factors are very heterogenous.

On the contrary, conventional IRFDPs made from lithium disilicate failed often clinically to withstand posterior masticatory forces, so that the Kaplan-Meier survival rate was 57% after 5 years, 38% after 8 years and only 22% after 15 years [7,20]. The failures were caused mainly by fracture, debonding or a combination of debonding and fracture at the isthmus of one of the inlay retainers. The authors related the excessive failure rate to the high stresses at the adhesive interfaces when loading the pontics throughout chewing eccentrically. Furthermore, the relatively small area bonded to enamel and the big area bonded to dentin, which is less durable [21], might be responsible for losing the retention of the retainers. Consequently, after losing retention in the proximal inlay, the stability of the inlay retainer was limited to its fracture strength in the small isthmus area of the inlay, which could not withstand the chewing forces leading finally to fracture of the restoration.

Likewise, one clinical study on conventional zirconia-based IRFDPs reported an excessive failure rate (20%) as well as a high framework fracture rate (10%) over an observation period of only 12 months [22]. The cumulative 10-year survival and success rates of the same study were 12.1% and 0%, respectively [9]. Over an observation period of 10-year, the most observed common complication was chipping of the veneering material (66.7%), debonding (53.3%), as well as framework fractures (20%). The authors concluded that due to the poor survival for fully veneered zirconia-based IRFDPs, further design improvements for this type of restoration are needed before their implementation in general dental practice.

Hence, the present encouraging survival rate could not be related only to the fracture resistant framework material used (3Y-TZP zirconia), which was the same material used in the last-mentioned study, but it can be probably linked to the modified preparation and framework design, which seems to be of high relevance [23–27]. Consequently, loss of retention of at least one retainer was reported only for 4 IRFDPs

Table 1
Descriptive analysis of the reported complications for the 30 IRFDPs with their distribution up to 15.4 years (Location of the replaced teeth according to the FDI tooth numbering system).

	Replaced teeth	n		Complication form			
			Debonding	Chipping	Caries	Periodontitis	Complication free
Maxilla	15	1	0	0	0	0	1
	25	3	1	0	1	0	2
	16	6	0	1	0	0	5
	26	7	1	3	1	1	3
Mandible	35	2	0	0	0	0	2
	45	1	0	0	1	0	0
	36	6	2	1	2	0	2
	46	4	0	1	0	0	3
Total		30	4	6	5	1	18

(10.5%). Two of them led to the failure of the involved IRFDPs, and two could be managed through rebonding. Principally, the modified design was suggested to minimize torsion forces at the inlay-retainers when the pontics are loaded eccentrically and to enlarge the bonding surface within enamel [28,29]. Moreover, a luting resin that contains a phosphate monomer was used, which plays a fundamental role to achieve a long-lasting bonding to airborne-particle abraded zirconia [30,31]. In comparison to RBFDPs, an earlier study on two-unit cantilever metal-ceramic RBFDPs to replace canines, premolars, and molars reported higher debonding rate of 17.3% after a mean observation period of 9.4 years. The superior performance of zirconia IRFDPs with the modified design could be related to the use of zirconia, which is stiffer than metal and could better prevent bending and flexing of the retainer and this would reduce the stress applied to the bonding interface.

The most common reported complication was chipping of the veneering ceramic at the pontic area (19.4%), which is a well-known problem for veneered zirconia ceramic restorations [32]. Still these results are better than those reported for conventional fully veneered zirconia-based IRFDPs after 10 years (66.7%) [9]. A reason for that could be the monolithic design of the inlay retainer wing and the veneering of the pontic only, which is in contrast to the study of Ohlmann et al., in which all parts of the restoration were fully veneered with pressed ceramic [22]. Currently, through the introduction of more translucent zirconia materials, it is possible to eliminate the chipping problem as well as to improve the esthetic outcome of IRFDPs made from monolithic polished zirconia [10].

In terms of biological complications (secondary caries), which were reported to be 8.1% after 10 years, the current results are comparable to the data reported for conventional FDPs (8.1–9.5%) [33,34]. However, a study of posterior fixed-removable metal-ceramic RBFDPs showed a lower rate of secondary caries after ten years (5%). Moreover, loss of vitality was not reported for any of the abutment teeth. This might be due to the minimal invasive defect-oriented preparations with the margins being placed always within enamel and to the adequate bonding technique being followed.

Nonetheless, this clinical study incorporates some limitations which regard to the relatively small number of participants (n=30), which was chosen for ethical reasons as a previous study on IRFDPs with a different design and material showed undesirable outcomes [20], with the aim not to put too many patients at high risk with the new design. Hence, this study aimed to firstly verify the clinical validity of the new design if IRFDPs with a limited number of patients. Furthermore, the present study did not incorporate a control group reconstructed with conventional FDPs or RBFDPs. Therefore, the clinical outcome and complication rates of the involved IRFDPs can only be compared to published data in the literature.

Currently, a systematic review reported that IRFDPs are a viable treatment option for replacing a posterior missing tooth [13]. It emphasized that proper case selection, abutment preparation design, luting procedures, as well as restorative material are crucial factors for clinical success of IRFDPs. However, it has to be considered, that the

included investigations were very heterogenous with regard to the framework material as well as the design. Only one included investigation reported on results with a zirconia ceramic framework.

A minimally invasive alternative to IRFDPs could be two-unit RBFDPs, particularly for premolar-sized spans, and when the prospective abutment tooth is sound with no existing caries or filling. So far, the evidence for this treatment option is still limited [35]. In an actual prospective clinical investigation, twenty-four abutment teeth received a minimally invasive tooth preparation, limited to enamel [36]. The tooth preparation was extended to the lingual-proximal area and an occlusal rest was prepared in areas with no antagonistic contacts. Each two-unit RBFDP replaced a premolar-sized span for missing canines and posterior teeth. After an initial mean observation period of 22.5 months, all cantilever zirconia ceramic RBFDPs survived with no reported complication. However, the pontic width of these posterior two-unit RBFDPs was limited to the width of a premolar and molars had been replaced with two separated two-unit RBFDPs [36], while in the current study most pontics were in the size of molars. Another similar retrospective study on 27 two-retainer zirconia RBFDPs showed a survival rate of 100% and a success rate of 96.3% over a mean observation time of 53 ± 39 months [4].

Nowadays the body of evidence is growing for a better clinical performance of two-unit cantilever RBFDPs comparing to fixed-fixed RBFPDs to replace single anterior missing teeth or premolar-sized spans [4,14,35,36]. However, the current study was started at 2007, and at that time posterior RBFDPs had usually a three-unit fixed-fixed or fixed-removable design [37,38]. Moreover, the majority of the involved abutment teeth 85 % were moderately restored or defected so that the chief bonding surface was mainly in dentin, and the mass of the replaced teeth (23 out of 30) were first molars of molar-span (10–12 mm). Furthermore, as a small pilot study of 30 IRFDP in 30 patients we had to keep one design in order to have an acceptable power of our results, because the main aim of the study was to evaluate the clinical outcome of the modified design of the IRFDPs.

Hence, a further limitation of the study is that in 3 cases where a second premolar had to be replaced and the first premolars were sound, a two-unit RBFDPs could be an advanced minimal invasive alternative to 3-unit fixed-fixed IRFDPs. Furthermore, in the other 4 cases where second premolar had to be replaced and the abutment teeth were both restored a two-unit IRFDPs could be a further minimal invasive alternative to 3-unit fixed-fixed IRFDPs [26,27].

5. Conclusion

The long-term clinical performance of modified IRFDPs was favorable after 10 years. Therefore, IRFDPs can be recommended as a substance-preserving treatment option to replace a missing tooth in the posterior region if the abutment teeth involve smaller restorations, particularly in cases where implant placement is not indicated.

Ethics

We confirm that any aspect of the work covered in this manuscript that has involved patients has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.

CRediT authorship contribution statement

M. Sad Chaar: Project administration, Methodology, Formal analysis, Investigation, Writing – original draft. Nicole Passia: Investigation, Validation, Resources, Investigation, Writing – review & editing. Merlind Becker: Investigation, Resources, Data curation, Writing – review & editing. Matthias Kern: Conceptualization, Methodology, Writing – review & editing, Supervision.

Declaration of Competing Interest

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

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