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CLINICAL RESEARCH

Fiber-reinforced composite fixed dental prostheses: A 4-year prospective clinical trial evaluating survival, quality, and effects on surrounding periodontal tissues

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ABSTRACT

Statement of problem. Although fiber-reinforced composite fixed dental prostheses (FRC FDPs) are a reliable treatment option for the restoration of single missing teeth, comparatively few prospective clinical trials (PCT) exist.

Purpose. The purpose of this PCT was to evaluate the survival, quality outcome, and effect of FRC FDPs on periodontal health over 4 years.

Material and methods. Twenty-six consecutive patients (16 men, 10 women) receiving FRC FDPs with preimpregnated unidirectional fiber reinforcement were included in the trial. Eighteen FRC FDPs were placed in the maxilla and 8 in the mandible. Data from baseline, 12-, 36-, and 48-months of follow-up were recorded, and the prostheses were classified as "success," "survival," or "failure." Periodontal parameters (probing depth, clinical attachment level, plaque index, and bleeding index were assessed, and the quality was rated according to modified United States Public Health Service (USPHS)/Ryge or World Dental Federation (FDI) criteria.

Results. Functional survival at 4 years was 73.5% (95% confidence interval [CI], 52.9-87.3) with 17 FRC FDPs still functioning. Twelve of these were classified as "success" and 5 as "survival." Overall survival was 53.0% (95% CI, 30.4-74.4). Six FRC FPDs failed completely. Periodontal parameters did not change over the observation period. Regression analysis showed that probing depth and clinical attachment level did not influence the survival of FRC FDPs. According to USPHS/Ryge/FDI criteria only "wear" and "surface luster" increased significantly over 4 years.

Conclusions. The survival rate of FRC FPDs confirms existing data. Negative effects on periodontal health were not seen over the period of observation. Aging effects such as wear were recorded and indicated that FRC FPDs are at risk of disintegration, as they are composed of a fiber framework and veneering composite resin. (J Prosthet Dent 2018;119:47-52)

The investigation of fiber-reinforced composites (FRC) for dental use started in the late 1980s and early 1990s.[1] After the initial reports of material development and testing,[2-8] clinical evaluations of FRC fixed dental prostheses (FRC FDPs) were also published.[9] Research and clinical evaluations started with the aim of finding alternative, metal-free, adhesively fixed, interim and definitive restorations to replace single or multiple missing teeth.

Today, after 25 years of research, FRC FDPs are recognized as a valuable treatment option[10] and are a treatment alternative to metal-ceramic or ceramic resin-bonded FDPs and conventional tooth-supported FDPs. In 2009, in their systematic review, van Heumen et al[11] reported an estimated overall survival rate for FRC FDPs of 73.4% after 4.5 years. In the same year, the group also presented 5-year data for anterior FRC FDPs, with a functional survival rate of 64% and an overall survival of 45%.[12] In 2010, they published 5-year data for FRC FDPs in the posterior area, reporting a functional survival rate of 77.5% and an overall survival rate of 71.2%.[13] These survival rates are below those

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Clinical Implications

The current perspective that FRC FDPs are a minimally invasive, easily repairable treatment option was confirmed by this clinical trial. A functional survival of approximately 74% was found over the 4-year trial, and no effects on periodontal health were observed.

reported for conventional tooth-supported FDPs, which are in the range of 86.2% (estimated 5-year survival of glass-infiltrated alumina FDPs) and 94.4% (metal-ceramic FDPs).[14]

FRC FDPs are unique in their structure, because they are composed of an individual, handmade fiber framework covered with varying amounts of veneering composite resin. Depending on the fabrication process, the FDPs are either fabricated fully or partially extraorally, or they are fabricated completely intraorally,[15,16] making them prone to fabrication errors. In addition, their clinical performance is influenced by the quality of the fiber-matrix interface. Impaired interfacial adhesion entails inefficient load transfer from the matrix to the fibers, thus promoting inhomogeneous stress distribution and endangering the sustainability of the prosthesis.[17] It can be assumed that process and fabrication quality have a high impact on clinical survival. Therefore, individually fabricated FRC FPDs could be at higher risk for clinical failure.

FRC FDPs have also been compared with metal-ceramic and ceramic-resin-bonded prostheses by Miettinen and Millar,[18] who also listed advantages and disadvantages of the different treatment alternatives. They reported that long-term clinical data are available for metal-ceramic resin-bonded prostheses with good survival yet poor esthetics. They concluded that fiber-reinforced and ceramic resin-bonded FDPs have an uncertain long-term prognosis but superior esthetics. According to those authors, fiber-reinforced restorations additionally offer repair capability to prolong functional survival, and ceramic restorations provide superior biocompatibility with reduced plaque accumulation. Their meta-analysis yielded favorable estimated 3-year survival rates ranging up to 82.8% for metal-ceramic, 88.5% for fiber-reinforced, and 72.5% for ceramic-resin-bonded prostheses.[18] Other investigators reported acceptable survival rates[19] and higher patient satisfaction with resin-bonded prostheses for single tooth replacement than conventional FPDs[20] and reported that resin-bonded prostheses had lower costs.[21]

The disadvantages of FRC FDPs include the surface characteristics of the composite resin which are inferior compared with those of metal or ceramic, with resultant increased plaque accumulation,[22] which could lead to periodontal disease and loss of attachment. Therefore, the purpose of the present clinical study was to evaluate the survival, quality parameters, and periodontal status of FRC FDPs in a cohort of nonselected but consecutive (representative) patients over a period of 4 years in a prospective design under clinical conditions. It was hypothesized that an FRC FDP after extended service might affect periodontal health.

MATERIAL AND METHODS

The local ethics committee approved the study (S-011/2009). The inclusion criteria were as follows: participants were willing to receive an FRC FDP to replace a single missing tooth, in good general health, were not a member of the dental staff or a dental student, were physically able to practice oral hygiene, between 18 and 85 years of age, not pregnant or nursing, had not taken antibiotics during the previous 30 days, and did not require antibiotic prophylaxis before dental treatment. Participants with bruxism were not excluded from the study. All participants who met the inclusion criteria gave written informed consent.

Twenty-six consecutive patients receiving an FRC FDP in the Department of Conservative Dentistry, University of Heidelberg, between January 2009 and May 2011 were scheduled for inclusion in the prospective clinical trial. Baseline and annual follow-up examinations were performed according to published protocols.[15,16]

Dentists specializing in restorative dentistry carried out the treatment according to in-house fabrication protocols. The FRC FDPs were either surface-retained or embedded in minimal preparations on abutment teeth. They replaced 1 missing tooth in the anterior or posterior area. Retention on abutment teeth had either a fixed-fixed design (3-unit FRC FDP) or a cantilever design (2-unit FRC FDP). The fabrication and insertion processes were standardized following direct or semidirect protocols.[15,16]

Following the manufacturer's instructions, single-tooth pontics were reinforced by 1 unidirectional fiber bundle. The semidirect technique required the chairside fabrication of the pontic, using a silicone model (KwikkModel nature-Systempackung; R-dental Dentalerzeugnisse GmbH). Subsequently, pontics were inserted adhesively (Optibond FL; Kerr Corp, Tetric Evo Ceram and Tetric Evo Ceram Flow; Ivoclar Vivadent AG), using FRC material (everStick C&B; GC Europe). The direct technique required complete fabrication of the pontic intraorally using the same materials.

Annual clinical examinations followed a standardized protocol.[15,16] The protocol included anamnesis, oral examination, standardized intraoral photographs, recording of probing depth (PD), clinical attachment level (CAL),

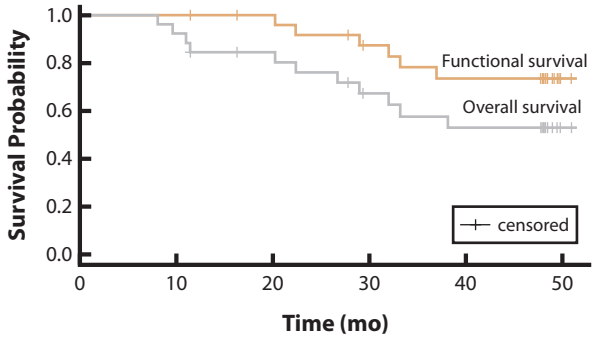

Figure 1. Kaplan-Meier analysis of overall and functional survival of FRC FDPs (n=26). Overall survival rate for FRC FDPs after 48 months was 53.0% (95% confidence interval [CI]: 30.3-74.4). Functional survival rate for FRC FDPs after 48 months was 73.5% (95% CI: 52.9-87.3). FRC FDP, fiber-reinforced composite fixed dental prostheses.

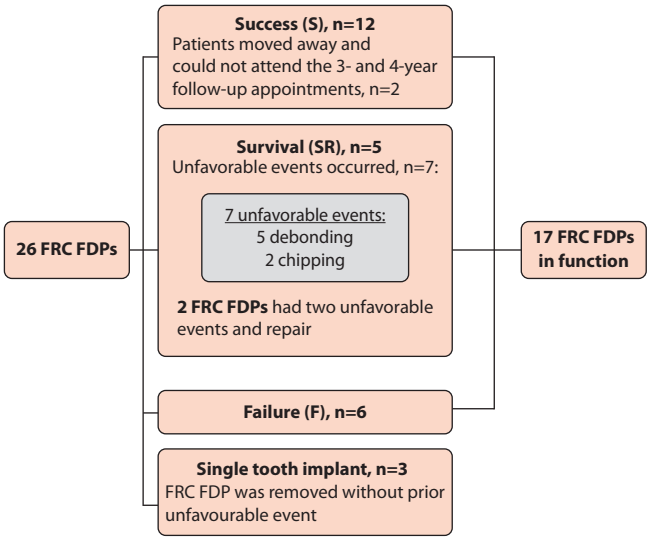

Figure 2. Life cycle and failure analysis of FRC FDPs (n=26). FRC FDP, fiber-reinforced composite fixed dental prosthesis.

gingival bleeding index (BI),[23] and Turesky plaque index (PI)[24] on 6 sites per tooth. Clinical quality rating was done according to the modified United States Public Health Service (USPHS)/Ryge or World Dental Federation (FDI) clinical criteria.[25,26] The study incentive was a professional tooth cleaning and oral hygiene instruction at the end of each follow-up appointment. Two examiners (C.F., T.W.) obtained the data. Examiners were calibrated in a clinical setting according to the standardized protocol. Ambiguous intraoral findings were observed by both the examiners and were discussed to find consistent ratings. They used diagnostic optical light (Sirolux F; Dentsply Sirona), diagnostic probes, and binocular loupes (magnification ×2.5). The examiners also calibrated themselves by performing modules on the Website www.e-calib.info.[25,26]

When an FRC FDP was completely lost, making repair impossible, it was registered as a "failure." When less severe unfavorable events occurred such as unilateral or bilateral debonding, chipping fractures, or delamination, the restorations were repaired at a subsequent recall appointment, and unfavorable events were documented. These situations were defined as "survival." Restorations with no failure or unfavorable events were classified as "success." If participants elected to receive an implant-supported restoration and the FRC FDP was still intact when it was removed, it was classified as neither a failure nor an unfavorable event but was censored at the end of the individual observation period.

Exploratory statistical analyses were conducted (α=.05 for all tests). Respective *P* values and 95% confidence intervals (CI) are of a descriptive nature. Categorical data were described by absolute and relative frequencies. Continuous data were described by the arithmetic mean ±SD. Because of the nature of the data, nonparametric statistical methods were applied for group comparisons. The Kruskal-Wallis test was used to evaluate significant differences in continuous variables between groups, whereas the Friedman test was used to compare more than 2 dependent samples for continuous outcomes. Analysis of survival rates of the prostheses was carried out using the Kaplan-Meier method.[27] Asymptotic pointwise 95% CIs were given for the observation period of 48 months. Two survival times were defined: functional survival, the time from treatment to complete failure (clinical events that could be repaired were not regarded as a failure in this analysis); and overall survival, the time from treatment to any failure (complete failure or clinical event with repair [defined as survival], whichever came first). Observations with no events in the respective analyses were censored at the end of the individual observation period. Cox regression analysis was performed to evaluate the influence of periodontal parameters PD and CAL on overall and functional survival. Statistical analysis was done using statistical software (R v3.2.0; www.r-project.org).

RESULTS

The group of 26 participants consisted of 16 men and 10 women (mean 36 ±15 years of age). Each participant had 1 FRC FDP. Eighteen FRC FDPs were located in the maxilla and 8 in the mandible. The prostheses were made of preimpregnated, unidirectional, FRC (everStick; GC Europe), using the direct (n=9) or semidirect (n=17) technique. Retention on the abutment teeth was either surface retention (n=11) or minimally invasive cavity preparation (n=15). Sixteen FDPs had a fixed-fixed design (3-unit FRC FDP), with extension wings on both adjacent teeth. In 10 prostheses, the cantilever design (2-unit FRC FDP) was used. All FRC FDPs were inserted adhesively with the same bonding system (Opti bond FL; Kerr Corp). Two participants were unable to attend their

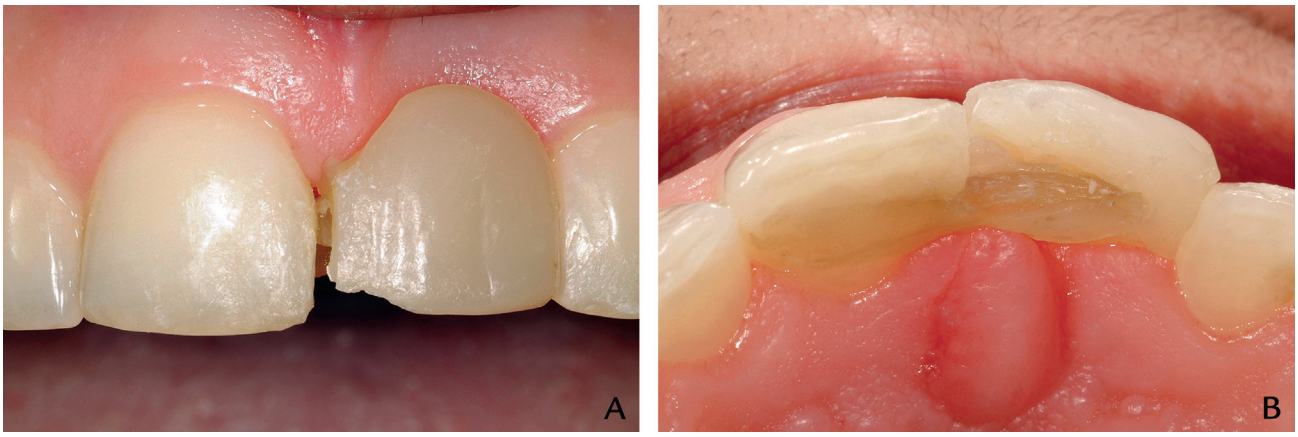

Figure 3. Clinical example of unfavorable event (partial debonding of pontic from fiber-reinforced composite). A, Facial view. B, Occlusal view.

Table 1. Mean ±SD values of oral hygiene parameters

	Mesiobuccal		Central Buccal		Distobuccal		Mesiolingual		Central Lingual		Distolingual		
Parameter	**T0**	**T4**	**T0**	**T4**	**T0**	**T4**	**T0**	**T4**	**T0**	**T4**	**T0**	**T4**	***P***
Probing depth (mm)	2.00 (0.22)	1.96 (0.77)	1.92 (0.41)	1.58 (0.59)	2.10 (0.48)	2.35 (1.37)	2.19 (0.89)	2.13 (0.69)	2.07 (0.64)	1.91 (0.73)	2.10 (0.43)	2.52 (1.27)	.172
Clinical attachment level (mm)	2.29 (1.82)	2.65 (2.14)	2.07 (2.06)	2.65 (2.40)	1.83 (1.54)	2.87 (2.00)	2.19 (1.89)	2.91 (1.95)	2.00 (1.77)	3.17 (2.35)	1.95 (1.40)	3.30 (2.00)	.295
Bleeding index (Mühlemann and Son)	0.10 (0.30)	0.19 (0.50)	0.10 (0.30)	0.27 (0.55)	0.15 (0.42)	0.14 (0.35)	0.20 (0.40)	0.18 (0.50)	0.07 (0.26)	0.18 (0.50)	0.12 (0.33)	0.22 (0.53)	.084
Turesky plaque index	1.00 (1.02)	1.95 (1.40)	0.78 (0.88)	1.41 (1.68)	1.12 (1.05)	1.81 (1.53)	0.83 (0.97)	1.45 (1.26)	0.71 (0.78)	1.32 (1.04)	0.90 (0.86)	1.64 (1.22)	.973

Probing depth, clinical attachment level, bleeding index, and plaque index from baseline (T0) and 48-month recall (T4). *P* values for statistical comparison (Kruskal-Wallis test) between locations with regard to differences between baseline (T0) and 48 months (T4).

3- and 4-year follow-up appointments because they had relocated.

Survival data are shown in Figures 1 and 2. The overall survival rate for the FRC FDPs after 48 months was 53.0% (95% CI, 30.4-74.4), and the corresponding functional survival was 73.5% (95% CI, 52.9-87.3) (Fig. 1). During the follow-up period, 6 FRC FDPs were damaged severely and were lost ("failure"). A total of 12 FRC FPDs were classified as "success." Five FRC FPDs had unfavorable events (n=7) and were classified as "survival." Two "survival" FRC FPDs had 2 unfavorable events. For each of them, a successful repair could be carried out. Details of FRC FDP performance can be found in an explicit lifecycle diagram according to van Heumen et al[12,13] (Fig. 2). The failure types of FRC FDPs were chipping and debonding (Fig. 3).

Periodontal parameters are shown in Tables 1 and 2. At baseline, the PDs ranged from 1.92 to 2.19 mm and showed no statistically significant differences for the 6 measuring points with respect to the differences between baseline and 4-year follow-up (range, 1.58-2.52 mm). Baseline values of the CALs ranged from 1.83 to 2.29 mm and showed no statistically significant differences for the 6 measuring points with respect to the differences between baseline and 4-year follow-up (range, 2.65-3.30 mm). Generally, the BI was low at baseline, with values between 0.07 and 0.20. The PI was also low at baseline, with values between 0.71 and 1.95. Both the BI and PI showed no statistically significant differences for the 6 measuring points with respect to differences between baseline and 4-year follow-up (range BI, 0.14-0.27; range PI, 1.32-1.95). Cox regression analysis showed that changes in PD and CAL did not influence overall and functional survival rates (Table 2).

Clinical evaluation data are shown in Table 3. A standard protocol for the clinical testing of restorative materials and procedures according to the modified

Table 2. Cox regression analysis of influence of PD, CAL, BI, and PI on overall and functional survival of FRC FDPs

Parameter	Coefficient	Hazard Ratio	*P*
Overall survival			
PD	0.2022	1.2241	.852
CAL	-0.6207	0.5376	.099
BI	1.2737	3.5740	.376
PI	-0.4074	0.6654	.690
Functional survival			
PD	1.4192	4.1340	.250
CAL	-0.4308	0.6500	.435
BI	3.0220	20.5321	.243
PI	-3.0169	0.0490	.055

BI, bleeding index; CAL, clinical attachment level; FRC FDP, fiber-reinforced composite fixed dental prostheses; PD, probing depth; PI, plaque index.

Table 3. Modified USPHS/Ryge criteria for evaluated FRC FDPs from baseline (T0) to 48-month recall (T4) in relative frequencies (%)

		Clinically Excellent					Clinically Good					Clinically Sufficient					Clinically Unsatisfactory					Clinically Poor	
Criteria		**T0**	**T1**	**T2**	**T3**	**T4**	**T0**	**T1**	**T2**	**T3**	**T4**	**T0**	**T1**	**T2**	**T3**	**T4**	**T0**	**T1**	**T2**	**T3**	**T4**	**T0–T4**	***P***
Esthetic parameters	Surface luster*	100	73	70	70	65	0	27	30	30	35	0	0	0	0	0	0	0	0	0	0	0	.012*
	Surface staining	85	65	52	50	40	15	27	38	44	60	0	8	10	6	0	0	0	0	0	0	0	.075
	Color stability, translucency	96	89	76	75	73	4	24	11	25	27	0	0	0	0	0	0	0	0	0	0	0	.406
	Anatomic form	92	77	81	87	73	8	23	19	6	20	0	0	0	6	7	0	0	0	0	0	0	.406
Functional parameters	Fracture and retention	100	69	90	75	80	0	19	10	19	13	0	4	0	0	0	0	0	0	0	0	0	.238
	Marginal adaptation (at abutment teeth)	92	77	81	81	73	8	23	19	19	27	0	0	0	0	0	0	0	0	0	0	0	.517
	Wear	100	77	76	81	93	0	23	24	6	0	0	0	0	13	7	0	0	0	0	0	0	.032*
	Patient's view	81	73	86	75	73	19	23	14	25	27	0	4	0	0	0	0	0	0	0	0	0	.406
Biological parameters	Postoperative hypersensitivity (abutment teeth)	100	92	100	100	93	0	8	0	0	7	0	0	0	0	0	0	0	0	0	0	0	1.00
	Recurrence of caries, erosion, abfraction	92	77	95	88	87	8	3	0	12	13	0	0	5	0	0	0	0	0	0	0	0	.248
	Tooth integrity (abutment teeth)	100	92	95	100	80	0	8	5	0	20	0	0	0	0	0	0	0	0	0	0	0	.406
	Periodontal response (abutment teeth)	81	50	48	69	67	19	46	47	19	27	0	4	5	12	7	0	0	0	0	0	0	.376
	Adjacent mucosa (pontic)	77	46	43	75	73	23	50	57	25	20	0	4	0	0	7	0	0	0	0	0	0	.166
	Oral and general health	92	77	86	75	80	8	23	14	19	20	0	0	0	6	0	0	0	0	0	0	0	.446

FRC FDP, fiber-reinforced composite fixed dental prosthesis; USPHS, United States Public Health Service. *Statistically significant ($P<.05$)

USPHS/Ryge or FDI clinical criteria was used.[23] The clinical quality rating (modified USPHS/Ryge or FDI clinical criteria) over 48 months showed that most of the restorations displayed excellent or good quality. Only a minority of FRC FDPs was rated "clinically sufficient," mainly in the categories "anatomic form," "wear," "recurrence of caries, erosion, abfraction," "periodontal response," "adjacent mucosa" and "oral and general health." None of the FRC FDPs was rated "clinically unsatisfactory" or "clinically poor." A statistically significant increase was seen over the observation period only for the criteria "wear" (P=032) and "surface luster" (P=.012).

DISCUSSION

This prospective clinical trial reports a moderate overall survival of 53.0% and a functional survival of 73.5% of FRC FDPs over the 48-month observation period (Fig. 1). These data are consistent with survival data for FRC FDPs.[11-13,15,16]

Most FDPs displayed excellent or good quality at follow-up (Table 3). Only a minority of FRC FDPs was rated "clinically sufficient," but the parameters "wear" and "surface luster" significantly deteriorated over the observation period (Table 3). Over longer periods, composite resin materials showed signs of abrasion and wear, although this was not recorded as an unfavorable event. The approach of van Heumen et al[12] was adopted. They also observed the wear of composite resin in several participants without recording it as an unfavorable event. Wear might be the first sign of volume loss and weakening of the FRC FDPs, which could result in subsequent failure, including chipping or delamination. The composite resin layer covering the fiber framework can be thin on surface-retained areas so that wear may expose fibers. Thus, the risk of unfavorable events (chipping, debonding) or complete failures of the FRC FDPs, as found in this study (Figs. 2, 3), could also increase.[12]

Other reasons for the described unfavorable events or failures could be the lack of support of the fiber framework within the pontic,[5] poor pontic design,[6] or the design of the prosthesis (3-unit versus 2-unit) and connector areas.[7,8] The aim in pontic design should be to fabricate the FRC FDP with as much strength as possible to endure the anticipated stresses in the oral environment but also to be able to repair it at any time during its service. The framework or pontic can be modified to increase the volume of composite resin and to increase fracture strength.[12]

Although treatment alternatives to FRC FDPs for single-tooth replacement such as cast metal FDPs, ceramic FDPs, or implant-supported crowns have better survival,[28,29] and although studies have shown that patients are willing to pay high fees (from USD$1600 to $2700) for indirect restorative or implant-based replacements of missing teeth in the posterior region,[30] there is a demand for cost-effective and minimally invasive treatment options for single-tooth replacement. FRC FDPs can provide such a solution and can be fabricated directly or semidirectly without laboratory costs. They are also suitable for children, adolescents, and patients with generalized systemic diseases or severe periodontal diseases.[31] For these patients, an appropriate and reasonable treatment solution must be supplied, for instance, in the form of an FRC FDP.

In the rehabilitation of periodontally compromised teeth, evidence shows that FRC FDPs provide excellent

functional and esthetic results without detrimental effects on abutment teeth.[32,33] This evidence is supported further by our data, as PD and CAL did not change significantly over the observation period (Table 1) and the regression analysis showed that changes in PD and CAL did not influence the overall and functional survival of FRC FDPs (Table 2). Additionally, BI and PI over the 48-month observation time demonstrated that the FRC FDPs could be easily cleaned.

As this was a limited single-center study, the different kinds of FRC FDPs were not homogenously distributed, and comparisons between anterior and posterior, inlay- and surface-retained, or 2-unit and 3-unit FRC FDPs could not be made because of the different group sizes. In addition, neither external nor internal controls could be used because of the limited availability of participants. However, the prospective design with 12-month follow-up intervals over 4 years is a strength of this investigation.

CONCLUSIONS

Based on the finding of this prospective clinical trial on the performance of FRC FDPs, the following conclusions were drawn:

1. Survival data showed a functional survival of 73.5% and an overall survival of 53.0%.
2. The most prevalent unfavorable events were debonding and chipping.
3. The periodontal parameters PD and CAL were unaltered over the follow-up period.
4. The composite resin material altered over the observation period as wear of FRC FDPs increased significantly.

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