Journal of Dentistry xxx (xxxx) xxx–xxx

Contents lists available at ScienceDirect

Journal of Dentistry

journal homepage: www.elsevier.com/locate/jdent

10-year randomized trial (RCT) of zirconia-ceramic and metal-ceramic fixed dental prostheses

Irena Sailer[a,*], Marc Balmer[b], Jürg Hüsler[b], Christoph Hans Franz Hämmerle[b], Sarah Känel[b], Daniel Stefan Thoma[b]

[a] Division for Fixed Prosthodontics and Biomaterials, University Clinics for Dental Medicine, University of Geneva, Switzerland
[b] Clinic of Fixed and Removable Prosthodontics and Dental Material Science, Center for Dental Medicine, University of Zurich, Switzerland

ARTICLE INFO

Keywords:
Zirconia
All-ceramics
Metal-ceramic
FDP
Long-term
Technical
Biologic

ABSTRACT

Objectives: To monitor zirconia-ceramic and metal-ceramic posterior FDPs with respect to survival and technical/biological complication rates.

Materials and methods: Fifty-eight patients received 76 3- to 5-unit posterior FDPs. The sites were randomly assigned to 40 zirconia-based (ZC) and 36 metal-based (MC) FDPs. FDPs were examined at baseline (cementation), at 6 months, at 1 year and then yearly up to 10 years. Technical outcomes were assessed using modified United States Public Health Service (USPHS) criteria. Biologic outcomes included probing depth, plaque, bleeding on probing and tooth vitality. Statistical analysis was performed applying Kaplan-Meier (KM) estimation, log-rank, Mann-Whitney and Fisher exact test.

Results: During the 10-year follow-up thirteen patients (17 FDPs) dropped out and 6 FDPs in 6 patients (5 ZC,1 MC) were considered catastrophic failures for technical and/or biological reasons. Forty-four patients with 53 FDPs (29 ZC, 24 MC) were available for examination. The median observation period was 10.3 years (ZC) and 10.0 years (MC). The 10-year KM survival estimate of ZC FDPs was 91.3% (95%CI:69.5;97.8) and 100% of MC FDPs. Minor chipping of the veneering ceramic and occlusal wear were found to a similar extent at ZC and MC FDPs. ZC FDPs demonstrated a significantly higher rate of framework fracture, de-bonding, major fractures of the veneering ceramic and poor marginal adaption. Biological outcomes were similar in both groups and between abutment and control teeth.

Conclusion: At 10 years, ZC and MC posterior FDPs resulted in similar outcomes for the majority of the outcome measures ($p > 0.05$).

1. Introduction

Socio-economic changes, improvements in oral prophylaxis and individually designed oral hygiene regimens followed by a regular maintenance led to a decrease in loss of teeth and a shift to more partially edentulous rather than edentulous patients [1,2]. In these patients there is a need for fixed dental prostheses (FDPs) replacing single or multiple missing teeth. Traditionally, metal-ceramic (MC) FDPs veneered with feldspathic ceramic were considered to be the gold standard [3,4]. Following the demands of clinicians and patients for metal-free reconstructions more recent developments focused on ceramics as framework material. Thereby, the high-strength ceramic zirconia was most promising due to its high flexural strength and fracture toughness [5,6]. The fracture rates of zirconia-based FDPs were low and to occurred at a similar rate as metal-based FDPs [7–11]. Reported shortcomings of zirconia-based FDPs, however, include an increased rate of veneering ceramic fractures and de-bonding of the reconstructions [7,8]. These shortcomings were in part attributed to a lack of precision when using early technologies of CAD/CAM techniques and a lack of anatomical support of the zirconia veneering ceramic. Moreover, the adhesion between zirconia frameworks and the respective veneering ceramics was questioned [12].

Clinical long-term data and randomized controlled studies (RCT) comparing zirconia-based and metal-based FDPs are still scarce. At the present, only a very limited number of non-randomized studies reporting 10-year outcomes of zirconia-ceramic FDPs or of alternative all-ceramic material such as lithium-disilicate and zirconia-reinforced alumina ceramics are available [13–15].

* Corresponding author at: Division for Fixed Prosthodontics and Biomaterials, University Clinics for Dental Medicine, University of Geneva, 1 rue Michel Servet, 1211, Geneva, Switzerland.
E-mail address: irena.sailer@unige.ch (I. Sailer).

https://doi.org/10.1016/j.jdent.2018.05.015
Received 23 January 2018; Received in revised form 22 May 2018; Accepted 25 May 2018

The aim of the present RCT was, therefore, to monitor whether or not the use of posterior FDPs with zirconia frameworks and metal frameworks resulted in similar outcomes with respect to survival and technical/biological complication rates. The null-hypothesis was that no differences would be found between the two types of FDPs.

2. Material and methods

2.1. Study design

The present study was designed as a randomized controlled clinical trial and performed according to the requirements of the Declaration of Helsinki. The study is registered in the German Clinical Trials Register (DRKS00006276). Although the study was designed before the introduction of the STROBE guidelines, the demands generally are fulfilled. Prior to the start of the trial, ethical approval was obtained from the local ethical committee and all patients signed an informed consent. The detailed study protocol was described in a previous publication [16].

2.2. Patients and reconstructions

Fifty-eight patients (27 female, 31 male) patients in need of at least one FDP in the posterior region of the maxilla or mandible were consecutively recruited and entered the clinical investigation. Patients were only included in the clinical trial if they were in good general health conditions, free from periodontal diseases and had no obvious signs of bruxism. The abutment teeth had to ensure sufficient tooth substance for a proper retention of the FDPs, to be vital or successfully endodontically treated. Seventy-six 3- to 5-unit posterior FDP sites were randomly assigned to FDPs either with zirconia frameworks (zirconia-ceramic FDPs;ZC) or metal frameworks (metal-ceramic FDPs;MC) by means of a computer-generated randomization list and using sealed envelopes. Forty ZC and 36 MC FDPs replacing premolars and molars were inserted (Table 1).

2.3. Prosthodontic procedures

For both types of FDPs the same treatment procedures were performed according to clinical procedures for metal-ceramic reconstructions. The preparation design of the abutment teeth followed the requirements for computer-aided manufacturing (CAM) [17]. In brief, teeth were prepared with a 1 mm circumferential shoulder, a 1.5 mm axial and 1.5–2 mm occlusal reduction, and a tapering angle between 6° and 10°. All frameworks were manually made out of modeling wax (ZTM Thiel, Erkodent, Pfalzgrafenweiler, Germany) and designed according to the manufacturer's recommendations. Specific care was taken to provide sufficient support for the veneering material. Prior to milling, the design of the ZC frameworks was optically scanned, digitized and enlarged to compensate the estimated sintering shrinkage of about 28% (Cercon brain, DeguDent, Hanau, Germany). The ZC frameworks were fabricated out of white-stage zirconia blanks by means of a CAM-system (Cercon, Degudent, Hanau, Germany) [18]. The MC frameworks were fabricated by means of the lost-wax technique [19].

Table 1
Overview of the examined FDPs including the number of FDP units per group in the full data set and in the reduced data set.

	3 units	4 units	5 units	
ZC FDPs	33	6	1	40
reduced	20	6	1	27
MC FDPs	34	1	1	36
reduced	29	1	1	31
Total	67	7	2	76
reduced	49	7	2	58

The wax models were cast out of a gold-alloy (Degudent U, Degudent, Hanau, Germany). The frameworks were veneered with the corresponding veneering ceramics (ZC:Cercon-Ceram-S; MC:Duceram-Plus, Degudent, Hanau, Germany). The interior surface of all FDPs was gently grit-blasted (granule-size 110 µm, pressure 2 bar for 10 s) and cleaned with alcohol. Prior to cementation of the FDPs the abutment teeth were pre-treated with a dentin primer (ED Primer, Kuraray). An alloy primer (Alloy Primer, Kuraray, Japan) compatible to the resin cement was used for the pre-treatment interior surfaces of the metal-based FDPs. All FDPs were adhesively cemented using the same resin cement (Panavia 21 TC, Kuraray, Osaka, Japan). If occlusal adjustments were performed after the insertion, the prostheses were thoroughly polished with ceramic polishers (Komet nos. 9425, 9426 and 9457 Brasseler, Savannah, USA).

2.4. Baseline and follow-up examinations

Immediately following cementation of the reconstructions, a baseline examination was performed. Patients were recalled at 6 months, at one year and then yearly up to 10 years of follow-up. All clinical examinations (data collection) were performed by the same clinical investigator (IS). At all time-points, the reconstructions were evaluated for survival, and for technical and biological outcomes.

Technical aspects were evaluated using modified USPHS (United States Public Health Service) criteria [20,21] (Table 2). In brief, the reconstructions were examined for framework fracture, chipping or fracture of the veneering ceramic, occlusal wear of the veneering ceramic, marginal adaptation and general anatomical shape of the FDPs.

All parameters were rated Alfa in case of no problems, Bravo in case of minor complication, Charlie if the complications were major and Delta if the reconstruction had to be removed due to the complication. Moreover, the rate of de-bonding was assessed.

In the event of complications, patients were informed and attempts were made to preserve the reconstructions. Biological outcome measures at abutment teeth and the respective contra-lateral teeth included: probing depth (PD), probing attachment level (PAL), absence or presence of plaque (plaque control record; PCR), bleeding on probing (BOP) and abutment tooth vitality. Tooth vitality was tested both at abutment and contra-lateral control teeth with CO_2. Occlusal and functional relationships between FDPs and opposing jaws were recorded. Finally, peri-apical x-rays of the abutment teeth and clinical photographs of the reconstructions were taken.

2.5. Statistical analysis

Descriptive statistics are based on all data, whereas for the statistical test only one FDP per patient was used, which was selected at random in case more than one FDP were available in a patient. This formed the reduced data set for statistical tests. The random selection was performed by the statistician before analyzing the data somehow.

The reconstructions were rated as *survived* if they were present (with/without complications) at time of follow-up, and as *success* if they were free from any technical (rated Alfa) or biological incidents over the whole observation period in all evaluated parameters.

The analysis of the 10-year survival rate of zirconia-based and metal-based FDPs was performed by use of Kaplan-Meier survival statistical method. The 95% confidence intervals (CI) were added for the discussion of the relevance of the findings.

Patients lost to follow-up were censored. The statistical comparisons on the two survival curves of the FDP groups are using the log-rank test based on the reduced data set.

For the comparisons of PD, PAL, PCR and BOP between test and contralateral control teeth, we calculated the differences of the paired data and applied the Wilcoxon signed rank test for the analyses within a group and the Mann-Whitney test for the analyses between the two