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All-ceramic, bi-layered crowns supported by zirconia implants: Three-year results of a prospective multicenter study

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ABSTRACT

Objectives: To determine the clinical and patient-reported outcomes of bi-layered, all-ceramic posterior single crowns (SCs) supported by zirconia implants in an uncontrolled, prospective, multicenter study.
Methods: In two centers, 60 patients received 71 one-piece zirconia oral implants to be restored with either SCs (n = 49) or three-unit fixed dental prostheses (n = 11). Of these patients, 45 implants were restored with all-ceramic, zirconia-based posterior SCs (one per patient). Survival rates of implants and reconstructions were assessed, and technical success was evaluated according to modified U.S. Public Health Service (USPHS) criteria. Furthermore, patient-reported outcome measures (PROMs) were assessed by applying visual analog scales (VAS). Kaplan-Meier (KM) plots and log-rank tests were used for success/survival analyses. The Wilcoxon matched-pairs signed-rank test was used to evaluate time effects on response variables (PROMs, USPHS criteria).
Results: Forty patients with 40 SCs could be evaluated after 36.7 ± 1.2 months. No SC was replaced, resulting in 100% survival. The KM success estimate was 87.5% (two chippings, one restoration margin, and one contour were rated Charlie). In general, the incidence of chipping ($p = .0005$) and occlusal roughness ($p = .0003$) was frequent. Compared with the pre-treatment patient surveys (67–93%), all surveys at prosthetic delivery except for speech ($p = .139$) showed significantly improved VAS scores (81–94%; $p < .0001$). Thereafter, no decrease in satisfaction could be observed over time until the 3-year follow-up (86–93%; $p \geq .390$).
Conclusion: Veneered, zirconia-based SCs supported by zirconia implants satisfied patients' needs highly. However, significant incidence of chipping and roughness of the veneering ceramic may compromise the clinical long-term outcome for this indication.
Clinical significance: Posterior, zirconia-based SCs supported by zirconia oral implants entirely survived the follow-up period of 3 years, but two major chippings, one a significant marginal opening and one pronounced over-contouring, resulted in a reduced KM success estimate of 87.5% after 36 months of observation.

1. Introduction

The German Oral Health Study (DMS) periodically collects key oral health and dental care indicators (e.g., mucosal abnormalities, caries, periodontitis, and tooth loss) across four age cohorts in a cross-sectional, socio-epidemiological design [1]. The fifth edition (DMS V), published in 2016, showed a prevalence of 2.1 and 11.1 missing teeth in younger adults (aged 35 to 44 years) and younger elderly (aged 65 to 74 years), respectively [2,3]. In both groups, tooth loss was mostly located in the area of premolars and molars. When it is time to replace these teeth located in load-bearing areas, several treatment options, ranging from fixed to removable prostheses, are available.

In the case of single tooth gaps with neighboring teeth worth preserving, a fixed dental prosthesis (FDP) is one of the most chosen treatment options. This type of restoration represents a cost- and time-effective treatment with a favorable outcome. Comparing a recent review of the literature analyzing the clinical outcome of tooth-supported FDPs [4] with another one published 13 years ago [5], an obvious trend

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toward all-ceramic restorations can be observed. Besides technical complications observed in zirconia-based FDPs (high incidence of veneer chippings), supporting teeth are at risk of biological complications such as secondary caries or loss of vitality and subjected to an extensive removal of tooth structure [6]. Therefore, an implant-supported single crown (SC) might be a less invasive treatment option to prevent adjacent teeth from biological complications.

Single implant treatment can be considered a predictable treatment with high survival rates in the long term [7]. To date, not only the restoration but also the implant can be fabricated out of a ceramic material, allowing for a completely metal-free approach. Oral implants made from yttria-stabilized tetragonal zirconia polycrystals (Y-TZP) proved to be reliable in prospective clinical evaluations with an outcome comparable to titanium implants [8]. Regrettably, data on the restoration of these implants are scarce. Because market-available zirconia implants are mostly designed as one-piece implants comprising an endosseous, transmucosal, and intraoral part in a single piece, the restoration has to be cemented to the implant abutment comparable to tooth-supported reconstructions. Especially in posterior regions, the same polycrystalline ceramic material (Y-TZP) as used for ceramic implant production proved to be a reliable substructure for the fabrication of highly esthetic, implant-supported, bi-layer crowns [9]. For both tooth- and implant-supported, zirconia-based SCs, survival rates seem to be comparable to those of conventional porcelain-fused-to-metal (PFM) crowns [10]. However, for posterior zirconia-based bilayer restorations in particular, and for implant-supported restorations in general, the most common technical reason for failure is fracture of the veneering material [10,11]. The lack of a periodontal ligament, the rigidity of implants, and impaired proprioception might be responsible for higher chipping ratios in implant-supported restorations [12].

Several suggestions were made for improving the chipping resistance of zirconia-based restorations [13], among others addressing the phase composition of the veneering ceramic. In a recent clinical trial evaluating the restoration of zirconia oral implants with zirconia-based SCs and FDPs, a lacking crystalline phase of the veneering ceramic resulting in reduced flexural strength was considered one of the major factors contributing to an unacceptable occurrence of severe veneer fractures resulting in a high failure rate of 23.4% after 5 years of observation [14]. Therefore, the aim of this study was to determine the clinical and patient-reported outcomes of bi-layered, all-ceramic, posterior single crowns (SCs) comprising CAD/CAM-fabricated zirconia frameworks hand-layered with a leucite-reinforced feldspathic ceramic of increased flexural strength and a slightly higher mismatch of the coefficient of thermal expansion (framework > veneer, resulting in a more pronounced compression stress in the veneering ceramic) supported by zirconia implants.

2. Materials and methods

2.1. Study design

This multicenter study represents a prospective cohort investigation. The included centers were (1) Medical Center, University of Freiburg (Germany), Department of Prosthetic Dentistry, and (2) Center of Dental Medicine, University of Zürich (Switzerland), Clinic for Fixed and Removable Prosthodontics and Dental Material Science. The study protocol was approved by the ethics committee of the Canton of Zürich (StV 08/10) and by the ethics commission of the Medical Center Freiburg (241/08). The study was registered in the German Clinical Trials Register (ID: DRKS00000226) and is, therefore, available in the World Health Organization (WHO) International Clinical Trials Registry Platform. Informed consent was obtained from all patients prior to their inclusion. Recruitment was done between April 2010 and July 2012. This multicenter study was designed and performed considering the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement for cohort studies (http://www.strobe-statement.org).

2.2. Participants

Sixty partially edentulous patients asking for an implant-supported, single-tooth restoration or a three-unit fixed dental prosthesis (FDP), irrespective of the jaw, were recruited, provided they were 20–70 years old, showed a good health status, were compliant, were in need of an implant-supported restoration, had sufficient bone volume in the area of interest, showed a stable occlusal relationship, and no signs of pronounced bruxism (such as attritions and fractures on the natural teeth or reconstructions, no pain on muscular palpation, no pain-causing joint sound, and no self-reported clenching habits). Reasons for exclusion were alcohol or drug abuse, smoking of more than 10 cigarettes per day, severe bruxism or other destructive habits, and health conditions not permitting the surgical procedure.

The supporting cylindroconical and screw-type, one-piece zirconia implants (ceramic.implant prototype; vitaclinical, VITA Zahnfabrik; Bad Säckingen, Germany) comprised platforms of 4.0, 4.5, and 5.5 mm. The surgical procedures and the methodology for measuring the tissue response have been described earlier [15]. In total, 60 patients were recruited to receive 11 FDPs and 49 SCs. To obtain a clear indication for the present evaluation of posterior single crowns, three patients with three anterior crowns were excluded from the analysis. Eleven FDPs in 11 patients were not evaluated, because feldspathic veneered FDPs on zirconia implants do not conform to the manufacturer's recommendation.

2.3. Clinical and laboratory procedures

Information on the clinical and laboratory procedures was provided in detail in precedent publications reporting preliminary results after 12 months of observation [15,16]. Key points were as follows. The implants were immediately temporized with prefabricated provisional reconstructions comprising slight occlusal contacts (shimstock foil of 8 µm thickness could be pulled through). After a healing period of at least 8 (mandible) or 16 weeks (maxilla), respectively, impressions were taken (Impregum; 3 M Espe, Seefeld, Germany) and digitized (inEos scanner; Sirona, Bensheim, Germany). CAD/CAM-fabricated (Cerec inLab® software, inLab® MC XL 4-axis milling device; Sirona) zirconia frameworks (In-Ceram YZ, VITA Zahnfabrik) were hand-layered with a leucite-reinforced feldspathic ceramic (VM9, VITA Zahnfabrik) according to the manufacturer's instructions. All SCs were adhesively cemented using a dual-curing resin cement (RelyX Unicem Aplicap; 3 M Espe). In case of a subgingival cementation line, retraction cords were placed to facilitate cement removal. Centric and dynamic occlusions were controlled (12 µm occlusion foil, 8 µm shimstock foil) both on the restoration and the residual dentition to avoid any excessive forces.

2.4. Baseline and follow-up examinations

At baseline (post-cementation) and again after 6, 12, 24, and 36 months of function, the restorations were examined clinically. These appointments included (1) a visual and tactile inspection of the restorations, (2) a control of static and dynamic occlusion, (3) impression taking, and (4) intraoral photographs of the restorations and neighboring teeth. Biological and technical complications were documented and the required treatment applied, if necessary.

2.4.1. Clinical outcome

The restorations were evaluated in five categories (framework fracture, chipping of the veneering ceramic, occlusal roughness, marginal integrity, and contour of the restoration; Table 1) according to modified USPHS criteria [17]. SCs within a range of excellence were rated Alpha, whereas SCs showing minor deviations from the ideal were judged to be Bravo. SCs showing clinically unacceptable defects that could be intraorally repaired to a clinically acceptable level were rated