

Fourteen-year evaluation of posterior zirconia-based three-unit fixed dental prostheses.

A prospective clinical study of all ceramic prosthesis.

In the present prospective clinical study, 37 patients (16 males, 21 females) needing at least 1 posterior FDP in the maxillary and/or the mandibular arches were recruited. The mean age of patients was 45.3 ± 11.6 years, with a minimum age of 21 and a maximum of 68 years. All patients were recruited at the Department of Prosthodontics of the University "Federico II" of Naples (Italy) from November 2004 to April 2005 (baseline) and provided a written informed consent. The study fulfilled the requirements of the Helsinki declaration and was approved by the ethical committee of the same University. All the included patients met the following inclusion criteria:

- good general health;
- ASA I or ASA II according to the American Society of Anesthesiologists;
- good periodontal health;
- Angle class I occlusal relationship;
- minimum of 20 teeth;
- good oral hygiene;
- no evident signs of occlusal parafunctions and/or temporomandibular disorders.

Moreover, the abutment teeth had to fulfill the following inclusion criteria:

- periodontal health (absence of tooth mobility, absence of furcation involvement);
- proper positioning in the dental arch (tooth axes adequate for a FDP);
- sufficient occlusal-cervical height of the clinical crown (≥ 4 mm) for the retention of a FDP;
- vital or endodontically treated to a clinically sound state;
- opposing natural teeth or fixed prostheses.

The following conditions caused the patients exclusion from the study:

- subjects preferring implant-supported prostheses;
- high caries activity (according to the American Dental Association Caries Risk Assessment Form for age > 6);
- occlusal-gingival height of the abutment teeth < 4 mm;
- reduced interocclusal distance or supraerupted opposing teeth;
- unfavorable crown-to-root ratio (up to 1:1 as minimum ratio);
- severe wear facets, clenching, bruxism (identifiable during clinical examinations or reported during anamnestic interviews);
- presence of removable partial dentures;
- pregnancy or lactation.

Forty-eight 3-unit posterior zirconia FDPs were fabricated; 11 patients received 2 FDPs each. The pontic element replaced either a first or a second premolar or a first molar. Twenty-four FDPs were located in the maxilla replacing 12 premolars and 12 molars; the other 24 FDPs were placed in the mandible substituting 9 premolars and 15 molars. A first premolar mesial cantilever was designed for a maxillary prosthesis.

Prosthodontic procedures

Four experienced and calibrated prosthodontists performed all the clinical procedures. The patients were prepared by means of professional oral hygiene and core build-ups, endodontic therapies and post-and-core placement if necessary were performed before the prosthodontic procedures. Alginate impressions were made in order to obtain study gypsum casts and fabricate diagnostic wax-ups, self-polymerizing resin customized impression trays and acrylic temporary restorations. Silicon indexes obtained from the diagnostic wax-up were used to check proper tooth preparation and achieve abutments fulfilling the requirements of the CAD-CAM workflow for framework production:

- margin design: 1 mm circumferential rounded chamfer and rounded cavo-surface angles to prevent stress concentrations;
- axial reduction: 1.5 mm;
- occlusal reduction: 1.5-2 mm;
- total occlusal convergence angle: 10°-14°.

The slightly subgingival margins of the preparations respected the biologic width. A self-polymerizing resin was used to relines intraorally the acrylic resin temporary restorations that were then cemented with a eugenol-free luting agent. Occlusal adjustments of the provisional restorations were performed when necessary. After tooth preparation, 10 to 14 days were waited in order to consent the recover of soft tissues from possible preparation injuries before making the final impressions. Two non-impregnated retraction cords were positioned around abutment teeth before the full-arch impression procedure. Customized autopolymerizing acrylic impression trays and polyether materials were used. A self-polymerizing A-silicone was used to register the interocclusal relationships. Then, the provisional restorations were cemented. Master casts of super hard gypsum were mounted in a semi-adjustable articulator with a die spacer (<30- μ m thick) applied at the occlusal and axial surfaces of the abutments, starting 1 mm above the preparation margins. The CAD-CAM, was used to digitize the master casts. The sintering shrinkage was compensated by enlarging the scanned data by 20-25%. The milling center milled the 1st generation presintered partially stabilized tetragonal zirconia 3Y-TZP frameworks from presintered zirconia blanks, then sintered to full density. An ovate pontic was used to replace missing premolars, while a modified ridge-lap pontic was designed for missing molars. The minimum retainer thickness was 0.6 mm and the minimum connector surface area was 9 mm². A digital caliper with an accuracy of 0.01 mm was used to measure the framework thickness. Then, the accuracy of fit of zirconia frameworks was evaluated intraorally using a silicon disclosing agent; if necessary, geometry adjustments were made on the abutments transferring any pressure spot to teeth surfaces. The same experienced dental technician veneered all the frameworks; a feldspathic ceramic specifically dedicated to zirconia and a conventional powder build-up veneering technique were used and the adequacy of the coefficient of thermal expansion (CTE) of the veneering ceramics was carefully checked. Then, the FDPs were glazed and polished. The thickness of veneering ceramics was measured with a digital caliper with an accuracy of 0.01 mm and ranged between

0.55 and 0.98 mm on the retaining abutments and between at level of the connectors. The final zirconia FDPs were tried-in intraorally to evaluate internal and marginal adaption using a silicon disclosing agent. Furthermore, proximal and occlusal contacts were checked with articulating ribbon; occlusal adjustments were performed when necessary. Abutments were degreased with 80% ethanol. In order to ease the removal of cement remnants, the external surfaces of the FDPs were isolated using liquid paraffin before cementation. The intaglio surfaces of zirconia FDPs were conditioned by means of mild sandblasting with 110 µm alumina particles at 0.2 MPa . A resin luting agent was used to cement the FDPs and the cement excesses were removed by means of a plastic scaler. If necessary, fine-grit diamond burs were used to make further occlusal adjustments and the modified surfaces were meticulously polished with a ceramic polishing system.

Baseline evaluation

Two external, calibrated and experienced clinicians blind to the prosthodontics procedures performed the baseline evaluation, recorded 7 days after the cementation of FDPs. As regards periodontal evaluation, tooth mobility, plaque control record, probing pocket depth, probing attachment level, bleeding on probing (BOP) at the abutment sites (test) and at the contralateral, not restored teeth (control) were assessed. Cold carbon dioxide was used to evaluate pulp vitality of test and control teeth. After making alginate impressions for study casts, the clinical evaluators recorded the occlusal relationships between the FDPs and the opposing arches. Clinical photographs of the FDPs and periapical X-rays of the abutment teeth were taken. Furthermore, the static and dynamic and the static occlusal contacts were checked and recorded photographically. All the patients rated the overall functional and esthetic outcomes of the restorations by means of Visual Analog Scales (VASS) ranging from 0 to 10.

Follow up-examinations

After the baseline evaluation, all the patients were recalled after 6 months and then annually, over a whole observational period of 14 years. The same evaluations assessed at the baseline were repeated and the relative data were recorded. Any proximal recurrent decays and/or periapical pathologies were checked by means of X-rays. The United States Public Health Service (USPHS) criteria were used to report technical and esthetic complications; the FDPs were examined entirely and the worst record was used for rating.

Statistical analysis

A dedicated software (SPSS 17, SPSS Inc., Chicago, IL, USA) was used to make descriptive statistics. The 14-year cumulative survival rate of the zirconia FDPs was calculated by means of Kaplan-Meier analysis. Two independent curves for patients wearing 1 or 2 FDPs were analyzed separately. In order to compare these curves, a log-rank test was performed. The patient receiving the only cantilevered restorations was excluded from the statistical analysis, in order not to introduce a pure confounder. The periodontal parameters of control

and test teeth between the baseline and the 14-year follow-up were evaluated using the Wilcoxon test, with a level of significance set at $p < 0.05$.

Results

After 14 years of clinical function, no patient was lost at follow-up or censored and consequently all the 48 3-unit zirconia FDPs were available for examination. The survival rate was 98% while the success rates were 91% and 99% for patients wearing 1 and 2 FDPs, respectively, as reported in the Kaplan-Meier graph considering complications as events.

There were no statistically significant differences between the survival curves of patients with 1 or 2 FDPs, as shown by the log-rank test ($p < 0.05$). During the entire period of observation, 5 minor cohesive fractures of the veneering ceramics were observed (10.4%): at the 1-year recall, the first chipping was detected on the distal connector of a maxillary premolar; after 2 years of clinical function, the examiners detected 2 more chippings of the veneering ceramics, 1 on the occlusal surface of a mandibular molar and 1 on the distal connector of a maxillary molar in a patient wearing 2 FDPs; at the 9-year recall, the examiners observed 1 mesial-lingual chipping on a maxillary first premolar and 1 mesial-lingual chipping on a mandibular first premolar. The patients did not notice such cohesive fractures since the chipped areas did not impair function; consequently, the surfaces were carefully rounded and polished and the FDPs remained in situ for further observation.

Moreover, 1 decementation (2.1%) of a mandibular FDP was detected after 10 years of clinical function; after thoroughly cleaning and degreasing both the abutment teeth and the restoration, the FDP was cemented using the same resin cement. After 11 years of serviceability, 1 catastrophic fracture (2.1%) was detected in the same patient experiencing the previous decementation; the abutment teeth were intact and the soft tissues were stable, consequently, the restorations was replaced by a new zirconia FDP.

At the baseline, 82 abutments (85.5%) were vital and they all remained vital, after 14 years of observation. The follow-up examinations showed no significant differences in the average periodontal parameters between test and control teeth. Moreover, neither signs or symptoms of proximal decay nor radiographic evidence of periapical pathologies were detected during the entire follow-up period.

The mean values of the outcomes reported by patients were recorded using VAS judgments: the overall functional score was 9.3 (± 1.4) while the average esthetic value was 9.0 (± 0.9), where 0 meant “not satisfied at all” and 10 meant “fully satisfied”. All the patients declared to be pleased with chewing efficiency and esthetics of the restorations, although slight gingival recession were observed in some cases; this report was probably due to the absence of grey metal frameworks that allowed the patients not to complain about esthetics. Excluding the subject who experienced a catastrophic fracture, all the patients in which chipping occurred did not report any significative functional discomfort, apart from minimal surface roughness that was polished and sporadic food impaction on the lingual aspect of connectors and in contact areas. As regards mechanical resistance to fracture, all the frameworks but the fractured one scored Alpha. In terms of occlusal wear, 6 restorations opposing natural teeth rated Bravo; 2 of them opposed previous chipped restorations. The Wilcoxon test performed for the analyzed periodontal parameters at baseline vs 14-year recall on

test and contralateral control teeth showed no statistically significant differences ($p>0.05$) for probing pocket depth, probing attachment level, plaque control record and bleeding on probing.

