Novel ceria-stabilized tetragonal zirconia/alumina nanocomposite as framework material for posterior fixed dental prostheses: Preliminary results of a prospective case series at 1 year of function

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Objective: To examine the clinical performance of veneered ceria-stabilized tetragonal zirconia/alumina–nanocomposite (Ce-TZP/A–nanocomposite) frameworks for three-unit fixed dental prostheses (FPDs). Method and Materials: Eight patients in need of one FDP replacing one premolar or molar were included in this case series. Eight Ce-TZP/A–nanocomposite FDP frameworks were fabricated with a CAD/CAM system (Hint-Els) and veneered with a zirconia veneering ceramic (Vintage ZR, Shofu). The FDPs were cemented with resin cement (baseline) and were evaluated at baseline; 2 weeks; and 3, 6, and 12 months after cementation. For the technical evaluation, the USPHS criteria were used. The biologic outcome was judged by comparing the plaque control record (PCR), bleeding on probing (BOP), and probing pocket depth (PPD) of the abutment teeth (test) and untreated contralateral teeth (control). Radiographs were made at baseline and at 6 and 12 months of follow-up. The data were descriptively analyzed. Results: The mean observation period of the eight examined FPDs was 12.8 ± 1.1 months. The survival rate of the FDPs was 100%. Furthermore, no technical or biologic complications were found. No differences of the mean (m) PCR (test: 0.1 ± 0.1, control: 0.2 ± 0.2), mBOP (test: 0.2 ± 0.2, control: 0.1 ± 0.1), and mPPD (test: 2.6 ± 0.8, control: 2.6 ± 0.6) were found between test and control teeth. Conclusions: Ce-TZP/A nanocomposite was found to be a reliable framework material at 1 year of function. Longer observation periods and randomized controlled clinical trials including more patients are needed to validate these findings. (Quintessence Int 2010;41:313–319)

Key words: CAD/CAM, ceria-stabilized, fixed dental prosthesis, framework, zirconia, zirconia/alumina nanocomposite

In recent years, there has been an increasing demand for the replacement of missing teeth with all-ceramic fixed dental prostheses (FDPs). However, when posterior teeth were replaced, high failure rates of the all-ceramic FDPs were reported. To date, four clinical studies are available presenting 5-year results of all-ceramic FDPs. Two of these studies analyzed glass-infiltrated alumina as framework material. In these investigations, FDP failure rates of 10% and 12% were reported.
The third and the fourth studies, however, analyzed the high-strength ceramic zirconia as framework material. With frameworks made of zirconia, the failure rate of the FDPs was significantly lower than for frameworks with glass-infiltrated alumina. In the clinical studies, failure rates of those FDPs ranged from 0% to 2.2%.

The most frequent reason for failure of FDPs made of glass-infiltrated alumina was fracture of the ceramic framework. Interestingly, after the same observation period for zirconia-based FDPs, fracture of framework was a rare clinical complication.

Recently, a new type of zirconia ceramic was developed as framework material, the ceria-stabilized tetragonal zirconia/alumina (Ce-TZP/A) nanocomposite. This new zirconia ceramic variation offers superior mechanical properties compared to conventional yttrium-stabilized (Y) TZP. Although the flexural strength of this new ceramic is in the same range as that of conventional Y-TZP, its fracture toughness is significantly higher. The homogenous dispersion of an alumina phase in the TZP matrix of this new nanocomposite suppresses the grain growth and increases the hardness, elastic modulus, and hydrothermal stability of the tetragonal zirconia.

One critical factor that had to be considered before the clinical introduction of Ce-TZP/A nanocomposite was that new veneering ceramics would possibly be needed for this new type of zirconia. Therefore, the compatibility of the available zirconia veneering ceramics to the new Ce-TZP/A nanocomposite was analyzed in recent laboratory studies. In one study, the fracture strength and crazing resistance of Ce-TZP/A nanocomposite frameworks, veneered with a commercially available ceramic, was compared to veneered sintered and hot isostatically pressed (HIP) Y-TZP. The results showed that the fracture load of veneered Ce-TZP/A nanocomposite single crowns was similar to that of veneered Y-TZP crowns. Furthermore, the study showed even beneficial fracture patterns of the veneered Ce-TZP/A nanocomposite crowns compared to the Y-TZP crowns. While the Y-TZP crowns failed because of fracture of the veneering ceramic, including the ceramic framework (catastrophic failure), at Ce-TZP/A nanocomposite crowns, in most cases, solely chippings of the veneering ceramic occurred, without involvement of the ceramic framework.

To date, no clinical studies of FDPs with Ce-TZP/A nanocomposite frameworks are available to validate these promising laboratory findings. The aim of the present case series was therefore to assess the clinical performance of veneered Ce-TZP/A nanocomposite frameworks for posterior three-unit FDPs.

METHOD AND MATERIALS

Study design and patient selection
All procedures and materials of this prospective case series were approved by the local ethical committee, and the included patients provided informed consent.

Eight generally healthy patients fulfilling the following criteria were included: one missing mandibular or maxillary premolar or molar, a healthy periodontium before the restorative treatment phase, a plaque control record (PCR) below 30%, and probing pocket depths (PPDs) of the abutment teeth of 4 mm or less.

Periodontal or endodontic treatment was performed when necessary.

All patients underwent comprehensive dental care and were instructed to maintain a high level of oral hygiene. Patients with parafunctional habits such as bruxing or clenching were excluded.

Prosthodontic procedures
Four patients were treated by experienced clinicians and four patients by undergraduate students under strict guidance by experienced clinicians. Treatment was performed according to standard techniques applied for metal-ceramic reconstructions. The procedures were published in detail elsewhere and will therefore be briefly summarized with respect to the abutment tooth preparation.

The abutment teeth were prepared as follows (Fig 1): margin with a circumferentially rounded shoulder (width 1.0 mm), tapering angle of 6 to 10 degrees for both premolars and molars, and occlusal reduction of 1.5 to 2.0 mm.
In case of a lack of dentin for an adequate preparation, a composite resin core buildup (Syntac Classic/Tetric Classic, Ivoclar Vivadent) was fabricated. Upon completion of tooth preparation, vital tooth abutment surfaces were sealed by means of a bonding system (Syntac, Ivoclar Vivadent). Impression of the jaw with the abutment teeth was made by means of a polyether impression material (Permadyne, 3M ESPE). Provisional restorations were fabricated using a provisional composite resin material (Pro Temp, 3M ESPE) and cemented with a eugenol-free temporary cement (Freegenol, GC America).

**Fabrication of the restorations and cementation**

The working casts were scanned (HiScan, Hint-Els), and an appropriate framework was designed (Fig 2). Presintered Ce-TZP/A nanocomposite blanks were used (Nanozir, Hint-Els). The frameworks were machined by means of a computer-aided design/computer-assisted manufacture (CAD/CAM) milling machine (hiCut, Hint-Els) and subsequently sintered to full density in a specialized furnace (hiTherm, Hint-Els). The frameworks were veneered (Vintage ZR, Shofu) by one dental technician. For the sintering of the veneering ceramic the technician used a conventional furnace (D4, Dekema). The firing schedule was performed following the instructions of the veneering ceramic manufacturer. The FDPs were veneered onto the zirconia crown margins (see Figs 2 and 3).

Before cementation, the abutment teeth were cleaned (Clean Polish, Kerr Hawe). The internal surfaces of the FDPs were cleaned with ethanol and subsequently silanized (Clearfil Porcelain Activator, Kuraray). The FDPs were adhesively cemented with one resin cement (Panavia TC, Kuraray) according to the manufacturer’s instructions (Fig 3).

In situations in which the occlusion required adjustment, the reshaped surfaces were meticulously polished with polishing disks (Sof-Lex Pop-on Discs, 3M ESPE).
Baseline and follow-up examinations

At baseline and at 2 weeks, 3, 6, and 12 months after insertion, the technical and biologic outcome of the reconstructions was evaluated.

Technical evaluation. The technical outcome of the FDPs was assessed by means of the US Public Health Service (USPHS) criteria. For the analysis of the surface of the veneering ceramic over time, impressions of the FDPs were made at each follow-up visit using a highly viscous A-silicone impression material (President Jet, Coltène). These impressions were poured with epoxy resin, resulting in highly accurate replicas of the FDPs. The surface of the replicas was analyzed by means of scanning electron microscopy (SEM) with a magnification of 5,000× (SEM CS4, CamScan).

Biologic examination. Biologic parameters were assessed at the abutment (test) teeth and at contralateral control teeth immediately following cementation of the reconstructions. The plaque control record (PCR), bleeding on probing (BOP), and probing pocket depths (PPD) were assessed at six sites per tooth. Pulp vitality of the abutment and control teeth was tested using carbon dioxide. Radiographs of the FDPs were made at baseline, and at the 6- and 12-month visits.

Postoperative data collection forms, radiographs, and clinical photographs were used as documentation tools.

Finally, patients were asked whether they were satisfied with the esthetic and functional outcome of their reconstructions by means of polar questions (yes/no).

RESULTS

The eight patients (four men, four women) with the eight FDPs were followed for a mean observation period of 12.8 ± 1.1 months. The mean age of the patients was 58.5 ± 5.6 years (range 49 to 69 years). The eight FDPs were all in the mandible. Three FDPs replaced premolars and five replaced molars.

No failure of an FDP occurred, and the survival rate was therefore 100%. Interestingly, in addition to the good clinical stability of the frameworks, the performance of the veneering ceramic was good. No chippings or fractures of the veneering ceramic were observed.

The technical evaluation revealed very good initial USPHS ratings for all FDPs, which remained almost unchanged during the follow-up period (Table 1). Only two parameters, marginal integrity and occlusal wear, exhibited slight changes over time, and the number of FDPs with lower ratings increased over time (see Table 1).

One FDP exhibited clinically relevant occlusal wear of the veneering ceramic (C rating) at the 12-month visit (see Table 1 and Figs 4 and 5a). The resin replica of this FDP was thoroughly analyzed by means of the SEM (Figs 5b and 5c) to differentiate between clinically visible roughness and a potential ceramic chipping. The analysis revealed that pronounced occlusal wear, not chipping, was the reason for the roughness (see Figs 5b and 5c).

Another technical parameter that exhibited changes during the 12 months of follow-up was marginal adaptation. At the clinical
service at six of the eight FDPs, the margins were detectable with a probe at a clinically acceptable level (B rating).

The biologic evaluation of the FDPs showed no differences between test and control teeth regarding the mean (m) PCR, mBOP, and mPPD at baseline, and at the follow-up examinations (Table 2). No secondary caries was found.

Only very few biologic problems were observed. One patient presented with post-operative sensitivity after cementation; however, the sensitivity subsided after 6 months. Furthermore, at 12 months of observation, periodontal problems were found at an abutment tooth of one patient. A second molar abutment tooth exhibited a PPD of 11 mm.

This molar received a root canal treatment through the reconstruction to treat the combined periodontal-endodontic lesion.

<table>
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<th>Table 2</th>
<th>Mean values and SDs of the biologic parameters at baseline and 12 months of clinical service</th>
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<td>Test sites</td>
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<td>Baseline 12 mo</td>
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<tr>
<td>PPD (mm)</td>
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<td>BOP</td>
<td>0.1 ± 0.1</td>
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<td>PCR</td>
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Units for BOP and PCR are +/- (+ = 1, - = 0).

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DISCUSSION

At 12 months of observation, the new Ce-TZP/A nanocomposite FDPs exhibited a survival rate of 100%. Within the limitations of the present case series, the new framework material was found to be clinically reliable. Furthermore, the performance of the veneering ceramic was very good at this new type of zirconia ceramic. No chipping or fracture of the veneering ceramic occurred.

The performance of the zirconia frameworks in the present case series is in accordance with the findings of various other studies analyzing zirconia as framework material in posterior regions of the jaws. In these studies, survival rates of 98.8% to 100% of zirconia-based FDPs were reported, however, after longer observation periods of up to 5 years. Hence, a longer observation time of the FDPs in the present case series, and additional studies of Ce-TZP/A nanocomposite–based reconstructions with a higher sample size, are needed to verify the positive primary findings. Furthermore, comparison of the present results with the ones of metal-ceramic FDPs (golden standard) is needed in the future. As an example, two meta-analyses observed failure rates of only 8% and 10% of FDPs with metallic frameworks after 10 years. These results are considered to be the benchmark for new types of FDP.

Besides good mechanical strength of the framework, the stability of the veneering ceramics is one further prerequisite for the clinical success. The fact that no chippings occurred in the present case series is very promising. Problems such as chipping or fracturing of the veneering ceramic were the main technical complication in previous studies analyzing Y-TZP. Metal-ceramic or alumina-ceramic FDPs exhibited lower complication rates of the veneering ceramic than zirconia-based FDPs. Clinical studies reported chipping or fracture rates of the metal veneering ceramic of only 2.5%. Even more, with veneered glass-infiltrated alumina FPDs no failures of the veneering ceramic were observed at all after 5 years of clinical function. Veneered Y-TZP frameworks, however, showed varying chipping rates. One study reported 15.2% of chipping after 5 years. Another study reported a chipping rate of 15% after 2 years. In a third study using a prototype ceramic, however, chipping of the veneering ceramic occurred at only 4.3% of the FDPs 18 months after insertion. In contrast to the previously mentioned findings with zirconia veneering ceramic, in the present case series, no chippings or fractures of the veneering ceramic were observed at all. Again, it has to be considered that the number of observed reconstructions was small.

The results of previous laboratory studies show that the veneering ceramic for Ce-TZP/A nanocomposite has to be chosen carefully. Based on a recent laboratory study, the veneering ceramic Vintage ZR was chosen as veneering material in combination with the Ce-TZP/A nanocomposite in the present study. At the 12-month examination, moderate occlusal wear of the veneering ceramic was visible at three FDPs, of which one reached a clinically unacceptable level. This finding is in accordance with previously published results. Before final conclusions on the compatibility of the veneering ceramic used in the present case series and the new framework material can be drawn, however, longer observation periods and studies with a higher sample size are needed similar to those of studies with Y-TZP frameworks.

Finally, the biologic outcome of the FDs in the present case series was good and corresponded to findings of previous studies. Therefore, it can be summarized that veneered Ce-TZP/A nanocomposite frameworks for posterior three-unit FDs exhibited similar clinical performance as those with Y-TZP frameworks at 1 year of function.

CONCLUSIONS

At 12 months of clinical service, Ce-TZP/A nanocomposite proved to be a promising and reliable framework material for posterior FDs. Yet, before final conclusions can be drawn, longer observation periods, studies with more patients, and randomized clinical long-term trials are needed to validate the clinical performance of this first preliminary case series.
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REFERENCES