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ORIGINAL ARTICLE

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Two-year evaluation of a new nano-ceramic restorative material

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Abstract The purpose of this prospective study was to evaluate the clinical performance of a new restorative material (Ceram·X) in combination with a new primer–adhesive (K-0127). One operator placed two Class I or II restorations in molars of 43 patients. One molar was restored with Ceram·X/K-0127, the other one with Tetric Ceram/Syntac Classic. At baseline, after 1 and 2 years, the restorations were evaluated by one evaluator using modified Ryge's criteria. After 2 years, 31 patients were examined. One Ceram·X-restoration had to be removed for root canal treatment due to pulpitis. Thus, failure rate of Ceram·X was 3.2% and of Tetric Ceram, 0%. In both groups, no sensitivity, no recurrent caries, and no changes in surface texture were recorded after 2 years. One restoration in each group showed slight changes in color stability (score B). Marginal discoloration (score B) was found concerning three Ceram·X-restorations (10.0%) and two Tetric Ceram-restoration (6.5%). Marginal integrity was score B for four Ceram·X-restorations (13.3%) and for four Tetric Ceram-restorations (12.9%). No statistically significant differences were found ($p>0.05$). After 2 years of clinical service, 96.8% of Ceram·X/K-0127 and 100% of Tetric Ceram/Syntac Classic restorations were in place and performed clinically well.

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Introduction

Micro-hybrid composites have increasingly been used as a restorative material in the posterior area and have proved successful. The decreasing acceptance of the traditional amalgam by patients and the increasing demands for aesthetic restorations in molars and premolars are responsible for these changes [5].

In 1997, a new type of resin composite was introduced to dentistry: the organically modified ceramic ("ormocer"). Multifunctional urethane and thioether methacrylate alkoxysilanes have been developed as sol–gel precursors for synthesis of inorganic–organic copolymer composite materials for dental applications [33]. By hydrolysis and polycondensation reactions, the alkoxysilyl groups of the silane promote the formation of an inorganic Si–O–Si network, while the methacrylate groups are still available for light-activated organic polymerisation.

Compared to the micro-hybrid composite Tetric Ceram (Ivoclar-Vivadent, Schaan, Liechtenstein), resistance of the ormocer, Definite (Degussa, Hanau, Germany), to abrasion was higher [17]. In vitro cytotoxicity of Definite was lower than that of Tetric Ceram after 14 days of aging in saliva [32]. Regarding polymerization shrinkage, there was no difference between ormocers (1.7 to 2.8% per volume) and modern hybrid composites (1.5 to 3% per volume) [11, 26, 29, 30].

The ormocer-based, nano-ceramic composite, Ceram·X (Dentsply DeTrey, Konstanz, Germany), was developed after introduction of the nanotechnology in dentistry. Ceram·X contains glass fillers (1.1–1.5 μm) but differs from conventional hybrid composites by two important features: methacrylate-modified silicon dioxide containing nano-filler (10 nm) substitute the microfiller that is typically used in hybrid composites (agglomerates of silicon dioxide particles). According to the manufacturer's data, filler concentration is 76% by weight and 57% by volume.

Furthermore, most of the conventional resin matrix is replaced by a matrix full of highly dispersed methacrylate modified polysiloxane particles (2–3 nm). According to the manufacturer's information, these nano-ceramic particles are inorganic–organic hybrid particles. Both, nano-ceramic particles and nano-fillers have methacrylate groups available for polymerization. Ceram·X does not contain triethylene glycol dimethacrylate (TEGDMA). TEGDMA was found mutagenic and cytotoxic in vitro [8, 28]. Moreover, TEGDMA is suspected of having growth-stimulating effects on the caries-associated microorganisms, *Streptococcus sobrinus* and *Lactobacillus acidophilus* [9].

The aim of this prospective study was to evaluate the clinical performance of Ceram·X in combination with the new adhesive K-0127 for Class I and Class II restorations in permanent posterior teeth. In contrast to conventional adhesives that contain water, ethanol, or acetone as solvent, the new primer-adhesive K-0127 (Dentsply DeTrey) contains tert-butanol.

Tetric Ceram served as control, as it performed well in a 4-year clinical evaluation (cumulative failure frequency of 7.5%) [31]. In another study of Class II restorations in small posterior lesions, a 4.5% failure rate after 2 years was found [13]. Tetric Ceram was used in combination with the adhesive Syntac Classic (Ivoclar-Vivadent) as this is a high-quality adhesive that proved successful in combination with the composite Tetric [27].

Materials and methods

From November 2002 to January 2003, every patient who was found to need at least two Class I or Class II restorations at the annual examination at the authors' clinic was invited to join the study. The subjects were representatives of patients attending German dental practices. Forty-three patients (23 female and 20 male) participated and provided written informed consent to participate in the study which was approved by the ethics committee of the Albert-Ludwigs-University of Freiburg. Exclusion criteria were pregnancy, medication during the past 3 months, allergies against resin, and severe systemic diseases. The participants consented to restoration of one molar with the composite, Tetric Ceram (Ivoclar-Vivadent) and another molar with the nano-ceramic composite, Ceram·X (Dentsply DeTrey). Tooth location, and afterwards, distribution of materials was randomized by means of a computer-generated randomization list. One dentist, well experienced with both materials, placed all pairs of restorations.

Vital first and second permanent molars, with Class I or Class II lesions were included, even if cusps had to be replaced. Teeth with pulpal pain, endodontically treated teeth, and teeth with direct pulp capping were excluded.

If required, an anesthetic agent was given (Ultracain DS; Aventis, Frankfurt, Germany). Rubber dam (Silikon-Dam; Roeko, Coltene/Whaledent, Langenau, Germany) was used for all restorations. Cavity preparation was limited to removal of carious tissue and/or old filling material. For finishing the cavosurface margins, finishing burs (40-μm grain size) were used for the occlusal margins and Sonicsys-system (Sonicsys micro from no. 28 to no. 33; KaVo, Biberach, Germany) was used in proximal areas. No bevelling of the cavity margins was performed. It was not recorded if cervical margins were situated apical to the cementoenamel junction. No cavity liners for indirect pulp capping, and no cavity bases were applied in addition to the adhesive.

For Class II restorations, a matrix system (Composi-Tight Sectional Matrix Retainer System; Garrison Dental Solutions, Spring Lake, MI, USA) was employed. For restorations with Ceram·X phosphoric acid (36%, DeTrey Conditioner 36; Dentsply DeTrey) and total-etch technique were used. Enamel was etched for 30 s and dentin for 15 s. The cavity was then thoroughly rinsed with air/water spray for at least 15 s and carefully dried so that the dentin surface had a slightly shiny appearance. The adhesive K-0127 (Dentsply DeTrey) was applied using an applicator (microbrush). After smooth air flow, the adhesive was light-cured for 10 s using a daily controlled light curing unit (750 mW/cm^2; Elipar Highlight; 3M ESPE, Seefeld, Germany). Tetric Ceram was used in combination with the adhesive Syntac Classic (Ivoclar-Vivadent) according to the manufacturer's recommendation. Therefore, the enamel was selectively etched for 30 s (phosphoric acid, 37%; Ivoclar-Vivadent).

The cavity was thoroughly rinsed and the remaining water was reduced by air flow. Primer was applied for 15 s, and the cavity was dried by smooth air flow. Adhesive was applied for 10 s. After repeated air flow, Heliobond (Ivoclar-Vivadent) was applied, smoothly air streamed and light-cured for 20 s. Both restorative materials were applied with compules using horizontal incremental placement technique (maximum: 2-mm layer). Increments were light-cured for 20 s for Ceram·X and for 40 s for Tetric Ceram according to manufacturers' instructions. Finally, each filling surface was light-cured for 20 and 40 s, respectively. Restorations were polished and finished using diamond finishing burs, polishing discs (Sof-Lex; 3M, Borken, Germany), silicone polishers (Enhance; Dentsply DeTrey), HaWe Occlubrush (Kerr, Orange, CA, USA) and finishing strips (Sof-Lex; 3M). The occlusion and articulation were controlled. No special procedures were adopted to manage the oxygen-inhibited layer.

One to ten days after placement (baseline), the restorations were examined by another dentist using modified Ryge's criteria (Table 1) [1, 4, 25]. This single evaluator was blinded to group assignment. Follow-up examinations were carried out after 1 and 2 years by the same evaluator. In contrast to Ryge's criteria, instead of the surrounding enamel, a previously light-cured composite sample from the same batch served as reference for evaluation of the color stability because at the time of the study, only one color (A2) of Ceram·X was available. This sample was 2-mm thick, was light-cured for 20 s using the aforementioned light curing unit and was stored dark and dry. Postoperative hypersensitivity to cold and sensitivity to percussion were recorded. If a removal of a restoration was indicated, this restoration was noted as failure.

For each parameter of each group, statistical analysis was done using the Friedman-test (two-way analysis on ranks) for changes from baseline to 1- and 2-year data. The two groups were compared for each parameter using the Sign-test. Level of significance was set at $p \leq 0.05$. All statistics were performed using SAS 8.2 (SAS Institute, Cary, NC, USA).

Results

About 75% of the restorations were Class II restorations and 25% were Class I restorations. The minimum buccooral width of each restoration was greater than or equal to one-third the distance between cusp tips. Cusps were restored in 31% of all restorations.

After 1 year, 37 patients were examined. Six patients refused to attend the 1-year recall. One Ceram·X restoration had to be removed for root canal treatment 9 months after placement because the tooth showed hypersensitivity to cold and to percussion. This tooth had been filled with a deep occlusal-distal Amalgam restoration and had shown secondary caries before it was restored with Ceram·X. Thus, failure rate of Ceram·X was 2.7% and of Tetric Ceram, 0%. Thirty-seven Tetric Ceram restorations and 36 Ceram·X restorations were examined (Table 2). Neither score C nor score D was observed. All Class I restorations were scored A for all criteria.

Thirty-one patients attended the 2-year recall. Twelve patients refused to participate. Also after 2 years, neither score C nor score D was recorded. Failure rate was 3.2% due to the aforementioned restoration. For all criteria, every Class I Ceram·X restoration remained as score A.

Just after placement, 9.3% (n=4) of the Ceram·X restorations and 7.0% (n=3) of the Tetric Ceram restorations showed slight symptoms of postoperative sensitivity including hypersensitivity to cold and sensitivity to percussion. However, no replacement of a restoration or endodontic treatment was necessary for that reason. No postoperative sensitivity was recorded after 1 and 2 years in any case (Table 2).

No significant difference between the two groups was observed after 1 and 2 years concerning all criteria ($p>0.05$; Sign-test). Neither between 1-year and baseline data nor between 2-year and baseline data were significant differences found in both groups with regard to all criteria ($p>0.05$; Friedman test).

Discussion

The failure rate of 3.2% of Ceram·X after 2 years was caused by the tooth which had been treated endodontically. It remains unclear whether the new material caused the pulpitis or not. Maybe, an asymptomatic pulpitis (due to secondary caries) and a positive pulp vitality test pretended a healthy pulp tissue already before the restoration with Ceram·X. Rosin et al. found two (of 150) Class II ormocer restorations (Definite in combination with Etch & Prime 3.0) which had to be removed after 1 year (1.3% failure rate) [24]. Lopes et al. observed two Definite/Etch & Prime 3.0 restorations (5.3%) that had to be removed after 2 years due to crevices with exposure of dentin or base [16]. Oberländer et al. found a failure rate of 9.6% after 1 year with the same material in a multicenter study [22]. Within 1 year after placement, two of 52 Class II Definite restorations had to be replaced due to bulk fractures. Two restorations were found clinically not acceptable (score C) due to deep crevices with dentin or base exposed. Another restoration exhibited secondary caries and was replaced. In reviews of controlled prospective and retrospective studies, annual failure rates of 0 to 9% of composite restorations were ascertained [12, 18]. Therefore, with regard to failure rates, it can be concluded that both Ceram·X and Tetric Ceram performed well.

Postoperative sensitivity has been attributed to several factors, including dentin etching and bacterial penetration of the pulp, occlusal discrepancies, deformation of cusps by shrinkage stress, and deformation of composite by

Table 1 Criteria and scores of modified Ryge's criteria for clinical evaluation of the restorations

Criteria/score	A	B	C	D
Color stability	Restoration matches cured material sample	Slight mismatch between restoration and sample	Strong mismatch between restoration and sample	
Marginal discoloration	No visual evidence of marginal discoloration	Marginal discoloration has not penetrated in pulpal direction	Marginal discoloration has penetrated in pulpal direction	
Marginal integrity	Explorer does not catch and/or no crevice is visible	Explorer catches and crevice is visible, but no exposure of dentin and restoration is not mobile	Explorer penetrates crevice defect extended to amelo-dentinal junction	Restoration is fractured, mobile, or missing
Recurrent caries	No caries present	Caries present associated with the restoration		
Anatomic form	Restoration is continuous with existing anatomic form	Restoration is discontinuous with existing anatomic form, but missing material is not sufficient to expose dentin	Sufficient material lost to expose dentin	
Surface texture	Surface texture similar to polished enamel	Surface texture gritty (similar to white stone)	Coarse surface pitting	

Table 2 Changes from score A to score B after 1 year and after 2 years, and postoperative sensitivity (number of restorations)

A → B	After 1 year		After 2 years	
Material	Ceram·X; *n*=36	Tetric Ceram; *n*=37	Ceram·X; *n*=30	Tetric Ceram; *n*=31
Criteria				
Marginal integrity	3 (8.3%)[a]	4 (10.8%)[b]	4 (13.3%)[b]	4 (12.9%)[a]
Color stability	1 (2.8%)[a]	1 (2.7%)[a]	1 (3.3%)[a]	1 (3.2%)[c]
Recurrent caries	0	0	0	0
Marginal discoloration	2 (5.6%)[a]	1 (2.7%)[c]	3 (10.0%)[a]	2 (6.5%)[c]
Anatomic form	0	1 (2.7%)[a]	1 (3.3%)[c]	2 (6.5%)[a]
Surface texture	0	0	0	0

Postoperative sensitivity					
At baseline		After 1 year		After 2 years	
Ceram·X; *n*=43	Tetric Ceram; *n*=43	Ceram·X; *n*=36	Tetric Ceram; *n*=37	Ceram·X; *n*=30	Tetric Ceram; *n*=31
4 (9.3%)[c]	3 (7.0%)[b]	0	0	0	0

[a]One of the teeth had cusps replaced
[b]Two of the teeth had cusps replaced
[c]None of the teeth had cusps replaced

occlusal forces [2, 3, 23]. In the present study, about one of ten patients—both in the Ceram·X and in the Tetric Ceram-group—showed slight symptoms of postoperative sensitivity at baseline. This fact may be explained by the large size of restorations in the present study. However, after 1 and 2 years, no postoperative sensitivity was found. Rosin et al. and Oberländer et al. also found postoperative sensitivity (6.4 and 3.8%, respectively) after placement of Definite restorations [22, 24]. After 1 year, there were still teeth (about 0.5%) with slight postoperative sensitivities. Lopes et al. found no postoperative sensitivity at baseline and after 1 and 2 years [16]. Low polymerization shrinkage of the restorative materials preventing cuspal fracture or high mechanical properties that prevent a pumping action of dentinal fluid may explain the lack of postoperative sensitivity after 1 and 2 years in the present study.

Color stability was tested using a light-cured sample from the same batch because at the time of the study, only one color (A2) of Ceram·X was available. The sample was stored dark and dry as this type of storage method shows least color changes [15]. However, it should be mentioned that minor changes occur even with this storage method (ΔE<1 after 180 days for composites and ormocers with respect to the curing times used in the present study) [15]. As only one restoration in each group showed slight changes, color stability of both materials was acceptable after 2 years.

Only three restorations with slight marginal discolorations (10.0%) of Ceram·X after 2 years also point to good material properties concerning shrinkage of the composites and bond strength of the adhesive. The ormocer Definite, in combination with the adhesive Etch & Prime 3.0 revealed more marginal discolorations (18.8%) after 1 year [24]. Oberländer et al. found 38% of the restorations with marginal discolorations after treatment with the same ormocer and adhesive after 1 year [22]. Rosin et al. made the adhesive responsible for the marginal discolorations and assumed that bond failures have major negative consequences [24]. All-in-one adhesives were less effective than total etch systems or self-conditioning systems with two-step application in vitro [6, 14, 20]. This may well explain the presence of recurrent caries and the high failure rate (9.6%) observed after 1 year by Oberländer et al. [22].

The Ceram·X restorations with score B concerning marginal integrity (13.3%) had margins where the explorer slightly caught. No crevice was observed in both groups. Excess of composite, insufficient restorations, and little breakouts of composite caused by occlusal discrepancies may be reasons for catching explorers. Lopes et al. found 13.2% of Definite/Etch & Prime 3.0 restorations scored B and 5.2% scored C [16]. Rosin et al. found 5.0% restorations with detectable margins (score B) after evaluation of Definite in combination with Etch & Prime 3.0 after 1 year [24]. One restoration (0.3%) had to be replaced because of a marginal gap (score C). In vitro studies have shown that the all-in-one adhesive Etch & Prime 3.0, was less effective than total etch systems concerning dentin and enamel bond strength [7, 10, 19]. Although a total etch technique was used in the present study, the percentage of marginal discolorations scored B was similar to the one found by Rosin et al. and Lopes et al. [16, 24]. This may be explained by the large restorations with cusps restored partially. Thus, the restorations had higher occlusal loads. Rosin et al. excluded teeth if cusps had to be replaced [24]. However, in contrast to the studies of Rosin et al. and Lopes et al., no restoration was scored C in the present study [16, 24].

No secondary caries was observed. This fact points to a tight seal. In earlier studies, 3.8% of Class II Definite restorations (two of 52; Definite/Etch & Prime 3.0) showed secondary caries after 1 year [22]. Another evaluation

revealed no secondary caries of 38 Definite restorations after 2 years [16].

It is disputable whether simplifying an adhesive system leads to a compromise concerning adhesion to structurally different tissues as enamel and dentin. In fact, significant higher bond strengths for multi-bottle adhesives than for primer-adhesives were determined [14]. However, modern one-bottle dentin adhesives can have similar bond strengths like three-step-systems [20]. Furthermore, the comparison of selective etch technique in combination with self-conditioning systems with the total etch technique leads to different results. Bond strengths to dentin of self-conditioning systems with separate application of primer and adhesive were in the range of those of two- and three-step total etch systems [14, 20, 21]. However, in the present study, no differences between the multi-bottle adhesive Syntac Classic group (selective etch technique) and the primer-adhesive K-0127 group (total etch technique) was observed concerning marginal integrity and marginal discoloration. These criteria depend on the effectiveness of the adhesive system.

Only score A for the surface texture suggest good polishability and low abrasion values. In an earlier study, 4.7% of the Definite restorations showed small fractures after 12 months. One restoration (0.3%) showed a large fracture and had to be replaced [24]. Oberländer et al. [22] found that 13% of the restorations fractured. In the present study, neither Tetric Ceram nor Ceram·X revealed any fractures. This is an indicator for good mechanical and physical properties of both materials.

Conclusions

After 2 years of clinical service, 96.8% of the Ceram·X/K-0127 and 100% of the Tetric Ceram/Syntac Classic restorations were in place and performed clinically well. Statistical significant differences between the groups were observed for none of the criteria. However, it should be noted that conclusions from an interim analysis such as this should be drawn with some reservation. Further clinical evaluations after longer periods are necessary.

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