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SHORT COMMUNICATION

Marginal adaptation of a low-shrinkage silorane-based composite: 1-year randomized clinical trial

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Abstract The aim of the present study was to examine the marginal adaptation of a new low-shrinkage silorane-based composite material (Filtek™ Silorane, 3M-Espe) by comparing it with a methacrylate-based composite material (CeramX™, Dentsply DeTrey). In particular, we wanted to test the hypothesis that reduced polymerization shrinkage would improve the marginal adaptation. Seventy-two patients participated in the study. A total of 158 restorations were placed in 80 premolars and 78 molars. Only Class II restorations were included, and each patient could contribute with more than one tooth. The restorations were scored at baseline and after one year. While statistical comparison of marginal adaptation at follow-up indicated better performance of CeramX™ both occlusally and approximally ($p=0.01$ and $p<0.01$), the low kappa value (32%) reflects the difficulty to assess marginal adaptation clinically. The reduction in polymerization shrinkage demonstrated in the laboratory was not clinically significant in the present study.

Keywords Randomized clinical trial · Resin composite · Class II · Marginal adaptation · Low-shrinkage

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Introduction

In the effort to improve composite materials, particular attention has been paid to polymerization shrinkage. Shrinkage may generate stress, which, in turn, can lead to cusp deflection which increases the risk of stress-induced enamel fracture and postoperative pain [1–3]. Shrinkage may also cause microleakage, marginal staining, and gap formation [4–6]. Gap formation could be an important factor in the development of caries, because it may act as a retention groove [7].

To reduce the problem of polymerization shrinkage, a new low-shrinkage composite material (Filtek™ Silorane, 3M-ESPE, Germany) based on a methacrylate-free resin has been introduced. This material contains traditional filler particles, whereas the conventional resin is replaced by silorane monomers. Silorane monomers are polymerized by a contraction-neutral ring-opening, process which reduces volume shrinkage to 1% compared with 1.7–3.5% in methacrylate-based materials [8]. Silorane-based composites have been thoroughly investigated in the laboratory, and promising results have been obtained regarding biocompatibility and mechanical characteristics including reduced polymerization shrinkage [6, 8–13].

Laboratory findings should, however, be substantiated by clinical investigations. The aim of the present study was therefore to conduct a randomized clinical trial investigating the marginal adaptation of Filtek™ Silorane by comparing it with another, methacrylate-based, composite material (CeramX™). In particular, we wanted to test the hypothesis that reduced polymerization shrinkage would improve the marginal adaptation.

Materials and methods

Patients

Seventy-two patients, who required a total of 158 restorations, participated in the study. Most of the patients were recruited from the Treatment Planning Clinic at the School of Dentistry, Faculty of Health Sciences, Aarhus University, Arhus, Denmark. Others were employees at the School of Dentistry or friends and family members of those participants who were recruited from the School of Dentistry.

Only patients registered for Class II restorations of premolars and molars were included in the study, and each patient could contribute with more than one tooth. Indication for treatment included primary caries, caries associated with the restoration, fracture, and cosmetic demands. Only vital teeth without preoperative symptoms were included in the study.

Power calculation for the present study is based on results from a previous study that compared the clinical behavior of sandwich restorations with resin-based composite restorations. In that study, the incidence of marginal defects after 1 year was 80% [14]. Power calculations showed that in order to detect a 30% reduction in defective margins, the minimum number of teeth in each group should be 36 (α 0.05, β 0.20). We decided to include 80 teeth in each group in order to compensate for patient loss at follow-up.

After patients had given their informed consent, the teeth were randomized into two treatment groups (Filtek™ Silorane and CeramX™) using computer-generated random numbers. The randomization used patients as blocks and was balanced within patient, or nearly balanced, if an odd number of teeth were included. The study was approved by the Central Denmark Region Committees on Biomedical Research Ethics # 20070064 and registered at the Danish Data Protection Agency # 2007-41-0722 and ClinicalTrials.gov # NCT00738647. It was reported according to the recommendations described in the CONSORT statement [15, 16].

Clinical procedures

All the restorations were placed by the same dentist (M.S.). Rubber dam (non-latex dental dam isodam, Sigma Dental Systems, Germany) was applied, and if necessary, interguards (InterGuard, Ultradent Products, South Jordan) were used. The cavities were excavated with water-cooled diamond burs (Horico, Pfingst, USA) and steel burs (Meizinger, Hager & Meisinger, Germany) without bevelling the margins. Cavity preparations were made as small as possible, ensuring removal of carious tissue. Contoured titanium matrices (KerrHawe, Switzerland) and wooden wedges were used. Very deep cavities were lined with calcium hydroxide paste (Alkaliner, 3M-ESPE, USA). Two different adhesive systems designed for each of the materials were used. The adhesive system for Filtek™ Silorane (Silorane System Adhesive, 3M-ESPE) was a two-step self-etch primer and bond, whereas the adhesive system for CeramXTM (XenoIII, Dentsply DeTrey, Denmark) was a single-step self-etch primer and bond. Adhesive procedures were made according to the recommendations of the manufactures. The composite material was applied in oblique incremental layers not exceeding 2 mm. When necessary, an instrument for approximal contouring (Contact Pro, Zacho-Rønvig Dental, Denmark) was used, and each layer was light-cured for 40 s with LE-Demetron 1. Restorations were adjusted to occlusion and articulation and finished with a diamond bur (Raptor, Zacho-Rønvig Dental), and round-, pear-, or flame-shaped diamond burs (Intensiv, Intensiv SA, Switzerland). Final polishing was done using rubber points (Identoflex, KerrHawe), and approximally the cavities were polished with strips (Sof-Lex, 3M-ESPE, USA).

Assessment

The study was double-blinded as neither the patients nor the evaluator was aware of the treatment. It was impossible to blind the operating dentist (M.S.) because she had to follow the different treatment procedures for the two materials.

A set of explorers (Deppeler, Switzerland) specifically designed for clinical evaluation of marginal adaptation was used [17]. This set included explorers with defined tip diameters to categorize marginal gaps. Marginal adaptation had four different scores: (0) excellent, (1) gap detectable with a 150 μm explorer, (2) gap detectable with a 250 μm explorer, and (3) gap detectable with a ball-ended 0.5 mm explorer (Deppeler).

Restorations were scored by one experienced dentist/evaluator (L-L.K) at baseline (2–3 weeks after placement) and after 1 year. Double examination of restorations was performed both at baseline and follow-up by (L-L.K) to assess the intra-observer reliability. At follow-up, observed agreement was 55% for marginal adaptation; 42 (55%) of 77 scores agreed, 32% differed one score, and 13% differed two scores. Unweighted kappa values for marginal adaptation were 56% at baseline and 32% at follow-up.

Statistical analysis

Data were analyzed using STATA10. In each treatment group, continuous baseline characteristics were summarized by a mean and a standard deviation (SD), and frequency tables were obtained for categorical variables. Approximal scores for marginal adaptation were registered at four sites (approximal/mesial, gingival/mesial, approximal/distal, and gingival/distal). In the analysis, the mean of the four approximal scores was computed for each restoration, and these scores were then categorized into four groups using the cut points: 0.5, 1.5, and

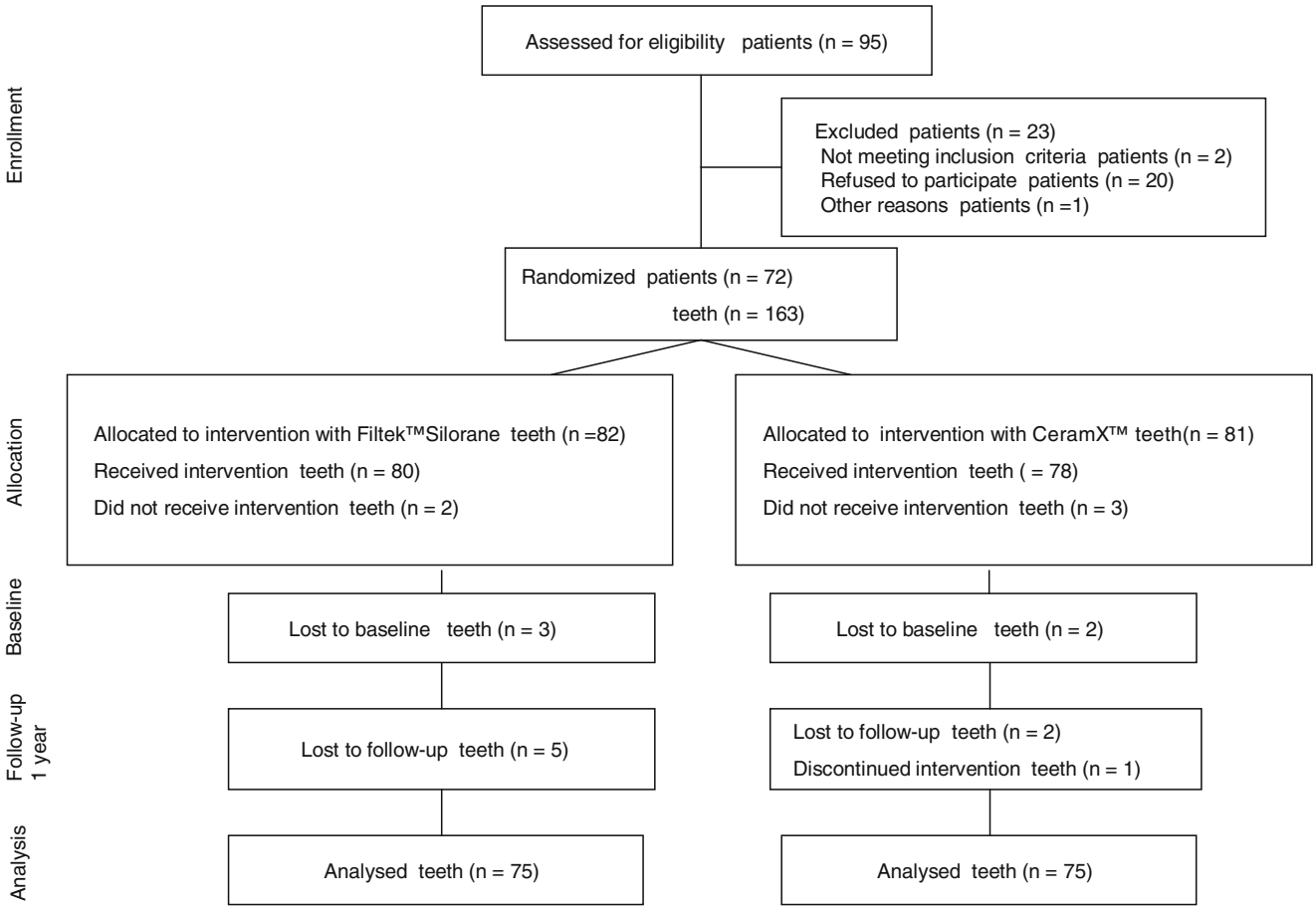

Fig. 1 Flowchart of patients and number of restorations through each stage of the study

2.5. Cross-tables were used to describe changes in marginal adaptation from baseline to follow-up. Marginal adaptation was compared for the two materials using ordinal logistic regression, adjusting for the effect of clustering of teeth within patients. Additional adjustments were made for restoration size and baseline score. The treatment difference was expressed as an odds ratio with 95% confidence intervals (CI), which describes the odds of a higher score for CeramX™ relative to the odds for a higher score of Filtek™ Silorane. An odds ratio smaller than one therefore indicated that CeramX™ performed better than Filtek™ Silorane and an odds ratio larger than one indicated that Filtek™ Silorane performed better than CeramX™. A p value of 0.05 was selected as the level of statistical significance.

Results and discussion

Patients were recruited from August 2007 to October 2007. Randomization and treatment of the patients took place from October 2007 to March 2008. Baseline evaluation was made 2–3 weeks after treatment. Patients were recalled for follow-up from November 2008 to March 2009 with an average observation time of 398 days (SD: 29 days). The flow of participants and number of restorations through each stage of the study are shown in Fig. 1. One restoration was excluded from follow-up because the tooth had endodontic treatment and no longer met the inclusion criteria. Drop-out in this study was 5%. Baseline characteristics of the study population are given in Table 1. Patients received an average number of 2.2 restorations (min. 1, max 9).

Table 1 Baseline characteristics of patients and restorations

	Filtek™ Silorane	CeramX™
Mean age ± SD	45±12	46±12
Females	68	62
Males	12	16
Restorations	80	78
Premolars	41	39
Molars	39	39
Mean number of surfaces per restoration ± SD	2.4±0.6	2.7±0.7

Table 2 Distribution of restorations according to score for marginal adaptation occlusally (a) and approximally (b) at baseline and at follow-up

Baseline	Follow-up									
	Filtek™ Silorane					CeramX™				
	Score 0	Score 1	Score 2	Score 3	Total	Score 0	Score 1	Score 2	Score 3	Total
(a)										
Score 0	**0**	1	1	8	10	**0**	1	7	4	12
Score 1	0	**0**	2	5	7	0	**0**	1	6	7
Score 2	0	0	**4**	27	31	0	1	**11**	24	36
Score 3	0	0	4	**21**	25	0	0	4	**14**	18
Total	0	1	11	61	73	0	2	23	48	73
(b)										
Score 0	**0**	0	2	2	4	**1**	3	6	0	10
Score 1	0	**4**	15	6	25	1	**3**	15	1	20
Score 2	0	1	**22**	12	35	1	7	**20**	7	35
Score 3	0	0	1	**4**	5	0	0	4	**2**	6
Total	0	5	40	24	69	3	13	45	10	71

Bold figures indicate unchanged scores from baseline to follow-up

At baseline, no statistically significant differences between the two materials were found in marginal adaptation either occlusally (OR 0.75; 95% CI, 0.42–1.34; p=0.33) or approximally (OR 0.89; 95% CI, 0.51–1.55; p=0.67).

During the follow-up period, higher occlusal marginal adaptation scores (indicating an inferior marginal adaptation) were obtained for the Filtek™ Silorane (60%, 44/73) than for the CeramX™ (59%, 43/73) restorations (Table 2a). Corresponding figures for approximal marginal adaptation were 54% (37/69) for the Filtek™ Silorane restorations and 45% (32/71) for the CeramX™ restorations (Table 2b). Some of the restorations scored lower at follow-up than at baseline, probably due to measurement error.

At follow-up, the marginal adaptation of CeramX™ outperformed Filtek™ Silorane both occlusally and approximally (Table 3).

It is notable that adjustment for clustering produced only minor changes in the precision of the estimates. Further adjustment for size of restoration and baseline score also disclosed minor changes in the estimates.

Bias was minimized by randomization, by blinding of the dentist evaluating the restorations, and by having only one examiner evaluate all the restorations. An intra-observer agreement at follow-up on the scoring of marginal adaptation of 55% shows that marginal adaptation is difficult to assess clinically. This is also reflected in the finding that some restorations scored lower at follow-up than at baseline. This may be explained partly by difficulties in distinguishing between gaps, wear, overfilling/underfilling and partly by difficulties in discriminating between very small discrepancies.

The external validity of this study was influenced by the facts that it was conducted at a dental school and that the same dentist placed all the restorations. One could argue that neither the patients nor the dentist were representative of their respective populations. The outcome of this study was dependent not just on the patients and materials used. The outcome may also have been affected by other factors like the skills of the operator, isolation method, type of light source, and finishing instruments. The results of the present study therefore cannot be directly related to everyday dental practice.

Our findings indicate that other factors than polymerization shrinkage of the composite material are important for the

Table 3 Odds ratios for marginal adaptation of CeramX™ compared with Filtek™ Silorane at follow-up

	Unadjusted			Adjusted for clustering			Adjusted for clustering and size of the restoration			Adjusted for clustering, size of the restoration, and marginal adaptation at baseline		
	OR	95% CI	p Value	OR	95% CI	p Value	OR	95% CI	p Value	OR	95% CI	p Value
Occlusal	0.38	0.18–0.84	0.02	0.38	0.18–0.81	0.01	0.34	0.15–0.75	0.01	0.34	0.15–0.78	0.01
Approximal	0.29	0.14–0.59	0.01	0.29	0.17–0.52	<0.01	0.33	0.18–0.60	<0.01	0.29	0.15–0.59	<0.01

marginal adaptation. In this study, two different adhesives, designed for each material, were used. Therefore, our results are based on a combined treatment with adhesive and composite material, both of which may influence on the marginal adaptation.

An observation period of 3–5 years has been recommended for the evaluation of all aspects of clinical performance of composite restorations [17, 18]. As the focus of this study was on polymerization shrinkage, a shorter observation period was chosen. Ideally, the marginal adaptation as a consequence of polymerization shrinkage should be assessed at baseline, because polymerization shrinkage takes place during placement of the restoration. After placement of the restoration, other clinical factors like wear and degradation may change the marginal adaptation. We decided to report both results from baseline and from 1 year follow-up, because excess composite material left behind after the polishing procedures hampered the assessment at baseline.

Filtek™ Silorane and CeramX™ have shrinkage values of 1% and 2.6%, respectively [8, 19]. Although this difference is distinct in the laboratory, it was difficult to show the effect in the clinic, where so many factors influence the final restoration. The incremental layering technique could reduce the effect of polymerization shrinkage because this technique results in a general decrease of the polymerization shrinkage [20]. A reduction in polymerization shrinkage of a few percent may therefore be difficult to demonstrate in the clinic.

Conclusion

In this study, the reduction in polymerization shrinkage demonstrated in the laboratory was not clinically significant.

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Conflicts of interest The authors declare that they have no conflict of interest.

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