Clin Oral Invest (2015) 19:245–251
DOI 10.1007/s00784-014-1238-x

ORIGINAL ARTICLE

Five-year evaluation of a low-shrinkage Silorane resin composite material: A randomized clinical trial

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Received: 15 January 2014 / Accepted: 24 March 2014 / Published online: 1 April 2014

Abstract
Objectives The aim of the present study was to investigate the clinical performance of a low-shrinkage silorane-based composite material (Filtek™ Silorane, 3 M-Espe) by comparing it with a methacrylate-based composite material (Ceram•X™, Dentsply DeTrey).
Material and methods A number of 72patients (158 restorations) participated in the study. After 5 years, a total of 107 restorations (52 Filtek™ Silorane, 55 Ceram•X™) in 48 patients were evaluated. Only class II restorations were included. All the restorations were placed by the same dentist, and the restorations were scored by one experienced dentist/evaluator. Materials were applied following the manufacturer's instructions. The primary outcome was marginal adaptation. Secondary outcomes were: marginal discoloration, approximal contact, anatomic form, fracture, secondary caries, and hypersensitivity.
Results After 5 years, no statistically significant differences between the two materials were found in marginal adaptation either occlusally (p=0.96) or approximally (p=0.62). No statistically significant differences were found between the two materials in terms of approximal contact, anatomic form, fractures, or discoloration. Secondary caries was found in two teeth (Filtek™ Silorane). One tooth showed hypersensitivity (Ceram•X™).
Conclusion Restorations of both materials were clinically acceptable after 5 years. This study did not find any advantage of the silorane-based composite over the methacrylate-based composite, which indicates that the low-shrinkage of Filtek™ Silorane may not be a determinant factor for clinical success in class II cavities.
Clinical relevance This paper is the first to evaluate the 5-year clinical performance of a low-shrinkage composite material.

Keywords Randomized clinical trial · Resin-based composite · Class II · Silorane · Low-shrinkage

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Introduction

Resin-based composite restorations have improved considerably since they were introduced in the 1960s. Composites specifically designed for restoration of posterior teeth have been widely used during the last three to four decades, and the number of composite restorations placed per year has increased dramatically during the last 10–15 years [1, 2].

The most frequently reported reasons for replacement of composite restorations are secondary caries and fractures [3–11]. To reduce the risk of secondary caries, the development of new materials has mainly focused on the improvement of the marginal adaptation in order to avoid gap formation between the tooth and the restoration.

To reduce the problem of polymerization shrinkage and gap formation, a low-shrinkage composite material (Filtek™ Silorane, 3 M-ESPE, Germany) has been introduced. This material is based on silorane monomers with traditional filler particles. Silorane monomers polymerize by a contraction-neutral ring-opening process which reduces volume shrinkage to 1 % compared with 1.7 to 3.5 % in methacrylate-based materials [12–14]. 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 [12, 15–20].

The aim of the present study was to conduct a randomized clinical trial investigating the clinical performance of Filtek™ Silorane by comparing it with a methacrylate-based, composite material (Ceram•X™, Dentsply DeTrey, Germany).

The null hypothesis was that there would be no statistically significant differences in clinical performance between the two restorative systems after 5 years.

Materials and methods

Patients

A number of 72 patients, providing 158 restorations at baseline, participated in the study. After 5 years [1,780 days, standard deviation (SD) 45 days, min. 1,675 days, max. 1,875 days], 107 (52 Filtek™ Silorane, 55 Ceram•X™) restorations in 48 patients were evaluated. The average age of the patients was 50.5 years (SD 12.3 years, min. 22.9 years, max. 72.8 years).

Most of the patients were recruited from the Treatment Planning Clinic at the Department of Dentistry, Health, Aarhus University, Aarhus, Denmark. Others were employees at the Department of Dentistry or friends and family members of those participants who were recruited from the Department 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 a restoration, fracture, and cosmetic demands. Only vital teeth without preoperative symptoms were included in the study.

In a previous study, the incidence of marginal defects after 1 year was 80 % [21]. 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). As we did not know the rate of dropout, 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, their teeth were randomized into two treatment groups (Filtek™ Silorane and Ceram•X™) using computer-generated random numbers. The randomization used patients as blocks (based on the number of teeth to be restored) and was balanced within patient, or nearly balanced, if an odd number of teeth was included. If, for example, a patient was assigned for four restorations, the computer-based randomization, would secure that half of the restorations were made with each material. For an odd number of restorations, e.g. five, three of them would be restored with one material and two with the other material. 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 Clinical Trials.gov # NCT00738647. It was reported according to the recommendations described in the CONSORT Statement [22, 23].

Clinical procedures

All the restorations were placed by the same dentist (MS). Local anesthetic was offered before treatment. 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, 3 M-ESPE, USA).

Bonding

Two different adhesive systems designed for each of the materials were used. The adhesive system for Filtek™ Silorane (Silorane System Adhesive, 3 M-ESPE) was a two-step self-etch primer and bond, whereas the adhesive system for Ceram•X (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 adhesive procedures for Filtek™ Silorane were as follows: The cavity was gently air-dried with two to three brief bursts. Before use, the self-etch primer bottle was shaken to make the liquid less viscous. The primer was massaged over the entire surface of the cavity with a microbrush for 15 s, and then gently air-dried until the primer was spread to an even film. The primer was light-cured for 10 s with LE-Demetron1 (KerrHawe) that has a constant light energy output of 1,100 mW/cm^{-2}. The adhesive bond bottle was also shaken before use. The bond was applied to the entire cavity with a microbrush, after which a gentle stream of air was applied until the bond was evenly spread. The bond was light-cured for 10 s with LE-Demetron1.

Adhesive procedures for Ceram•X™ were as follows: Liquids were mixed together with a microbrush for at least 5 s. The cavity was air-dried, and the mixture of etchant, primer, and adhesive was applied generously onto the cavity surface for at least 20 s with a microbrush. The adhesive was spread uniformly applying a gentle stream of air until it stopped flowing and then light-cured with LE-Demetron1 for 10 s.

Insertion

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.

Finishing

Restorations were adjusted to occlusion and articulation and finished with a diamond bur (Raptor, Zacho-Rønvig Dental, Denmark) 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, 3 M-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 (MS) because she had to follow the different treatment procedures for the two materials.

The primary outcome was marginal adaptation, and the secondary outcomes were: marginal discoloration, approximal contact, anatomic form, fracture, secondary caries, and hypersensitivity. A set of hand instruments (Deppeler, Switzerland) specifically designed for clinical evaluation of dental restorations was used. These instruments included explorers with defined tip thicknesses to categorize marginal gaps, and metal blades with defined thicknesses for evaluation of approximal contact. 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). Approximal contact was assessed according to the size of the approximal space: *0* a dental floss (Colgate Total, Colgate-Palmolive, Denmark) could pass, *1* blade 50 μm could pass, and *2* blade 100 μm could pass. Secondary caries was scored as *0* no caries, *1* inactive caries, *2* active caries without cavity, and *3* active caries with cavity. Fracture and discoloration were diagnosed by visual inspection and scored on a binary scale (yes/no). For pulp vitality test, the electrical pulp tester (Pulppen, B-1000, Denmark) was used. The tooth was lubricated with water to facilitate the conduction of electrical impulses, and the probe tip was placed on an intact surface within the incisal two thirds of the crown. A "tingling" sensation felt by the patient, at any level of the scale, was considered to be a positive response. Finally, the examiner assessed treatment need (need for repair or replacement of the restoration).

Restorations were scored by one experienced dentist/evaluator (ID) after 5 years. Double examination of restorations was performed to assess the intraobserver reliability. At 5-year follow-up, observed agreement ranged from 69.2 % for marginal adaptation to 100 % for treatment need. Weighted kappa were 74 % for approximal contact, 100 % for anatomic form, 64 % for discoloration, 84 % for secondary caries, and 41 % marginal adaptation.

Statistical analysis

Data were entered twice in Epidata to correct typing errors, and then transferred to STATA IC 12 for analysis.

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, discoloration and caries 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 2.5.

Data for approximal contacts were dichotomized between scores 0 and 1, because only score 2 was considered clinically unacceptable.

Marginal adaptation, approximal contact, and discoloration were compared for the two materials using logistic regression analysis with adjustment for the effect of clustering of teeth within patients. For marginal adaptation, additional adjustments were made for restoration size. Stata release 12 was used for all statistical calculations. A p value of 0.05 was selected as the level of statistical significance.

Results

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 5-year follow-up from September 2012 to February 2013 with an average observation time of 1,780 days (SD 45 days). The flow of participants and number of restorations through each stage of the study are shown in Fig. 1. A total of 32 % of the restorations were lost to 5-year follow-up. Characteristics of the restorations evaluated after 5 years are given in Table 1. Patients examined after 5 years had, in average, 2.2 restorations (min. 1, max. 9) included in the study. The number of restorations made with Ceram•X™ were slightly bigger than the number of restorations made with Filtek™ Silorane (Table 1). As an indicator of the caries risk for each tooth, gingival inflammation was recorded both

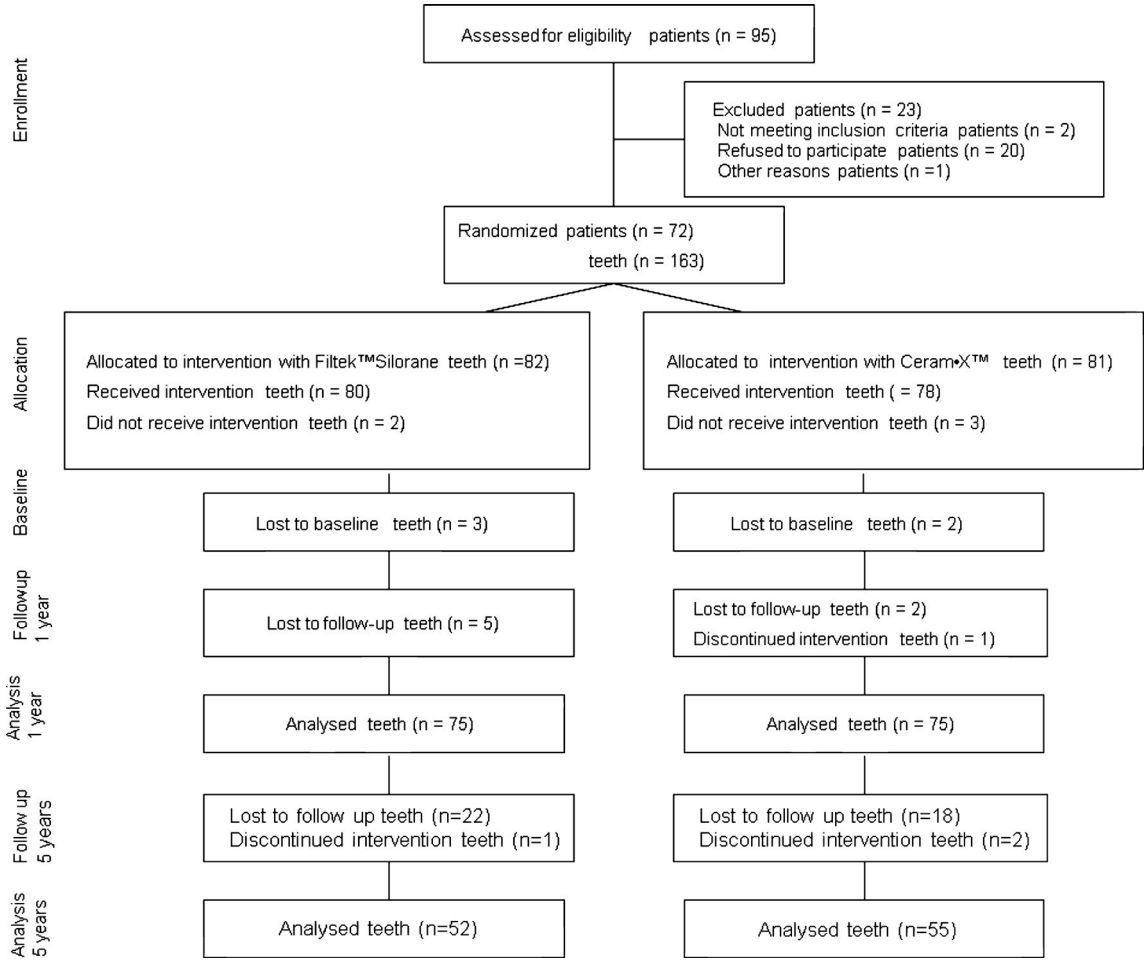

Fig. 1 Flowchart: Patients and number of restorations through each stage of the study

at baseline and follow-up with no significant difference between the two groups.

At 5-year follow-up, no statistically significant differences between the two materials were found in marginal adaptation either occlusally ($p=0.96$) or approximally ($p=0.62$) (Tables 2 and 3). Adjustment for size of restoration produced only minor changes in the precision of the estimates occlusally ($p=0.78$) and approximally ($p=0.55$)

In general, higher scores for marginal gaps were found for occlusal surfaces than for approximal surfaces (Tables 2 and 3).

No statistically significant differences were found between the two materials in terms of approximal contact ($p=0.22$), anatomic form ($p=0.23$), fractures ($p=0.76$), or discoloration ($p=0.89$).

Secondary caries was found in two teeth (Filtek™ Silorane). Both of the lesions were active, but only one of them had a cavity. Inactive caries was found in two teeth (Filtek™ Silorane).

Table 1 Characteristics of restorations after 5 years

	Filtek™ Silorane	Ceram•X™
Number of restorations	52	55
Restorations in females	43	43
Restorations in males	9	12
Premolars	29	30
Molars	23	25
Mean number of surfaces per restoration	2.4	2.7

Table 2 Marginal adaptation for occlusal surfaces of Filtek™ Silorane and Ceram•X™ at 5-year follow-up

	Filtek™ Silorane	Ceram•X™	Total
Excellent	0	0	0
Gap>150 μm	1	0	1
Gap>250 μm	2	2	4
Ball-ended	48	50	98
Not recorded	1	3	4
Total	52	55	107

Table 3 Marginal adaptation for approximal surfaces of Filtek™ Silorane and Ceram•X™ at 5-year follow-up

	Filtek™ Silorane	Ceram•X™	Total
Excellent	0	2	2
Gap >150 μm	3	6	9
Gap >250 μm	17	17	34
Ball-ended	28	26	54
Not recorded	4	4	8
Total	52	55	107

A total of 99 teeth (49 Filtek™ Silorane, 50 Ceram•X™) were tested for vitality. They were all vital. One tooth showed hypersensitivity (Ceram•X™).

At 5-year follow-up, out of 107 restorations, six were repaired (four Filtek™ Silorane, two Ceram•X™), and five were replaced (3 Filtek™ Silorane, 2 Ceram•X™). Characteristics and reasons for repairs and replacements are shown in Table 4. All replacements were caused by cusp fractures (all in premolars). Five repairs/replacements were placed in molars, six in premolars. Six of the repairs/replacements were placed in the upper jaw, five in the lower jaw. The average size of the restorations in the repair/replacement group was 2.5 surfaces, whereas an average of 2.6 surfaces was found in the whole group. The average age of the patients in the repair/replacement group was 49.3 years, compared with 50.5 years in the whole group.

Discussion

In this study, both materials were clinically acceptable after 5 years.

Bias was minimized by randomization, and by blinding of the dentist evaluating the restorations. Dropout in this study was 35 % patients (32 % restorations). According to power calculations at the beginning of the study, the number of teeth in each group should be 36 (α 0.05, β 0.20). As the randomization used patients as blocks and was balanced within patient, the dropout affected both materials equally. There is no reason to believe that the restorations lost to follow up differed significantly from the rest of the restorations, as the reasons for patient dropout was mainly disease in the family or relocation to other cities. Patients had, in average, 2.2 restorations (min. 1, max. 9) included in the study. It can be advocated to include a maximum of two restorations per patient to improve the external validity. As the randomization process in this study ensured that the assignment of material was balanced within patient, we agreed to include more restorations per patient.

The most predominant reason for repairs and replacements was fractures. Most of them were cusp fractures, which may be a late result of stress induced by the polymerization shrinkage in combination with fragile tooth substance following the preparation. The fractures may have been prevented if the preparations had been made with cuspal coverage.

In general, higher scores for marginal gaps were found at occlusal surfaces than for approximal surfaces, indicating that heavy occlusal load affects the marginal adaptation negatively. However, occlusal surfaces are easy to clean and the risk of secondary caries is only minor, wherefore these defects did not demand repair or replacement of the restorations.

The present study made use of hand instruments specifically designed for early clinical evaluation of the marginal adaptation of dental restorations. This set of instruments has previously been described in a paper on recommendations for conducting controlled clinical studies of dental restorative materials [24, 25]. Although this set of instruments was used, the relatively low kappa values (41 %) reflect that it is difficult

Table 4 Data for repairs and replacements at 5-year follow-up

Treatment	Reason for treatment	Material	Tooth number	Number of surfaces per restoration	Gender	Age of the patient
Repair	Secondary caries	Filtek™ Silorane	37	2	Female	53
Repair	Food impaction	Ceram•X™	36	2	Male	34
Repair	Wear	Filtek™ Silorane	36	3	Female	58
Repair	Wear	Filtek™ Silorane	24	2	Male	62
Repair	Fracture	Filtek™ Silorane	16	3	Female	51
Repair	Fracture	Ceram•X™	36	2	Male	23
Replacement	Cusp fracture	Filtek™ Silorane	35	2	Female	67
Replacement	Cusp fracture	Filtek™ Silorane	25	2	Male	62
Replacement	Cusp fracture	Filtek™ Silorane	15	3	Female	40
Replacement	Cusp fracture	Ceram•X™	25	3	Female	52
Replacement	Cusp fracture	Ceram•X™	25	3	Female	40

to assess the marginal adaptation clinically. One evaluator examined all the restorations, and therefore the interobserver reliability is unknown for this study.

Our findings indicate that other factors than polymerization shrinkage are important for the marginal adaptation. First, the findings might be affected by the use of two different adhesive systems and not solely by the material characteristics of the composite material. However, previous studies have found this to be of minor importance [26], [27]. Second, other material characteristics like the flexural modulus may affect the marginal quality of the restoration [28].Volume shrinkage is only one aspect influencing the marginal adaptation, but more important is shrinkage stress, which is reflected by the viscoelastic properties of the material. Reduced polymerization shrinkage can lower the internal stresses in the material, but other factors like the flexural modulus may counteract this and induce shrinkage stress, which in turn may hamper the marginal quality.

Filtek™ Silorane and Ceram•X™ have shrinkage values of 1 and 2.6 %, respectively [12, 29]. Such a minor difference may be difficult to demonstrate in the clinic although it is distinct in the laboratory. In addition, the incremental layering technique could mask the effect of polymerization shrinkage because this technique results in a general decrease of the polymerization shrinkage [24]. A reduction in polymerization shrinkage of a few percent may therefore not be of any particular clinical importance.

This study evaluated the clinical performance of a low-shrinkage composite compared with a hybrid resin composite. At the 5-year follow-up, both materials showed good durability and clinical performance. This indicates that other important variables than polymerization shrinkage determine the durability of a composite restoration. These findings are in accordance with previous studies that evaluated the clinical performance of Filtek™ Silorane after 1 year [30, 31].

Another study [32] found that placement in molars, in cavities with high number of surfaces, and in lower jaw teeth were all variables that affected the final result of the restorations negatively. These findings could not be verified in our study, showing five repairs/replacements in molars and six in premolars. Besides, the repairs/replacements were distributed equally among upper and lower jaw, and the restorations in the repair/replacement group did not include more surfaces than the restorations in the whole group (Table 4).

Conclusion

The null hypothesis, that there would be no statistically significant differences in clinical performance for the two materials was accepted. Restorations of both materials were clinically acceptable after 5 years. This study did not find any advantage of the silorane-based composite over the methacrylate-based composite, which indicates that the low shrinkage of Filtek™ Silorane may not be a determinant factor for clinical success in class II cavities after 5 years.

Acknowledgments This study was supported by 3 M-Espe and Dentsply who both provided the restorative materials. We owe our thanks to 3 M-Espe for donating gifts of appreciation to the patients. The study was supported by The Research Foundation of Aarhus University.

Conflict of Interest The funders had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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