

ABSTRACT**SEM-study of a low-shrinkage composite**

Introduction – Shrinkage during polymerization of resin-based composite materials may lead to gap formation and hamper the marginal adaptation of the restorations. To reduce the problem of polymerization shrinkage, a new composite material (Filtek™ Silorane, 3M-ES-PE, Germany), with a reduced shrinkage, has been marketed.

Objective – To investigate whether reduced polymerization shrinkage improves the marginal adaptation of composite restorations.

Material and methods – A total of 156 scanning electron microscopy (SEM) pictures (78 baseline, 78 follow-up) of the occlusal part of Class II restorations in molars were included in the study. The restorations originated from a randomised clinical trial, conducted in 2007–2009 which compared the clinical performance of a low-shrinkage composite material (Filtek™ Silorane) with that of a methacrylate-based composite material (Ceram•X™mono). Epon-casts of the restorations were used for SEM pictures at $\times 16$ magnification. Pictures from baseline and follow-up (398 days, SD 29 days) were randomised and the examiner was blinded to the material and the age of the restoration. Stereological measurements were used to calculate the length and the width of the marginal discrepancies.

Results – No statistically significant difference in gap formation and chipping was found between the two materials.

Conclusion – The results of the present study do not support the hypothesis that reduced polymerization shrinkage improves the marginal adaptation.



Marginal adaptation of a low-shrinkage silorane-based composite: A SEM-analysis

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Of particular interest in the evaluation of composite filling materials is the marginal adaptation of the restorations.

Marginal adaptation may be influenced by polymerization shrinkage because contraction stress may cause de-bonding at the tooth-composite interface with an increased risk of gap formation, micro-leakage, marginal staining, deformation of the tooth cusps and postoperative pain (1-6). Gap formation could be an important contributor to the development of secondary caries and may affect the pulpal health of a tooth (7).

In an attempt to solve problems related to polymerization shrinkage, a low-shrinkage composite material (Filtek™ Silorane) based on a new resin chemistry with silorane monomers has been developed (8).

The high quality of modern composite materials has made it more difficult to see changes in the quality of restoration margins, which, in turn, has increased the need for more sensitive methods to assess the early changes of the marginal adaptation (9). Scanning electron microscopy (SEM) is a method that can be used for closer examination of the restoration margins

KEY WORDS

Composite resins;
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because of its ability to magnify and reveal details. Clinical trials of composite restorations therefore often deploy SEM (10-13). Numerous methods have been used to evaluate the marginal adaptation on SEM-pictures. Often the degree of marginal breakdown/gaps is described, based on the observer's subjective

judgement, such as percentages of the total marginal length (12-15). The present study deployed stereological techniques to assess the marginal adaptation quantitatively.

Our hypothesis was that reduced polymerization shrinkage improves the marginal adaptation of composite restorations. The aim was therefore to compare the marginal adaptation of Filtek™ Silorane (shrinkage 1 %) with Ceram•X™ mono (shrinkage 2.6 %) (8,16).

Materials and Methods

A total of 156 SEM pictures (78 baseline pictures, 78 follow-up pictures) of the occlusal part of Class II restorations in molars were included in the study. The restorations originated from a randomized clinical trial, conducted in 2007-2009 which investigated the clinical performance of Filtek™ Silorane (3M-ESPE, Germany) compared with Ceram•X™ mono (Dentsply DeTrey, Germany) (17). A total 72 patients (158 restorations placed in premolars and molars) were included in the randomised clinical trial. All restorations in molars (39 Filtek™ Silorane, 39 Ceram•X™ mono) were examined in this study (Fig. 1). Most of the restorations were placed in females (92 % Filtek™ Silorane, 72 % Ceram•X™ mono). The average age of patients treated with Filtek™ Silorane was 43 years and 45 years for patients treated with Ceram•X™ mono. Both studies took place at the School of Dentistry, the Faculty of Health Sciences, Aarhus University.

Clinical procedures were made according to the recommendations of the manufacturers. A different adhesive system was designed for each of the materials, namely 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 Ceram•X™ mono (XenolII, Dentsply DeTrey, Denmark) was a single-step self-etch primer and bond. Impressions of the restorations (Extrude, polyvinyl siloxane, heavy and medium body; KerrHawe SA, Switzerland) from both baseline and 1-year follow-up were used for producing Epon casts (TAAB Laboratories Equipment Ltd, England). Each cast was treated ultrasonically, mounted on a stub, and coated with a thin layer of carbon and 15-nm platinum. After coating, the casts were stored in an Exicator with Silica gel "C" orange until SEM (MaXim 2040 EnVac SEM, CamScan, UK) at 16x magnification.

Gap length and width were chosen as primary criterions because they were the most clinically relevant results of reduced polymerization shrinkage. Secondary criterions were excess composite material (length) and chipping (length and width).

The number of restorations included in this study was based on power-calculations described in the randomized clinical trial (17). No separate power-calculations were made for this investigation.

Calibration, randomization, and blinding

Before assessment of the pictures, the examiner (M.S.) was trained and calibrated in the process of scoring SEM pictures by

Flow-chart

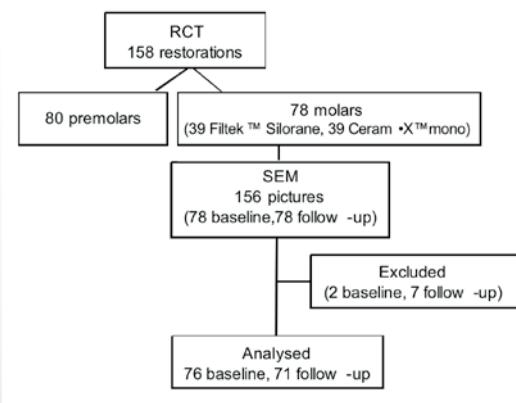


Fig. 1. Outline of restorations from the RCT-study to this study.

Fig. 1. Oversigt af fyldninger fra RCT-studiet til dette studie.

Marginal characteristics

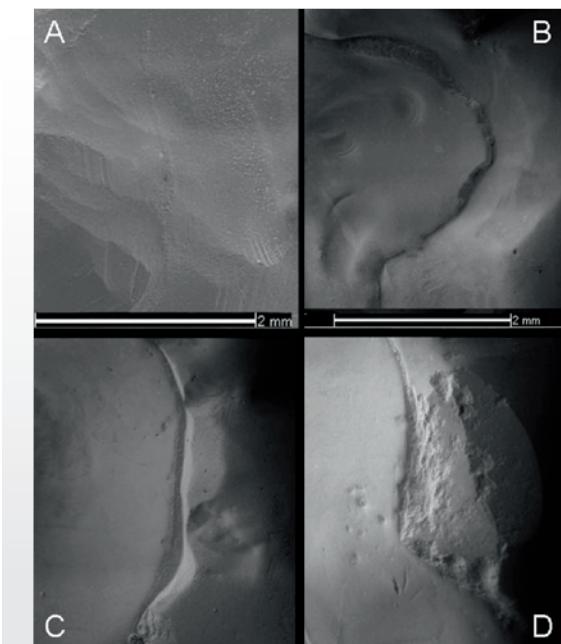


Fig. 2. Smooth margin (A), excess composite material (B), gap (C), chipping (D) (original magnification 16 x).

Fig. 2. Glat fyldningskant (A), overskud (B), spalte (C), chipping (D) (original forstørrelse 16 x).

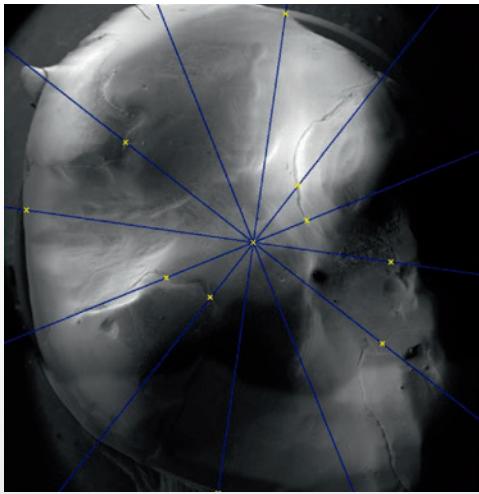
2D isotropic test lines

Fig. 3. 2D isotropic test lines, superimposed on a SEM-picture, to calculate the width of the discrepancies (original magnification 16 x).

Fig. 3. 2D isotrope test linjer, lagt oven på et SEM-billede for at beregne bredden af kantdefekterne (original forstørrelse 16 x).

evaluating the same set of SEM pictures with different methods and at different time intervals. A set of guidelines was agreed upon to assist the examiner in differentiating between the scores.

SEM pictures from baseline and 1-year follow-up were randomized using a random-number generator on a computer. The examiner was blinded to the material and the age of the restoration. Tooth location and the extent of the restoration (surfaces included) were known to the examiner.

Assessment

A 2D Nucleator (18) was used for stereologic measurements calibrated to the magnification of the pictures. The following characteristics were assessed:

- Smooth margin (Fig. 2A)
- Excess composite material, measured in multiples of 10 µm (Fig. 2B)
- Gap, measured in multiples of 10 µm (Fig. 2C)
- Chipping, measured in multiples of 10 µm (Fig. 2D)

To calculate the average width of gaps and chipping 12 2D isotropic test lines were superimposed on each picture and the width of the discrepancy was measured (Fig. 3). Each measurement was made orthogonally to the 2D discrepancy.

To calculate the length of the discrepancies (excess, gap, and chipping) the examiners used 16 parallel horizontal lines and 16 parallel vertical lines with a random start (Fig. 4). At

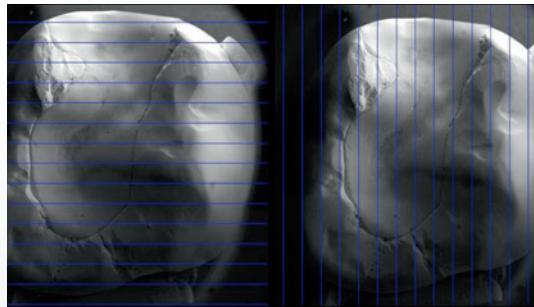
Parallel lines

Fig. 4. Horizontal and vertical test lines, superimposed on a SEM-picture, to calculate the length of the discrepancies (original magnification 16 x).

Fig. 4. Horizontale og vertikale testlinjer, lagt ovenpå et SEM-billede for at beregne længden af kantdefekterne (original forstørrelse 16x).

each point where the lines were crossing the margin of the restoration, a score was made, and the number of each score for excess, gap, and chipping was calculated. The length of the discrepancies (B) was calculated by the formula:

$$B = \frac{\pi}{2} \cdot D \cdot \sum L$$

where D is the distance between the test lines and L is the frequency of the intersection between test lines and discrepancy (excess, gap, or chipping).

Statistical analysis

Data were entered twice in Epidata to correct typing errors, and then transferred to STATA10 for analyses.

Based on the stereological measurements the average width of gap and chipping was calculated for each restoration. Pictures with smooth margins were coded separately to avoid an erroneous influence on the means for marginal discrepancies.

Means and standard errors were used to describe the distribution of each marginal discrepancy. Unadjusted comparisons were made by un-paired t-tests. An analysis of covariance was used to adjust for restoration size; further adjustment for clustering was obtained by use of robust standard errors. The secondary outcome, chipping, was only adjusted for restoration size because none of the restorations with chipping appeared in the same individual.

A P-value of 0.05 was selected as the level of statistical significance.

Results

A total of 156 SEM pictures from baseline (2-3 weeks after treatment) and follow-up (398 days, SD: 29 days) were available from the randomized clinical trial. Two baseline-pictures and seven follow-up pictures were excluded from the study before assessment because of inferior quality of either the casts or the pictures.

At baseline 76 pictures were assessed. Among these 58 (28 Filtek™ Silorane, 30 Ceram•X™ mono) had smooth margins and 18 (10 Filtek™ Silorane, 8 Ceram•X™ mono) showed marginal discrepancies in terms of excess (9 Filtek™ Silorane, 4 Ceram•X™ mono), gap (1 Filtek™ Silorane, 5 Ceram•X™ mono), or both excess and gap (1 Ceram•X™ mono).

At follow-up, 71 SEM pictures were analysed. Among these one (Ceram•X™ mono) had a smooth margin and 70 (33 Filtek™ Silorane, 37 Ceram•X™ mono) showed marginal discrepancies (excess, gap or chipping). Restoration characteristics at follow-up of the 70 pictures with discrepancies are shown in Table 1. The average number of surfaces included in the Filtek™ Silorane restorations was smaller than the average number of surfaces in Ceram•X™ mono restorations. No statistically significant difference could be found in margin length.

Among the discrepancies at follow-up, 30 were excess (15 Filtek™ Silorane, 15 Ceram•X™ mono), 69 were gap (32 Filtek™ Silorane, 37 Ceram•X™ mono) and 24 were chipping (12 Filtek™ Silorane, 12 Ceram•X™ mono). No statistically significant differences in occurrence of any of the three discrepancies were found between the two materials.

For length and width of gap, and chipping, no statistically significant differences were found (Table 2). A statistically significantly reduced length of excess for the conventional composite restorations (Ceram•X™ mono) was found. However, this difference was not statistically significant after adjustment for size of restoration and clustering. Two fractures were scored at follow-up; one fracture with each material.

Discussion

The hypothesis that reduced polymerization shrinkage improves the marginal adaptation could not be supported by this stu-

dy. No statistically significant difference was shown for gap formation and chipping.

Study bias was minimized by randomization and blinding and, only one examiner evaluated all the SEM pictures. Previous studies (19,20), have recommended measurement particularly of the width of the gaps, in order to elucidate the relationship between the width of marginal gaps and recurrent caries. Therefore, stereological estimates were made, enabling quantification, (length and width), of the discrepancies. Although, the development of secondary caries is limited the first years after placement, marginal gaps probably play a role in the development of secondary caries, but the risk of caries is highly dependent on gap location, with the proximal cervical area at the greatest risk of caries development (19,21). It should be stressed that only occlusal surfaces were investigated in this study; therefore the results cannot predict the long-term clinical outcome of the restorations.

Coefficients of variation could not be given for this study, as it is an inherent feature of the stereological method to place the superimposed lines differently each time a picture is analysed. The examiner's ability to reproduce the measurements is therefore not known.

CLINICAL RELEVANCE



New resin-based composite materials, designed with improved material characteristics, are constantly introduced to the market. For the clinician it can be difficult to estimate the clinical importance of a specific material characteristic. Polymerization shrinkage is considered an important characteristic of restorative materials. This paper examines, through the use of scanning electron microscopy, the effect of a reduced polymerization shrinkage on the marginal adaptation of a newly developed low-shrinkage composite. This study did not support the hypothesis that reduced polymerization shrinkage will improve the marginal adaptation.

Material	Number of surfaces per restoration			Margin length		
	Mean (SE*)	Difference (95 % CI**)	P-value	Mean (SE)	Difference (95 % CI)	P-value
Filtek™ Silorane	2.4 (0.11)	0.4 (0.7; 0.0)	0.04	20.2 (1.03) mm	1.5 (-1.2; 4.3) mm	0.27
Ceram•X™ mono	2.8 (0.13)			0.27 (0.93) mm		

*SE: standard error of the mean; **CI: konfidensinterval

Table 1. Restoration characteristics at follow-up for Filtek™ Silorane and Ceram•X™ mono.

Table 1. Fyldhningstørrelse og kantlængde ved followup for henholdsvis Filtek™ Silorane og Ceram•X™ mono.

Only two-dimensional measurements of the discrepancies were possible with this method. Three-dimensional measurements can be made with other methods like X-ray micro-computed tomography (6,22); however, these methods are used in laboratory studies on extracted teeth, and can therefore only mimic a clinical situation by artificially ageing the restorations. In contrast, we used casts provided from the randomised clinical trial and were therefore able to include a large number of restorations that had been exposed to every-day intra-oral conditions.

At baseline 58 out of 76 pictures were scored with smooth margins. Some of these smooth margin scores may be attributed to excess of composite material left behind after the polishing procedures, which makes the margin of the restoration less distinguishable. This excess could mask gaps between the tooth and the restoration induced by polymerization shrinkage. Consequently, the effect of reduced polymerization shrinkage could have been hidden to the observer until the excess eventually fractured. At follow-up, only one out of 71 restorations was scored with a smooth margin, and it was much easier to see the margins of the restorations on these pictures compared with pictures from baseline (Fig. 5). However, at follow up other factors, such as the general ageing due to degradation of the adhesive and heavy masticatory forces, for example, could contribute to reduced marginal adaptation and thus mask the immediate effect of polymerization shrinkage induced by light-curing of the material during the restorative procedures.

The presence of excess composite material at baseline, which fractures off after some time, may question immediate re-etching of cavo-surface margins followed by sealing with a low-viscosity resin film, as previously discussed in some studies (23-25). It may therefore be better to seal the margins after some months, when the excess has been worn or fractured off.

The lack of correlation between polymerization shrinkage shown in the laboratory and marginal adaptation in the clinic may have different explanations. Excess of composite material, as discussed above, made it practically impossible clinically to measure the immediate effect of reduced polymerization shrinkage at baseline. Furthermore, gap formation depends on the restorative as well as the adhesive material. A low-shrinkage material with a poorer adhesive can result in worse margins than a high shrinkage with an excellent adhesion. As different adhesives are used for the two materials it might be difficult to conclude in general that low shrinkage does not contribute to better margins.

It is commonly assumed that *in-vitro* test results are predictive of clinical performance. However, there is a general lack of data that defines the threshold values of a specific parameter as polymerization shrinkage necessary *in-vitro* to improve the clinical performance. In this study the two materials had shrinkage values of 1% and 2.6%, respectively. Thus, *in-vitro* results indicated superiority of

Filtek™ Silorane but the improvement shown *in-vitro* may have been too small to be of clinical significance in this study.

In accordance with previous findings (10,26,27), this study has identified some of the shortcomings related to the assessment of a clinical outcome (marginal adaptation) in relation to a laboratory finding (polymerization shrinkage).

Stereologic measurements of the gap width may be valuable to determine the relation between gap width and recurrent occlusal caries. One year is too short an observation time to assess this because of the slow progression of a caries lesion and a longer observation time is therefore recommended.

In conclusion, no statistically significant difference between the two materials was shown for gap formation and chipping. The hypothesis that reduced polymerization shrinkage will improve the marginal adaptation is not supported in this study.

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Marginal characteristics

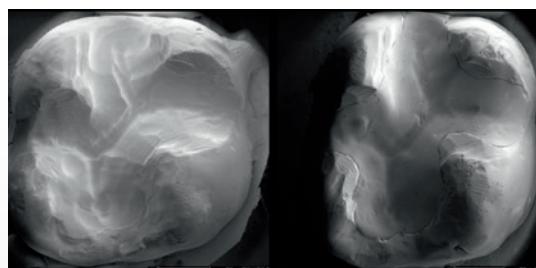


Fig. 5. Baseline (left) and follow-up (right) picture of the occlusal part of a class II restoration in tooth 16 (OD) (original magnification 16 x).

Fig. 5. Baseline (venstre) og followup (højre) billede af den okklusale del af en klasse II-fyldning i tand nummer 16 (OD) (original forstørrelse 16 x).

	Material	No. of restora-tions	Unadjusted			Adjusted for size of restoration and clustering		
			Difference	95 % CI**	p-value	Difference	95 % CI**	p-value
Gap length mm	Filtek™Silorane	32	9.12 (0.98)	1.80 (-0.62 ; 4.23)	0.14	1.63 (-0.90 ; 4.15)	0.20	1.63 (-0.85 ; 4.10)
	Ceram•X™mono	37	10.92 (0.75)					0.20
Gap width mm	Filtek™Silorane	32	0.04 (0.00)	0.00 (-0.01 ; 0.01)	0.35	-0.01 (-0.02 ; 0.00)	0.17	-0.01 (-0.02 ; 0.00)
	Ceram•X™mono	37	0.03 (0.00)					0.18
Excess composite material mm	Filtek™Silorane	15	4.84 (0.97)	-2.14 (-4.23 ; -0.06)	0.04	-1.78 (-4.01 ; 0.45)	0.11	-1.80 (-4.00 ; 0.40)
	Ceram•X™mono	15	2.69 (0.32)					0.11
Chipping length mm	Filtek™Silorane	12	2.56 (0.61)	-0.04 (-4.23 ; 1.51)	0.96	0.06 (-1.49 ; 1.60)	0.94	
	Ceram•X™mono	12	2.53 (0.44)					
Chipping width mm	Filtek™Silorane	12	0.40 (0.09)	0.09 (-0.15 ; 0.33)	0.43	0.10 (-0.16 ; 0.36)	0.42	
	Ceram•X™mono	12	0.49 (0.08)					

*SE: standard error of the mean; **CI: konfidensintervalz

Table 2. Results at follow-up for primary and secondary outcomes according to material and level of adjustment.

Table 2. Resultater for de primære og sekundære outcomes ved follow-up, fordelt på materiale og antal justeringer.



ABSTRACT (DANSK)

SEM-undersøgelse af et plastmateriale med lav kontraktion

Introduktion – Kontraktion i forbindelse med lyspolymerisering af plastfyldninger kan føre til spaltedannelse og dermed skade fyldningernes kanttilslutning. For at mindske problemerne med polymerisationskontraktion har man markedsført et nyt materiale (Filtek™ Silorane, 3M-ESPE, Tyskland) med en reduceret kontraktion.

Formål – Studiets formål var at undersøge, om en reduceret polymerisationskontraktion forbedrer kanttilslutningen af plastfyldninger.

Materiale og metode – I alt 156 scanning elektron mikroskopiske (SEM)-billeder (78 fra baseline, 78 fra followup) af okklusalfladen på molarer indgik i undersøgelsen. De undersøgte fyldninger blev lavet i forbindelse med en randomiseret klinisk

undersøgelse, foretaget i 2007-2009, som sammenlignede de kliniske egenskaber for Filtek™ Silorane med Ceram-XTMmono (Dentsply DeTrey, Tyskland). Ud fra epoxyaftryk af fyldningerne blev der fremstillet SEM-billeder af fyldningerne i 16 x forstørrelse. Billeder fra baseline og followup (398 dage, SD 29 dage) blev randomiseret således, at undersøgeren var blindet over for fyldningernes alder. Ligeledes var undersøgeren blindet over for type af fyldningsmateriale. Stereologi blev anvendt til at beregne længde og bredde af kantdefekterne.

Resultater – Der var ikke statistisk signifikant forskel på spalte-dannelse eller "chipping" ved de to materialer.

Konklusion – Studiets resultater understøtter ikke hypotesen om, at en reduceret polymerisationskontraktion forbedrer fyldningernes kanttilslutning.

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