

APPLICATION OF FILTEK SILORANE-INITIAL OBSERVATIONS AND PROSPECTIVE CLINICAL TRIAL FOR 12 MONTHS

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SUMMARY:

Polymerization shrinkage and related adverse effects are still considered a major problem of dental composites. To solve this problem different approaches are offered. Currently, 3M ESPE developed a new monomer system based on cationic ring opening, the goal is to create a composite material with low polymerization shrinkage called siloran. **Aim:** To investigate the clinical presentation of Filtek™ Silorane Low Shrink Posterior Restorative for an observation period of 12 months. **Material and methods:** The study included 36 patients. Total of 66 restorations are made. They were evaluated using modified USPHS criteria of Ryge and Cvar. After their assessment, restorations were captured with a digital camera and X-rays were taken in parallel technique. On control examination after one year, 31 patients (63 restorations) were available for the study. Same parameters were assessed and new digital pictures and X-rays were made. The statistics was made with software SPSS version 17. For statistical analysis a Criterion Pirson (χ^2) was used. **Results:** With the exception of one of the criteria, it was shown that no statistically significant difference exists between the baseline and after one year ($p > 0,05$). Only the criterion surface of the filling was found to have statistically significant difference ($p < 0,05$)

Key words: Filtek Silorane, clinical study, composite, class two

INTRODUCTION:

Polymerization shrinkage and related adverse effects are still considered a major problem of dental composites. This is particularly true in obturation of the distal segments of the dentition, where cracks, marginal staining, postoperative sensitivity and secondary caries appear¹.

Different approaches are offered to solve this problem:

- Incorporating new components: a glass-alkaline filler particles radiating functional ions (calcium fluoride) to inhibit bacterial activity and reduce demineralization², silver ions with antimicrobial activity³. However, this approach is

not designed to cope with the contraction itself, and the consequences thereof.

- Reducing the size of filler particles to 0,005-0,01 mm in nanofilled composites, increasing the percentage of filler particles, especially in condensable composites⁴.

- Incorporation of the glass fibers in the composition of composites, the introduction of ormocer technology⁵.

- Introduction of the Spiro-ortho-carbonate (SOC) materials, that can withstand cationic polymerization with volume expansion.

Until now the main strategies for dealing with the problem are to reduce the amount of the resin (bis-GMA, UDMA, BPDMA, etc.) by reducing the size of inorganic particles and increasing the filler load⁶. Polymerization shrinkage is an immanence of the dimetacrylates used to this day as an organic matrix. Regardless of reducing them, the problem of shrinking remains. The application of organic matrix of different chemical nature seems most logical way to tackle this problem.

Currently, 3M ESPE developed a new monomer system based on cationic ring opening, the goal is to create a composite material with low polymerization shrinkage-called siloran^{6,7}. As a commercial product based on this structure, on the market appeared Filtek™ Silorane Low Shrink Posterior Restorative - first posterior composite material with less than 1% shrinkage on polymerization according to the manufacturer. This is material which is more experimental and laboratory researched and there are very few publications on the clinical behavior⁸.

AIM:

To investigate the clinical presentation of Filtek™ Silorane Low Shrink Posterior Restorative for an observation period of 12 months.

MATERIAL AND METHODS:

The study included 36 patients. They are informed about the nature of the study and signed informed consent. Each of them received at least one obturation with Filtek

Silorane. Total of 66 restorations are made. Selected cases met the following criteria:

second class, primary or secondary carious lesions with gingival base located next to or above the cement-enamel border (detectable by diagnostic X-ray or during preparation), the presence of adjacent teeth for restoration of contact points, and antagonists.

To restore contact with adjacent teeth we used Palodent sectional Matrix System-Darway, Inc. and rings BiTine-Dentsply Caulc. For polymerization we used light curing unit "Bluedent LED Smart" - D&A Electronics Ltd, Bulgaria. Color selection was made before preparation, while the tooth is still hydrated. In the preparation of the cavities, minimally invasive, adhesive approach was used. Where necessary, caries detector (Sable seek-Ultradent, Inc USA) was used. After isolation of the operative field, cavity was flushed with chlorhexidine and dried.

The application of the adhesive system was according to manufacturer's instructions.

It contains two bottles self-etch primer and bond. It should be noted that due to its different chemistry this adhesive system is incompatible with "traditional" composite materials with organic matrix of methacrylate type.

During obturation of the cavities the centripetal technique (Bichacho 1994) was used. Each layer was applied

with a thickness of no more than 2.5 mm and then cured for 40 seconds. Finishing and polishing were done with discs, brushes and polish paste.

Restorations were evaluated using modified USPHS criteria of Ryge and Cvar. Monitoring parameters are: colour, discoloration on the composite-enamel border, anatomic form, marginal adaptation, surface finishing, secondary caries, contact point, changes in interdental papilla. Evaluation was done by two clinicians not involved in the study. In case of disagreement, the evaluators discussed it to find consensus. After their assessment, restorations were captured with a digital camera and X-rays were taken in parallel technique.

On control examination after one year, 31 patients (63 restorations) were available for the study. Same parameters were assessed and new digital pictures and X-rays were made.

The statistics was made with software SPSS version 17. For statistical analysis a Criterion Pirson (χ^2) was used. The working hypothesis for each of the parameters verified is that there was significant difference in the evaluations made during the observation period.

RESULTS:

With the exception of one of the criteria, it was shown that no statistically significant difference exists between the baseline and after one year ($p > 0,05$).

Time	"colour"													
	oscar			alfa			bravo			charlie			Total	
	N	P %	Sp %	N	P %	Sp %	N	P %	Sp %	N	P %	Sp %	N	P %
baseline	50	75,76	43,3	16	24,24	42,85	0	0,00	0,00	0	0,00	0,00	66	100
12 month	41	65,08	14,7	22	34,92	47,67	0	0,00	0,00	0	0,00	0,00	63	100

$$\chi^2 = 4,86 \quad p > 0,05$$

Time	discoloration on the composite-enamel border										
	alfa			bravo			charlie			Total	
	N	P %	Sp %	N	P %	Sp %	N	P %	Sp %	N	P %
baseline	66	100,00	0,00	0	0,00	0,00	0	0,00	0,00	66	100
12 month	62	98,41	12,50	1	1,59	12,50	0	0,00	0,00	63	100

$$\chi^2 = 2,19 \quad p > 0,05$$

Time	anatomic form										
	alfa			bravo			charlie			Total	
	N	P %	Sp %	N	P %	Sp %	N	P %	Sp %	N	P %
baseline	63	95,45	20,83	3	4,55	20,83	0	0,00	0,00	66	100
12 month	60	95,24	21,30	3	4,76	21,30	0	0,00	0,00	63	100

$$\chi^2 = 0,01 \quad p > 0,05$$

Time	marginal adaptation										
	alfa			bravo			charlie			Total	
	N	P %	Sp %	N	P %	Sp %	N	P %	Sp %	N	P %
baseline	66	100,00	0,00	0	0,00	0,00	0	0,00	0,00	66	100
12 month	60	95,24	21,30	3	4,76	21,30	0	0,00	0,00	63	100

$\chi^2 = 3,3$ $p < 0,05$

Time	surface finishing										
	alfa			bravo			charlie			Total	
	N	P %	Sp %	N	P %	Sp %	N	P %	Sp %	N	P %
baseline	66	100,00	0,00	0	0,00	0,00	0	0,00	0,00	66	100
12 month	57	90,48	29,35	6	9,52	29,35	0	0,00	0,00	63	100

$\chi^2 = 4,86$ $p < 0,05$

Time	secondary caries										
	alfa			bravo			charlie			Total	
	N	P %	Sp %	N	P %	Sp %	N	P %	Sp %	N	P %
baseline	66	100,00	0,00	0	0,00	0,00	0	0,00	0,00	66	100
12 month	63	100,00	0,00	0	0,00	0,00	0	0,00	0,00	63	100

$\chi^2 = 2,13$ $p > 0,05$

Time	contact point										
	alfa			bravo			charlie			Total	
	N	P %	Sp %	N	P %	Sp %	N	P %	Sp %	N	P %
baseline	66	100,00	0,00	0	0,00	0,00	0	0,00	0,00	66	100
12 month	61	96,83	17,53	2	3,17	17,53	0	0,00	0,00	63	100

$\chi^2 = 3,1$ $p > 0,05$

Time	changes in interdental papilla										
	alfa			bravo			charlie			Total	
	N	P %	Sp %	N	P %	Sp %	N	P %	Sp %	N	P %
baseline	66	100,00	0,00	0	0,00	0,00	0	0,00	0,00	66	100
12 month	61	96,83	17,53	2	3,17	17,53	0	0,00	0,00	63	100

$\chi^2 = 2,18$ $p > 0,05$

Only the criterion surface of the filling was found to have statistically significant difference ($p < 0,05$).

DISCUSSION:

Amalgam and composites are the most commonly used materials for restoration of distal teeth as the relative share of composites is increasing steadily. This is necessitated by

the growing trend towards even greater demands of patients for aesthetic restorations of the distal segments of the dentition. There are also studies that show similar durability of composites and amalgams fillings in a prolonged period of observation⁹. It is a common opinion that the main problem with composites is the polymerizational shrinkage. As a consequence of this, is regarded the appearance of fissures,

marginal staining, postoperative sensitivity and secondary caries. So far have been offered various approaches for the solution of this problem, but they are all connected with optimizing the size and saturation with inorganic fillers. The shrinkage is due to the dimetacrylate matrix- the essential component of all currently manufactured dental composites.

3M ESPE developed a new monomer system based on an opened cationic ring, as the goal is to be created a composite material with polymerizational shrinkage of less than 1 %, named siloran^{6,7}. Currently for this material there is mainly laboratory and experimental studies. With the current study was conducted one of the first clinical tests of the material. This greatly restricts the ability to compare the obtained results to others.

The presence of statistically significant difference for the criterion "surface of filling" can be explained by the fact that assessment "alpha" is given to a surface smooth as a enamel. Maybe the evaluators were very critical in the evaluation, it is known that there is no material to replace all the qualities of the enamel and this especially applies for its smooth, polished surface.

The results from in vitro studies can give us some information about clinical behaviour of this material. Two of them compare the degree of bacterial adhesion to silorane and methacrylate based composite material^{10,11}. The first one finds no statistically significant difference in adhesion of *Candida albicans* between test composites, including silorane, and the lowest is adhesion of ormoer and compomer. In the other study the subjects are different types *Streptococcus mutans*, and for three of them lower adhesion to silorane, compared with other composites was reported.

On one hand this corresponds to the obtained in this study results for the criteria "secondary caries". There is no statistically significant difference 12 months compared to the beginning, i.e. there are not favorable conditions for adhesion of *Streptococcus mutans* and other microorganisms along the borders of the filling. On the other hand, the obtained statistically significant difference for the criterion "surface filling" implies there will be easier adhesion of microorganisms on the rough surface. It will be of interest to see the results of the control examinations for a longer period of observation.

In another in vitro examination¹² has been registered a change in colour and surface of the silorane composite and four known dimetacrylate composites according to SIE-LAB colour scale. Disc-shaped samples that are subjected to an artificial light-induced aging with plasma lamp are used. Colour changes were measured at different time intervals- beginning, 24, 48, 72, 120, 192 hours. Generally materials show decrease in L*(white-black) and a*(red-green) and the values of b*(blue-yellow) are increasing. A great exception is Filtek Silorane, where values of a* and b* remain the same. The change in E(ΔE) for all materials is a linear function of

time, as it is smallest for Filtek Silorane and Herculite XRV. The conclusion of the authors is that silorane composite is presented best in terms of stability of colour compared to dimetacrylate composites. These results are identical to the obtained by us estimates in clinical conditions for the criterion "right colour".

In a research analyzing the polymerizational stress, silorane shows smaller values than the dimetacrylate composites¹³. Other authors compared the strength and modulus of elasticity of the silorane with dimetacrylate composites. There are not found any statistically significant differences in terms of the strength, while the modulus of elasticity of the silorane is slightly lower¹⁴. These indicators- polymerization stress, modulus of elasticity, have a relation toward marginal adaptation, change of colour along the borders of the cavity and hence the development of secondary caries. For all of the three criteria we did not receive statistically significant difference. Since in silorane there is a lack of oxygen inhibited layer, this has motivated scientists to explore the bond between the separate layers in incremental layering of the material¹⁵. They concluded that the bond between the layers is slightly weaker than the one in the dimetacrylate composites. Whether this has any clinical impact is difficult to assess from the present study. Two other studies^{16,17} examine the hydrolytic stability of the silorane composites in organic liquid simulants and aqueous solution. The authors conclude that the stability and insolubility of silorane makes them suitable for use in conditions of the oral cavity.

Yesilyurt et al., test in laboratory conditions the effects of food on hardness and flexural strength of the silorane and of three dimetacrylate composites¹⁸. In clinical setting these parameters would affect the fracture and abrasion resistance of the filling. Both studied parameters are not affected by the effect of food in silorane, while for the dimetacrylate composites there is a significant decrease in both hardness and flexural strength. This was confirmed from our clinical observation- there were no fractures and localized abrasion.

In another study is examined the relation between the type of matrix (silorane and dimetacrylate), and the marginal leakage in vitro¹⁹. The results show that in silorane it is not observed any leakage, unlike the other group. In the present study are made and evaluated only fillings of silorane composite. It would be more indicating if for each patient are made two fillings- one with a composite with dimetacrylate base, and the other - with silorane. This maybe a subject of future studies.

CONCLUSION:

In the conditions of this study Filtek Silorane Low Shrink Posterior Restorativ performed well for an observation period of 12 months.

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