

Clinical Evaluation of Silorane and Nano-hybrid Resin Composite Restorations in Class II Cavities up to 3 Years

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Clinical Relevance

Both nano-hybrid and silorane-based resin composites performed similarly in Class II restorations for up to three years except for marginal adaptation where silorane-based composite demonstrated significant marginal deterioration.

SUMMARY

In this study, the clinical performance of a silorane-based resin composite (SC) vs a nano-hybrid resin composite (NHC) was evaluated in Class II cavities. From January 2012 to

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February 2013, a total of 29 patients (eight men, 21 women; mean age, 24 ± 5 years) received 29 pairs of restorations using both SC (Filtek Silorane, 3M ESPE) and NHC (Filtek Z550, 3M ESPE) materials. Patients were followed until February 2015. One operator performed all restorations using the corresponding adhesive resins according to the manufacturers' instructions. Two calibrated independent examiners evaluated the restorations at one week, six months, and then annually using the modified United States Public Health Service (USPHS) criteria for anatomic form, marginal adaptation, color match, surface roughness, marginal discoloration, secondary caries, and postoperative sensitivity. Changes in the USPHS parameters were analyzed with the McNemar test ($\alpha=0.05$). The mean observation period was 31.2 months. Marginal adaptation was the only parameter that showed a significant difference and was worse for SC than NHC ($p=0.012$). At the final recall, 17 restorations from the SC group and five from the NHC group received a score of 1 (explorer catches). These scores were significantly different be-

tween baseline and final recall for SC ($p < 0.001$) but not for NHC ($p > 0.05$). Both NHC and SC performed similarly in Class II restorations up to three years except for marginal adaptation, for which the latter demonstrated significant deterioration at the final recall compared with baseline.

INTRODUCTION

Since their introduction, dental composites have undergone many structural changes in order to achieve easier application and better clinical results. Their low cost, better optical properties, and less need for preparation made them the first choice of material for posterior direct restorations as opposed to other materials.¹ They also have shown acceptable prognoses according to some clinical studies.^{2,3} However, the longevity of posterior resin restorations remains a matter of concern among clinicians, given that some other studies reported failures generally after 5 to 6 years.^{1,4,5} According to these clinical studies, the most frequently reported defects and failures are fractures, secondary caries, and marginal leakage that is often attributed to polymerization shrinkage.^{1,4,5}

Despite many improvements in dental adhesive technologies, polymerization shrinkage remains a problem because it is caused by an exchange of van der Waals forces in shorter covalent bond spaces during the conversion of monomers into a polymer network.⁶ Polymerization shrinkage generates stresses between the tooth and the restoration and may increase the risk of early failure.⁵ Current adhesive technologies aim for achieving “low-shrinkage” materials. With higher filler content and incorporation of prepolymerized resin fillers, the absence of low-molecular-weight diluents and the use of high-molecular-weight monomers, methacrylate-based resin composite materials present less polymerization shrinkage.⁵

Alternative efforts have been made by introducing an epoxide ring-opening polymerization type of chemistry.⁷ Siloranes, a new class of ring-opening monomers, comprise two molecules: siloxane, which makes the material hydrophobic, and oxirane, with volumetric shrinkage of 0.99 vol%.⁸⁻¹⁰ With this low polymerization shrinkage, the incidence of microleakage, secondary caries, postoperative sensitivity, and enamel fractures are claimed to decrease.¹¹ Siloranes have clinically acceptable physical, biological, and mechanical properties, and the performance of such resins is similar^{12,13} or superior^{14,15} to that of methacrylate-based resins.

Although clinical trials are costly and time-consuming, and prediction of the clinical results on the basis of a single or multiple *in vitro* studies may be desirable,¹ the overall clinical behavior of resin restorations is multifactorial and unlikely to be predicted by either of the methods alone. Because siloranes are recently introduced adhesive restorative technologies, they have not been evaluated widely *in vivo*.^{16,17} Thus, the objective of this clinical evaluation was to investigate the longevity of silorane-based resin composite (SC) vs a methacrylate-based nano-hybrid resin composite (NHC) for posterior Class II restorations. The null hypothesis tested was that there would be no statistically significant differences between the two resin composite materials.

METHODS AND MATERIALS

The brands, manufacturers, chemical composition, and batch numbers of the materials used in this study are listed in Table 1.

Study Design

The Ethics Committee of Istanbul University approved this clinical study (2012/644-1047). Patients in need of at least two posterior restorations were recruited for the study. Inclusion criteria were as follows: Adults of at least 18 years of age, with good oral hygiene, having at least two primary approximal caries in the posterior teeth having an antagonist tooth in occlusion, being mentally in a good state to provide written consent to participate in the clinical study, and willing to attend the scheduled follow-up appointments. Exclusion criteria included no systemic diseases, presence of teeth with severe periodontal problems, extensive caries that need to be treated endodontically, and/or composite or amalgam replacements.

Placement of Restorations

From January 2012 to February 2013, one operator with experience in adhesive dentistry (more than 18 years since graduation) placed two pairs of restorations in 29 patients (eight men, 21 women; mean age, 24 ± 5 years). Following cavity preparation, the decision to apply the test or control material was randomized by tossing a coin; the distribution of restorations is shown in Table 2.

Isolation of the preparation was achieved with suction and cotton rolls. When the remaining dentin thickness was very thin, to perform indirect pulp capping, calcium hydroxide paste (Dycal, Dentsply

Table 1: The Brand, Type, Manufacturer, and Chemical Composition of the Main Materials Used in This Study

Brand	Type	Manufacturer	Chemical Composition
Silorane Self-etch Primer	Dentin primer	3M ESPE AG, St Paul, MN, USA	Phosphorylated methacrylates, bis-GMA, HEMA, water, ethanol, silane-treated silica filler, Vitrebond copolymer, initiators, stabilizers
Silorane Bond	Adhesive bond	3M ESPE AG	Hydrophobic methacrylates, phosphorylated methacrylates, TEGDMA, silane-treated silica filler, initiators, stabilizers
Filtek Silorane	Low-shrink resin composite	3M ESPE AG	Organic matrix: 3,4-epoxycyclohexylethylcyclopolymethylsiloxane, bis-3,4-epoxycyclohexylethylphenylmethylsilane, yttrium fluoride, camphorquinone, iodonium salt, initiators, stabilizers
Ultra-Etch	Etching gel	Ultradent, South Jordan, USA	35% phosphoric acid
Adper Single Bond 2	Etch-&-rinse dental adhesive	3M ESPE AG	bis-GMA, HEMA, dimethacrylates, ethanol, water, a novel photoinitiator system, and a methacrylate functional copolymer of polyacrylic and polyitaconic acids
Filtek Z550	Resin composite	3M ESPE AG	bis-GMA, UDMA, TEGDMA, bis-EMA Filler: silica, zirconia Particle size: 0.6 to 10 μ 78.5 wt%, 63.3 vol%
Abbreviations: bis-EMA, Bisphenol A ethoxylated dimethacrylate; bis-GMA, Bisphenol A diglycidyl methacrylate; HEMA, 2-hydroxyethyl methacrylate; TEGDMA, Triethylene glycol dimethacrylate; UDMA, Urethane dimethacrylate.			

Caulk, Milford, DE, USA) was placed in the deepest part and covered with a resin-modified glass ionomer liner (Glass-Liner, Willmann & Pein GmbH, Hamburg, Germany) and polymerized. Silorane Self-Etch Primer (3M ESPE Dental Products, St Paul, MN, USA) was scrubbed on the cavity walls of the preparation for 15 seconds, gently air-thinned, and photo-polymerized for 10 seconds with an LED device (Elipar Free Light, 3M ESPE AG, Germany; ≥ 400 mW/cm²). Silorane Bond was applied with a brush to the cavity walls, air-thinned, and photo-polymerized for 10 seconds. SC (Filtek Silorane, 3M ESPE AG) was then placed incrementally and photo-polymerized separately for 40 seconds.

The adhesive for the control group was an etch-and-rinse system. Enamel margins and dentin were etched simultaneously with 35% phosphoric acid (Ultra-Etch, Ultradent, South Jordan, UT, USA) for 20 seconds. Following water rinsing for approximately 10 seconds, the cavity was dried for one to two seconds to prevent desiccation. Adper Single Bond 2 (3M ESPE Dental Products) was applied for 15 seconds using a microbrush, gently air-thinned, and photo-polymerized for 10 seconds. The NHC (Filtek Z550, 3M ESPE Dental Products) was then placed in 2-mm thickness incrementally and photo-polymerized for 40 seconds. All restorations were finished and polished with abrasive disks (Sof-Lex

Finishing and Polishing Systems, 3M ESPE AG) and rubber cups (Jiffy Polishers, Ultradent, South Jordan, UT, USA).

Patients were given routine oral hygiene instructions and asked to contact the clinician if they perceived any problems with the restored teeth.

Evaluation

Two specialist dentists who were blinded to the study groups evaluated the restorations. In cases of differing scores, the observers reevaluated the restorations and reached a consensus. At baseline (one week following restoration placement for evaluation of postoperative sensitivity), six months, and for final recall, the restorations were evaluated using modified United States Public Health Service (USPHS) criteria¹⁸ for the following parameters: anatomical form, marginal adaptation, color match, surface roughness, marginal staining, secondary caries, and postoperative sensitivity (Table 2).

Statistical Analysis

Statistical analysis was performed using SPSS 11.0 software for Windows (SPSS Inc, Chicago, IL, USA). The McNemar test was used to evaluate the difference between the two materials. A *p*-value of <0.05 was considered to indicate statistical significance.

Table 2: *Distribution of Restored Teeth and Restoration Types in the Maxilla and Mandible*

	Filtek Silorane		Filtek Z550	
	MO/DO	MOD	MO/DO	MOD
Maxilla				
Premolars (n)	6	0	6	1
Molars (n)	7	2	6	1
Mandible				
Premolars (n)	2	0	7	0
Molars (n)	9	3	7	1
Total (N)	24	5	26	3
	29		29	
<i>Abbreviations: MO/DO, mesioocclusal/distoocclusal; MOD, mesioocclusodistal.</i>				

RESULTS

The distribution of restored teeth and restoration types in the maxilla and mandible are presented in Table 2. USPHS evaluation scores for the SC and NHC groups are provided in Table 3.

All patients (100%) attended the final recall visit. The mean observation period was 31.2 months. Indirect pulp capping was performed in nine restorations in the SC group and five in the NHC group.

At baseline, one restoration from each group (one with indirect pulp capping) was scored as 1 (sensitivity disappeared in one week) for postoperative sensitivity (Table 4). At baseline and the six months recall, no statistically significant difference was observed in any parameter ($p > 0.05$). At the final recall, the only parameter that showed a significant

Table 3: *Modified United States Public Health Service (USPHS) Criteria*

Category	Score		Criteria
	Acceptable	Unacceptable	
Anatomical form	0		The restoration is continuous with tooth anatomy
	1		Slightly undercontoured or overcontoured restoration; marginal ridges slightly undercontoured, contact slightly open (may be self-correcting); occlusal height reduced locally
		2	Restoration is undercontoured, dentin or base exposed; contact is faulty, not self-correcting; occlusal height reduced, occlusion affected
		3	Restoration is missing partially or totally, fracture of tooth, shows traumatic occlusion; restoration causes pain in tooth or adjacent tissue
Marginal adaptation	0		Restoration is continuous with existing anatomic form; explorer does not catch
	1		Explorer catches; no crevice is visible into which explorer will penetrate
	2		Crevice at margin, enamel exposed
		3	Obvious crevice at margin; dentin or base exposed
		4	Restoration mobile, fractured, or missing
Color match	0		Very good color match
	1		Good color match
	2		Slight mismatch in color, shade, or translucency
		3	Obvious mismatch, outside the normal range
		4	Gross mismatch
Surface roughness	0		Smooth surface
	1		Slightly rough or pitted
	2		Rough, cannot be refinished
		3	Surface deeply pitted, irregular grooves
Marginal discoloration	0		No discoloration evident
	1		Slight staining, can be polished away
	2		Obvious staining cannot be polished away
		3	Gross staining
Caries	0		No evidence of caries contiguous with the margin of the restoration
		1	Caries is evident contiguous with the margin of the restoration
Postoperative sensitivity	0		No sensitivity
	1		Sensitivity lost in one week
		2	Continuous sensitivity

Table 4: Summaries of USPHS Evaluations Expressed in Percentage at Baseline and up to Final Recall

Criteria	Baseline		6 months		Final Recall	
	SC, n (%)	NHC, n (%)	SC, n (%)	NHC, n (%)	SC, n (%)	NHC, n (%)
Anatomic form						
0	29 (100)	29 (100)	29 (100)	28 (96.55)	27 (93.1)	26 (89.65)
1	0 (0)	0 (0)	0 (0)	1 (3.45)	2 (6.89)	3 (10.35)
2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Marginal adaptation						
0	29 (100)	29 (100)	28 (96.55)	27 (93.1)	12 (41.38)	24 (82.76)
1	0 (0)	0 (0)	1 (3.45)	2 (6.89)	17 (58.62)	5 (17.24)
2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Color match						
0	29 (100)	29 (100)	28 (96.55)	29 (100)	27 (93.1)	28 (96.55)
1	0 (0)	0 (0)	1 (3.45)	0 (0)	2 (6.89)	1 (3.45)
2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Surface roughness						
0	29 (100)	29 (100)	28 (96.55)	28 (96.55)	28 (96.55)	25 (86.21)
1	0 (0)	0 (0)	1 (3.45)	1 (3.45)	1 (3.45)	4 (13.79)
2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Marginal discoloration						
0	29 (100)	29 (100)	28 (96.55)	28 (96.55)	28 (96.55)	26 (89.65)
1	0 (0)	0 (0)	1 (3.45)	1 (3.45)	1 (3.45)	3 (10.35)
2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Secondary caries						
0	29 (100)	29 (100)	29 (100)	29 (100)	29 (100)	29 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Postoperative sensitivity						
0	28 (96.55)	28 (96.55)	29 (100)	29 (100)	29 (100)	29 (100)
1	1 (3.45)	1 (3.45)	0 (0)	0 (0)	0 (0)	0 (0)
2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

difference was marginal adaptation being worse for SC than NHC ($p=0.012$). In total, 17 restorations from the SC and five from the NHC group received a score of 1 (explorer catches). The scores were significantly different between baseline and final recall for the SC group ($p<0.001$) but not for the NHC group ($p>0.05$).

DISCUSSION

Due to their optical and clinical properties, resin composites have become the favored restorative materials for direct posterior restorations, despite

some shortcomings. Advances in material formulations, such as advanced filler morphologies and contributions in monomer technology are expected to improve the clinical success of resin composites.¹⁹ In this regard, siloranes have been introduced to dentistry as alternatives to methacrylates due to their hydrophobicity and decreased polymerization shrinkage.^{20,21} The goal in developing siloranes was to create a material with reduced polymerization shrinkage and less polymerization stress.¹⁹ Limited clinical studies are available that involve silorane-based materials.^{16,17,22}

In our study, we compared the clinical behavior of silorane and a conventional methacrylate-based NHC. Laboratory investigations of silorane have generally revealed that this material exhibits properties at least as good as those of methacrylate-based resin composites.²³⁻²⁵ Therefore, the results of our clinical investigation may contribute to knowledge about the clinical success of siloranes. Both materials tested showed successful clinical outcomes after 37 months.

A similar clinical study with three years of follow-up indicated no statistically significant difference in any parameter between SC and methacrylate-based composite resins according to the modified USPHS criteria.²² According to our clinical observations at the final recalls, only the marginal adaptation criteria showed a significant difference. Margin-related problems such as discoloration and chipping of material were usually observed in recalls up to 24 months, which is considered a medium time frame.²⁶ In this study, the scores were worse for SC (17 restorations) than NHC (five restorations). The worse scores for marginal adaptation could have originated from the degradation of the adhesive interface as a result of slow hydrolysis. Monomers in adhesive systems generally absorb water and chemicals from the oral environment, which eventually affects the adhesion and can result in deleterious effects on marginal adaptation over time.^{22,27}

SC had its own adhesive system and was applied according to the manufacturer's instructions. The primer, including HEMA and bis-GMA, was applied directly on dentin tissues and photo-polymerized; the adhesive resin, including TEGDMA, was then applied and photo-polymerized again for 10 seconds. The high content of HEMA and water in the self-etching primer makes the adhesive systems more hydrophilic, increasing the susceptibility of the hybrid layer to water absorption and, consequently, reducing the durability of the adhesion.²⁸ It has already been shown that HEMA-containing adhesive systems are most prone to hydrolysis, generally resulting in a decline in mechanical properties.²⁹ However, the application of a hydrophobic bonding resin decreases this permeability and improves bonding stability.¹⁰ In addition, it was found that the mildly acidic (pH=2.7) silorane self-etching primer caused demineralization of the superficial dentin, incorporated the smear layer, chemically bound with calcium in hydroxyapatite,¹⁰ and bonded to tooth tissue more strongly. The worse marginal adaptation score may not be related only to the possible degradation of the adhesive system of the SC over time because the chemical bonding of the

adhesive to tooth tissues improved the adhesion of the material.

In a five-year clinical observation, the clinical behavior of three restorative systems were evaluated, including a SC and a methacrylate-based composite combined either with an etch-and-rinse or a self-etch adhesive.³⁰ Deterioration of the marginal adaptation was observed with all restorative systems, whereas marginal staining was more frequently seen only around the restorations performed with self-etch adhesives for both SC and methacrylate-based composites. It is possible that using the etch-and-rinse technique could have resulted in more reliable clinical performance on the basis of the marginal quality of the restorations. However, Duarte and others³¹ concluded in their *in vitro* study that a SC is compatible only with its dedicated adhesive. Thus, the use of well-established different adhesive protocols could not be used with SC. Similarly, in an *in vitro* study, silorane exhibited significantly lower shrinkage forces and better marginal adaptation than did a methacrylate-based composite.³² The worse observations for SC in our study differed from their results. These findings also could be related to the polishability of SC because for that criterion, one restoration for SC and four for NHC were scored as 1, indicating that the polishability of NHC was not better than that of SC.

Adebayo and others³³ showed lower bond strength with siloranes than with methacrylate-based composites, which also supports our significant differences for the marginal adaptation criteria. Similar to our findings, one clinical trial that examined a methacrylate-based composite resin and silorane in Class II cavities revealed that the marginal adaptation of the silorane was inferior to that of the methacrylate-based resin composite, both occlusally and approxinally.¹⁶ On the other hand, one other study found no statistically significant difference in the clinical performance between the restorative materials (nano-hybrid, packable, and silorane) except for marginal adaptation.³⁴ Silorane showed worse marginal adaptation at the end of their three-year observations. Similar to the results of previous studies,^{34,35} significantly worse scores were obtained for the marginal integrity of SC than a methacrylate-based resin composite.

It has also been reported that choosing products from the same manufacturer will favor chemical interaction between the resin composite and the corresponding adhesive system.³⁶ In this clinical study, NHC (Filtek Z550) was used in combination with the Adper Single Bond 2, products from the

same manufacturer (3M ESPE AG). Five restorations received a score of 1 for the marginal adaptation criteria for NHC, and this result was better than that for SC. In fact, SC was also applied with its own adhesive system from the same manufacturer. Apart from the polishability of the restorations, the type of adhesive system could be related to the success of the marginal adaptation criteria. SC was bonded with a two-step self-etching adhesive, whereas NHC was applied with a two-step etch-and-rinse adhesive. The difference in application procedures of these adhesive systems could affect the marginal durability of these restorations after three years of clinical service.

None of the available clinical studies emphasized the superiority of SC over methacrylate-based resin composites with minimum of six months and maximum of five years evaluation period, despite the excellent performance reported by the manufacturer.^{16,17,22,30,34,35,37} We can conclude that both restorative materials tested were clinically acceptable after three years of service. The null hypothesis was rejected due to the statistically significant difference in the criterion of marginal adaptation. Long-term clinical observations are required to fully assess the performance of this material introduced to dentistry with promising expectations.

CONCLUSIONS

From this study, the following could be concluded:

1. Both SC and NHC showed acceptable clinical performance over an evaluation period of three years for posterior Class II restorations when used in conjunction with their corresponding adhesive systems.
2. Significant marginal deterioration was observed for SC restorations compared with NHC at final recall.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Ethical Committee of Istanbul University. The approval code for this study is 2012/644-1047.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature

or kind in any product, service, and/or company that is presented in this article.

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