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ORIGINAL ARTICLE

Clinical evaluation of microhybrid composites in noncarious cervical lesions: 24-month results

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Abstract

Objective: To evaluate the clinical performance of two different microhybrid resin composites in noncarious cervical lesions (NCCLs) after 24 months.

Subjects and Methods: Ninety-seven NCCLs were restored with either TPH Spectrum (n = 48) or Filtek Z250 (n = 49) using an etch-and-rinse adhesive in 20 patients. The restorations were clinically evaluated using modified United States Public Health Service criteria for retention, color match, marginal discoloration, marginal adaptation, surface texture, anatomic form, postoperative sensitivity, and secondary caries. The restorations were assessed 1 week after placement (baseline) and after 6, 12, and 24 months. Restoration survival rates were calculated using the Kaplan–Meier procedure estimator, and a log-rank test was used to compare the survival distributions (P < 0.05). Statistical analysis was undertaken using Pearson's Chi-square test and Fisher's exact test to assess differences among the restorative materials (P < 0.05). Cochran's Q-test was employed for evaluating differences in the same restorative material between recall periods.

Results: The retention rates were 100% at 6 months, 89.6% and 91.8% at 12 months, and 85.4% and 89.8% at 24 months for TPH and Z250, respectively. TPH showed a statistically significant difference in marginal discoloration between the baseline and 24 months results (P < 0.05). Both TPH and Z250 showed statistically significant differences in marginal adaptation between the baseline and 24 months results (P < 0.05).

Conclusion: Over the 24-month period, both microhybrid resin composites demonstrated acceptable clinical results in NCCLs.

Key words: Clinical evaluation, microhybrid resin composites, modified United States Public Health Service criteria, noncarious cervical lesions

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Introduction

The term "noncarious cervical lesion" (NCCL) describes the loss of hard dental tissue at the cement–enamel junction without caries, a condition that increases in incidence as people become older.[1] The causes of these lesions are multifactorial and include erosion, abrasion, abfraction and/or occlusal stress, and frequently require adhesive restoration.[1,2]

Restoration of NCCLs is necessary to reduce hypersensitivity, to prevent further tooth structure loss, and to provide esthetics. A variety of restorative materials have been used for the restoration of NCCLs, such as resin composites, polyacid-modified resin composites (compomers), and conventional and/or resin-modified glass ionomers. In the past two or three decades, resin composites and polyacid-modified resin composites have been most widely used. Owing to their esthetic properties and ease of handling characteristics, microhybrid resin composites have become a more popular alternative to glass ionomer materials.[3] Microhybrid resin composites offer high wear resistance and adhesive capacity to dental tissues because they

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incorporate bonding systems that maintain the marginal seal over long periods and perform well clinically in terms of all evaluation criteria, such as surface texture, marginal integrity, anatomical form, and color match.[4]

Laboratory tests may provide useful information about the potential performance of a restorative material. However, clinical studies are important for predicting the longevity of a material under oral conditions, and for assisting dental practitioners in choosing the best material for restoring NCCLs to provide the best clinical outcome for the patient.[5,6]

The objective of this study was to evaluate the 24-month clinical performance of two different microhybrid composite resins in NCCLs. The null hypothesis was that both restorative materials will obtain comparable results and achieve acceptable clinical performance according to the modified United States Public Health Service (USPHS) criteria (retention, color match, marginal discoloration, marginal adaptation, surface texture, anatomic form, postoperative sensitivity and secondary caries) at the end of the evaluation period.

Subjects and Methods

Twenty patients (8 females, 12 males, mean age 58.9 years) who required restoration of at least one pair of NCCLs participated in this study. Lesions at least 1 mm deep and involving both the enamel and dentin of vital teeth without mobility or pulpal involvement were included in the study. Patients with extremely poor oral hygiene, a history of bruxism or xerostomia, severe medical complications, or severe chronic periodontitis were excluded from the study. All restored teeth were in occlusion and had proximal surfaces in contact with an adjacent tooth.

The patients were selected from the Department of Restorative Dentistry, School of Dentistry, Baskent University, Ankara, Turkey. The protocol was approved by the Baskent University Ethics Committee on Investigations Involving Human Subjects (Protocol No: D-KA13/01). Written informed consent was obtained from each participant prior to treatment.

A total of 97 cervical lesions were restored with two microhybrid composite resins, TPH Spectrum (n = 48) (Dentsply, De Trey, Konstanz, Germany) and Filtek Z250 (n = 49) (3M ESPE, St. Paul, MN, USA), in conjunction with a two-step etch-and-rinse adhesive (Adper Single Bond 2; 3M ESPE). All materials were used according to the manufacturers' instructions [Table 1]. All lesions were restored by the same investigator. Teeth were cleaned with pumice-water slurry using a rubber prophylaxis cup and rinsed with water before the restorative procedures. The distribution of materials and tooth locations were randomized by tossing a coin. However, interference in the randomization procedure within individual patients was permitted to equally distribute materials and tooth numbers.[7] Isolation was accomplished using cotton rolls and a saliva suction device. All restorations were performed without local anesthesia and without beveling the enamel margins. In each patient, at least two cervical lesions were restored either with TPH Spectrum or Filtek Z250. Resin composites were applied in increments not exceeding 2 mm and were polymerized with a quartz tungsten halogen light-curing unit (Hilux 200, Benlioğlu Dental Ankara, Turkey) for 40s. The light-curing unit was monitored periodically with a hand-held radiometer (Demetron, Kerr, Orange, CA, USA) to confirm that it had a power output of 600 mW/cm^2. After polymerization, the restorations were finished with an ultrafine diamond finishing bur (Diatech Dental Products, Charleston, USA) and polished with slow speed polishing cups and points (Eveflex Polisher, EVE Ernst Vetter GmbH, Germany) and aluminum oxide polishing discs (Soflex, 3M ESPE). Distribution of the restorations according to the type of tooth and arch is shown in Table 2.

Table 1: Materials used in the study

Material	Type	Composition	Application mode
TPH Spectrum Dentsply, De Trey, Konstanz, Germany Batch number: 1206000471	Microhybrid	Bis-GMA, bis-EMA, TEGDMA Ba Al borosilicate glass (<1.0 μm average particle size), colloidal silica, initiators/stabilizers (77 wt%; 57.1 vol%)	Apply in one increment, light cure (40 s)
Filtek Z250 3M Dental Products, St. Paul, MN, USA Batch number: N380435	Microhybrid	Bis-GMA, bis-EMA, UDMA, photo initiators, stabilizers Zirconium/silica filler (0.01-3.5 μm) (84.5 wt%, 60 vol%)	Apply in one increment, light cure (40 s)
Single Bond 2 3M Dental Products, St. Paul, MN, USA Batch number: N245106	Two-step etch-and-rinse adhesive	HEMA, bis-GMA, dimethacrylates, ethanol, water, metharylatedpolyalkenoic acid, copolymer, initiator, silane-treated nanofillers	Apply etchant to tooth surface for 30 s for enamel, 15 s for dentin. Rinse for 10 s and blot excess water with a cotton pellet. Apply two consecutive coats of adhesive for 15 s with gentle agitation. Gently air dry for 5 s. Light cure for 10 s

Bis-EMA=Ethoxylated bisphenol A dimethacrylate; Bis-GMA=Bisphenol-glycidyl methacrylate; HEMA=2-hydroxyethyl methacrylate; TEGDMA=Triethyleneglycoldimethacrylate; UDMA=Urethane dimethacrylate; GPDM=Glycerol phosphate dimethacrylate

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Two calibrated, experienced investigators who were not the operator in the study, evaluated the restorations with the aid of a dental loupe with × 5 magnification after 1 week (baseline) and 6, 12 and 24 months, according to the modified USPHS criteria consisting of retention, color match, marginal discoloration, marginal adaptation, surface texture, anatomic form and secondary caries [Table 3].[8] The investigators were unaware of which material had been used, creating a double-blind study. When disagreement arose during the evaluation, the examiners were required to reach a forced consensus. Presence or absence of pre- and post-operative sensitivity to stimuli (spontaneous, water spray, air blast, and pressure from an explorer) was also evaluated. The restorations were scored as follows: Alfa represented the ideal clinical situation, Bravo was clinically acceptable, and Charlie represented a clinically unacceptable situation, and the restoration would be replaced.

The statistical analysis was performed using SPSS 16.0 software (SPSS, Chicago, IL, USA). The survival rates of restorations were calculated using the Kaplan–Meier procedure estimator, and a log-rank test was used to compare the survival distributions of the restorations ($P < 0.05$). Pearson's Chi-square test and Fisher's exact test were used to assess differences between the restorative materials ($P < 0.05$). Cochran's Q-test was also employed to evaluate differences in the same restorative material between recall periods.

Results

The recall rates at 6, 12 and 24 months were 100% because all patients were available for clinical evaluation.

The retention rates of both materials were 100% at the 6-month recall. At the 12-month recall, five TPH Spectrum and four Filtek Z250 restorations had been lost (retention rates of 89.6% and 91.8%, respectively). After 24 months, a total of seven TPH and five Z250 restorations had been lost (retention rates of 85.4% and 89.8%, respectively). Table 4 shows the distribution of lost restorations with regard to arch and region. The log-rank test indicated no statistically significant difference among the survival rates of restorative materials after 24 months [Figure 1].

The results of the clinical evaluation at baseline and at the 6, 12 and 24 months follow-up with respect to color match, marginal discoloration, marginal adaptation, surface texture, anatomic form, postoperative hypersensitivity and secondary caries are reported in Table 5. The statistical comparison between the results at baseline and after 24 months of clinical service yielded a significant increase for TPH Spectrum restorations in marginal discoloration ($P < 0.05$). In addition, the poorer marginal adaptation was noted for both TPH Spectrum and Filtek Z250 restorations at the 24-month recall ($P < 0.05$). No statistically significant difference was detected between the restorative materials in any of the other criteria at any of the evaluation periods ($P > 0.05$). Eleven patients with 43 lesions were hypersensitive before the restorative procedures. None of the teeth presented postoperative sensitivity at any of the follow-up recalls.

Discussion

This study investigated clinical performance over 24 months of two different microhybrid resin composites, TPH Spectrum, and Filtek Z250. Both restorative materials showed acceptable clinical performance in NCCLs. The null hypothesis had to be accepted because the differences between the two restorative materials did not prove to be significant.

We found that the restorative materials had acceptable retention rates, including a retention rate of 100% at

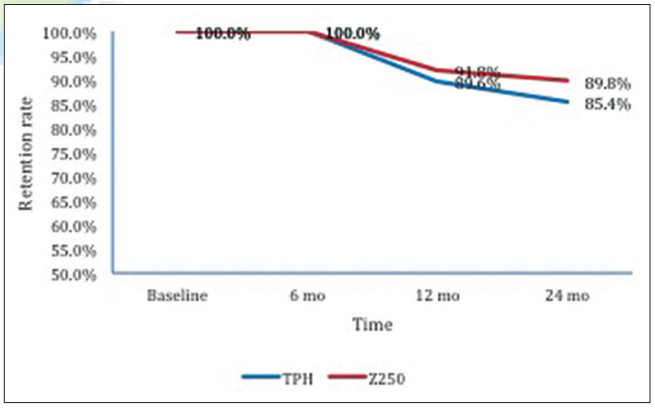

Figure 1: Cumulative survival rate of restorations

Table 2: Distribution of restorations at baseline

Composite type	Maxilla					Mandible					Total
	Anterior			Posterior		Anterior			Posterior		
	Central	Lateral	Canine	Premolar	Molar	Central	Lateral	Canine	Premolar	Molar	
TPH Spectrum	4	2	9	12	2	3	1	2	11	2	48
Filtek Z250	5	4	5	10	8	1	3	1	12	0	49
Total	9	6	14	22	10	4	4	3	23	2	97
		29		32			11		25		
			61					36			

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the 6-month recall. However, the rates were lower than expected after 12 and 24 months; this decrease for both materials may have been caused by the absence of mechanical roughening of sclerotic dentin, which is resistant to acid etching.[9] NCCLs are usually sclerotic, and different levels of sclerosis in these lesions can affect the retention of restorations.[10] In the hypermineralized surface layer, sclerotic casts obliterate the dentinal tubules and make the dentin substrate less susceptible to acid demineralization.[11] Another reason for failure was flexure at the cervical region caused by excessive occlusal forces together with the compromised adhesion between the sclerotic dentin and the restorative material.[12] Most NCCLs have a relatively small c-factor, signifying that the mechanical properties of the composite used are less important, and the actual adhesive performance is the main determinant affecting this result.[13]

The adhesive system employed in this study (Single Bond 2, 3M ESPE) takes advantage of the polyalkenoic acid copolymer derived from the glass ionomer chemical bonding concept.

Table 3: Modified USPHS criteria

Retention	A - No loss of restorative material
	C - Any loss of restorative material
Color match	A - Matches tooth
	B - Acceptable mismatch
	C - Unacceptable mismatch
Marginal discoloration	A - No discoloration
	B - Discoloration without axial penetration
	C - Discoloration with penetration in pulpal direction
Marginal adaptation	A - Closely adapted, no crevice is visible
	B - Crevice is visible, explorer will penetrate
	C - Crevice in which dentin is exposed
Surface texture	A - Enamel-like surface
	B - Surface rougher than enamel, clinically acceptable
	C - Surface unacceptably rough
Anatomic form	A - Continuous
	B - Slight discontinuity, clinically acceptable
	C - Discontinuous, failure
Postoperative sensitivity	A - Not present
	B - Sensitivity with diminishing intensity
	C - Constant sensitivity without diminishing intensity
Secondary caries	A - No caries present
	C - Caries present

A=Alfa; B=Bravo; C=Charlie; USPHS=United States Public Health Service

The polyalkenoic acid copolymer has been reported to form Ca-polyalkenoate complexes at the superficial region of the hybrid layer and within the superficial 3 μm of dentinal tubules.[14] These complexes might stabilize the bonded interface by providing water stability and a stress-relaxing effect, mainly in sclerotic dentin, such as that presented in Class V cavities.[15] However, this polymer also has some disadvantages, in that its hydrophilic formulation is responsible for making the material a permeable membrane after polymerization. Polyalkenoic acid copolymer can allow cured adhesives to absorb an extensive amount of water over time, due to the multiple pendant carboxylic acid groups along its linear backbone, decreasing the cohesive strength of this adhesive layer.[16] Similarly, it was also shown that etch-and-rinse adhesive systems demonstrated greater nano-leakage than self-etch adhesives when applied to dentin tissue.[16] The relative retention loss may also be related to this fact. However, the clinical effectiveness of different adhesive systems has been evaluated in previous research, and it was found that Single Bond exhibited similarly high retention rates and better marginal quality when compared with other adhesive systems.[17,18]

With regard to the marginal discoloration criterion, there was a statistically significant difference between the results at baseline and at 24-month for TPH Spectrum restorations. Marginal discoloration is one of the first clinical signs that cervical restorations have to be replaced.[2,19] In some studies examining composite materials, the frequency of marginal discoloration differed depending on the material tested.[20,21] However, one factor that strongly influences marginal discoloration is the type of enamel conditioning used.[22] In a study in which composite restorations were placed without enamel etching, the frequency of marginal discoloration increased rapidly, with about 40% of restorations already displaying stained margins after 2 years.[22] However, Kubo *et al.*[23] reported less marginal discoloration for etch-and-rinse adhesives compared with self-etch systems.

In this study, for the marginal adaptation criterion, there was a significant difference in Bravo scores between the baseline and 24 months results, and the incidence of poor marginal adaptation increased over time for both TPH Spectrum and Filtek Z250 restorations. The relationship

Table 4: Distribution of retention failures after 24 months

Composite type	Maxilla		Mandible		Total	Retention rate (%)
	Anterior	Posterior	Anterior	Posterior		
TPH Spectrum	3	1	1	2	7	85.4
Filtek Z250	0	3	0	2	5	89.8
Total	3	4	1	4	12	
	7		5			

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Table 5: Clinical findings according to modified USPHS criteria after 6, 12, and 24 months

Evaluation criteria	Baseline		6 months		12 months		24 months	
	TPH Spectrum (*n*=48)	Filtek Z250 (*n*=49)	TPH Spectrum (*n*=48)	Filtek Z250 (*n*=49)	TPH Spectrum (*n*=43)	Filtek Z250 (*n*=45)	TPH Spectrum (*n*=41)	Filtek Z250 (*n*=44)
Color match								
A	48	49	48	49	43	45	41	35
B	0	0	0	0	0	0	0	0
C	0	0	0	0	0	0	0	0
Marginal discoloration								
A	48	49	48	49	38	43	35	41
B	0	0	0	0	5	2	6	3
C	0	0	0	0	0	0	0	0
Marginal adaptation								
A	48	49	48	49	38	41	35	39
B	0	0	0	0	5	4	6	5
C	0	0	0	0	0	0	0	0
Surface texture								
A	48	49	48	49	43	43	41	42
B	0	0	0	0	0	2	0	2
C	0	0	0	0	0	0	0	0
Anatomic form								
A	48	49	48	49	43	45	41	35
B	0	0	0	0	0	0	0	0
C	0	0	0	0	0	0	0	0
Postoperative sensitivity								
A	48	49	48	49	43	45	41	35
B	0	0	0	0	0	0	0	0
C	0	0	0	0	0	0	0	0
Secondary caries								
A	48	49	48	49	43	45	41	35
C	0	0	0	0	0	0	0	0

A=Alfa; B=Bravo; C=Charlie; USPHS=United States Public Health Service

between marginal adaptation and marginal discoloration has been examined in many studies.[23-25] However, Kubo *et al.* reported that not all marginal defects resulted in marginal discoloration.[23] Additionally, marginal defects ought to be a less common reason to replace cervical restorations than marginal discoloration.[26]

In the current study, similar results were recorded for both arches; however, some researchers observed a higher failure rate in the mandible than in the maxilla.[27] It has been shown that the location of the cervical lesion in the mouth may also affect the retention rate of the restoration.[18] We noted that many more restorations were lost in the posterior region than the anterior region in this study. This may be due to the stress created by occlusal loading, which is not only distributed in structures such as the enamel and dentin, but is also concentrated in areas such as the composite and adhesive layer.[28]

In general, the risk of postoperative hypersensitivity is supposed to be higher for etch-and-rinse adhesives than for self-etch adhesives.[13] However, we found that preoperative hypersensitivity resolved after placement of the restoration and hypersensitivity was not reported at any evaluation period.

The advantages of using a rubber dam when performing operative procedures are well known. These benefits include isolation of the field and potentially improved properties of dental materials. However, in a busy practice, it is often impossible to place a rubber dam owing to time constraints. In the current study, rubber dam isolation was not used during placement of the restorations. Cotton rolls were preferred as they are the most practical form of isolation. A systematic review by Heintze *et al.*[29] reported that the isolation method did not significantly influence the clinical behavior of cervical restorations.

Conclusion

Within the limitations of this study, we found that noncarious cervical restorations placed with two different microhybrid resin composites exhibited similar and acceptable clinical performance after 24 months.

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