1 Year Clinical Evaluation of Microhybrid Composites used in the Restoration of Non-Carious Cervical Lesions

Duygu Tuncer, Çiğdem Çelik, Kıvanç Yamanel, Neslihan Arhun

Department of Restorative Dentistry, School of Dentistry, Baskent University, Ankara, Turkey.

Abstract

Aim: Microhybrid composite resins are commonly used to treat non-carious cervical lesions. The aim of this double blind study was to compare the 12-month clinical performance of cervical restorations placed with the use of two different microhybrid composite resins.

Methods: 20 patients with at least one pair of non-carious cervical lesion participated in this study. Ninety-seven cervical lesions were restored with either TPH Spectrum (n=48) or Filtek Z250 (n=49) using a two-step etch & rinse adhesive (Single Bond 2) Restorations were evaluated using modified USPHS criteria after 6 and 12 months. The statistical comparison of resin composites for each category was performed with the Pearson chi square test and the performance of restorations at the baseline, 6 months and after 12 month recall time was evaluated by Mc Nemar's test ($p<0.05$).

Results: The recall rate of the patients was 100% at each evaluation period. The retention rates were 100% at six months,89,6% and 91,8% at 12-months for TPH and Z250, respectively and no statistically significant difference was observed with respect to each evaluation criteria ($p>0.05$).

Conclusion: Cervical restorations placed with two different microhybrid composites and a two-step etches and rinse system showed satisfactory clinical performance after 12-months.

Key words: Clinical evaluation, Etch and rinse adhesive, Microhybrid composite, Modified USPHS, Non-carious cervical lesions

Introduction

Non-carious Cervical Lesions (NCCLs) which may be caused by erosion, abrasion and/or occlusal stress, abfraction, are commonly observed in clinical practice [1]. These slowly progressing clinical lesions with multiple etiologies offer unique challenges to adequate dental restorations [2]. They are characterized by the presence of sclerotic dentin that has been physiologically and pathologically altered, resulting in partial or complete obliteration of the dentinal tubules by the presence of sclerotic casts. Patency of tubules is found in sensitive areas, which are usually sparsely distributed among occluded tubules. Epidemiological reports estimate the prevalence at up to 97% with approximately 7-16.6% of the population showing pathological wear requiring treatment [3].

The treatment plan of NCCLs should begin with the most conservative technique including non-invasive preventive measures and oral hygiene instructions including controlling the etiological factor and extend to more invasive operative measures like restoring and occlusal adjustment [4]. Restoration of NCCLs may be necessary to relieve hypersensitivity, to prevent further tooth structure loss, and to improve esthetics. Unfortunately however, the longevity of resin-based composite restorations for NCCLs presents challenges to the clinicians [5]. The main reasons for failures were flexure at the cervical region caused by parafunctional forces and the compromised adhesion between the sclerotic dentinand the restorative material since previously existing etiological excessive occlusal forces may not be impeded after restoration placement [6].

Currently, for the restoration of NCCLs, a large variety of restorative materials having diverse esthetic and bonding characteristics have been used, such as composite resins, polyacid-modified resin composites (compomers), glass-ionomer cements, and resin-modified glass-ionomer cements. Among these materials, composite resins and glass ionomer cements which have advanced functional properties [7] are preferred to conserve sound tooth structure.

Although *in vitro* researches provide insight to predict potential *in vivo* performance of the materials, clinical trials are necessary to verify laboratory results and to evaluate long-term adhesive performance since multiple dependent variables sometimes may not be simulated *in vitro* [2].

The objective of this study was to evaluate twelve-month clinical performance of two different microhybrid composite resins in non-carious cervical lesions. The null hypothesis was clinical performance of two microhybrid composite resins would not be different.

Material and Methods

Patient selection

Patients who needed restorations for NCCLs were selected from those who attended to the Restorative Dentistry Department of Baskent University, School of Dentistry. Patients with extremely poor oral hygiene or with a history of bruxism or xerostomia, severe medical complications, or severe chronic periodontitis were excluded from the study. The lesions had to be non-carious, non-retentive, at least 1 mm deep, and involve both enamel and dentin of vital teeth without mobility and pulpal involvement. Every tooth included in the study was in occlusion with natural tooth and had a proximal contact with the adjacent tooth. Ethics Committee of Baskent University reviewed and approved the protocol and consent form which were used for the study. Prior to enrollment, the patients read, understood, and signed the consent form. Eight female, 12 male, totally 20 participants were selected with a mean age 58.9 (age range 27-83).

Corresponding author: Duygu Tuncer, Department of Restorative Dentistry, School of Dentistry, Başkent University, 11.sokak No: 26 Bahçelievler 06490, Ankara, Turkey, Tel: +90 312 2151336; Fax: 90-312-2152962; e-mail: duygukayaoglu@yahoo.com

Operative procedures

All lesions were restored by an investigator from the Department of Restorative Dentistry. Before restoring the lesions, teeth were cleaned with pumice-water slurry using a rubber prophylaxis and then rinsed with water. In order to secure contamination, operating field was isolated with cotton rolls and a suction device. Local anesthesia was not used during the restorative procedures unless requested since no preparation was performed.

A total of 97 cervical lesions were restored; with two microhybrid composite resins, TPH Spectrum (n:48) (Dentsply, De Trey, Konstanz, Germany) and Z-250 (n:49) (3M ESPE, St. Paul, MN, USA) in conjunction with a two-step etch-rinse adhesive Single Bond 2 (3M ESPE, St. Paul, MN, USA). All materials were used according to the manufacturers' directions (*Table 1*).

In each patient, at least two cervical lesions were restored; one with TPH and the other one with Z250. Resin composites were applied not exceeding 2 mm increments and light cured with a quartz tungsten halogen light curing unit (Hilux 200, Benlioğlu Dental Ankara, Turkey) for 40 seconds. The power output of the light-curing unit wasmonitored periodically with a hand-held radiometer (Demetron, Kerr, Orange, CA, USA) and determined with a power output of 600 mW/cm^2.

After polymerization, finishing was accomplished with an ultrafine diamond finishing bur (Diatech Dental Products, Charleston, USA) and polishing was accomplished with slow speed polishing cups and points (Eveflex Polisher, EVE Ernst Vetter GmbH, Germany) and aluminum oxide polishing discs (Soflex, 3M ESPE, St. Paul, MN, USA). Distribution of the restorations according to the type of tooth and arch is shown in *Table 2*.

Clinical evaluation

Two independent and calibrated, experienced examiners evaluated the restorations with the aid of a dental loupe with X5 magnification at baseline, 6 and 12 months. Modified United States Public Health Service (USPHS) criteria were used to evaluate the restorations at baseline, after 6 and 12 months (*Table 3*). The evaluated categories were retention, color match, marginal discoloration, marginal adaptation, surface texture, postoperative hypersensitivity, and secondary caries [8]. Presence or absence of preoperative sensitivity to stimuli (spontaneous, the waterspray, air blast, and the pressure from the explorer) were also evaluated. The examiners were unaware of which material had been used, creating a double-blind study. When disagreement arose during evaluation, the examiners had to reach a forced consensus.

The restorations were scored as follows: Alfa represented the ideal clinical situation, Bravo was clinically acceptable, and Charlie represented a clinically unacceptable situation.

Statistical evaluation

The statistical analyses were carried out with the SPSS 16.0 software package (SPSS, Chicago, IL, USA). The statistical comparison of resin composites for each category was performed with the Pearson chi square test and the performance of restorations at the baseline and after 6 and 12 month recall times was evaluated by McNemar's test ($p<0.05$).

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 [77 wt%;, 57.1 vol% ,<1.0 mm average particle size], colloidal silica, initiators/stabilizers	Apply in one increment, light cure [40 seconds]
Filtek Z250 3M Dental Products, St. Paul, MN, USA Batch Number:N380435	Microhybrid	Bis-GMA, Bis-EMA, UDMA, photo initiators, and stabilizers Filler Zirconium/silica filler [0.01–3.5 mm]: 84.5wt%] , 60 vol% [	Apply in one increment, light cure [40 seconds]
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, İnitiator, silane-treated nanofillers	Apply etchant to tooth surface 30 sec for enamel, 15 sec for dentine. Rinse for 10 sec and excess water was blotted with a cotton pellet. Apply two consecutive coats of adhesive for 15 sec with gentle agitation. Gently air thin for 5 sec. Light cure for 10 sec.
Bis-EMA = ethoxylated bisphenol a dimethacrylate; Bis-GMA = bisphenol-glycidyl methacrylate; HEMA = 2-hydroxyethyl methacrylate; TEGDMA = triethyleneglycoldimethacrylate; UDMA= urethane dimethacrylate, GPDM: glycerophosphoric acid dimethacrylate			

Table 2. *Distribution of the number of restorations at baseline.*

Composite Type	Maxilla					Mandibula					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 Z 250	5	4	5	10	8	1	3	1	12	0	49
	9	6	14	22	10	4	4	3	23	2	97
	29			32		11			25		
	61						36				

Results

The overall recall rate was 100% as all patients were available for the entire evaluation period. A total of 97 restorations of 20 patients (48 for TPH, 49 for Z250) were evaluated at baseline and 6 month's recall. At 12-month recall, a total of 88 restorations of 20 patients (43 for TPH, 45 for Z250) were observed. Five TPH and 4 Z250 restorations were lost, resulting in a retention rate of 89.6% and 91.8%, respectively. *Table 4* shows the distribution of lost restorations with regard to jaws and regions. The difference in the retention rates of the tested composite restorations were not statistically significant ($p<0.05$) (*Table 4*).

Table 5 summarizes the evaluated data for each criterion per group at each evaluation time. For each evaluated criteria, there were no statistically significant differences between the baseline, 6 month and 12-month recall in both TPH and Z250 restorations ($p<0.05$). No statistically significant difference was detected between the composite resins in any of the evaluation criteria at both 6 and 12 month recall ($p>0.05$). None of the restorations had secondary caries during the evaluation period. 11 patients with 43 lesions were hypersensitive before restorative procedure. None of the teeth presented hypersensitivity at any follow up recall.

Discussion

Laboratory tests provide useful information to the potential performance of a restorative material and its handling, but such tests cannot adequately examine the clinical performance of the material. Previously, the physical properties such as flexural strength, modulus of elasticity of TPH Spectrum and Filtek Z250 were evaluated in an *in vitro* study [9]; however, their clinical performance was not reported by a clinical study for the restoration of NCCLs. Thus, the present randomized controlled clinical study investigated the short term performance of these two different microhybrid composite resins.

The original United States Public Health Service (USPHS) criteria were developed more than 40 years ago and since then it became less sensitive for identifying differences between current materials [10]. Therefore, modified USPHS criteria have been widely used in clinical studies. The USPHS criteria use a grading system based on observations however, it is relatively difficult to obtain agreement on secondary caries, marginal discoloration and marginal adaptation. In many cases, the relative insensitivity of the USPHS evaluation system during short and medium term clinical trials (<3-5 years) may be misinterpreted [11].

In clinical studies, the success of a material is indicated by its longevity, which makes retention rates the most important evaluation criteria. American Dental Association (ADA) guidelines require provisional acceptance if no more than 5% of the restorations have been lost at the six-month recall and, in order to obtain full acceptance, the cumulative incidence of clinical failures in each of two independent clinical studies has to be lower than 10% of lost restorations after 18 months [12]. Likewise, retention rates of the restorative materials used in this study are found to be acceptable with a retention rate 100%, as they meet the 5% failure rate called for in the ADA guidelines at six months recall. At one-year recall, TPH Spectrum and Filtek Z250 had a retention rate

Table 3. *Modified USPHS criteria [15].*

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
Secondary Caries	A - No caries present C - Caries present
A*=Alfa,* ***B****=Bravo,* ***C****=Charlie*	

Table 4. *Distribution of Retention Failures after 12 months.*

Composite	Maxilla		Mandibula		Total	Retention Rate
	Anterior	Posterior	Anterior	Posterior		
TPH Spectrum	2	1	1	1	5	89,6%
Filtek Z250	0	2	0	2	4	91,8%
Total	2	3	1	3	9	
	5		4			

Table 5. *Clinical evaluation of restorations according to the modified USPHS criteria.*

		Marginal Discoloration			Marginal Adaptation			Color Match			Secondary Caries			Postoperative Hypersensitivity			Surface Texture		
TPH Spectrum	n*	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
Baseline	48	48 [100%]	0 [0%]	0 [0%]	48 [100%]	0 [0%]	0 [0%]	48 [100%]	0 [0%]	0 [0%]	48 [100%]	0 [0%]	0 [0%]	48 [100%]	0 [0%]	0 [0%]	48 [100%]	0 [0%]	0 [0%]
6 month	48	48 [100%]	0 [0%]	0 [0%]	48 [100%]	0 [0%]	0 [0%]	48 [100%]	0 [0%]	0 [0%]	48 [100%]	0 [0%]	0 [0%]	48 [100%]	0 [0%]	0 [0%]	48 [100%]	0 [0%]	0 [0%]
12 month	43	38 [88,4%]	5 [11,6%]	0 [0%]	38 [88,4%]	5 [11,6%]	0 [0%]	43 [100%]	0 [0%]	0 [0%]	43 [100%]	0 [0%]	0 [0%]	43 [100%]	0 [0%]	0 [0%]	43 [100%]	0 [0%]	0 [0%]
Filtek Z250	**n***	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**C**		**A**	**B**	**C**	**A**	**B**	**C**
Baseline	**49**	49 [100%]	0 [0%]	0 [0%]	49 [100%]	0 [0%]	0 [0%]	49 [100%]	0 [0%]	0 [0%]	49 [100%]	0 [0%]		49 [100%]	0 [0%]	0 [0%]	49 [100%]	0 [0%]	0 [0%]
6 month	**49**	49 [100%]	0 [0%]	0 [0%]	49 [100%]	0 [0%]	0 [0%]	49 [100%]	0 [0%]	0 [0%]	49 [100%]	0 [0%]		49 [100%]	0 [0%]	0 [0%]	49 [100%]	0 [0%]	0 [0%]
12 month	**45**	43 [95,6%]	2 [4,4%]	0 [0%]	41 [91,1%]	4 [8,9%]	0 [0%]	45 [100%]	0 [0%]	0 [0%]	45 [100%]	0 [0%]		45 [100%]	0 [0%]	0 [0%]	43 [95,6%]	2 [4,4%]	0 [0%]

of 89.6% and 91.8%, respectively. The retention rate of TPH Spectrum was below the border of the ranges of ADA guidelines after one year. However, it should be kept in mind that there should be two independent clinical studies to deny full acceptance. Long-term follow up is in progress currently. Besides, previous *in vivo* studies reported that the first 6-24 months appear as the critical periods for the development of deteriorations such as retention loss, marginal adaptation failures, marginal discoloration etc. [13].

The adhesive system employed in this study (Single Bond, 3M ESPE) takes advantage of the polyalkenoic acid copolymer derived from the glass ionomer chemical bonding concept. 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; this hydrophilic formulation is responsible for making the material a permeable membrane after its polymerization. Polyalkenoic acid copolymer can allow cured adhesives to absorb an extensive amount of water over time, due to the multiple pendent carboxylic acids along its linear backbone, decreasing the cohesive strength of this adhesive layer [16]. Likewise, it was also shown that etch-and-rinse adhesive systems demonstrated higher amounts of nano-leakage than self-etch adhesives when applied to dentin tissue [17]. The relative retention loss may also be related to this fact. However, the clinical effectiveness of different adhesive systems along with Single Bond were evaluated in previous researches and it was found that Single Bond showed high or similar retention rates and better marginal quality compared to other adhesive systems [2,18]. The *in vitro* performance of Single Bond was also of concern in different *in vitro* researches, the intimate adaptation of Single Bond to the dentin was evaluated by microleakage and bond strength testing. It was found that Single Bond showed less microleakage than Prime&Bond NT and shear bond strengths were comparable [19,20].

Scleroticdentin is a common substrate that occurs in response to toothwear caused by attrition, abrasion, abfraction or erosion. This substrate has demonstrated to be a challenge for bonding procedures. Sclerotic dentin and tubule occlusion by mineral crystals are present most of the time in non-carious cervical lesions. Additionally, many parts of the wedge- shaped cervical lesion contain a hypermineralized surface that is resistant to acid etching. The presence of a hyper-mineralized surface layer, bacteria and sclerotic casts obliterates the dentinal tubules and makes the dentin substrate less susceptible to acid demineralization [21]. Indeed, these factors are responsible for the lower microtensile bond strengths verified in these types of lesions when compared to similar areas artificially prepared in normal teeth [22]. In the present study, the retention loss of the restorations may be due to the scleroticdentin structure of the non-carious cervical lesions that is resistant to applied acid etching.

The mechanical properties of composites depend on many factors related to the composition of the materials,

such as the type and quan¬tity of the monomers used, their degree of conversion, type and size of the inorganic fillers, type of silanization and the amount of initiators present [23]. It has been suggested that clinical retention of an adhesive restoration depends not only on retention capacity of the adhesive system, but also the viscoelastic properties [24], fracture strength, toughness, hardness and wear resistance of the restorative material [25]. However, despite these considerable differences in the organic/filler nature of the resin composite clinical studies comparing those different resin composite restorations demonstrated only minor differences [25].

The comparison of two microhybrid resin composite types may be critized in the current literature; however, various *in vitro* and *in vivo* researches were found in dental literature reporting *in vitro* or clinical performance of two microhybrid resin composites [26-28]. Earlier clinical studies [29,30] also indicated that microfilled composite resins showed higher retention rates in NCCLs than hybrid composite resins. The authors speculated that the composite resins with lower elastic modulus sustained lower stresses at the adhesive interfaces generated by occlusal forces, since the composite resin was able to flex with the tooth. However, recent clinical studies [31,32] revealed no difference in retention rates between microfilled and hybrid composite resins. It should also kept in mind that the adhesive system used along with these resin composite types are also of fundamental importance.

In the present study, at 1 year recall, the retention rates of TPH Spectrum and Filtek Z250 were 89,6% and 91.8% respectively, showing similar retention rates. Therefore the null hypothesis was accepted. Similarly, Browning et al. [31] did not find any difference between the retention rates of a microfilled and a hybrid resin composite after 24 months. Also Van Meerbeek et al. [33] have observed high retention rates of Class V cavities restored either with a microfilled (low modulus of elasticity) or a hybrid composite (high modulus of elasticity) composite after 2 to 3 years.

Inevitably, the present study can be criticized that the duration of the study is insufficient to confirm long-term suitability of the tested materials. In restorative dentistry literature, there are various reports that evaluated the short term clinical performance of the resin based materials in NCCLs and their consecutive follow up reports are published in the following years [34,35].

It has been shown that allocation of the cervical lesion in the mouth may also affect the retention rates of restorations. In the current study, similar results have been determined in both arches, but some authors observed a higher failure rate in the mandibular arch with respect to the maxillary arch [36]. Heymann et al. [29] suggested that this finding may be the result of greater flexure of mandibular teeth with greater difficulty of moisture control. In the present study, much more restorations were lost in the posterior region than anterior. It may be due to the stress created by occlusal loadings which is not only distributed in structures such as enamel and dentin, but also concentrated in areas as the composite and adhesive layer [37].

Beveling of the enamel margins might also affect the retention of restorations. It has been reported that beveling of the enamel margins of non-carious cervical lesions may provide higher retention rates of restorations. As no beveling procedure was performed in the present study, the lost restorations may be attributed to this factor [38].

Overall, there were no statistically significant differences between the baseline values and those measured after 6 months and one year for any of the criteria evaluated. No bravo scores were evaluated for each criterion at six months recall. The loss of marginal adaptation is one of the most important factors that determine the failure of a restoration and the reason for replacement [39]. In the present study, Z250 restorations showed 4 and TPH restorations showed 5 bravo scores in marginal adaptation which is still acceptable at 12 month recall. Likewise, marginal discoloration was observed around some restorations, but there were no statistically significant differences for this criterion between the materials at the end of 12 months. Postoperative hypersensitivity and secondary caries were not reported after each evaluation period.

Conclusion

Within the limitations of the present study, non-carious cervical restorations placed with two different microhybrid composites exhibited similar clinical performance after 12 months.

Conflicts of Interest

All my affiliations, corporate or institutional, and all sources of financial support to this research are properly acknowledged, except when mentioned in a separate letter. I certify that do not have any commercial or associate interest that represents a conflict of interest in connection with the submitted manuscript.

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