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Clinical Research

A 24-month Follow-up of Flowable Resin Composite as an Intermediate Layer in Non-carious Cervical Lesions

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Clinical Relevance

After 24 months of evaluation, the use of Filtek Flow as a liner under Filtek Z250 restorations did not improve the clinical performance of Class V restorations.

SUMMARY

This study compared the clinical performance of a microhybrid resin composite to lined Class V restorations or to those restorations without a flowable resin composite over a 24-month period. Nineteen patients with at least 2 pairs of equivalent cervical erosion/attrition/abfraction lesions, under occlusion, were enrolled in this study. A total of 74 restorations were placed, half for each group (Single-Bond + Filtek-Flow + Filtek Z250 or Single-Bond + Filtek Z250). According to the manufacturers' instructions, 2 calibrated operators placed all restorations. Two other independent examiners evaluated the restorations at baseline and after 24 months, according to the USPHS criteria and modified criteria for color match. The classic alpha score was divided into A1 for "not detectable" and A2 for "slightly discernible" filling. Statistical analysis was conducted using Fisher's exact test (α=0.05). For each group, 8 restorations were lost after 24 months (retention rate of 89.2%). All the restorations showed a trend toward dark yellowing after 24 months (color match A2).

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DOI: 10.2341/05-116

INTRODUCTION

Non-carious loss of dental hard tissue at the cervical region is a very common clinical condition, due to the fact that the prevalence and severity of these lesions have been found to increase with age (Levitch & others, 1994). When investigating the clinical effectiveness and/or techniques of adhesives, studies should involve non-carious Class V adhesive restorations for which there are many causes. Cervical lesions present no macro-mechanical undercuts, and they are widely available in patients with better than average oral hygiene (Van Meerbeek & others, 2003). These lesions require at least 50% bonding to dentin, and they are usually found in anterior teeth and premolars with good clinical access.

Ineffective bonding commonly results in restoration loss, which is the most objective evaluation parameter of clinical studies (Peumans & others, 2005). This

Table 1: *Material, Batch #, Composition and Mode of Application of Materials*

Material	Composition	Mode of the Application
Single Bond (3M ESPE)	1. Scotchbond—37% phosphoric acid 2. Adhesive—Bis-GMA, HEMA, dimethacrylates, polyalkenoic acid copolymer, initiators, water and ethanol	Acid-etch (15 seconds); rinse (15 seconds); air-dry (30 seconds); dentin rewetted with water (moist technique); application of 2 coats of adhesive systems, brushing for 10 seconds each; air-dry for 10 seconds at 20 cm; light-curing (10 seconds–600 mW/cm^2)
Filtek-Flow (3M ESPE)	Bis-GMA, TEGDMA, dimethacrylate polymer, zirconium/silica filler. Additional contents: stabilizers, catalysts and pigments. Particle size (average diameter 1.5 μm) and approximately 68% wt filler load.	Application of one increment (<1.5 mm); Light-curing (30 seconds–600 mW/cm^2).
Filtek Z250 (3M ESPE)	Bis-GMA, UDMA, Bis-EMA and TEGDMA, Silica filler. Additional contents: stabilizers, catalysts and pigments. Particle size (average diameter:0.6 [0.01-3.5]) and approximately 83% wt filler load.	Incremental placement (<1.5mm); Light-curing (30 seconds–600 mW/cm^2).

explains why non-carious cervical lesions are used as clinical models to evaluate the efficacy of dentin bonding agents in non-retentive tooth cavities, as recommended by the American Dental Association (2001). For provisional acceptance, dentin and enamel adhesive materials require no more than 5% of the restorations be lost and no more than 5% of the restorations show microleakage at the 6-month recall. In 2 independent clinical studies, in order to obtain full acceptance, the cumulative incidence of clinical failures after 18 months has to be lower than 10% of lost restorations and 10% of microleakage.

Table 2: *Dentin Sclerosis Scale*

Category	Criteria
1	No sclerosis present. Dentin is light yellow or whitish in color with little discoloration; opaque, with little translucency or transparency.
2	More than category 1 but < halfway between categories 1 and 4.
3	Less than category 1 but > halfway between categories 1 and 4.
4	Significant sclerosis present. Dentin is dark yellow or even discolored (brownish), has a glassy appearance, with significant translucency or transparency evident.

(*) Based on scale developed by Dr Steven E Duke of the University of Texas Health Science Center at San Antonio and modified by the Department of Operative Dentistry at the University of North Carolina, School of Dentistry (Swift & others, 2001).

The performance of several adhesive systems has been tested, and the retention of etch-&-rinse adhesive systems has clearly improved over earlier systems (Van Meerbeek & others, 1994, 2003). However, the retention rates of these etch-&-rinse adhesive systems still vary significantly over a period of 1 to 3 years (Van Dijken, 2000; Tyas & Burrow, 2002; Baratieri & others, 2003). Premature failure of the restoration is partially due to the restorative material. There is a widespread theory that high modulus restorative materials are unable to flex in the cervical region when tooth structure is deformed under load and, therefore, the restorative materials can be displaced from the cavity (Heymann & others, 1991). As a result, materials with low elastic modulus, such as microfilled composites (Heymann & others, 1991; Levitch & others, 1994), flowable resins (Unterbrink & Liebenberg, 1999; Li & others, 2006) and glass ionomer cements (Loguercio & others, 2003; Burgess & others, 2004) have been indicated for the restoration of cervical lesions, with the aim of absorbing the stresses generated during the polymerization shrinkage of composites and the mechanical loading in which the teeth are subjected during function.

This study evaluated the use of flowable composites as an intermediate layer between the adhesive and composite (Loguercio & others, 2005). In the past, few randomized clinical trials of this kind have been conducted.

METHODS AND MATERIALS

The materials employed in this study were the flowable resin composite Filtek-Flow (3M ESPE, St Paul, MN, USA), the Single-Bond adhesive system (3M ESPE) and the microhybrid resin composite Filtek Z-250 (3M ESPE). Table 1 details their compositions.

The University of São Paulo Committee on Investigations Involving Human Subjects approved the protocol and consent form for this study. Patients enrolled in this study were healthy and had at least 20 teeth. Those patients with poor hygiene or bruxism were not included in the study. At least 2 pairs of equally-sized cervical lesions (erosion/attrition/abfraction) under occlusion were required for each patient. The lesions had no undercuts, and no more than 50% of the cavo-surface margin could involve enamel. The cervical wall had to be located in cementum. Lesions not classified as criteria 2 and 3 of dentin sclerosis (Table 2), and exhibited hypersensitivity, were excluded from the study (Swift & others, 2001).

All patients were informed of the nature and objectives of this study; however, they were unaware of the location of each material. Written informed consent was also

obtained from all participants prior to starting treatment. Out of the 40 patients evaluated, only 19, with a mean age of 40 years (range 19-63 years; median 41), were selected. Seventy-four restorations were placed, 37 for each group. Distribution of the restorations was similar, between maxillary (41) and mandibular (33) arches, and about 65% of the restorations were placed in premolars (48) and 35% were placed in anterior teeth (18 in incisors and 8 in canines).

Restoration Procedures

Under the supervision of an experienced clinician, undergraduate students placed all restorations. The clinician placed 2 restorations, explaining in detail all the steps the undergraduate students should follow carefully during restoration placement. The students then placed approximately 5 restorations each. These restorations were carefully evaluated by the experienced clinician. The restoration deficiencies were shown to the students prior to starting the study.

Each patient received at least 2 restorations. A coin was tossed in order to determine the experimental treatment for 1 of the 2 cavities. The lesions were prepared as follows: 1) anesthesia (Citanest, Dentsply, Petrópolis, RJ, Brazil); 2) cleaning with pumice and water (SS White Prod Odontol Ltda, Petrópolis, RJ, Brazil) in a rubber cup (ref #8040RA and #8045RA, KG Sorensen, Barueri, SP, Brazil), followed by rinsing and drying; 3) shade selection (Z-250 shade guide/3M ESPE); 4) rubber dam isolation (SS White Prod Odontol Ltda, Petrópolis, RJ, Brazil); 5) new oral prophylaxis. No additional retention or bevel was performed. The materials were then inserted according to the manufacturer's instructions.

In Group 1, Single-Bond was applied according to Table 1. Then, a single increment (± 1.5 mm) of Filtek-Flow was placed and light-cured for 40 seconds (Figure 1). The lesions were incrementally filled with Filtek Z250 (± 3 increments). Each increment was light cured for 30 seconds, using a VIP light unit set at 600 mW/cm^2 (BISCO, Schaumburg, IL, USA). In Group 2, the lesions were restored, similar to the anterior group, except that Filtek Flow was not employed as an intermediate layer. All restorations were finished with fine-grained diamond burs (ref #1190F and #2135F, KG Sorensen). After 1 week, the restorations received a final polishing with Sof-Lex Pop-On (3M ESPE).

Clinical Evaluation

Clinical evaluation was done at baseline and after 24 months, according to the USPHS criteria adapted by Barnes and others (1995). The categories evaluated were retention, color match, anatomic form, marginal integrity and marginal discoloration, postoperative sensitivity and secondary caries. Modified color match criteria were used (Reusens, D'hoore & Vreven, 1999). The classic *A* score (mismatch in color, and translucency is within the acceptable range of tooth color and translucency) was divided into *alpha 1* for "not detectable" filling and *alpha 2* for "slightly discernible" filling (Reusens & others, 1999). Two other independent and calibrated examiners performed the evaluation, using a mirror and double probe after tooth prophylaxis. These examiners were unaware of which material had been used in the restorations. An initial agreement of at least 85% between evaluators was necessary. When disagreement occurred during the evaluation, a consensus had to be made between evaluators before the patient was dismissed.

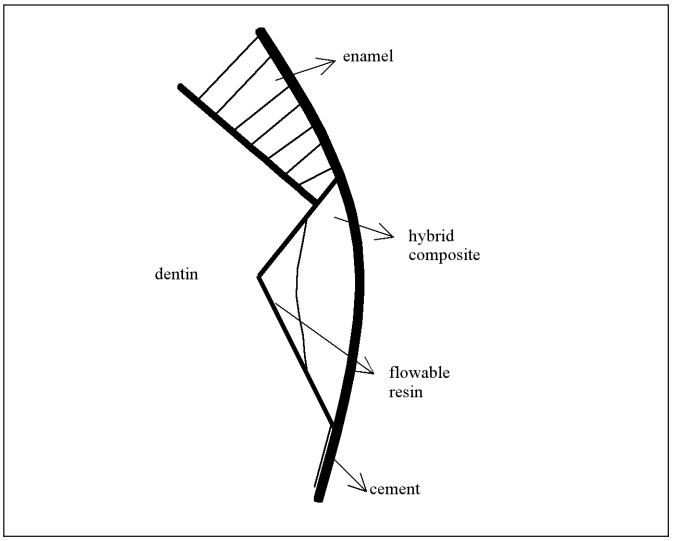

Figure 1. *Schematic drawing showing the configuration of the restoration and the region where the flowable composite was applied.*

Descriptive statistics were used to explain the frequency distributions of the evaluated criteria. Differences in ratings of the 2 materials at baseline and after 24 months were tested with the Fisher's exact test. Significant differences were considered to be present when $p<0.05$, as a measurement of agreement between the examiners, Cohen's Kappa statistic was used (Landis & Koch, 1977)

RESULTS

The Cohen's Kappa statistics (0.89) showed strong agreement between the examiners. After 24 months, all restorations and patients were available for evaluation. The results appear in Tables 3 and 4. No restorations presented secondary caries throughout the evaluation period. The restorations preserved anatomic form and marginal adaptation. Cavosurface discoloration was not observed after 24-month evaluation.

Eight restorations (4 in each group) were lost after 24 months. The retention rate for both groups was 89.2% ($p>0.05$). With regard to color match, 2 types of presentations were done. The first used the USPHS crite-

Table 3: *Number of evaluated restorations in retention, anatomic form, marginal adaptation, interfacial staining, secondary caries, postoperative sensitivity and color match for each group according USPHS criteria.*

Evaluation Criteria	Scores	Baseline		24 Months	
	↓	Group 1	Group 2	Group 1	Group 2
Retention	A	37	37	33	33
	B	--	--	04	04
	C	--	--	--	--
Anatomic Form	A	37	37	37	37
	B	--	--	--	--
	C	--	--	--	--
Marginal Adaptation	A	37	37	35	34
	B	--	--	02	03
	C	--	--	--	--
Interfacial Staining	A	37	37	35	33
	B	--	--	02	04
	C	--	--	--	--
Secondary Caries	A	37	37	37	37
	B	--	--	--	--
	C	--	--	--	--
Postoperative Sensitivity	A	37	37	37	37
	B	--	--	--	--
	C	--	--	--	--
Color Match	A	37	37	37	37
	B	--	--	--	--
	C	--	--	--	--

Table 4: *Number of evaluated restorations in color match for each group according to Reusens, D'hoore and Vreven criteria (1999).*

Evaluation Criteria	Scores	Baseline		24 Months	
	↓	Group 1	Group 2	Group 1	Group 2
Color Match	A1	37	37	18	14
	A2	--	--	19	23
	B	--	--	--	--
	C	--	--	--	--

ria, which enables these results to be compared with other studies. The second presentation divided the classic "Alpha" score in A1 and A2 to allow for better discrimination and to measure slight changes. As seen in Table 3, when restorations were classified classically, all restorations received an "alpha score." However, using the modified criteria (Table 4), the restorations were given score A2, due to the trend toward dark yellowing after 24 months. The difference between the baseline and 24-month evaluation was statistically significant ($p<0.05$).

DISCUSSION

One of the most important factors in the retention of non-carious cervical lesions is bonding to the cavity walls, because such cavities lack inherent macro mechanical retention. However, several other factors can directly influence the retention of Class V restorations; for example, occlusion, dentin sclerosis and patient age (Levitch & others, 1994; Powell, Johnson & Gordon, 1995; Van Dijken, 2000). Correct diagnosis of the cause of the lesion beforehand is essential; otherwise, low, short-term retention rates may be observed, regardless of the restorative material used (Bayne & others, 1991).

It is widely known that the etiology of non-carious cervical lesions is multifactorial (Levitch & others, 1994). Patients with a history of bruxism or clinical evidence of other forms of traumatic occlusion generally impose greater occlusal stresses on their teeth. Increased flexure in the cervical region, resulting from greater occlusal stresses, could result in restoration debonding.

Therefore, patients who suffer from bruxism were excluded from this study. In order to reduce flexural forces in the cervical region of the restored teeth, when selected patients were diagnosed as having centric and eccentric occlusal contacts and wear facets (malocclusion), efforts were first directed toward eliminating this causative or predisposing factor before starting restorative treatment. Because masticatory forces may vary from tooth type to tooth type, for the 2 restorative approaches used, another important factor that was controlled in this study was the selection of patients with Class V cavities on homologous teeth.

One attempt that was used to maximize the retention rates of Class V restorations was placement of low elastic modulus materials. These materials can act as "elastic buffers," since they have sufficient flexibility to resist polymerization shrinkage stress and favorably dissipate stresses produced by thermal variations, water absorption and occlusal loads across the interface. Some studies have shown an enhanced performance of composite restorations when an additional intermediate elastic layer was placed between the resin composite and dentin substrate. A better dissipation of shrinkage stresses (Kemp-Scholte & Davidson, 1990a; Choi, Condon & Ferracane, 2000; Ausiello, Apicella & Davidson, 2002), lower microleakage (Stainec & Kawakami, 1993; Choi & others, 2000; Li & others, 2006) and improved marginal adaptation (Kemp-Scholte, Davidson, 1990a, b) has already been reported.

As mentioned in the introduction, flowable resin composites present low elastic modulus (Braga, Hilton & Ferracane, 2003) and, thus, may be employed for cavities that suffer from tooth flexure (Levitch & others, 1994). In addition, flowability is regarded as a desirable handling property that allows for good wetting along the cavity walls, thus improving adaptation of the restorative material to the cavity walls. A previous study has demonstrated that stresses generated by the polymerization shrinkage of Filtek Z250 were significantly reduced when this composite was combined with Filtek-Flow (Braga & others, 2003).

However, an earlier report on the results of this investigation concluded that the use of flowable composites as an intermediate layer did not improve the retention rates of Class V restorations (Loguercio & others, 2005). One explanation was the short period of evaluation (12 months). However, no statistical difference was observed between the 12- and 24-month findings, indicating that other factors apart from the presence of a stress-absorbing layer, account for the retention rate of composite Class V restorations.

In fact, the literature has not reached a consensus on whether or not low-modulus materials can improve the clinical performance of Class V restorations. Browning, Brackett and Gilpatrick (2000) and Van Meerbeek and others (2003) have observed high retention rates of Class V cavities restored either with a microfilled (low modulus) or a hybrid composite (high modulus) composite after 2 to 3 years. Tyas and Burrow (2002), Baratieri and others (2003) and Belluz and others (2004) also demonstrated similarity between the retention rates of microfilled/hybrids and flowable composites after 3 to 4 years. Differences among the flowable composites and adhesive systems employed may account for such variation (Bayne & others, 1998; Labella & others, 1999; Tjandrawinata, Irie & Suzuki, 2005). When combined with Filtek Z250, Braga and others (2003) have shown that not all flowable composites are equally capable of reducing stresses from polymerization shrinkage. This may also explain the variation found in microleakage studies that aim to evaluate flowable composites as liners (Tung, Estafan & Scherer, 2000; Leevailoj & others, 2001; Loguercio & others, 2002; Li & others, 2006).

A closer analysis of studies which demonstrate low retention rates of Class V restorations (Tyas & Burrow, 2002; Baratieri & others, 2003; Belluz & others, 2004) shows that they employed the same adhesive system: an acetone-based etch-&-rinse system One Step (BISCO). In a recent systematic review of the literature (Peumans & others, 2005), it was demonstrated that One Step did not meet ADA guidelines in most clinical trials. Nearly 50% of the Class V restorations restored with One-Step debonded during 3 years of clinical function (van Dijken, 2000; Tyas & Burrow, 2002; Baratieri & others, 2003). This adhesive system seems to be inappropriate for clinical use, since this has been a common finding in clinical trials.

On the other hand, the adhesive system employed in this investigation (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 (Van Meerbeek & others, 1996). These complexes might stabilize the bonded interface by providing water stability and a stress-relaxing effect (Perdigão & others, 2000), mainly in sclerotic dentin, such as that presented in Class V cavities.

It is important to emphasize the use of clinical trials to adequately evaluate the performance of these materials. Both Single Bond and One Step adhesive systems show high bond strength values in laboratory evaluations (Nakajima & others, 2000; Reis & others, 2003); however, their clinical performance seems to differ greatly.

In regard to the color match of Filtek Z250, the same dark yellowing (score A2) observed in the 12-month report (Narhi & others, 2003; Loguercio & others, 2005)

was observed after 24 months. This finding is difficult to explain, because only 1 resin composite was employed in this study. In addition, discoloration is usually found in composites with high organic content, such as microfilled resin, not a microhybrid, such as Filtek Z250 (Reusens & others, 1999). This indicates that use of this resin composite in anterior teeth might cause esthetic problems in the short-term and long-term. Further studies should be conducted to evaluate these hypotheses.

CONCLUSIONS

The use of Filtek Flow as an intermediate layer did not improve the clinical performance of Class V restorations after 24 months of evaluation. Filtek Z250 showed a trend towards dark yellowing after 24 months.

(Received 22 August 2005)

Acknowledgements

This investigation was supported in part by PIBIC/CNPq and UNOESC/Joaçaba/SC grants. The materials were donated by the manufacturer (3M ESPE). The authors are grateful for the help provided by the undergraduate students Karina Renata Matté and Grasielli Montibeller.

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