

Clinical Evaluation of a Flowable Resin Composite in Non-Carious Class V Lesions: Two-Year Results

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Clinical Relevance

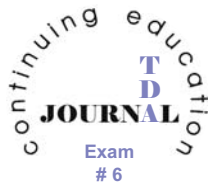
No significant difference was observed in the overall clinical performance between a flowable resin composite and a conventional hybrid resin composite. The use of a flowable resin composite in prepared teeth can be advocated as an acceptable restorative material in non-carious Class V lesions.

Summary

This *in vivo* study evaluated the clinical performance and appearance of a flowable resin composite and a hybrid resin composite over two years. Twenty-eight (28) pairs of restorations of a flowable resin composite and a conventional hybrid resin composite were placed in non-carious, asymptomatic facial Class V lesions. The restorations were evaluated at baseline, six, twelve, eighteen and twenty-four (6, 12, 18 and 24) months, using modified Ryge/USPHS criteria. No significant difference ($p < 0.05$) was observed in the performance or appearance of both materials.

Introduction

Non-carious cervical lesions commonly occur in the adult dentition.¹ A small caries free asymptomatic lesion may not require treatment; however, deep defects, even when asymptomatic and not



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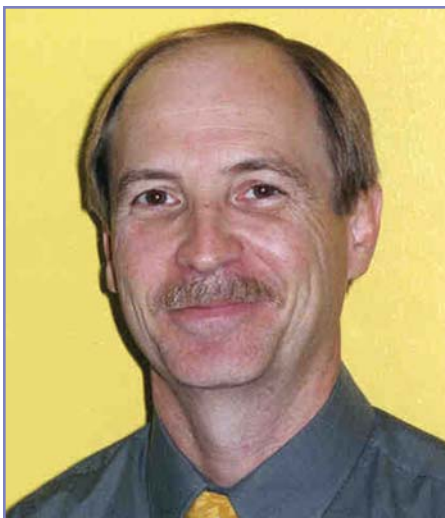
carious may present esthetic dilemmas for patients. These areas may also be a source of food or plaque entrapment and in some cases present the potential for fracture. Even small, relatively insignificant lesions may be sensitive to temperature changes or contact when brushing. No standard exists as to when or how to treat these lesions; however, the extension and depth of the defect as well as the etiology should be taken into account when deter-

mining the need for treatment.²

Resin composites have been used for several decades for restoring both carious and non-carious Class V lesions. These materials are esthetically pleasing, free of mercury, and have the ability to bond to tooth structure when appropriately used in conjunction with a bonding agent. In spite of these favorable aspects, resin composites are not without their problems.

A primary disadvantage of resin composites is volumetric shrinkage, which occurs during polymerization. Although improvements continue to be made in these materials, resin composites still shrink two to four percent (2-4%) upon polymerization.^{3,4,5} This shrinkage can result in marginal gap formation, fracture of the tooth structure, tearing of the adhesive or may result in deformation of the tooth structure.⁶ Another disadvantage of resin composites is in the coefficient of thermal expansion between the resin and tooth structure. It has been reported that these thermal expansion differences are as much as three to four times as great as that of tooth structure.⁷

Flowable composites were introduced for clinical use in the mid 1990s based in part on the desire for an injectable material as well as handling characteristics. These materials were developed by increasing the resin content of more tradi-



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tional resin composites at the expense of the filler content.⁸ As a result, the viscosity of the material is reduced to make it easily pass through a syringe applicator. Decreasing the filler content also decreases the elastic modulus, which results in the ability of the material to flex and better absorb polymerization

shrinkage stress;⁹ however, the more resin matrix that is present, such as that found in flowable resins, results in a greater coefficient of thermal expansion when compared to a conventional resin composite.¹⁰

Multiple uses of flowable resins have been suggested including: repair of non-carious marginal defects;¹¹ conventional restorative applications; build-up and block-out materials; liners and luting agents, among others. It has been suggested that flowable resin composites may reduce void formation and thus microleakage of the restoration.^{12,13} It has also been proposed that a combination of flowable and hybrid resins may be beneficial in certain applications; however, this may be dependent on bulk filling, separate or co-curing of the materials and may also be dependent on lesion size.⁷ Additionally, at least one study resulted in the recommendation that flowable resins might be clinically effective in reducing post operative sensitivity.¹⁴ Although some data and clinical studies exist regarding flowable resins, some of these recommendations have been put forth by the manufacturers without clinical research to verify their efficacy.¹⁵ The technique used in applying the restoration may also have an impact.

This study examined the clinical performance of a conventional hybrid resin composite and a flowable resin composite in non-carious Class V lesions with minimal cavity preparation. A bonding agent was utilized with each restoration in accordance with the manufacturer's instructions followed by the placement of either a flowable or conventional hybrid resin composite.

Methods and Materials

This study was conducted according to the guidelines of the University of Tennessee Institutional Review Board and with written informed consent obtained

	Prisma TPH			
	Incisors	Canines	Premolars	Molars
Maxillary	3	4	6	2
Mandibular	5	4	4	0
	Revolution			
	Incisors	Canines	Premolars	Molars
Maxillary	3	3	6	2
Mandibular	5	4	5	0

from each participant. Fifty-six (56) asymptomatic, non-carious Class V lesions in fourteen (14) healthy adult patients were selected. All lesions selected and included in this study were located on the facial surface. The median patient age was sixty-four (64) years and ranged from forty-four (44) to eighty-one (81) years. Each patient presented with one or more pair of cervical lesions. The restorative material was randomly selected for the first tooth in each pair, and the lesion, with which it was paired, received the alternate restorative material. Although there was not an equal distribution in the number of restorations in all patients, paired restorations utilizing both materials were placed in each patient. This allowed for an equal number of hybrid and flowable resin restorations within the patient regardless of the total number of restorations placed in that individual. No patient received fewer than two restorations and no one received more than eight restorations. The distribution of teeth utilized in this study is found in **Table 1**.

All teeth were prepared and restored by the same operator (LWS) with rubber dam isolation. Prior to isolation, an appropriate shade was selected. Although all lesions were non-carious, a minimal preparation was performed in all teeth. This preparation consisted of roughening the axial wall with a 330 bur (Brassler USA, Savannah, GA 31419, USA) and placement of a retention groove in the gingival floor dentin approximately 0.2mm inside the dentinoenamel junction with a one-quarter round bur (Brassler USA). A forty-five degree (45°) bevel of approximately 0.5mm was placed on the enamel cavosurface margins with a flame shaped tungsten carbide finishing bur H48LF.012 (Brassler USA). Gingival margins located in cementum or dentin were not beveled.

Upon completion of the preparation, the teeth were etched with Caulk Tooth Conditioner Gel (Dentsply/Caulk, Milford, DE 19963, USA), for fifteen (15) seconds, then thoroughly rinsed for fifteen (15) seconds. The preparation was then lightly air dried, leaving the dentin moist. ProBOND Primer (Dentsply/ Caulk) was

applied for thirty (30) seconds, ensuring a moist dentin surface was maintained. The preparation was then gently air dried for five (5) seconds. Utilizing a small, clean brush, a thin uniform layer of ProBOND Adhesive (Dentsply/Caulk) was applied to the etched and primed tooth structure. Excess adhesive was removed with a gentle air spray. The adhesive was light cured for ten (10) seconds with a visible light curing unit, Optilux 501 (Kerr USA, Orange, CA 92867, USA) at 850 mW/cm.² This light was used for light curing the bonding agent as well as both of the resin composites used in this study.

The selected resin composite was then placed following manufacturers' instructions.

For those teeth restored with the hybrid resin composite, Prisma TPH (Dentsply/Caulk) was selected. This material was placed incrementally with a forty (40) second continuous light cure following each increment. The final increment was light cured for forty (40) seconds. For those lesions restored with the flowable resin composite after application of the dentin bonding agent, a layer of Revolution Formula 2 (Kerr USA), was applied along the axial wall and gingival margin. This first layer was cured for forty (40) seconds. Subsequent layers were incrementally placed, each increment being light cured for forty (40) seconds, including a final light cure of forty (40) seconds.

All restorations were finished, first by the use of a number twelve (#12) surgical blade at the gingival margin, followed by sequential finishing and polishing with Soflex Disks (3M Dental Products, St. Paul, MN 55144, USA) moving from coarse to extra fine.

At baseline, six, twelve, eighteen and twenty-four (12,18,24) months, the restorations were evaluated clinically by

Table 2

Modified Ryge/USPHS Rating System

Category	Score	Criteria	Method
Retention	Alpha	No loss of restorative material	Visual inspection and explorer
	Charlie	Loss of restoration	
Color Match	Alpha	Matches tooth	Visual inspection
	Bravo	Acceptable mismatch	
	Charlie	Unacceptable mismatch	
Marginal Discoloration	Alpha	No discoloration between tooth structure and restorative material	Visual inspection
	Bravo	Non penetrating marginal discoloration which can be polished away	
	Charlie	Discoloration has penetrated margin in pulpal direction	
Caries	Alpha	No caries present	Visual inspection
	Charlie	Caries present	
Anatomic Form	Alpha	Contiguous, appropriate anatomic form	Visual inspection and explorer
	Bravo	Restoration is undercontoured but clinically acceptable	
	Charlie	Severely undercontoured and clinically unacceptable	
Marginal Adaptation	Alpha	Closely adapted, no detectable margin	Visual inspection and explorer
	Bravo	Detectable marginal discrepancy clinically acceptable	
	Charlie	Marginal crevice, clinically unacceptable	

two other calibrated investigators utilizing modified Ryge/USPHS criteria. The list of the criteria used can be found in **Table 2**. All restorations were evaluated with 2.5X magnification (General Scientific Corporation, Ann Arbor, MI 48103). Throughout the course of the study, the

evaluators were unaware of which material had been utilized. Any discrepancy between the evaluators was resolved prior to the patient's dismissal.

Statistical analyses were performed on data from each interval using Weibull and Kaplan-Meier parametric and non-

parametric analysis.

Results

All patients and restorations were clinically evaluated within forty-eight (48) hours of restoration insertion and at six-month (6) intervals for the first eighteen

Table 3

Results of Clinical Evaluation for Flowable and Hybrid Resin Composite

	Prisma TPH															
	Retention		Color Match			Marginal Discoloration			Caries		Anatomic Form			Marginal Adaptation		
	A	C	A	B	C	A	B	C	A	C	A	B	C	A	B	C
Baseline n=28	28	0	26	2	0	28	0	0	28	0	28	0	0	28	0	0
Six mos	28	0	25	3	0	28	0	0	28	0	28	0	0	28	0	0
Twelve mos	28	0	25	3	0	28	0	0	28	0	28	0	0	26	2	0
Eighteen mos	28	0	25	3	0	25	3	0	28	0	26	2	0	24	4	0
Twenty-four mos	27	0	25	2	0	23	3	1	26	1	25	2	0	23	3	1
	Revolution 2															
	Retention		Color Match			Marginal Discoloration			Caries		Anatomic Form			Marginal Adaptation		
	A	C	A	B	C	A	B	C	A	C	A	B	C	A	B	C
Baseline n=28	28	0	25	3	0	28	0	0	28	0	28	0	0	27	1	0
Six mos	28	0	24	4	0	28	0	0	28	0	28	0	0	27	1	0
Twelve mos	28	0	24	4	0	28	0	0	28	0	28	0	0	25	3	0
Eighteen mos	28	0	24	4	0	26	2	0	28	0	27	1	0	24	4	0
Twenty-four mos	27	0	24	3	0	26	1	0	27	0	26	1	0	24	3	0

Table 4

**Comparison Between TPH and Revolution
Using the Kaplan-Meier Product Limit Estimate
and the X2 found with Both Log Rank and the Wilcoxon Test**

Property	Chi-Sq (log rank)	Prob>Chi-Sq	Chi-Sq (Wilcoxon)	Prob>Chi-Sq
Retention	nd*	nd	nd	nd
Color Match	0.3377	0.5611	0.3204	0.5713
Margin Discoloration	1.4005	0.2366	1.3038	0.2535
Caries	0.0007	0.9793	0.0007	0.9793
Anatomic Form	1.9650	0.1610	1.9650	0.1610
Margin Adaptation	0.4560	0.9950	0.3989	0.5276

nd* Not determined because both data sets are identical, a condition that leads to mathematical anomalies. For none of the groups was Prob> χ^2 less than α (0.05), hence none of the differences observed are statistically significant.

(18) months. One of the patients passed away between the eighteen (18) and twenty-four (24) month evaluations. As a result, 96.4 percent of the restorations were examined at the twenty-four-month (24) evaluation. Complete results at each interval are listed in **Table 3**.

No restorations were lost during the course of this study. All restorations were clinically sound and only one restoration exhibited caries at the twenty-four-month (24) evaluation. Approximately seven percent (7%) of the restorations exhibited marginal discoloration at a level of Bravo, indicating the staining could be polished away. The one restoration with subsequent caries also received an evaluation of Charlie for both marginal discoloration and marginal adaptation. The anatomic form was maintained throughout the course of the study.

No significant difference between the materials was found at any interval or in the overall performance or appearance throughout the course of this study (Weibull parametric analysis, Kaplan-Meier non-parametric analysis; $p < 0.05$). The calculations were performed with JMP software, version 3.2.6 (SAS Institute Inc., Cary, NC, 27513). The calculations included the censoring of the restorations that were unavailable after eighteen (18) months into the study. The censoring time was set at eighteen (18) months. All restorations remaining at twenty-four (24) months were censored at twenty-four (24) months. Statistical analysis can be found in **Table 4**.

Discussion

The purpose of this clinical study was to evaluate the clinical performance of a flowable resin composite with a conven-

tional hybrid resin composite. Revolution Formula 2 (Kerr, USA) was selected for this study due to the fact that as a material, it held a large share of the flowable resin composite market at the time this study was initiated. Although the product selected for this study was based on market share, it should be noted that a wide variety of flowable resin composites exist. Currently, no standards have been established regarding the material formulation for flowable resins. Laboratory studies have indicated that flowable materials present a wide range of mechanical and physical properties.¹⁵ This lack of standardization and resulting variation in material properties may ultimately impact their clinical performance.

For example, filler particle size may vary from $< 5\mu$ to 14μ .¹⁶ Filler weight may vary from forty-four percent (44%) to as much as seventy-eight percent (78%) and filler volume may vary as well. In terms of mechanical properties, a wide range exists among flowable resins in terms of compressive strength, flexure strength, tensile strength and toughness,⁹ all of which may have an impact on clinical performance.

In addition to manufacturer variation in the formulation of flowable resins, other factors may influence the clinical performance of these materials. The choice of curing light (quartz tungsten halogen, plasma arc, LED, or argon laser) can affect polymerization shrinkage and conversion rate of resins.¹⁷ Slow start polymerization has been suggested as a method to reduce marginal microleakage in Class V composite resin restorations, although this appears to be material dependent.¹⁸ The polymerization shrinkage of flowable composites appears to have

higher shrinkage than traditional non-flowable composite¹⁹ due to their high resin content.

Another major factor in the success of any composite restorative material is the selection and proper use of the bonding agent. Multiple generations of dentin bonding agents are currently on the market with one-, two- and three-step systems. Technique sensitivity, advantages, disad-

vantages of these systems and performance of dentin bonding agents are well documented and beyond the scope of this paper; however, it is sufficient to say that success of any resin is dependent on the meticulous use of the appropriate bonding agent.

One- and two-year studies provide relatively short term clinical data; however, the results of this study provide supportive clinical evidence for the use of flowable resin composite as a restorative material in non-carious Class V lesions. Controlled clinical trials of longer duration and utilizing different resins and bonding agents would be beneficial in providing further information regarding the clinical performance of these materials.

Conclusions

There was no statistical difference in the use of Revolution Formula 2 when compared to Prisma TPH in prepared, non-carious Class V lesions. No differences existed at baseline, six, twelve, eighteen and twenty-four (6, 12, 18 and 24) month recall visits. Due to the wide variety of flowable resin composites on the market, additional long term clinical studies are recommended with these and other materials.

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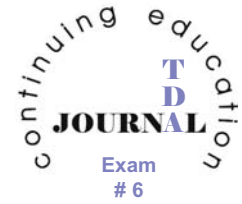
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| <ol style="list-style-type: none"> 1. A primary disadvantage of resin composites is: <ol style="list-style-type: none"> a. Roughness b. Porosity c. They fall out d. Volumetric shrinkage 2. Flowable composites were introduced for clinical use in the: <ol style="list-style-type: none"> a. U.S. Army b. 1960 ADA Annual meeting c. 1974 d. Mid 1990s 3. The shrinkage occurs because of: <ol style="list-style-type: none"> a. UV curing light b. Laser curing light c. Diet plan d. Polymerization 4. Shrinkage can result in: <ol style="list-style-type: none"> a. Marginal gap formation b. Fracture of the tooth structure c. Tearing of the adhesive d. All the above 5. What is the result of decreasing the filler content of resin composites? <ol style="list-style-type: none"> a. Viscosity is increased b. Viscosity is not affected c. Viscosity is destroyed d. Viscosity is decreased | <ol style="list-style-type: none"> 6. For several decades, resin composites have been used for: <ol style="list-style-type: none"> a. Class V carious lesions b. Class V non-carious lesions c. Only Class II lesions d. Both a and b 7. The coefficient of thermal expansion between tooth structure and resin has been reported to be: <ol style="list-style-type: none"> a. Equal b. Less than tooth structure c. Twenty times more than tooth structure d. Three to four times more than tooth structure 8. How does decreasing the filler content affect the elastic modulus? <ol style="list-style-type: none"> a. It has no effect b. It results in reduced flex c. It decreases the elastic modulus d. It increases the elastic modulus 9. Flowable resins may be used for: <ol style="list-style-type: none"> a. All below b. Conventional restorative applications c. Luting agents d. Build-up/block-out 10. Combining flowable and hybrid resins may: <ol style="list-style-type: none"> a. Reduce micro-leakage b. Discolor more quickly c. Be incompatible d. Increase sensitivity |
|--|--|

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