

Clinical study of the self-adhering flowable composite resin Vertise Flow in Class I restorations: six-month follow-up

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Abstract

Purpose: The aim of this study was to evaluate over a 6-month follow-up period the clinical outcome of restorations performed with a new self-adhering flowable composite resin. **Materials and methods:** Forty Class I restorations were placed between January and March 2009 using a self-adhering flowable composite resin (Vertise Flow, Kerr, Orange, CA, USA). Restorative procedures were performed following manufacturers' instructions. The restorations were assessed for post-operative sensitivity, marginal discoloration, marginal integrity, secondary caries, maintenance of interproximal contact and fracture at baseline, as well as after 1 day, 1 week, 1 month, 3 months and 6 months of clinical service. **Results:** No restoration was affected by post-operative sensitivity at any recall. At the 6-month clinical evaluation, all the 40 restorations scored "alfa" for secondary caries, vitality test, interproximal contacts integrity, retention and fracture. About marginal discoloration/marginal integrity, 37 of the 40 restorations scored "alfa" at the six-month recall. Two restorations showed minimal discoloration and a minimal defect of the marginal integrity, thus receiving a 'bravo' score. One restoration received a 'charlie' score for marginal discoloration and integrity. **Conclusions:** All the evaluated restorations remained in place and in acceptable conditions over the 6-month follow-up period. No post-operative sensitivity was recorded at any evaluation.

Key Words: *Adhesive systems, Flowable composite resin, Class I restoration*

Introduction

The use of composite resins has considerably increased in recent years, concurrently with the improvement of their performances.¹⁻³ Despite such constant improvement, polymerization contraction stress remains a challenge. Post-operative sensitivity, marginal discoloration, secondary caries, and loss of restoration may be associated with curing shrinkage and stress derived from

shrinkage.⁴ The cavity configuration (C-factor), i.e. the ratio of bonded surface area to the un-bonded or free surface area, plays a determinant role in stress development.⁵ C-factor is particularly unfavorable in Class I cavities, exhibiting a ratio of 5 bonded walls to one free surface.⁵⁻⁷ The use of a bonding agent is therefore generally indicated in order to resist the stress that develops during curing. Unfortunately, the adhesive systems may not be completely effective at counteracting the curing stress of the restorative composite resin, thereby microleakage and gap formation at composite/tooth interface have been observed in clinical conditions.⁸⁻¹⁰

The negative effect of polymerization shrinkage can be reduced using appropriate layering technique¹¹⁻¹³ and incremental curing.¹³⁻¹⁴ Another factor possibly influencing stress development is the elastic behavior of the composite resin. In stiffer materials, the forming polymer chains have restricted relative mobility during the polymerization process, leading to the development of higher stress. For

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this reason, the use of a less rigid resin has been proposed for the restoration of cavities with an unfavorable C-factor.⁷ Composite resins with a reduced filler load and a lower modulus of elasticity marketed as “flowable” composites have been used for this purpose.¹⁵⁻¹⁸

In addition to the development of a lower stress, flowable composite resins offer the advantage of favorable handling properties. Their viscosity is such that material placement is eased and adaptation to cavity walls is improved.

Flowable materials have been proposed as liners under an hybrid composite resin, with the function of stress-absorbing layer,¹⁹⁻²³ or for stand-alone use. Flowable composite resins have also found applications in pit and fissure sealing,²⁴ orthodontic brackets bonding²⁵, and restoration of small-sized class I cavity.²⁶

As flowable composite resins do not have adhesive properties per se, the combined use of a dental bonding system is necessary. Among dental adhesive systems, all-in-one adhesive systems are gaining popularity mainly due to their simplified handling. These single-bottle systems are chemically based on a complex mixture of hydrophilic and hydrophobic monomers in water and organic solvents. Their adhesion process is based on the self-etch approach and combines etching, priming and bonding into a single applications step.^{4,27-30} The exclusion of rinsing and drying steps is indeed an attractive clinical advantage of all-in-one systems, since the contamination risk is reduced and the bonding procedure is less sensitive to possible over-drying or over-wetting mistakes.^{31,32} Despite the attractiveness of their simplified handling, single-step adhesives are still matter of research, in order to further evaluate relevant aspects of their bonding mechanism, such as the etching potential in various clinical situations and bond durability.³³⁻³⁵

Recently, an innovative resin-based material, combining the properties of self-adhesion and flowability was developed (Vertise Flow, Kerr, Orange, CA, USA), introducing a new category of restorative materials defined as “self-adhering composite resins”.

These materials are claimed to eliminate the need for a separate bonding application step, thus simplifying the direct restorative procedure. For this reason, Vertise Flow may be considered to start the 8th generation of dental adhesive systems or to represent a cross-link between all-in-one adhesive systems and flowable composite resins.

The aim of the present prospective 6-month clinical trial was to evaluate in vivo the clinical behavior of small-sized Class I restorations made with Vertise Flow.

Materials and Methods

Approval to the clinical study was preliminarily given by the Ethical Committee of the University of Siena. A consecutive sample of 40 patients in need of a Class I restoration was selected from the pool of patients accessing the department of Restorative Dentistry of the University of Siena. Patients’ written consent to the trial was obtained after having provided a complete explanation of the aim of the study.

Inclusion criteria

Males and females aged 18-60 years in good general and periodontal health were included.

Exclusion criteria

Patients with the following factors were excluded from the clinical trial:

1. Age < 18 years;
2. Known pregnancy;
3. Disabilities;
4. Potential prosthodontic restoration of teeth;
5. Pulpitic, non-vital or endodontically treated teeth;
6. (Profound, chronic) periodontitis;
7. Deep carious defects (close to pulp, < 1mm distance) or pulp capping;
8. Heavy occlusal contacts or history of bruxism;
9. Systemic disease or severe medical complications;
10. Allergic history concerning methacrylates;
11. Rampant caries;
12. Xerostomia;
13. Lack of compliance;
14. Language barriers.

Test stimuli and assessment

Before restoring the tooth, a pain measurement was performed utilizing a simple pain scale based on the response method. Response was determined by a 1-second application of air from a dental unit syringe (at 40-65 p.s.i. and approximately 20°C), directed perpendicularly to the root surface at a distance of 2 cm and by tactile stimuli with a sharp #5 explorer. The patient was asked to rate the perception of the sensitivity experienced during this thermal/evaporative stimulation by placing a mark on a 0-10 visual analog scale, in which 0 indicated absence of pain and 10 excruciating pain. In order to translate these rating into easily understood pain levels, a score system was developed. Score 0 was defined as no pain, scores 1-4 as mild sensitivity (which was provoked by the dentist air blast), and scores 5-10 as strong sensitivity (which was spontaneously reported by

Table 1

Performance criteria according to Ryge. For post-operative sensitivities, mean value and standard deviation is provided (1 = lowest sensitivity, 10 = highest sensitivity)

Criteria and number of restorations evaluated at baseline		[n=40] Class I with Vertise			
		alfa	bravo	charlie	delta
Marginal discoloration and integrity	40	40	0	0	0
Secondary caries	40	40	0	0	0
Vitality test	40	40	0	0	0
Interproximal contacts	40	40	0	0	0
Retention	40	40	0	0	0
Fracture	40	40	0	0	0
GROUP 1 (KERR)		No	Yes	Mean	SD
Post-operative sensitivities	40	40	0	0	0

Table 2

Performance criteria according to Ryge. For post-operative sensitivities, mean value and standard deviation is provided (1 = lowest sensitivity, 10 = highest sensitivity)

Criteria and number of restorations evaluated at 1 day recall		[n=40] Class I with Vertise			
		alfa	bravo	charlie	delta
Marginal discoloration and integrity	40	40	0	0	0
Secondary caries	40	40	0	0	0
Vitality test	40	40	0	0	0
Interproximal contacts	40	40	0	0	0
Retention	40	40	0	0	0
Fracture	40	40	0	0	0
GROUP 1 (KERR)		No	Yes	Mean	SD
Post-operative sensitivities	40	40	0	0	0

the patient during drinking and eating). Only patients scoring low on the visual analog scale were included in the study, whereas high score cases were excluded by the assumption that irreversible pulp inflammation might be sustaining the high sensitivity. The status of the gingival tissues adjacent to the test sites was observed at baseline and at each recall. Patients were recalled to the department for testing post-operative sensitivity at baseline, after 1 week, 1 month, 3 months and 6 months.

Clinical Procedure

Two different operators performed the clinical procedures. Class I restorations were of small dimensions and did not have to involve functional areas. Only if a preliminary occlusion check excluded that the cavity preparation would extend to functional areas was the patient included

in the study. Following anesthesia, rubber dam was placed, all carious structures were excavated, and any restorative material was removed. Preparation was performed using conventional diamond burs in a high-speed hand piece, with no bevel on margins. The preparation design was dictated by the extent of decay. After the complete excavation of the carious lesion, and before applying the restoration, the occlusion was again checked in order to definitively exclude the possibility that the restoration could be placed in direct functional areas. The teeth were restored following manufacturer's instructions. A small amount of Vertise Flow was applied into the cavity with the included dispenser tip. This first thin layer (no more than 0.5mm in thickness) was brushed on the cavity surfaces for 15-20s. After brushing, a 20s polymerization was performed with a DEMI LED light

Table 3

Performance criteria according to Ryge. For post-operative sensitivities, mean value and standard deviation is provided (1 = lowest sensitivity, 10 = highest sensitivity)

Criteria and number of restorations evaluated at 7 day recall		[n=40] Class I with Vertise			
		alfa	bravo	charlie	delta
Marginal discoloration and integrity	40	40	0	0	0
Secondary caries	40	40	0	0	0
Vitality test	40	40	0	0	0
Interproximal contacts	40	40	0	0	0
Retention	40	40	0	0	0
Fracture	40	40	0	0	0
		No	Yes	Mean	SD
Post-operative sensitivities	40	40	0	0.	0

Table 4

Performance criteria according to Ryge. For post-operative sensitivities, mean value and standard deviation is provided (1 = lowest sensitivity, 10 = highest sensitivity)

Criteria and number of restorations evaluated at 1 month recall		[n=40] Class I with Vertise			
		alfa	bravo	charlie	delta
Marginal discoloration and integrity	40	38	1	1	0
Secondary caries	40	40	0	0	0
Vitality test	40	40	0	0	0
Interproximal contacts	40	40	0	0	0
Retention	40	40	0	0	0
Fracture	40	40	0	0	0
		No	Yes	Mean	SD
Post-operative sensitivities	40	40	0	0	0

curing unit (Kerr, Orange, CA, USA). Then, the cavity was filled in bulk unless the thickness of the single increment would exceed the limit for effective polymerization. In the latter case the cavity two layers had to be stratified and singularly cured to fill the cavity. Following an additional 20s polymerization, the filling was contoured using 12-Blade Carbide Burs and 40µm-grit Diamond Burs. Then, the restoration surface was finished with Carbide Burs at 30 Blades and 20µm-grit Diamond Burs. Final polishing was performed with Opti1Step Polisher (KerrHawe, Bioggio, Switzerland). The restorations were placed in the time period between January and March 2009, and examined at baseline, after 1 day, 1 week, 1 month, 3 months, and 6 months by a different operator who had been blinded with regard to the restorative material used. At each recall, data regarding post-operative sensitivity,

stability and longevity were collected with reference to the Ryge criteria.³⁶ Postoperative sensitivity, was assessed as the patient comfort with the restoration under function, cold and warm stimuli, and a gentle air stream. Sensitivity was defined by a scale from 0-10, as described above. The other evaluated clinical parameters were: marginal discoloration and integrity, secondary caries, fracture, vitality test, retention and interproximal contacts.

Results

The results at each recall are shown in Tables 1-6. After 6 months of clinical service, all the 40 restorations made with Vertise Flow were scored "alfa" for secondary caries, vitality test, interproximal contacts integrity, retention and fracture. Of the 40 restorations, 37 scored alfa, 2 bravo and 1 charlie for marginal discoloration and integrity. In

Table 5

Performance criteria according to Ryge. For post-operative sensitivities, mean value and standard deviation is provided (1 = lowest sensitivity, 10 = highest sensitivity)

Criteria and number of restorations evaluated at 3 month recall		[n=40] Class I with Vertise			
		alfa	bravo	charlie	delta
Marginal discoloration and integrity	40	37	2	1	0
Secondary caries	40	40	0	0	0
Vitality test	40	40	0	0	0
Interproximal contacts	40	40	0	0	0
Retention	40	40	0	0	0
Fracture	40	40	0	0	0
		No	Yes	Mean	SD
Post-operative sensitivities	40	40	0	0	0

Table 6

Performance criteria according to Ryge. For post-operative sensitivities, mean value and standard deviation is provided (1 = lowest sensitivity, 10 = highest sensitivity)

Criteria and number of restorations evaluated at 6 month recall		[n=40] Class I with Vertise			
		alfa	bravo	charlie	delta
Marginal discoloration and integrity	40	37	2	1	0
Secondary caries	40	40	0	0	0
Vitality test	40	40	0	0	0
Interproximal contacts	40	40	0	0	0
Retention	40	40	0	0	0
Fracture	40	40	0	0	0
		No	Yes	Mean	SD
Post-operative sensitivities	40	40	0	0	0

particular, 1 bravo and 1 charlie score were assigned after 1 month, while another restoration was scored Bravo at the 3-month recall. In accordance with Ryge criteria, the restoration scored Charlie for marginal discoloration/marginal integrity was a candidate for replacement at the 1-year control. No restored tooth showed post-operative sensitivity at any recall.

Discussion

Despite their large use, the data available in the literature regarding the use of flowable composite resins for posterior restorations do not provide a conclusive evidence. The reason why the issue remains controversial is also that the clinical outcome of flowable composite restorations can not merely be ascribed to the intrinsic material properties, but should also be related to other

factors, such as cavity extension, layering technique, and curing dynamic.^{11,37-39} The discordant research findings on flowable composite resins may also be explained by the large variability of products in this category, that may lead to different experimental results. The lower filler content leads to a lower modulus of elasticity, thus reducing curing stress. Yet, the lightly filled resin undergoes a greater polymerization shrinkage.¹⁶⁻¹⁸ The higher matrix content may also contribute to increased water solubility, possibly affecting the restorations long-term performance. The reduced filler load may also impair the resistance to deformation of the restorations during function. Due to their inferior mechanical properties, flowable composite resins are generally not recommended as stand-alone restorative materials especially in cavities with high-stress occlusal function.^{7,16,17}

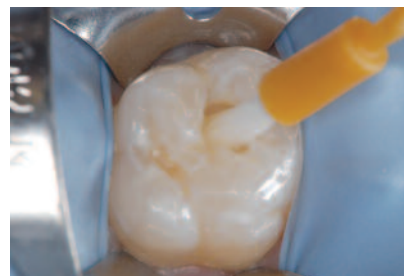
Class I restoration performed with Vertise Flow.



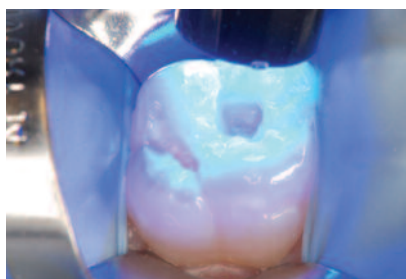
Pre-operative view.



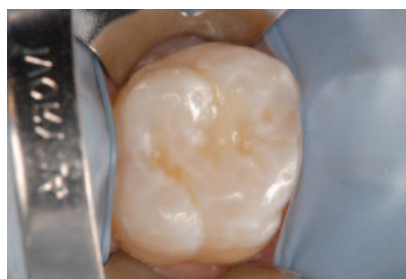
First layer placement.



Brushing for 20s.



20s polymerization of the first layer.



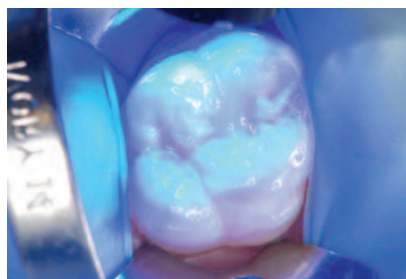
Cavity fill-up.



First layer placement of the second restoration.



Brushing for 20s.



20s final polymerization.



Diamond bur 20µ.



Opti1Step Polisher.



Restorations after contouring-finishing-polishing.



6 month follow up.

In such cavities, the use of a flowable material is instead recommended for lining, in order to produce a stress-absorbing layer.^{38,40} When used as an intermediate layer between adhesive system and hybrid composite, the flowable provides the elasticity to absorb the stress

generated by the overlaying, more rigid composite.^{20-23,41-43} Conversely, in small-sized cavities, the use of a flowable composite as a stand-alone restorative material has been proposed.¹⁵ In a small-sized cavity no heavy functional stress is expected to occur, as most of the occlusal forces

are resisted by the residual tooth structure. A point of criticism that has been raised toward the use of a flowable composite as a stand-alone material regards its lack of sculptability that would make layering difficult. In small Class I restorations, however, this issue is not critical as a layering technique is not mandatory. The main advantage of incremental technique is in fact that the volume reduction of each increment is compensated by the next increment, thus the polymerization shrinkage of the last layer only may effectively damage the bond.⁷ Loguercio et al.⁴⁴ reported that the layering technique did not significantly improve the bond strength in small cavities. Similarly, Tjan et al.⁴⁵ revealed that, in comparison with the one-bulk technique, incremental placement could not substantially improve adaptation to cavity walls in small cavities. He et al.³⁸ stated that the incremental technique may be effective only when the cavity size is large.

In the present study, an innovative, recently formulated material was tested. Vertise Flow is a flowable resin with adhesive properties, not requiring any additional adhesive step. According to the manufacturer the bonding mechanism is primarily based on the chemical bond between the phosphate functional group of GPDM monomer and calcium ions of the tooth. A micromechanical bond resulting from an interpenetrating network between Vertise Flow polymerized monomers and dentin collagen fibers also contributes to adhesion (Vertise Flow Product Manual, November 2009).

It was the specific objective of this study to verify clinically whether the new self-adhesive flowable composite is able to establish an effective seal, thus avoiding post-operative sensitivity phenomena. The manufacturer recommends a great attention to some of the steps that the clinician has to perform in the clinical use. Differently from traditional flowable systems, the material does not have an underlying bonding agent. For this reason, for proper handling of the material the manufacturer indicates as crucial the achievement of a proper contact of the material with the tooth substrate, as well as an appropriate brushing motion. A brushing motion of 15-20s is required with a thin layer of material (0.5mm). As the accuracy of the brushing motion is of great importance, specific applicators are supplied for adequately dispensing the material. Brushes with bristles of proper elasticity are also supplied by the manufacturer. After brushing, the material has to be cured for 20s. The reason why Vertise Flow requires a longer polymerization time in comparison with conventional adhesives or other marketed flowable composites is that adhesive monomers tend to have a slower response to light curing than non-adhesive monomers. The less efficient curing mechanism could be

attributed to the mono-functionality of Vertise Flow adhesive monomers in comparison with di-functional monomers of traditional composites or to the hydrophilicity of the adhesive monomers.

Beside post-operative sensitivity, other clinical aspects related to improper marginal sealing, such as recurrent caries, marginal discoloration, and loss of retention were also evaluated in time. Based on the collected data, the new material gave proof of a satisfactory clinical behavior. At the 6-month recall, no post-operative sensitivity was reported. Of the 40 performed restorations, only 3 showed limited marginal discoloration and a minor defect in marginal integrity. Therefore, at this stage of the prospective clinical trial, the claimed ability of Vertise Flow to achieve an effective sealing at the tooth-restoration interface was confirmed.

As for any new material, longer-term studies are needed in order to validate this initial promising behavior. Further investigations are also advised to assess whether the encouraging performance of the new material finds confirmation in other clinical applications, such as the use as a liner in larger Class I, Class II, and Class V cavities. In vitro and in vivo tests are currently being performed with these objectives.

Conclusion

Over a 6-month follow-up period, Class I restorations performed with Vertise Flow exhibited a satisfactory clinical performance. In particular, no post-operative sensitivity was reported at any time.

Clinical relevance: The results of this 6-month study demonstrated a successful clinical outcome of the self-adhering flowable composite resin Vertise Flow when used to restore small Class I cavities.

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