Original Article

A 24-Month Evaluation of Self-Adhering Flowable Composite Compared to Conventional Flowable Composite in Conservative Simple Occlusal Restorations: A Randomized Clinical Trial

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Abstract

Background: Self-adhering flowable composite (SAFC) simplified restorative procedures, especially when compared to conventional techniques. Self-adhering composite revolutionized restorative dentistry by merging advances of adhesive and restorative materials to generate the so-called "eighth generation." **Aims:** The objective of this clinical trial was to assess the clinical performance of SAFC compared to conventional flowable composite in minimally invasive occlusal cavities. **Settings and Design:** A total of 18 patients with conservative occlusal cavities received randomly two types of restorations in a split-mouth design. **Materials and Methods:** Vertise™ Flow or Filtek™ Z350XT Flowable was applied according to the manufacturer's instructions. All restorations were evaluated at baseline and after 24 months, respectively, by two blinded assessors using modified USPHS criteria. **Statistical Analysis Used:** Chi-square test was used for intragroup comparison between time points and intergroup comparison within each time point. A value of $P \leq 0.05$ was considered statistically significant. Relative risk was used to determine the clinical significance. **Results:** The results of the current study have revealed no statistically significant difference between both materials for all tested outcomes at baseline and after 24 months. **Conclusions:** SAFC revealed satisfactory clinical performance in restoration of minimally invasive occlusal cavities after 24-month follow-up.

Keywords: *24 months, clinical evaluation, flowable, resin composite, self-adhering, USPHS*

Introduction

Tooth-colored resin restorations are the main choice for conservative Class I preparations. Yet, some of its inherent characteristics such as the high modulus of elasticity, rheological properties, as well as difficulties in packing the material in a conservative preparation could be an obstacle to make it the clinician's first choice.[1] Therefore, a syringe delivery system and a flowable material could be an excellent solution for such problem, especially in case of inaccessible areas.[2] Nowadays, conservative approaches and minimally invasive dentistry demand the use of adhesive resin restorations that serve well in moderate- to small-sized preparations. Even though flowable resin restorations could be an excellent option, the mechanical shortcomings of the early versions of the material limited the credibility of such choice.[1]

A breakthrough has occurred by introducing nanotechnology to the flowable resin composites; this promised to enrich the clinical performance of these materials. It improved their mechanical properties to compete with some of the regular viscosity resin, especially due to the easier placement and adaptation to the inner cavity walls. However, it could be of high clinical significance to promote a simpler and easier method for using flowable resin composite in conservative cavity preparations.[3]

An ambitious step ahead was achieved by introducing self-adhering flowable composite (SAFC), uniting the advantages of both adhesive and restorative material technologies in a single application procedure (eighth generation). The SAFC promises fewer steps, less chance for application errors, and thus the least possible chair time; this could be a great value when dealing with uncooperative patients or for patients with multiple carious defects and implementing quadrant dentistry.[4,5]

Limited evidence-based data were provided in the literature concerning SAFC and its

How to cite this article: Shaalan OO, Abou-Auf E. A 24-month evaluation of self-adhering flowable composite compared to conventional flowable composite in conservative simple occlusal restorations: A randomized clinical trial. Contemp Clin Dent 2021;12:368-75.

Submitted : 04-Jul-2020
Revised : 27-Jul-2020
Accepted : 14-Aug-2020
Published : 21-Dec-2021

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Access this article online

Website: www.contempclindent.org

DOI: 10.4103/ccd.ccd_600_20

Quick Response Code:

clinical applications, especially in restoration of minimally invasive occlusal cavities. A randomized controlled clinical trial was performed to evaluate the clinical performance of SAFC to test the null hypothesis that SAFC will have similar performance to flowable composite in minimally invasive Class I cavities.

Materials and Methods

Procedures of this study were performed following the ethical standards of the Research Ethics Committee of Faculty of Dentistry, Cairo University, with reference number (16/4/12), all participants were informed about trial procedures, and consents were obtained. A protocol was registered in (PACTR) database "PACTR201602001477364."

A power analysis was designed to have adequate power to apply the statistical test of the research hypothesis and to evaluate the clinical performance of Vertise™ Flow (SAFC) compared to Filtek™ Z350XT Flowable (conventional flowable composite) in minimally invasive occlusal restorations after 24 months. Based on a previous study,[6] the probability of alpha (A) score was 0.837 and non-alpha score was 0.163 for conventional flowable composite for marginal adaptation (effect size w = 0.674), if the estimated probability of alpha (A) score was 0.9 and non-alpha score was 0.1 for SAFC (effect size w = 0.8). By adopting an alpha (α) level of 0.05 and power of 0.8, it was needed to study a total of 30 participants (15 per group) to be able to reject the null hypothesis. This was increased to 36 restorations (18 per group) to compensate for dropouts during follow-up. The sample size was calculated using G*Power version 3.1.9.2 for Windows (Franz Faul, Universitat Kiel, Dusseldorf, Germany) using Chi-square test.

Eligibility criteria

Participants with good oral hygiene and having bilateral occlusal small-sized occlusal carious lesions with an age range from 19 to 40 years were included; cavity preparation must not extend to any stress-bearing area and not exceeding ¼ of intercuspal distance. Participants with systemic conditions, history of allergy to methacrylates, rampant caries, physical or mental disabilities, smoking habit, xerostomia, evidence of severe parafunctional habits, or TMJ disorders and lack of compliance were excluded. Posterior teeth with deep carious lesions, evidence of loss of vitality or severe periodontal inflammation, mobility, dentin hypersensitivity, and possibility of prosthodontic restoration were not included in this study.

Participants were enrolled 1 month before conducting the trial, and eligible participants who approved were recruited according to the eligibility criteria [Figure 1]. Sequence generation was accomplished using simple randomization by generating numbers from 1:18 using (www.random.org). Each generated number represented assigning interventions either to the right or left sides of the oral cavity randomly in a split-mouth design. The dental practitioner obtained numbers from an opaque sealed envelope, which was prepared by the assistant, who was not involved in any of the clinical trial phases. Due to the differences in application protocol of restorative materials, the operator was not blinded to the material assignment, but the assessors and participants were blinded.

Cavity preparation

After local anesthesia and rubber dam isolation, minimally invasive simple occlusal cavity preparations were performed with buccolingual width not more than ¼ intercuspal distance, away from occlusal functional areas which were determined preoperatively using articulating paper.

Material application

Interventions were applied randomly according to the predetermined sequence generation. SAFC (Vertise™ Flow, Kerr, Orange, CA, USA) and conventional flowable composite (Filtek™ Z350XT Flowable, 3M ESPE, USA) were utilized according to the manufacturers' instructions [Table 1]. Modified USPHS criteria were applied to assess dental restorations by two blinded assessors at baseline (after 1 week) and after 24 months [Table 2]. If assessors had a conflict in assessing the score of any outcome, they discussed to reach for a consensus.

Statistical analysis

Statistical analysis was performed with MedCalc Statistical Software version 19 (MedCalc Software bvba, Ostend, Belgium). Chi-square test was used for intragroup comparison through follow-up periods and intergroup comparison within each follow-up. A value of $P \leq 0.05$ was considered statistically significant. Relative risk (RR) was used to determine the clinical significance after 24 months.

Results

The results of the current study have revealed no statistically significant difference between both materials for all tested outcomes after 24 months. Most of the restorations either in the Vertise™ Flow group or Filtek™ Z350XT Flowable group scored alpha (A) according to modified USPHS criteria [Figure 2]. Table 3 shows the frequency (n) and percentage of different outcomes assessed according to the modified USPHS criteria for both interventions.

Discussion

In vitro studies are of crucial value when testing the potential performance of a restorative material; yet, such tests are not accurately indicative to evaluate the clinical performance of the material or its actual handling characteristics. Moreover, *in vitro* studies cannot provide answers about the *in vivo* longevity of the tested tooth-colored restorations. The first 6–24 months' clinical

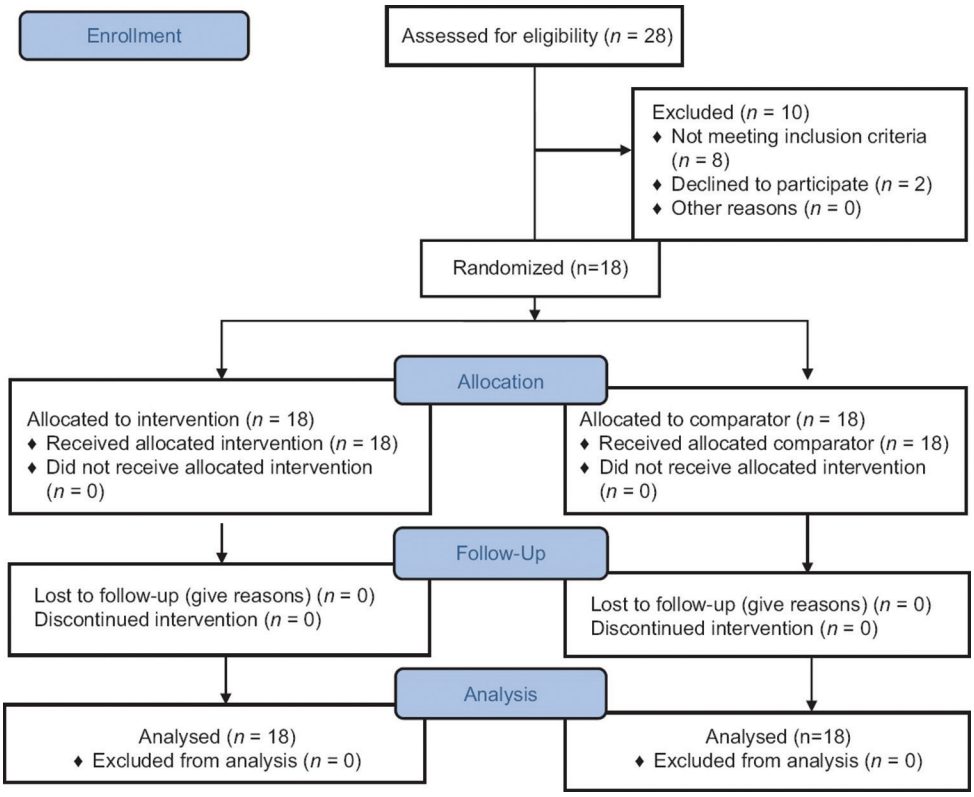

Figure 1: Consort flow diagram showing the process of case selection

performance of a restoration appears to be the decisive period for the development of deteriorations.[7] The available data in the literature considering the use of flowable composite in posterior restorations are inadequate and did not provide conclusive evidence. In addition to the large variability of products available in the dental market, considering this category may lead to different experimental results.[8] Early generation flowable composite restoratives were characterized by lower filler loading and inferior mechanical properties, which impaired the wear resistance of such restorations. For this reason, it was not indicated to use flowable composites in restoring cavities in high stress-bearing areas, especially in occlusal cavities.[9]

Nowadays, more conservative preparations permitted smaller Class I cavities, far from any heavy occlusal loading, which will be redistributed into the preserved remaining tooth structure. One systematic review evaluated using flowable resin composite in carious and noncarious lesions. It was challenged by the limited provided data about flowable composite, but the best available evidence in databases recommends using flowable composite in minimally invasive cavities.[10] SAFC is a new material introduced to the dental market, and it claimed to eradicate the need for a separate bonding step, thus simplifying the restorative procedure. For this reason, SAFC may be considered to start the eighth generation of bonding systems or to stand for a cross-link between simplified all-in-one adhesive systems and flowable composite.[11]

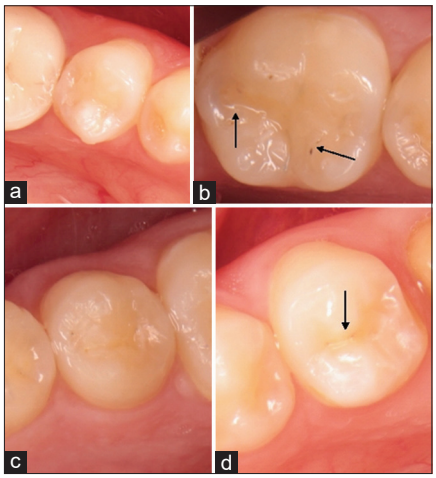

Figure 2: Clinical evaluation using modified USPHS criteria after 24 months. (a) Vertise™ Flow (alpha); (b) Vertise™ Flow (nonalpha); (c) Filtek™ Z350XT Flowable (alpha); (d) Filtek™ Z350XT Flowable (nonalpha)

Simplified restorative technique could be appealing to be used in pediatric dentistry or with debilitated patients and implementing quadrant dentistry; a clinical study of utilizing SAFC in occlusal restorations of primary teeth demonstrated good clinical results with predominating alpha scores after 1 year.[12]

The current study evaluated Vertise™ Flow, which is a SAFC with mild aggressiveness ~1.9, and it uses the functional monomer (glycerophosphate dimethacrylate [GPDM]) to condition enamel and

dentin simultaneously and a hydrophilic monomer (e.g., hydroxyethyl methacrylate) to promote bonding to dentin substrate by enhancing surface wetting and resin infiltration. This allowed SAFC to bond in a dual manner, chemically between the functional monomer and the hydroxyapatite of tooth structure and micromechanically, where the polymerized resin impregnates the collagen fibers and smear layer of dentin.[13] GPDM is a functional monomer that privileged having dual polymerizable groups that can react with monomers in both adhesive systems and resin composite, thus improving polymer network quality and upgraded physical properties of the adhesive layer.[14] Yet, one drawback was that GPDM revealed hydrophilicity, and greater demineralization of dentin than bonding to calcium of hydroxyapatite, producing unstable complexes of calcium phosphate deposits on the hydroxyapatite surface that might dissolve gradually in aqueous environment, thus weakening the interfacial integrity.[15] Another functional monomer such as 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP) can form stable complexes of calcium–phosphate.[16]

Filtek™ Z350XT Flowable is a nanofilled flowable composite with high filler loading. It was utilized in combination with universal adhesive system (Single Bond Universal) containing functional monomer MDP, thus providing chemical bonding and guaranteeing the quality and durability of bonding.[17] Acid etching using Scotchbond Universal Etchant was performed ahead for better bonding performance, especially with enamel.[18]

After 24 months, all dental restorations were assessed and all participants were examined with no dropouts. In the current study, self-adhering composite performed equivalent to conventional flowable composite after 24 months; therefore, the null hypothesis was accepted. Inconclusive evidence-based data were available in scientific databases about the clinical performance of SAFC.[8] One study evaluated Fusio Liquid Dentin (SAFC) in noncarious cervical lesions; it has shown a failure rate of 66% for retention, and clinical performance was unacceptable after 6 months only of service. The poor performance of the material may be attributed to lack of macromechanical retention and weak bonding due to hydrolytic instability of the functional monomer (4-META).[19] Another study evaluated Vertise™ Flow as a pit-and-fissure sealant; it had the poorest performance with the lowest retention, despite preceding it with phosphoric acid etching, and this may be attributed to its diminished flowability and absence of a prepared cavity.[20]

On the other hand, some clinical studies evaluated SAFC in minimally invasive Class I cavities.[8,12,13,21-23] It was observed that SAFC performed similarly to flowable composite in minimally invasive occlusal cavity preparation for up to 5 years; this was in agreement with the outcomes of the current research. In small-sized cavities, applying flowable composite as a stand-alone restoration was recommended.[6,8-10] In simple occlusal cavity preparations, even in conservative designs, the effect of macromechanical

Table 1: Materials' specifications, manufacturer's instructions, and composition

Product name	Instructions	Composition
Vertise™ Flow (Kerr, Orange, CA, USA) LOT #6025254	A thin layer of the material was applied (<0.5 mm) and agitated with moderate pressure using microbrush for 15-20 s Light cure for 20 s Cavity was completely filled with the material in increments ≤2 mm Light cure for 20 s	Matrix consists of GPDM, UDMA, and Bis-GMA. Fillers are composed of prepolymerized fillers, barium glass fillers, nanosized colloidal silica, and nanosized ytterbium fluoride with size range of 1 micron. Filler loading is approximately 70% by weight
Scotchbond™ Universal etchant (3M ESPE, USA) LOT #494871	Etchant was applied for 15 s and then rinsed for 15 s using air-water syringe Cavity was dried with gentle air stream	Water, phosphoric acid, synthetic amorphous silica, polyethylene glycol, and aluminum oxide
Single Bond Universal (3M ESPE, USA) LOT #587885	Adhesive was applied and agitated using microbrush for 20 s Adhesive was air thinned using gentle air for 5 s Adhesive was light cured for 10 s	MDP phosphate monomer, dimethacrylate resins, Vitrebond copolymer, HEMA, fillers, ethanol, water, initiators, and silane
Filtek™ Z350XT Flowable (3M ESPE, USA) LOT #N666970	Flowable composite was applied to fill the cavity in increments ≤2 mm Light cure for 20 s	Matrix consists of Bis-GMA, TEGDMA, and Bis-EMA. Fillers are composed of nonagglomerated/nonaggregated silica nanofillers and zirconia nanofillers and nanoclusters of agglomerated zirconia/silica with size range of 0.6-1.4 microns. Filler loading is approximately 65% by weight.

GPDM: Glycerol phosphate dimethacrylate; UDMA: Urethane dimethacrylate; Bis-GMA: Bisphenol A diglycidyl methacrylate; MDP: Methacryloxydecyldihydrogen phosphate; HEMA: 2-hydroxyethyl methacrylate; TEGDMA: Triethylene glycol dimethacrylate; Bis-EMA: Bisphenol A polyethylene glycol diether dimethacrylate

means of retention could have improved the overall performance of SAFC. This performance was different when SAFC was used as a pit-and-fissure sealant[20] or in noncarious cervical lesions;[19] this might be the reason for the different performances of SAFC in conservative simple occlusal cavities.

Table 2: Modified United States Public Health Service criteria for evaluation of dental restorations

Outcome	Score	Characteristics
Postoperative hypersensitivity	A	No postoperative sensitivity
	C	Sensitivity present
Retention	A	No loss of restoration
	C	Loss of restoration
Color match	A	Matches tooth
	B	Acceptable mismatch
	C	Unacceptable mismatch
Marginal discoloration	A	No discoloration between tooth structure and restorative material
	B	Nonpenetrating marginal discoloration which can be polished
	C	Discoloration has penetrated margin in pulpal direction
Marginal adaptation	A	Closely adapted, no detectable margin
	B	Detectable marginal discrepancy clinically acceptable
	C	Marginal crevice, clinically unacceptable
Anatomic form	A	Continuous, well contoured
	B	Slight discontinuity or slight undercontoured, clinically acceptable
	C	Discontinuous, sever undercontoured, clinically unacceptable
Surface texture	A	Smooth surface
	B	Surface rougher than enamel with no pores or craters, clinically acceptable
	C	Surface unacceptably rough with pores or craters
Secondary caries	A	No caries present
	C	Caries present

Assessment of retention, postoperative hypersensitivity, and secondary caries of both tested flowable materials have shown (alpha score) for all restorations after 24 months (P = 1.00). Even though at baseline in Filtek™ Z350XT flowable, 16 restorations scored alpha, two restorations revealed sensitivity; this may be attributed to etching with phosphoric eliminating the smear layer and opening up the dentinal tubules; sensitivity decreased over time and completely disappeared at 24-month evaluation. No sensitivity was recorded for Vertise™ Flow restorations at baseline or after 24 months; this is probably due to the dissolved the smear layer that kept the dentinal tubules sealed.[8,18] There is no risk for loss of retention, postoperative hypersensitivity, or secondary caries after 24 months (RR = 1 [95% confidence interval (CI): 0.0209–47.8503; P = 1.00]).

Marginal adaptation results revealed that all the restorations in both the groups scored alpha at baseline. After 24 months, three restorations scored bravo in the Filtek™ Z350XT Flowable group and four in Vertise™ Flow restorations; there was no statistically significant difference between both materials after 24 months (P = 0.6780). However, Vertise™ Flow deteriorated through time, and this was statistically significant (P = 0.0365). There is a lowered risk of inferior marginal adaptation with conventional flowable composite combined with etch-and-rinse adhesive systems after 24 months, and the risk was 33% lower than SAFC (RR = 1.3333 [95% CI: 0.3467–5.1272; P = 0.6755]).

Upon assessing marginal discoloration, at baseline alpha score was observed for all restorations in both the groups. After 24 months, only one restoration scored bravo in Filtek™ Z350XT Flowable compared to Vertise™ Flow restorations where five restorations scored bravo; but there was no statistically significant difference between both materials after 24 months (P = 0.3778). Yet, the Vertise™ Flow group

Table 3: Frequency (n) and percentage (%) of outcomes assessed according to modified USPHS criteria

Outcomes	Follow-up	Score	Vertise™ Flow, n (%)	Filtek™ Z350XT, n (%)	P/RR
Retention	Baseline	A	18 (100.0)	18 (100.0)	1.00 (NS)
		C	0 (0.0)	0 (0.0)	
	24 months	A	18 (100.0)	18 (100.0)	1.00 (NS)
		C	0 (0.0)	0 (0.0)	
P			1.00 (NS)	1.00 (NS)	RR=1 (95% CI: 0.0209-47.8503; P=1.00)
Postoperative hypersensitivity	Baseline	A	18 (100.0)	16 (88.9)	0.1513 (NS)
		C	0 (0.0)	2 (11.1)	
	24 months	A	18 (100.0)	18 (100.0)	1.00 (NS)
		C	0 (0.0)	0 (0.0)	
P			1.00 (NS)	0.1513 (NS)	RR=1 (95% CI: 0.0209-47.8503; P=1.00)

Contd...

Table 3: Contd...

Outcomes	Follow-up	Score	Vertise™ Flow, *n* (%)	Filtek™ Z350XT, *n* (%)	P/RR
Marginal adaptation	Baseline	A	18 (100.0)	18 (100.0)	1.00 (NS)
		B	0 (0.0)	0 (0.0)	
		C	0 (0.0)	0 (0.0)	
	24 months	A	14 (77.8)	15 (83.3)	0.6780 (NS)
		B	4 (22.2)	3 (16.7)	
		C	0 (0)	0 (0)	
P			0.0365*	0.0745	RR=1.3333 (95% CI: 0.3467-5.1272; *P*=0.6755)
Marginal discoloration	Baseline	A	18 (100.0)	18 (100.0)	1.00 (NS)
		B	0 (0.0)	0 (0.0)	
		C	0 (0.0)	0 (0.0)	
	24 months	A	13 (72.2)	17 (88.9)	0.3778 (NS)
		B	5 (27.7)	1 (11.1)	
		C	0 (0)	0 (0)	
P			0.0175*	0.3173 (NS)	RR=5.0000 (95% CI: 0.6467-38.6557; *P*=0.1230)
Color match	Baseline	A	18 (100.0)	18 (100)	1.00 (NS)
		B	0 (0)	0 (0)	
		C	0 (0)	0 (0)	
	24 months	A	16 (88.9)	15 (83.3)	0.6780 (NS)
		B	2 (11.1)	3 (16.7)	
		C	0 (0)	0 (0)	
P			0.1513 (NS)	0.0745 (NS)	RR=0.6667 (95% CI: 0.126-3.5262; *P*=0.6333)
Anatomic form	Baseline	A	18 (100.0)	18 (100.0)	1.00 (NS)
		B	0 (0.0)	0 (0.0)	
		C	0 (0.0)	0 (0.0)	
	24 months	A	15 (83.3)	16 (88.9)	0.3778 (NS)
		B	3 (16.7)	2 (11.1)	
		C	0 (0)	0 (0)	
P			0.0745 (NS)	0.1513 (NS)	RR=1.5000 (95% CI: 0.2836-7.9339; *P*=0.6333)
Surface texture	Baseline	A	18 (100.0)	18 (100.0)	1.00 (NS)
		B	0 (0.0)	0 (0.0)	
		C	0 (0.0)	0 (0.0)	
	24 months	A	14 (77.8)	15 (83.3)	0.6780 (NS)
		B	4 (22.2	3 (16.7)	
		C	0 (0)	0 (0)	
P			0.0365*	0.0745 (NS)	RR=1.3333 (95% CI: 0.3467-5.1272; *P*=0.6755)
Secondary caries	Baseline	A	18 (100.0)	18 (100.0)	1.00 (NS)
		C	0 (0.0)	0 (0.0)	
	24 months	A	18 (100.0)	18 (100.0)	1.00 (NS)
		C	0 (0.0)	0 (0.0)	
P			1.00 (NS)	1.00 (NS)	RR=1 (95% CI: 0.0209-47.8503; *P*=1.00)

RR: Relative risk; CI: Confidence interval; NS: Not significant, * Significant

worsened after 24 months, with a statistically significant difference ($P = 0.0175$). There is a lowered risk of marginal discoloration with conventional flowable composite combined with etch-and-rinse adhesive systems after 24 months, and the risk was 5 times lower than SAFC (RR = 5.0000 [95% CI: 0.6467–38.6557; $P = 0.1230$]).

The functional monomer GPDM dissolves gradually in moisture, hence affecting the interfacial integrity as mentioned earlier.[15] It was reported that Vertise™ Flow represented the highest water sorption when compared to other tested resin and that was related to the hydrophilic acidic phosphate group and the higher monomer content

of the material.[24] Furthermore, being a heterogeneous microfilled resin composite with filer content 70% by weight, Vertise™ Flow is vulnerable to hydrolysis due to additional water sorption at the resin–filler interface, which might enhance degradation of the material in the oral environment. This could explain why the marginal adaptation and marginal discoloration of SAFC could be inferior when compared to the baseline.[25]

As for color match, all the restorations in both the groups scored alpha at the baseline. After 24 months, three restorations scored bravo in the Filtek™ Z350XT Flowable group and two in Vertise™ Flow restorations; there was no statistically significant difference between both materials after 24 months (P = 0.6780). There is a lowered risk of inferior color match with SAFC after 24 months, and the risk was 33% lower than conventional flowable composite combined with etch-and-rinse adhesive systems (RR = 0.6667 [95% CI: 0.126–3.5262; P = 0.6333]).

Anatomic form assessment revealed that all the restorations in both the groups scored alpha at the baseline. After 24 months, two restorations scored bravo in the Filtek™ Z350XT Flowable group and three in Vertise™ Flow restorations; there was no statistically significant difference between both materials after 24 months (P = 0.3778). There is a lowered risk of inferior anatomic form with conventional flowable composite combined with etch-and-rinse adhesive systems after 24 months, and the risk was 50% lower than SAFC (RR = 1.5000 [95% CI: 0.2836–7.9339; P = 0.6333]).

Moreover, examining the surface texture showed that all the restorations in both the groups scored alpha at the baseline. After 24 months, three restorations scored bravo in the Filtek™ Z350XT Flowable group and four in Vertise™ Flow restorations; there was no statistically significant difference between both materials after 24 months (P = 0.6780). The surface texture in the Vertise™ Flow group was inferior when compared to baseline (P = 0.0365). There is a lowered risk of inferior surface texture with conventional flowable composite combined with etch-and-rinse adhesive systems after 24 months, and the risk was 33% lower than SAFC (RR = 1.3333 [95% CI: 0.3467–5.1272; P = 0.6755]).

Vertise™ Flow and conventional flowable resin composite used with an etch-and-rinse system showed similar clinical performance after 5-year follow-up. Significant changes were observed for both tested materials after 5 years for marginal adaptation and marginal discoloration when compared to baseline. These conclusions were in favor of the outcomes of this clinical trial.[23]

The results of the current study might emphasize the importance of using simplified restorative procedures but not on the expense of the quality and longevity of the restoration. Frequent and regular follow-up should be scheduled, especially with recently introduced restorative materials, to assess the clinical performance over extended follow-up periods.

Under the limitations of the current study, the following conclusions could be derived. SAFC has shown comparable clinical performance to conventional flowable composite after 24 months of clinical service in minimally invasive Class I cavity preparations. SAFC simplified the application procedure of flowable composite material with equivalent results to standard techniques.

Clinical recommendations

Randomized clinical trials are the decisive final step to assess new materials and techniques and to implement evidence-based guidelines for different clinical situations. Further long-term clinical studies are mandatory to confirm the outcomes of this study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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