©Operative Dentistry, 2021, **46-5**, 491-504

Clinical Research

Reliability of Class II Bulk-fill Composite Restorations With and Without Veneering: A Two-year Randomized Clinical Control Study

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Clinical Relevance

Veneering bulk-fill composites with conventional microhybrid composites is recommended for better clinical performance in Class II restorations.

SUMMARY

Bulk-fill composites are increasingly used in stress-bearing areas in posterior teeth, with a diversity of reports concerning their effectiveness and clinical reliability. The objective of this randomized clinical control study was to investigate the effectiveness of bulk-fill versus veneered bulk-fill Class II composite restorations. A double-blind split-mouth technique was employed in 80 subjects recruited for restoring Class II caries in one molar bilaterally in the same arch following respective inclusion and exclusion criteria and after obtaining written consent. While one molar was randomly restored with bulk-fill composite using the sealed-envelope technique, Tetric N-Ceram Bulk Fill (TBF), the contralateral was restored with a bulk-fill composite veneered with an increment of a heavy-body microhybrid

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http://doi.org/10.2341/19-290-C

composite—Tetric-Ceram HB (TBF/V). Box-only cavities were prepared and received etch-and-rinse adhesive bonding and Tetric N-Bond treatment before composite insertion. Restorations were assessed at 24 hours, 2 weeks, 6 months, 12 months, and 24 months for esthetic, functional, and biological quality employing the FDI ranking criteria. Friedman repeated-measures analysis of variance, the McNemar test, and the Cohen's kappa statistical test were used for statistical analysis. Over a 24-month interval, none of the test restorations were ranked as clinically unsatisfactory. In terms of functional criteria, clinically excellent restorations were significantly more prevalent in TBF/V than in TBF ($p<0.05$). For long-term satisfactory performance of Class II bulk-fill composites, an occlusal veneering increment of conventional heavy body microhybrid composite appears to be favorable.

INTRODUCTION

Direct resin-based composite restorations constitute a basic aspect of modern, everyday practice of restorative dentistry. Millions of composite restorations are annually inserted around the world.[1,2] The use of resin composites for restoring cavities in load-bearing locations in posterior teeth has been increasingly popular and more clinically reliable, owing to the considerable contemporary upgrading in materials manufacturing aimed at improving their longevity and clinical performance.[3-5] Among the main limitations of composite restorations are their polymerization shrinkage and their degradation potential over time.[2] Much research has been conducted to improve the clinical long-term biomechanical and esthetic effectiveness of composite. The incremental insertion of direct composite has long been implemented to assure the optimal degree of curing light penetration and thus the degree of conversion, which is a prerequisite for optimal physical and mechanical properties as well as the biocompatibility of the composite.[6] Moreover, incremental insertion reduces the configuration factor, and, hence, the interfacial contraction stresses enhance better adaptation to cavity walls and inhibit pulling actions on cusps, thus reducing the cracking of teeth and possible postoperative hypersensitivity.[7] However, incremental insertion is time consuming and invites a greater risk of air void inclusion, with adverse consequences on restoration quality and clinical performance.[8,9]

Bulk-fill composites were introduced to simplify restorative procedures and reduce the time of application of composite restorations. The manufacturing technology of these materials included basic compositional modifications in the resin matrix and photoinitiator system to enable adequate degree of conversion at 4-5 mm thick bulk application without increasing the interfacial contraction stresses or compromising the tooth-restoration interfacial bonds.[3,8-11]

The reliability and performance of bulk-fill composites have been increasingly studied in different *in vitro* and *in vivo* investigations.[3,8-10,12-16] While an *in vitro* marginal integrity study did not find a significant difference between bulk and incremental fill composites,[16] another study showed that the internal adaptation of incremental composites is better than that of bulk-fill composites,[17] and a third study reported better bonding quality at the cervical interfaces of bulk-fill in comparison to incremental fill Class II composite restorations.[18] A diversity of *in vitro* studies of bulk-fill composite have been conducted over the past few years that focused on the degree of conversion and depth of cure as well as on the physicomechanical properties and degradation potential with increasing concerns regarding their long-term durability and effectiveness in clinical service. Ilie and others found that the mechanical properties of bulk-fill composites place them in a category between nanohybrid and microhybrid composites, which might indicate the inferior clinical behavior of bulk-fill composites.[12]

Leprince and others found it essential, after studying some of their physical and mechanical properties, to veneer bulk-fill composites with conventional microhybrid composite.[13] Sunbul and others also suggested a veneer bulk-fill composite with a more degradation-resistant composite.[14] Similar findings were reported by El Gezawi and others.[15] *In vivo* studies including clinical evaluation and ranking of restorations have been given the greatest value in evidence-based practice, meta-analyses, and systematic reviews, and are the basis of justifying specific clinical procedures and restoration techniques.[3]

Randomized clinical control trials are essential evidence for new materials and treatments, as they provide standardized clues of clinical predictability and judgment.[19] Clinical trials with longer follow-up periods provide more reliable clinical judgment and constitute a sound basis for evidence-based practice. A recent systematic review and meta-analysis based on clinical studies performed over 12-72 months found similar performance of bulk-fill and conventional composite restorations.[6] However, shorter-duration clinical trials can still provide faster dissemination of essential information needed for decision making in everyday clinical practice.[20,21]

This study was designed to investigate the clinical reliability of Class II bulk-fill composite with and without a veneering layer of conventional microhybrid composite implementing the World Dental Federation (FDI) criteria for the ranking of restorations. The null hypothesis was that bulk-fill and veneered bulk-fill Class II resin composites perform similarly.

METHODS AND MATERIALS

This was a randomized clinical control study into the effectiveness of bulk-fill versus veneered bulk-fill Class II resin composite restorations employing the split-mouth technique. Eighty subjects were recruited following the inclusion and exclusion criteria listed. Patient recruitment, written consent, and follow-up procedures were performed in accordance with the ethical code and following the approval of the institutional review board of the university.

Sample Size Calculation

A total of 80 patients with a total of 160 Class II resin composite restorations divided into two study groups (n=80) were investigated. A sample size of 80 for each of the two study groups was considered satisfactory with respect to the previous reports of 3.2%-3.5% of annual failure by fracture of Class II resin composites, regarding two-tailed T statistics at α=0.05. An online free available sample size calculator was used to design our study sample size calculations (http://www.sample-size.net/means-effect-size/). Subjects were recruited from the outpatient clinic of the university, and follow-up occurred at five screening visits: 24 hours, 2 weeks, 6 months, 12 months, and 24 months after restoration.

Criteria

The inclusion criteria in this study were young adults (18-25 years): female (40) and male (40) patients with good oral hygiene, normal occlusion, no systemic disease, and regular use of a tooth brush twice daily. Based on the American Dental Association classification system, the selected molars, as viewed in digital bitewing radiographs indicated the presence of proximal caries extending into the DEJ beyond (D1) but not extending beyond the middle one-third of dentin (D2) (Figure 1A).[22,23] In each study subject, one molar on each side of the upper or lower arch was selected. Teeth selected for the study were in the same arch, with one molar on the right and the other on the left side following the split-mouth technique. Each of the molars selected for the study was in occlusion with natural sound antagonist occlusal tooth surfaces and each study restoration had proximal contact against a natural sound tooth surface.

The exclusion criteria were individuals with parafunctional clenching habits and bruxism. Furthermore, individuals with dry mouth, poor dietary habits of frequent consumption of carbohydrates (snacks more than three times a day), dental plaque index greater than 20%, multiple carious lesions, or frequent restorations were excluded from the study. Following many similar previous prospective clinical studies, caries risk assessment was not systematically performed in this study.[24-30]

Recruitment was performed after full-mouth screening by inspection using a mirror and explorer, DIAGNOdent Pen (Kavo, Biberach/Riß, Germany) carious lesion diagnosis, bitewing radiographs, and nonwaxed dental floss. DIAGNOdent Pen was used considering the clinical recommendations listed by Walsh.[31] Two independent calibrated investigators (RH, RA) carried out the screening exams and case selection. The purpose of the study was explained to the patients, and written consent with a time table showing the study intervals was signed by each patient. Before preparing the molars assigned for the study, recruited patients underwent full-mouth scaling and restoration of any carious lesions other than those included in the study. The procedures of cavity preparation, and restoration were performed bilaterally in the selected molars in one session.

A preliminary phase of manikin lab training of the three investigators (ME, RH, and AE) who participated in treating study subjects and the two follow-up evaluators (AA and KA) minimized human variables in cavity preparation, technique of restoration, and the clinical evaluation and ranking of restorations. A calibration was done between the independent screening examiners, operators, and evaluators using the Cohen Kappa (κ) index. Our κ interrater judgement scores for the different study aspects were $\kappa > 0.8$, indicating high levels of interinvestigator agreement.[32,33]

Cavity Preparation

Box-only Class II cavities were prepared on one proximal side of one right and one left molar tooth on the same arch after rubber dam isolation.[3] The preparation was started by gaining access through the enamel at the triangular fossa towards the proximal surface affected by caries using a round carbide bur number 1. The preparation was completed using a cylindrical diamond with a flat end. New burs were used for each study participant. Preparations were made using ultrahigh speed drills with abundant air–water cooling. The outline of the cavity was limited by caries extension and the need to free the proximal

contact. The buccal, lingual, and gingival margins were placed in the corresponding embrasure buccally, lingually, and gingivally. The width of the gingival seat was dictated by caries extension. All cavity margins were butt joints (Figure 1C).

Cavity Restorations

The materials used in the study are presented in Table 1. All prepared cavities received the etch-and-rinse bonding approach using the Tetric N-Bond bonding system (Ivoclar Vivadent, Schaan, Liechtenstein). All light-curing procedures were carried out using Ortholux Luminous Curing Light (3M Unitek, Monrovia, CA, USA), which is a high-intensity LED of 1500 mW/cm^2 energy output with a wavelength of 430-480 nm and a peak of 455-610 nm. The bonding procedures were as follows: 37% phosphoric acid was used for etching the preparation walls for 30 seconds, followed by water rinsing for 10 seconds, and air drying with oil- and water-free compressed air for 5 seconds. Cavity walls were then painted with the bond using microsponges. Air thinning of the bond was performed for 5 seconds, followed by light-curing for 20 seconds. All restorations were built against a wedged sectional matrix (PalodentV3 sectional matrix system, Dentsply DeTrey GmbH, Konstanz, Germany). One bulk-fill resin composite material [Tetric N-Ceram Bulk Fill (TBF), Ivoclar Vivadent] was randomly used for filling one cavity (restoration TBF) as one bulk increment of 4-mm thickness, which was then light cured for 40 seconds from an occlusal direction. A second layer of the same resin composite material was used to completely fill the cavity. Gold-plated plastic instruments were used to anatomically shape the surface of the composite before occlusal light curing for 40 seconds. The remainder of the occlusal fissure system in both the restorations received fissure sealing treatment (Figure 1D).

The wedge and sectional matrix were then removed. The restoration then received additional light curing from the buccal and lingual directions for 40 seconds each.[8,24] Our restorative procedure implemented three-point curing—occlusal, buccal, and lingual, in order to optimize the degree of curing at the deepest parts of the restoration that is relatively distant from the light-curing tip on occlusal curing.[8,34,35]

Occlusion was then checked using articulating paper, and premature contacts were removed using white stones. The cavity on the other side of the arch was restored in a similar manner, except for veneering the bulk-fill composite with a layer of microhybrid composite Tetric Ceram HB (Ivoclar Vivadent) of approximately 2-mm thickness to completely fill the cavity occlusally (restoration TBF/V), following a technique recommended by Leprince and others,[13] Sunbul and others,[14] and El Gezawi and others.[15] The quality of proximal contacts was assessed using dental floss and bitewing radiographs (Figure 1B).

Randomization

The split-mouth technique was employed in our investigation following the recommendation of Hickel and others.[36] Randomization was carried out employing an opaque, sealed-envelope technique. To avoid disclosure, the envelope was opened only at the time of the restoration. The restoration technique was known by the operator but was blind for the participating subject and the evaluator at all study intervals.[36]

Restoration Evaluation

Subjects were examined for the FDI criteria of the Class II restorations of the study at 24 hours, 2 weeks, 6 months, 12 months, and 24 months for their esthetic, functional, and biological quality in accordance with the FDI World Dental Federation criteria of clinical ranking of restorations.[3,36,37] Marginal gaps were assessed postoperatively with the aid of loupes (X3.53) and two dental explorers with tip diameters of 150-250 μm (MEDSY 560-1, MEDSY, Maniago, Italy). The

Table 1: *Materials Used in This Study*

Material	Description	Lot Number	Manufacturer
Tetric Ceram HB	A light-curing fine-particle microhybrid material based on a moldable ceramic	N03283	Ivoclar Vivadent, Schaan, Liechtenstein
Tetric N-Ceram Bulk Fill (TBF)	Bulk-fill resin composite material that allows the curing of 4-mm- thick layers	R65898	Ivoclar Vivadent, Schaan, Liechtenstein
Tetric N-Bond	Light-cured primer and adhesive, total-etch adhesive	R52704	Ivoclar Vivadent, Schaan, Liechtenstein
Fine Etch, etchant	37% phosphoric acid gel	FE1242	Spident Co., Ltd, Incheon, Korea

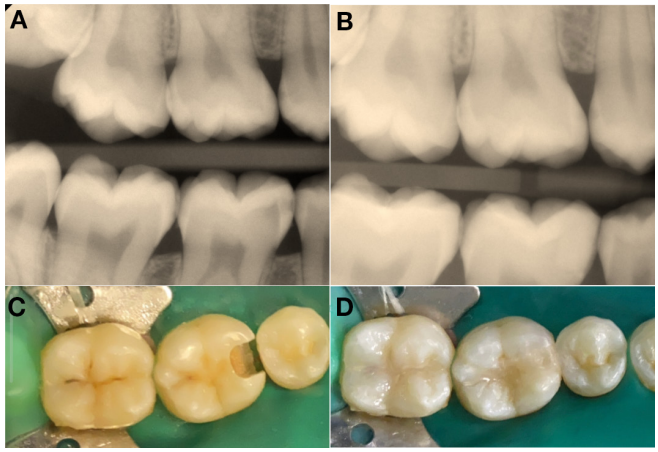

Figure 1. *Preoperative bitewing radiograph with proximal radiolucency D2 in tooth # 30 (A): postoperative bitewing radiograph, (B): box-only prepared cavity, (C): postoperative photograph of bulk-fill restoration (TBF), and (D): fissure sealing.*

marginal quality was ranked according to the FDI criteria;[16,37] see Table 2. Before each study interval, each explorer's tip diameter was measured by one investigator using a digital microscope (Hirox KH-7700, Tokyo, Japan) to assure accuracy. Blunted tip explorers were replaced by new ones.[38] Post-restoration hypersensitivity was ranked as a biological property, and the anatomic form and marginal discoloration were scaled as esthetic properties.

Patient Satisfaction Survey

A patient satisfaction survey was performed at each study interval by asking the patients to answer questions regarding their satisfaction with the restorations. A primary end point was determined by evidence of patient nonsatisfaction or clinically nonsatisfactory restoration, indicating the need for repair or remake.

At each study interval, each participating subject was asked to answer the following question: Are you satisfied with both the restorations? Answer-1: Yes, totally satisfied with both/one (right–left), answer-2: Yes, but one (right–left)/both show/shows slight sensitivity, food wedging between teeth, other, answer-3: No, I am not satisfied with one (right–left)/ both (sensitivity, food wedging between teeth, and other). Four investigators participated in restoration evaluation and data collection.

Demographic Data

The present study was conducted on 80 patients: 40 males (50%), and 40 females (50%), and the mean values for age were 23.1 (±4.6) years with a minimum of 18 and a maximum of 25 years.

Statistical Analysis

For each assessment criterion, the score numbers for restorations TBF and TBF/V were recorded for the respective study interval. The means and standard deviations were calculated and used for the statistical analysis. Differences in intergroup rankings after 24 months were analyzed using Friedman repeated-measures analysis of variance (α=0.05). Furthermore, differences in intragroup rankings at baseline and after 24 months were studied employing the McNemar test (a=0.05). Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0.

RESULTS

Qualitative data are presented as frequencies and percentages in Table 3. None of the test restorations at any of the study intervals was ranked as clinically unsatisfactory, necessitating repair or remake. Other than some reports of mild sensitivity or slight proximal wedging of food, none of the participating subjects reported a significant dissatisfaction, indicating the need for considerable intervention by restoration repair or replacement for any of the study restorations at any of the study intervals. Both study groups showed a time-dependent increase in the number of restorations showing deterioration in quality. Observations after 12 and 24 months showed that bulk-fill restorations (TBF) had significantly lower number of excellent restorations (Score I) and greater number of less quality scores than veneered bulk-fill restorations (TBF/V) in the incidence of fracture. Meanwhile, after 24 months of clinical service, bulk-fill restorations (TBF) showed significantly lower score I restorations with greater number of inferior quality scores than veneered bulk-fill restorations (TBF/V) regarding the quality of anatomical form and proximal contact.

Clinical Evaluation Outcome

Fracture

After 24 hours, 2 weeks, and 6 months, all restorations in the two groups had a score of I. After 12 and 24 months, TBF showed a significantly lower prevalence of restorations with a score of I with greater incidence of inferior quality scores than TBF/V (p=0.031, effect size=2.000, and p<0.001, effect size=1.692, respectively) denoting inferior performance of TBF. Regarding the changes by time, there was a statistically significant decrease in the prevalence of score I with greater incidence of inferior quality scores after 12 as well as 24 months in each group (p<0.001, effect size=0.221 and p<0.001, effect size=0.094, respectively).

Table 2: *Evaluation Criteria Following the FDI Ranking*

Study Intervals	Evaluation Criteria	1-Fracture and retention	2-Marginal Adaptation	3- Anatomic form (marginal ridge continuity)	4- Tightness of proximal contact	5- Marginal Discoloration	6- Postrestoration Hypersensitivity
24 hours 2 weeks 6 months 12 months 24 months	**Score I** Clinically excellent or very good	Restoration retained, no fractures or cracks	Harmonious outline, no gaps, no discoloration	Form is ideal	Normal contact point (floss or 25 µm metal blade can be inserted but not 50 µm blade)	No marginal or surface staining	No hypersensitivity, normal vitality
24 hours 2 weeks 6 months 12 months 24 months	**Score II** Clinically good	Small hairline crack	Marginal gap (<150 µm) Small marginal fracture removed by polishing	Form is only affected	Slightly too strong but no disadvantage	Minor marginal staining and/ or mild surface staining	Low hypersensitivity for a limited period of time, normal vitality
24 hours 2 weeks 6 months 12 months 24 months	**Score III** Clinically sufficient or satisfactory	Two or more or larger hairline cracks and/or chipping (not affecting the marginal integrity or proximal contact)	Gap <250 µm not removable Several small enamel or dentin fracture	Form differs but is not esthetically displeasing	Slightly too weak, no indication of damage to tooth, gingiva or periodontal structures (50 µm metal blade can pass easily, but not 100 µm)	Moderate marginal or surface staining	Premature/ slightly more intense Delayed or weak sensitivity; no subjective complaints, no treatment needed
24 hours 2 weeks 6 months 12 months 24 months	**Score IV** Clinically Unsatisfactory (but repairable)	Chipping fractures that damage marginal quality or proximal contacts; bulk fractures with or without partial loss (less than half of the restoration)	Gap > 250 µm or dentin/ base exposed Chip fracture damaging margin Notable enamel or dentin wall fracture	Form is affected and unacceptable esthetically. Intervention (correction) is necessary	Too weak (100-µm metal blade can pass) and possible damage (food impaction). Repair possible	Surface staining on the restoration, but not on the tooth. Restoration requires major correction	Premature/ very intense Extremely delayed/weak with subjective complaints Negative sensitivity. Intervention necessary but no replacement
24 hours 2 weeks 6 months 12 months 24 months	**Score V** Clinically Poor (replacement necessary)	Loss of restoration (partial or complete)	Filling is loose but in situ	Form is completely unsatisfactory and/or lost. Repair is not feasible or reasonable, replacement needed	Too weak and/or clear damage (food impaction) and/or pain or gingivitis, requires replacement	Surface staining is totally unacceptable, and the restoration needs to be replaced	Very intense, acute pulpitis or nonvital. Endodontic treatment is necessary, and restoration has to be replaced

Table 3: *Descriptive Statistics and Results of McNemar's Test, Wilcoxon Signed-Rank Test and Friedman's Test for the Comparisons Between Groups and Within Each Group*

Criteria	Time	Score	Group A (n = 80)		Group B (n = 80)		p-value (Between groups)	Effect size
			N	%	N	%		
	24 hours	Score I	80	100	80	100	NC†	
Fracture	2 weeks	Score I	80	100	80	100	NC†	
	6 months	Score I	80	100	80	100	NC†	
	12 months	Score I	68	85	74	92.5	0.031*	*OR* =2.000
	12 months	Score II	12	15	6	7.5		
	24 months	Score I	58	72.5	71	88.8	<0.001*	*OR* =1.692
	24 months	Score II	22	27.5	9	11.3		
	p-value (within group)		<0.001*		<0.001*			
	Effect size (*w*)		0.221		0.094			
Marginal gap	24 hours	Score I	80	100	80	100	NC†	
	2 weeks	Score I	80	100	80	100	NC†	
	6 months	Score I	75	93.8	78	97.5	0.250	*OR* =1.667
	6 months	Score II	5	6.2	2	2.5		
	12 months	Score I	67	83.8	70	87.5	0.250	*OR* =4.333
	12 months	Score II	13	16.3	10	12.5		*OR* =3.600
	24 months	Score I	62	77.5	67	83.8	0.063	*OR* =3.600
	24 months	Score II	18	22.5	13	16.3		
	p-value (within group)		<0.001*		<0.001*			
	Effect size (*w*)		0.165		0.128			
Anatomical form	24 hours	Score I	80	100	80	100	NC†	
	2 weeks	Score I	80	100	80	100	NC†	
	6 months	Score I	80	100	80	100	NC†	
	12 months	Score I	80	100	80	100	NC†	
	24 months	Score I	62	77.5	73	91.3	0.001*	*OR*=1.636
	24 months	Score II	18	22.5	7	8.8		
	p-value (within group)		<0.001*		<0.001*			
	Effect size (*w*)		0.225		0.088			
Marginal discoloration	24 hours	Score I	80	100	80	100	NC†	
	2 weeks	Score I	80	100	80	100	NC†	
	6 months	Score I	80	100	80	100	NC†	
	12 months	Score I	80	100	80	100	NC†	
	24 months	Score I	70	87.5	73	91.3	0.214	*r* = 0.139
	24 months	Score II	6	7.5	4	5		
	24 months	Score III	4	5	3	3.8		
	p-value (within group)		<0.001*		<0.001*			
	Effect size (*w*)		0.125		0.088			

Table 3: *Descriptive Statistics and Results of McNemar's Test, Wilcoxon Signed-Rank Test and Friedman's Test for the Comparisons Between Groups and Within Each Group (Continued).*

Criteria	Time	Score	Group A (n = 80)		Group B (n = 80)		p-value (Between groups)	Effect size
			N	%	N	%		
Proximal contact quality	24 hours	Score I	80	100	80	100	NC†	
	2 weeks	Score I	80	100	80	100	NC†	
	6 months	Score I	76	95	77	96.3	1.000	*OR*=4.000
	6 months	Score II	4	5	3	3.8		
	12 months	Score I	72	90	70	87.5	0.500	*OR*=0.028
	12 months	Score II	8	10	10	12.5		
	24 months	Score I	55	68.8	62	77.5	0.007*	*r* = 0.304
	24 months	Score II	11	13.8	13	16.3		
	24 months	Score III	14	17.5	5	6.3		
	p-value (within group)		<0.001*		<0.001*			
	Effect size (*w*)		0.232		0.168			
Postrestoration hypersensitivity	24 hours	Score I	72	90	74	92.5	0.500	*OR* =4.000
	24 hours	Score II	8	10	6	7.5		*OR* =2.500
	2 weeks	Score I	75	93.8	77	96.3	0.500	*OR* =2.500
	2 weeks	Score II	5	6.3	3	3.8		*OR* =4.000
	6 months	Score I	76	95	77	96.3	1.000	*OR* =4.000
	6 months	Score II	4	5	3	3.8		*OR* =0.013 *OR =0.013*
	12 months	Score I	77	96.3	76	95	1.000	*OR* =0.013
	12 months	Score II	3	3.8	4	5		
	24 months	Score I	69	86.3	72	90	0.250	*OR* =3.667
	24 months	Score II	11	13.8	8	10		
	p-value (within group)		<0.001*		0.006*			
	Effect size (*w*)		0.067		0.045			

** Significant at p ≤ 0.05, NC† = not computed, because the variable is constant.*

Marginal Gap

After 24 hours and 2 weeks, all restorations in the two groups had a score of I. After 6, 12, and 24 months, there was no statistically significant difference between the two groups (p=0.250, effect size=1.667; p=0.250, effect size=4.333; and p=0.063, effect size=3.600, respectively). Regarding the changes by time, there was a statistically significant decrease in the prevalence of score I with greater incidence of inferior quality scores after 6, 12, and 24 months in each group (p<0.001, effect size=0.165 and p<0.001, effect size=0128, respectively).

Anatomical Form

After 24 hours, 2 weeks, and 6 as well as 12 months, all restorations in the two groups had a score of I. After 24 months, TBF showed a statistically significant lower prevalence of restorations with a score of I and greater incidence of inferior quality scores than TBF/V (p=0.001, effect size=1.636) denoting inferior performance of TBF. Regarding the changes by time, there was a statistically significant decrease in the prevalence of score I with greater inferior quality scores after 24 months in each group (p<0.001, effect size=0.225 and p<0.001, effect size=0.088, respectively).

Marginal Discoloration

After 24 hours, 2 weeks, and 6 as well as 12 months, all restorations in the two groups had a score of I. After 24 months, there was no statistically significant difference between the two groups (p=0.214, effect size=0.139).

Regarding the changes by time, there was a statistically significant decrease in the prevalence of score I after 24 months with greater incidence of inferior quality scores in each group (p<0.001, effect size=0.125 and p<0.001, effect size=0.088, respectively).

Proximal Contact Quality

After 24 hours and 2 weeks, all restorations in the two groups had a score of I. After 6 and 12 months, there was no statistically significant difference between the two groups (p=1.000, effect size=4.000 and p=0.500, effect size=0.028, respectively). After 24 months, TBF showed a statistically significantly lower prevalence of scores I and II with greater incidence of inferior quality scores than TBF/V (p=0.007, effect size=0.304) denoting inferior performance of TBF. Regarding the changes by time, there was a statistically significant decrease in the prevalence of score I with greater incidence of inferior quality scores after 6, 12, and 24 months in each group (p<0.001, effect size=0.232 and p<0.001, effect size=0168, respectively).

Postrestoration Hypersensitivity

After 24 hours, 2 weeks, and 6, 12, and 24 months, there was no statistically significant difference between the two groups (p=0.500, effect size=4.000; p=0.500, effect size=2.500; p=1.000, effect size=4.000; p=1.000, effect size=0.013; and p=0.250, effect size=3.667, respectively). Regarding the changes by time, there was a statistically significant decrease in the prevalence of score I with greater incidence of inferior quality scores after 24 months in each group (p<0.001, effect size=0.067 and p=0.006, effect size=0.045, respectively).

Patient Satisfaction Survey

There was a statistically significant change in patient satisfaction by time (p<0.001, effect size=0.215). Total satisfaction with both the restorations was 90% after 24 hours, which increased to 93.8% after 2 weeks and 95% after 6 months. After 12 months, total satisfaction with both restorations decreased to 87.5%, and a further decrease was observed after 24 months to 66.3% (Figure 2).

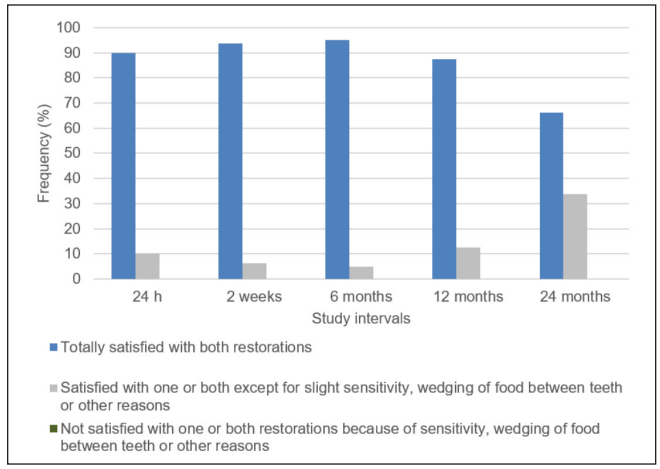

Figure 2. *Patient satisfaction through the study intervals. Abbreviation: h=hours.*

DISCUSSION

Our double-blind randomized clinical control study was performed over a 24-month follow-up because of strong limitations regarding patient availability over a longer duration. Nevertheless, longer duration follow-up might have provided more reliable outcomes. Another limitation of this study is the small size of the study restorations. More complex restorations would have been more prone to clinical failure and might have provided a broader image of restoration performance.[6]

In spite of previous reports indicating no gender differences in failure rate of dental restorations,[39] others listed age and gender among factors affecting longevity of restorations.[40,41] Furthermore, studies confirmed variations in values of biting forces in different gender and age groups, which might indicate different functional behavior of restorations in different genders.[42,43] One study assumed that the incidence of significantly more prominent wear of teeth in males than females is because of the ability of males to use heavier masticatory forces in addition to differences in life stresses and type of diet.[44] In our study design, we expected a gender ratio of the population close to 50/50.[45] Using equal gender distribution of participants might not be the best way to eliminate gender bias in clinical trials for different clinical disciplines.[46,47] However, we tried to provide a balanced interpretation of results and avoid possible age and gender influences by using a narrow age range, and equal number of male and female subjects.

Although previous reports have indicated low specificity of DIAGNOdent Pen, as it might give false positive readings with existing restorations or foreign substances, our study used DIAGNOdent Pen as a diagnostic aid for its reported validity, reliability, and high sensitivity as well as its *in vivo* fair positive correlation with radiographic scores.[48-50] The sensitivity of bitewing radiographs in detecting any proximal lesion was only 42%, which indicates the need for having an additional diagnostic tool. The accuracy of DIAGNOdent Pen in diagnosing proximal cavitated or noncavitated proximal caries in posterior teeth was found to be superior to digital bitewing radiography.[31]

During our screening, DIAGNOdent Pen was particularly helpful in diagnosing small proximal carious lesions where the DIAGNOdent Pen readings were confirmed by bitewing radiographs. This confirmed selecting only molars with proximal lesions extending beyond D1 but not beyond D2 for the current study purpose, avoiding unnecessary exposure to X-rays in case of absence of proximal lesions or overtreatment in cases of less extending lesions treatable by noninvasive approaches.[23,48,51,52] Furthermore, it was useful in screening occlusal surfaces to justify box-only preparations used in the current study.[31]

While Tetric N-Ceram is a bulk-fill resin composite with Ivocerin photoinitiator technology, and with 61% inorganic filler and 17% polymer filler with a total of 68% inorganic filler content by weight,[53,54] Tetric Ceram HB is a high-viscosity, heavy body, microhybrid composite with high filler loading of 81% by weight. Reports on Tetric Ceram HB claim that this composition and heavy body helps in packing and producing tight proximal contact and high wear resistance.[55-57]

Our findings indicated that Class II bulk-fill composite restorations show a satisfactory performance whether veneered with conventional microhybrid composite or not. None of the restorations used showed clinical failure necessitating repair or remake. This is in agreement with the previous findings of Loguercio and others,[19] who studied the clinical performance of Class II bulk-fill composites placed incrementally or as one bulk over 72 months. Moreover, these results are also in line with the meta-analysis of Veloso and others.[58]

Our results confirmed the time-dependent deterioration in restoration quality regardless of the technique of application. Although our two studied groups, TBF and TBF/V, showed similar excellent performance after 24 hours and 2 weeks, gradual significant deterioration in quality indicated by a reduction in the number of restorations ranked as Grade I was recognized thereafter in all assessment criteria. This is again in harmony with the previous findings of Loguercio and others[19] and Veloso and others.[58] Time-dependent degradation of both resin composite and resin adhesive bonds to tooth structure has been reported by many *in vitro* and *in vivo* studies.[4] Exposure to oral environmental conditions of humidity, functional mechanical loading, thermal cycling, pH cycling, and bacterial biochemical products as well as endogenous degrading enzymes, such as endogenous matrix metalloproteinases, progressively deteriorates the internal structure of resin dentin bonds and the collagen hybrid layer.[4,59] This biodegradation damages the polymeric matrix of resin structures and breaks down their bonds with the silane coupling agents due to the hydrolysis of Si-O-Si bonds of the silane.[60] This process leads to downgrading of the physical and mechanical properties of resin composite as well as the interfacial bonds to tooth structure.[4,59] Fatigue, chemical degradation, and worsening of mechanical properties, such as microhardness fracture toughness and flexure strength of resin composite as well as loss of fillers of the composite structure, are potential predisposing factors for clinical consequences of fracture, loss of occlusal anatomy, and tightness of proximal contacts. Similarly, a consistent time-dependent degradation in the quality of the restoration-tooth structure bonding might predispose marginal and interfacial gaps with greater potential for marginal discoloration, hypersensitivity, and recurrent caries.[60,61]

On the other hand, the degradation of resin bonds to tooth structure predisposes patients to leakage, marginal deterioration, and recurrent caries.[4,12,15,17,18] Factors such as the chemical make-up of the polymer matrix, filler size and size distribution, degree of polymerization, and quality of matrix systems used during insertion of resin composite have been listed among the factors influencing the form and function of resin composite restorations.[53] The significant correlation between surface microhardness and volume fraction of the fillers of resin composite has been reported by Leprince and others[13] as a basis explaining the inferior mechanical performance of bulk-fill composites in comparison to conventional composites. They reported variations in the mechanical properties of different bulk-fill composites relative to conventional resin composites. In their study, Tetric EvoCeram Bulk Fill showed similar properties to those of its conventional counterpart from the same manufacturer—Tetric EvoCeram. In our study, TBF was compared to TBF veneered with Tetric Ceram HB conventional microhybrid composite.[13]

Al-Nahedh and Alawami showed that the fracture resistance of Tetric-N Ceram Bulk Fill Class II composite restorations capped with a layer of conventional nanohybrid resin composite is greater than that of the uncapped Tetric-N Ceram bulk-fill restorations. However, they demonstrated that the performance of bulk-fill composites is material dependent.[62]

Changes in the occlusal anatomy and tightness of proximal contact occur due to wear of the resin composite. Fatigue wear, adhesive wear, abrasive wear, and corrosive wear are among the mechanisms reported for the wear of resin composite.[63] Accordingly,

variations in composition and chemical make-up as well as depth of cure in different resin composites have a deciding influence on the resistance of the respective resin composite to wear and hence on the clinical performance of resin composite restorations with respect to occlusal anatomy and tightness of proximal contact.[18,59] The high filler content of the high-viscosity Tetric Ceram HB claimed to superior packability might explain the superior functional performance of restoration B, where TBF has been veneered by an increment of approximately 2-mm thickness of Tetric Ceram HB relative to Restoration A of Tetric N-Ceram Bulk-Fill composites at 12 and 24 months follow-ups, respectively.[55] Recent reports indicated that the tightness of proximal contacts of bulk-fill composites is material dependent.[64]

The results of the current study indicated that none of the investigation subjects were unsatisfied with any of the study restorations. None of the studied restorations showed marked deterioration in any of the employed assessment criteria to the degree necessitating repair or remake at any of the study intervals. This is in line with the previous findings of Loguercio and others.[12]

Our results of the criteria for fracture, anatomical form, quality of proximal contact after 12- and 24-month intervals, which showed a significantly lower number of grade I, and excellent restorations in TBF relative to TBF/V might support the previous *in vitro* findings that the mechanical properties of bulk-fill composites of Ilie and others,[12] Leprince and others,[13] Sunbul and others[14] are inferior in mechanical properties, such as the elastic modulus and the flexure strength, to conventional composites due to the swelling behavior of bulk-fill composite and their greater degradation tendency over time compared with conventional composites.[13-15] An abrasive wear study showed that bulk-fill composites vary in their wear behavior, and no common conclusion can be drawn to include the entire brand of materials.

Other reports have shown that the differences between bulk-fill and conventional composites arise mainly from the greater depth of cure because of the increased translucency of bulk-fill composites, and that more clinical studies are needed to demonstrate the clinical performance of bulk-fill composites, particularly in large cavities where wear and fracture resistance are of primary interest.[14,65] According to our results, the given null hypothesis that TBF and VBF perform similarly was rejected, since VBF performed better than TBF restorations. Although the simplicity and application time savings in addition to minimizing the risks of air void incorporation between successive increments are reported objectives of employing bulk-fill composites, this should never be at the expense of the quality of clinical performance and long-term degradation resistance.[12,66,67]

The authors of the current investigation, based on their findings, recommend the veneering of bulk-fill composites in posterior stress-bearing locations with an increment of conventional microhybrid composite. Future studies should consider recurrent caries that have been reported together with fracture as the most common modes of failure of posterior composites.[14] Three years of clinical service has been recommended for such evaluation.[14] Accordingly, longer duration clinical trials are needed to confirm our findings over longer durations of clinical service and to consider the criterion of recurrent caries.[14] Systematic caries risk assessment models employing true risk factors is an element of consideration in studying the criterion of caries recurrence in future research.[28] Further clinical investigations should assess different bulk-fill composites before generalized conclusions can be drawn.

CONCLUSIONS

Within the limitations of the current study, the following conclusions can be drawn:

1. Both bulk-fill and veneered bulk-fill Class II restorations perform satisfactorily over 24 months of clinical service with no need for repair or remake.
2. Veneering bulk-fill composites with a layer of high-viscosity conventional microhybrid composite appears to be a better clinical practice for improved clinical performance.

Acknowledgements

This study did not receive any external financial support directed to its development, aside from the author's support and human and facilities' resource.

Regulatory Statement

The author represents that this study was conducted in accordance with all the provisions of the human subjects' oversight committee guidelines and policies of Imam Abdulrahman Bin Faisal University, Dammam, Saudi Arabia.

Conflict of Interest

The authors of the present study certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in the present article.

(Accepted 6 November 2020)

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Departments

Errata

Operative Dentistry apologizes for the errors in the following manuscripts.

AD Loguercio, LJC Vargas, MW Favoreto, HF Andrade, CP F Borges, A Dávila-Sánchez, A Reis, CP Mora; Effects of Microabrasion Prior to In-office Bleaching on Hydrogen Peroxide Permeability, Color Change, and Enamel Morphology. *Oper Dent* 1 November 2021 **46(6)** 661-668. doi: https://doi.org/10.2341/20-179-L

There are errors in the author order and contact list. The correct author order and author affiliations list should read (corrections are underlined):

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Additionally, the legend in Table 3 should read:

*Identical uppercase or lowercase letters in each column indicate statistically similar means (one-way ANOVA and Tukey test, α=0.05).

D Kaisarly, M ElGezawi, R Haridy, A Elembaby, A Aldegheishem, R Alsheikh, KS Almulhim; Reliability of Class II Bulk-fill Composite Restorations With and Without Veneering: A Two-year Randomized Clinical Control Study. *Oper Dent* 1 September 2021 **46(5)** 491-504. doi: https://doi.org/10.2341/19-290-C

There are errors in the author order and contact list and corresponding author information. The correct author order, author affiliations list, and corresponding author information should read (corrections are underlined):

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BM Moran, PK Ziegelmann, SB Berger, A Burey, T de Paris Matos, E Fernández, AD Loguercio, A Reis; Evaluation of Tooth Sensitivity of In-office Bleaching with Different Light Activation Sources: A Systematic Review and a Network Meta-analysis. *Oper Dent* 1 September 2021 **46(5)** E199–E223. doi: https://doi.org/10.2341/20-127-L

There are errors in the author names and contact list, in the Summary, and in the Results. The correct author spelling and author affiliations list should read (corrections are underlined):

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In the Methods paragraph of the Summary:

The sentence, "A comprehensive search was performed in PubMed, Bridge Base Online (BBO), Latin American and Caribbean Health Sciences Literature database (LILACS), Cochrane Library, Scopus, Web of Science, and grey literature without date and language restrictions on April 23, 2017 (updated on September 26, 2019)."

Should read (correction is underlined):

"A comprehensive search was performed in PubMed, Bibliografia Brasileira de Odontologia (BBO), Latin American and Caribbean Health Sciences Literature database (LILACS), Cochrane Library, Scopus, Web of Science, and grey literature without date and language restrictions on April 23, 2017 (updated on September 26, 2019)."

In the Study Selection paragraph in the Results section:

The sentence, "After title screening, 227 studies remained, and this number was reduced to 32 full texts that were assessed for eligibility (Figure 1)."

Should read (correction underlined):

"After title screening, 228 studies remained, and this number was reduced to 32 full texts that were assessed for eligibility (Figure 1)."