Clinical Evaluation of Sonic-Activated High Viscosity Bulk-Fill Nanohybrid Resin Composite Restorations in Class II Cavities: A Prospective Clinical Study up to 2 Years

Keywords

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ABSTRACT

This study evaluated the clinical performance of a bulk-fill resin composite in class II cavities for up to 2 years. Class II restorations (N=111) were made using a nanohybrid bulk-fill resin composite (SonicFill, Kerr Corp.) and evaluated following 1 week after placement, at 6 months, and thereafter annually up to 2 years using the United States Public Health Service (USPHS) criteria. The changes were analyzed using the McNemar test and the Kaplan-Meier method. No secondary caries was observed until the final recall. One restoration underwent endodontic treatment after 2 months following the restorative procedure and was deemed a failure. The overall success rate was 99.1%. Colour match deteriorated from a score of 0 to 1 in eight restorations from baseline to 6 months and six restorations showed marginal staining at final recall. Bulk-fill resin composite (SonicFill) showed acceptable clinical performance through 2 years of service but colour match to the tooth started to show some deterioration within the first 6 months.

INTRODUCTION

The traditional restorative material for posterior teeth, amalgam, is increasingly being replaced in favour of resin composite materials for direct restorations. This may be explained by the increasing concern over possible mercury intoxication, especially after the reports of the World Health Organization (WHO) about health risks associated with the use of mercury in dental amalgam and vaccines.[1] Improvements in adhesive restorative dentistry, and increases in patient demands for tooth coloured restorations also increased the use of adhesive technology in dentistry.

Adhesive restorative materials meet the requirements of minimally invasive dentistry and allow the clinicians to prevent the sound dental tissues.[2] Due to considerable improvements since their introduction in dentistry, the use of adhesive restorative materials has been extended to larger cavities with different prognoses. In such large restorations, due to the limited depth of polymerization and the possibility of polymerization shrinkage,

an incremental build-up of multiple layers (maximum 2 mm thickness each) is required.[3] Although incremental application of resin composites is essential for adequate light transmission through the material, this method has some disadvantages, such as the possibility of void formation, adhesive failures between composite increments and increased chair time.[4] Consequently, manufacturers have sought to develop faster and easier procedures and improved resin-based materials.[3] In this context, a new type of restorative material was recently introduced, the so-called bulk-fill resin composites that allow build-up of the restorations in increments of 4 mm or more. Thus, the bulk-fill technique makes routine adhesive restorations simpler and quicker with the application of decreased number of increments.[5]

The reported properties of bulk-fill composites, such as decreased polymerization shrinkage,[6] improved self-leveling ability,[7] reduced cuspal deflection,[8] and optimal bond strength,[5] could be considered favourable properties of such materials. In addition, some manufacturers have eliminated the disadvantages associated with shrinkage stress by making various modifications to the composition and polymerization kinetics of such materials. Typically, slower polymerization protocols are employed as a basic strategy in order to decrease the polymerization shrinkage.[9] Based on their viscosities and application techniques, bulk-fill resin composites are classified as low- and high-viscosity ones. The less favourable mechanical properties of low-viscosity bulk-fill resin composites (flowable) require finishing the restoration by adding a capping layer, composed of traditional resin composite.[10] However, SonicFill (Kerr, CA, USA) is a sonically activated material that allows building posterior restorations up to 5 mm thick in one step, unlike other flowable bulk-fill composites. The resin in this material with shrinkage stress: of 2.05% consists of bis-GMA, TEGDMA (5%), EBPDMA and fillers that react to sonic energy that in turn decreases its viscosity.

Accordingly, the material flows readily into the cavity allowing ease of application and good adaptation to the cavity walls. Once the sonication is terminated, viscosity of the material increases. Unlike other bulk-fill resin composites, this particular material is less translucent and as a result depth of polymerization does not depend on the translucency of the material after photo-polymerization.[11] Considering that many direct adhesive restorations are replaced due to clinical problems such as secondary caries, fractures, and marginal discoloration,[12,13] bulk-fill materials may present advantages to decrease the workflow at chairside.

The objective of this study therefore was to evaluate the clinical performance of sonic-activated high viscosity bulk-fill resin composite restorations (SonicFill) in class II cavities considering mechanical, biological and optical properties.

MATERIALS AND METHOD

STUDY DESIGN

The brands, manufacturers, chemical composition and batch numbers of the materials used in this study are listed in Table 1.

Ethical committee of Istanbul Medipol University approved this clinical study (10840098-17). Patients were given written informed consent to participate the study before treatment and to enrol a recall program at baseline (1 week), 6 months, and thereafter annually.

Table 1. Brands, types, chemical compositions and manufacturers of the main materials used in this study.

Brand	Type	Chemical composition	Manufacturer
Dycal	Calcium hydroxide liner	Paste: Disalicylate ester of 1,3, butylene glycol; calcium phosphate; calcium tungstate; zinc oxide; iron oxide Paste: Calcium hydroxide; ethyl toluenesulfonamide; zinc sterate; titanium dioxide; zinc oxide; iron oxide	Dentsply Caulk, Milford, DE, USA
Scotchbond Universal Etchant	Etching Gel	32% phosphoric acid, water soluble polymers, fumed siilica	3M ESPE, St. Paul, MN, USA
Kuraray S³ Bond	Self-etch adhesive	10-MDP, HEMA, bis-GMA, water, ethanol, silanized colloidal silica, camphorquinone	Kuraray, Osaka, Japan
SonicFill	Bulk-fill resin composite	Glass, oxide, chemicals 3-trimethoxysilylpropyl methacrylate, silicon dioxide, ethoxylated bisphenol-Adimethacrylate bisphenol-A-bis-(2-hydroxy-3-mehacryloxypropyl) ether, triethyleneglycoldimethacrylate Fillers: silica, Ba-glass (83.5 wt%; 69 vol%)	Kerr, Orange, CA, USA

INCLUSION AND EXCLUSION CRITERIA

Patients in need of removal of posterior old amalgam, composite restorations or having caries lesions were recruited in the study. Inclusion and exclusion criteria were as follows: Patients with good oral hygiene, teeth having an antagonist tooth in occlusion, being physically and psychologically in good state to provide written consent to participate in the clinical study and willing to attend the scheduled follow-up appointments. Exclusion criteria included presence of teeth with severe periodontal problems, present pulpal disease, teeth planned as abutment for fixed or removable prosthesis, allergic to adhesive restorative materials, pregnant or nursing, high caries risk and bruxism.

OPERATIVE PROCEDURES

From March 2013 to January 2014, two operators with experience in adhesive dentistry, more than 10 and 18 years since graduation, made the cavity preparations and placed posterior class II restorations (N=111) in the maxilla or mandible using bulk-fill resin composite (SonicFill, Kerr, Orange, CA, USA) in a total of 52 patients (37 females, 15 males; mean age: 27.2±11 years) at the university staff clinics.

Operative procedures were performed under local anaesthesia if necessary. The enamel or existing restorations were removed by diamond abrasives with high speed handpiece under constant water-cooling. Infected dentin in the cavity was removed by carbide round burs used with low-speed handpiece and no bevel was prepared.

Calcium hydroxide-based material (Dycal, Dentsply Caulk, Milford, DE, USA) was placed when the cavity floor was close to the pulp and coated with resin-modified glass ionomer (Glass Liner, Willmann & Pein GmbH, Hamburg, Germany). The operative field was cleaned with an air/water spray, gently air-dried, and then carefully isolated with cotton rolls and suction. A metal matrix band (Adapt SuperCap Matrices, Kerr) and wooden wedge were placed for separation. Then the enamel parts of the cavities were conditioned with 32% phosphoric etching gel (Scotchbond Universal Etchant, 3M ESPE, St. Paul, MN, USA) for 10 s. After the acid was rinsed with water, chlorhexidine (CHX) antibacterial solution (Consepsis, Ultradent, UT, USA) was applied for 10 s and waited for 10 s wait before air-drying. The adhesive (S3 Bond Plus, Kuraray, Osaka, Japan) was applied and scrubbed with a disposable brush on both enamel and dentin surfaces for 20 s according to the selective etching concept. The surfaces were gently air-dried for at least 5 s and photo-polymerized for 20 s (Guilin Woodpecker Medical Instrument Co., Ltd., China) according to the manufacturer's instructions. The power output of the unit was 1100 mW/cm^2 measured with a radiometer (Cure-Rite, Dentsply Caulk, Ontario, Canada) before placing the restoration. Bulk-fill resin composite was applied to the bonded cavities with sonication (SonicFill Handpiece, Kerr) and photo-polymerized for 40 s according to the manufacturer's instructions. Premature contacts were controlled using carbon paper, interproximal contacts were checked using dental floss and adjustments were made where needed. The restorations were finished under water-cooling with finishing burs and finally polishing was performed using discs (Opti Disc, Kerr) and rubber points (HiLusterPLUS Polishing System, Kerr).

EVALUATION

Two calibrated observers, independent from the operators, performed the evaluations. In cases of different scores, the observers re-evaluated the restorations and reached a consensus. When an intervention was necessary, the evaluators made a subjective decision for repair, partial or complete replacement. Restorations were evaluated 1 week after placement (baseline), at 6 months and thereafter annually up to 2 years using United States Public Health Service (USPHS) criteria with slight modifications[14] for the following parameters: anatomical form, marginal adaptation, colour match, marginal discoloration, surface roughness, postoperative sensitivity, and secondary caries (Table 2). In addition to USPHS outcomes, the restorations were evaluated for mechanical (chipping and fracture) and biological (endodontic failure) failures. Considering the history and frequency of former incipient caries lesions, the operator determined the caries risk for each patient. Patients were instructed to call upon any kind of complaint.

STATISTICAL ANALYSIS

Statistical analysis was performed using SPSS 21.0 software for Windows (SPSS Inc., Chicago, IL, USA). The inter-observer agreement with respect to the USPHS criteria is expressed as weighted Cohen's kappa. Generalized Estimating Equations (GEE) was used to analyze the changes in the follow-up scores of the restorations compared to baseline. Survival rate was calculated using Kaplan-Meier survival analysis. P values less than 0.05 were considered to be statistically significant in all tests.

RESULTS

The distribution of 111 restored teeth and restoration types in the maxilla and mandible are presented in Table 3.

All patients (100%) attended the final recall visit. The mean observation period was 16.7 months with a minimum of 2 months and a maximum of 25.5 months. Some patients received multiple restorations up to 5 restorations in some cases.

The Kappa score for agreement between the observer for screening USPHS criteria was 0.85. No postoperative symptoms were reported at baseline or final recall except one restoration, which received endodontic treatment due to periapical inflammation, developed 2 months following placement of the restoration and recorded as failure. No secondary caries, chipping or fractures were observed until the final follow up. The overall survival rate was 99.1% (Kaplan-Meier) *(Figure 1*).

None of the evaluated parameters showed significant difference between baseline and final follow up observations (p>0.05). The frequency of Score 1 (noticeable difference) for colour match (n=8; 7.3%), surface roughness (n=7; 6.2%) and marginal discoloration (n=6; 5.4%) tend to deteriorate over time compared to baseline measurements *(Table 4,* Figures 2a-d, Figures 3a-d). Five of the 8 restorations that received Score 1 for colour match were observed in the same patient who was a smoker.

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Table 2. List of modified United States Public Health Service (USPHS) criteria used for the clinical evaluations of the restorations.

Category	Score		Criteria
	Acceptable	Unacceptable	
Anatomical form	0		The restoration is continuous with tooth anatomy
	1		Slightly under- or over-contoured restoration; marginal ridges slightly undercontoured contact slightly open (may be self-correcting); occlusal height reduced locally
		2	Restoration is undercontoured, dentin or base exposed; contact is faulty, not self-correcting; occlusal height reduced, occlusion affected
		3	Restoration is missing partially or totally, fracture of tooth, shows traumatic occlusion; restoration causes pain in tooth or adjacent tissue
Marginal adaptation	0		Restoration is continuous with existing anatomic form; explorer does not catch
	1		Explorer catches; no crevice is visible into which explorer will penetrate
	2		Crevice at margin, enamel exposed
		3	Obvious crevice at margin; dentin or base exposed
		4	Restoration mobile, fractured, or missing
Color match	0		Very good color match
	1		Good color match
	2		Slight mismatch in color, shade, or translucency
		3	Obvious mismatch, outside the normal range
		4	Gross mismatch
Surface roughness	0		Smooth surface
	1		Slightly rough or pitted
	2		Rough, cannot be refinished
		3	Surface deeply pitted, irregular grooves
Marginal discoloration	0		No discoloration evident
	1		Slight staining, can be polished away
	2		Obvious staining cannot be polished away
		3	Gross staining
Caries	0		No evidence of caries contiguous with the margin of the restoration
		1	Caries is evident contiguous with the margin of the restoration
Post-operative sensitivity	0		No sensitivity
	1		Sensitivity lost in one week
		2	Continuous sensitivity

Table 3. Distribution of restored teeth and restoration types in the maxilla and mandible.

	Class II (MO or DO)		Class II (MOD)		Total
	Maxilla	Mandible	Maxilla	Mandible	
Premolars	21	15	15	2	53
Molars	16	20	14	8	58
Total	37	35	29	10	111

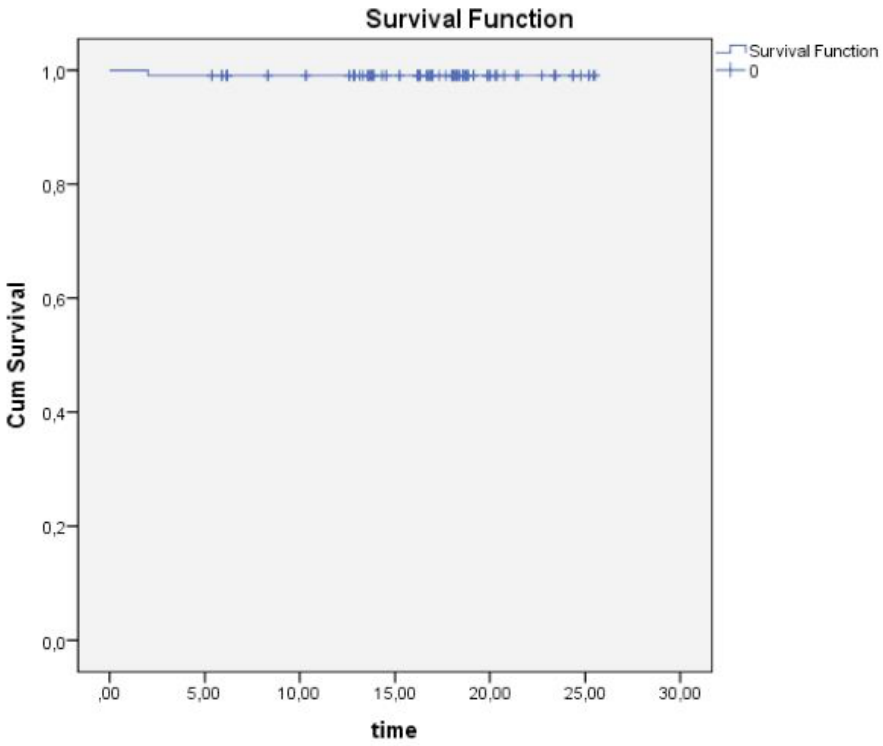

Figure 1: Event-free survival rates of bulk-fill resin composite restorations for class II cavities (N=111)

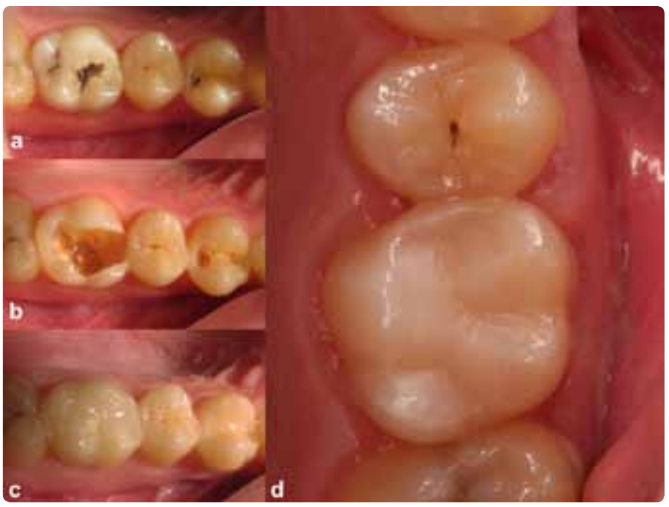

Figure 2a-d: Representative photos of a SonicFill restoration on the right 1st maxillary molar a) caries, b) cavity c) baseline situation and d) at final recall.

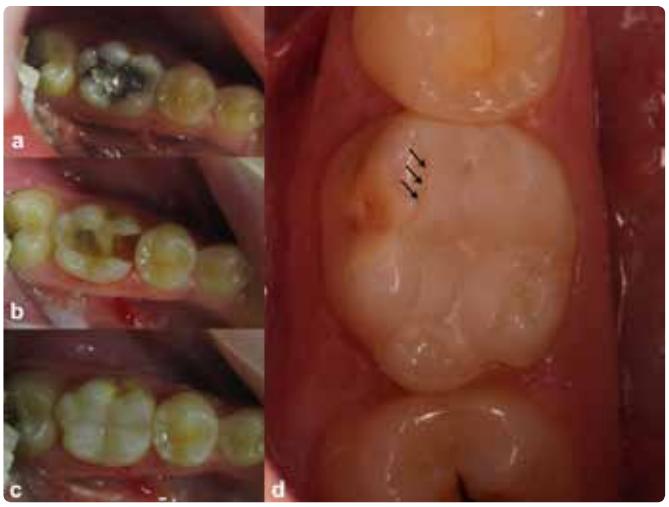

Figure 3a-d: Representative photos of a SonicFill restoration on the right 1st mandibular molar a) old filling, b) cavity, c) baseline situation and d) marginal deteriorations observed at final recall.

Table 4. Summaries of USPHS evaluations expressed in percentage at baseline and up to final follow-up.

Criteria		Baseline (n, %)	6 months (%)	Final Recall (%)
Anatomical form	0	111 (100)	109 (98.1)	109 (98.1)
	1	0 (0)	2 (1.9)	2 (1.9)
	2	0 (0)	0 (0)	0 (0)
	3	0 (0)	0 (0)	0 (0)
Marginal adaptation	0	111 (100)	107 (96.3)	108 (97.3)
	1	0 (0)	3 (2.7)	4 (3.7)
	2	0 (0)	0 (0)	0 (0)
	3	0 (0)	0 (0)	0 (0)
	4	0 (0)	0 (0)	0 (0)
Color match	0	111 (100)	103 (92.7)	103 (92.7)
	1	0 (0)	8 (7.3)	8 (7.3)
	2	0 (0)	0 (0)	0 (0)
	3	0 (0)	0 (0)	0 (0)
	4	0 (0)	0 (0)	0 (0)
Surface roughness	0	111 (100)	104 (93.7)	102 (91.9)
	1	0 (0)	7 (6.3)	7 (6.2)
	2	0 (0)	0 (0)	2 (1.9)
	3	0 (0)	0 (0)	0 (0)
Marginal discoloration	0	111 (100)	107 (96.3)	105 (94.6)
	1	0 (0)	4 (3.7)	6 (5.4)
	2	0 (0)	0 (0)	0 (0)
	3	0 (0)	0 (0)	0 (0)
Secondary caries	0	111 (100)	111 (100%)	111 (100)
	1	0 (0)	0 (0%)	0 (0)
Post-operative sensitivity	0	111 (100)	110 (99.09%)	109 (98.1)
	1	0 (0)	1(0.91%)	2 (1.9)
	2	0 (0)	0 (0%)	0 (0)

DISCUSSION

This study was undertaken in order to evaluate the clinical performance of one sonic-activated high viscosity bulk-fill resin composite (SonicFill) restorations in class II cavities. In recent years, various adhesive restorative materials have been introduced to overcome the disadvantages of traditional restoratives, including limited polymerization depth and shrinkage.[15,16] Some practical strategies such as alternative photopolymerization protocols,[13] the use of flowable cavity liners or incremental filling techniques have also been used to overcome these shortcomings. The incremental layering concept is the basic way to obtain sufficient conversion that is necessary to achieve clinically acceptable physical, mechanical, and biocompatible properties from resin-based materials.[16,17] However, this technique includes risks such as possible contamination between layers, and is time consuming.[18] Several attempts have been made to simplify the procedures of resin restorations. These have generally attempted to reduce the number of steps required and to incorporate a self-etching function. Bulk-filling technology is another simplification; in practice, this refers to placement of layers up to 4 mm thick.[19] The tested material in this study (SonicFill) is a single-step adhesive restorative material that combines the advantages of a flowable and universal resin composite without the need for any additional capping layer.

According to the previous *in vitro* studies, bulk-fill and nanohybrid resin composites presented similar mechanical properties such as flexural strength.[7,20] However, regarding other properties such as hardness and modulus of elasticity, bulk-fill resin composites are positioned somewhere between hybrid and flowable resin composites.[17,20] Alrahlah *et al.*[21] evaluated the depth of polymerization in several bulk-fill resin composites using Vicker's hardness profiles and reported SonicFill as the best one among the tested materials. In another study, depth of polymerization of SonicFill was not found statistically different from that of a traditional flowable composite but it showed the least polymerization shrinkage among the materials tested, including one traditional flowable and two bulk-fill resin composites.[22] According to the results of one other study, depth of polymerization in SonicFill was approximately 5 mm and the material presented the highest degree of conversion.[23] Other studies have reported that bulk-fill materials exhibit a gap formation similar to that of conventional resin composites.[4,24,25] In addition, SonicFill exhibited the highest microhardness among non-flowable resin composites tested and indicated that this was due to the high amount of inorganic fillers in this material.[26] The high filler load allows resin composite to sustain functional stress with improved interfacial adaptation due to its low viscosity during application.[23]

The findings of *in vitro* studies are important but clinical studies are also needed to predict the longevity of a material in the oral conditions.[27] In this study, patients with high caries activity, poor oral hygiene, or parafunctional habits were excluded. Thus, the sample represents non-risk patient population where the restorations were made in the posterior dentition. Some studies have reported that restorations placed in premolars show significantly better survival rates than those in molars.[28-30] This could be related to the greater occlusal forces sustained by molar restorations and the decreased access to the operating field when restoring molars. However, our findings do not confirm these results since similar performance was observed in both premolars and molars at least until the final follow up. The clinical behaviour of the restorations was also not affected by the cavity type (MO, DO versus MOD) in contrast to a previous study where the amount of restored surface had significant effect on the outcome.[31] The scores for three-faced restorations were worse than those for two-faced ones in a 10-year clinical evaluation.[31] In this study, 72 two-faced and 39 three-faced cavities in 53 premolars and 58 molars did not show a significant difference when mechanical failures were considered based on the cavity types. One maxillary premolar was endodontically treated which was considered a failure. According to the USPHS criteria however for colour match restorations that received Score 1 were generally premolars (6 premolars and 2 molars at the 6 months and final recalls). Long-term observations may change this trend. In this study, due to the highly busy schedule of the clinics where the study was conducted, isolation was achieved using cotton rolls and suction instead of rubber dam. In this regard, it has been reported that the clinical success of adhesive restorations do not change as a function of moisture-control methods.[32] Similarly, at the university settings where this study was conducted, due to the high number of patient intake per day, after calibration in order not to decrease the treatment workflow in the faculty clinics, two specialist operators performed cavity preparations. The performance of the tested filling material should be also followed in general practices where multiple operators are involved.

To date, limited number of clinical observations are available on bulk-fill resin composites. Two studies observed the clinical performance of flowable bulk-fill resin composite SDR (Dentsply, Caulk, USA), in Class I and Class II restorations up to 3 years.[16,19] In another study, 1 year clinical performance of a conventional posterior resin composite was compared to three different bulk-fill resin composites.[33] All these studies classified bulk-fill restorations acceptable, mainly with Alfa scores.

The durability of the material tested were clinically acceptable at the 2-year follow-up. Thus, this bulk-fill material could be indicated for large cavities with acceptable outcomes. Even though the evaluation period could be considered short term, colour match, surface roughness, and marginal discoloration were the most frequent changes encountered. Generally, marginal quality decreases over time due to physiological and chemical interactions with the oral environment, and the onset of degradation could lead to problems associated with the adhesive or the resin composite. With regard to the marginal discoloration criterion, four restorations received Score 1 at the 6 months but this increased to six restorations at the final recall. These findings could be attributed to the adhesive technique, namely enamel was etched for only 10 s, following the selective etching technique. It was previously reported that longer etching time resulted in better marginal quality.[34]

The colour stability of SonicFill was acceptable after 2 years, which may be related to the resin matrix and filler morphology. Eight restorations received Score 1 for colour match; five of these were in the same patient, who was a smoker. Smoking has been reported to change the colour of resin composites.[35] In terms of surface roughness, seven restorations received Score 1 and two restorations received Score 2. One previously clinical investigation noted SonicFill with 100% Score 1. Typically, significantly better polishability was reported for nanohybrid resin composites than microhybrid restorations due to the nanofiller additives.[36-38] Moreover, in a clinical study, a nanohybrid resin composite started to show surface deterioration at the 2-year recall.[39] Nanohybrid resin composites received significantly worse scores (Bravo: surface is rougher than enamel, clinically acceptable) for the criteria of surface roughness after 3 years, similar to our results at the final recall at 2 years.[40] The significant deteriorations in our study could be attributed to the polishability of the material. While in a previous *in vitro* investigation, nanohybrid resin composites showed the highest surface roughness values,[41] in two clinical studies, 3-year clinical performance of a flowable bulk-fill resin composite received only alpha scores for surface roughness.[16,19] However, in both studies, the bulk-fill composite was covered with an ormocer-based nanohybrid resin composite which was not practiced in this study.

Until the final follow up period, no caries was observed in any of the cases. It has to be noted that in this study, CHX has been used as a cavity disinfectant. The use of CHX to rinse the cavity after the application of the adhesive, in this case Scotchbond Universal, is not a common practice. However, the use of CHX was reported to act as an antibacterial agent.[42] For this reason, in order to reduce the levels of cariogenic microorganisms in the cavity, in this study, CHX was applied. In terms of caries formation, the long follow up results would show whether CHX use would be beneficial or not.

Due to the limited number of patients and short observation period, this study could be considered a pilot study but patients are being observed for long term follow up.

CONCLUSIONS

From this study, the following could be concluded:

1. Except one restoration that underwent endodontic treatment, the bulk-fill resin composite (SonicFill) tested for restoring class II cavities performed well in terms of biological and mechanical considerations after 2 years of clinical service.
2. In some cases, qualitative analysis indicated that colour match, surface roughness, and marginal discoloration parameters tend to become worse already within the first 6 months.

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DISCLOSURE

The authors declare that they have no conflict of interest.

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