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Research Article

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A 3-year retrospective study of clinical durability of bulk-filled resin composite restorations

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Conflict of Interest
No potential conflict of interest relevant to this article was reported.

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ABSTRACT

Objectives: This study aimed to assess the clinical longevity of a bulk-fill resin composite in Class II restorations for 3-year.
Materials and Methods: Patient record files acquired from the 40 patients who were treated due to needed 2 similar sizes Class II composite restorations were used for this retrospective study. In the experimental cavity, the flowable resin composite SDR was inserted in the dentinal part as a 4 mm intermediate layer. A 2 mm coverage layer with a nano-hybrid resin composite (CeramX) was placed on SDR. The control restoration was performed by an incremental technique of 2 mm using the nano-hybrid resin composite. The restorations were blindly assessed by 2 calibrated examiners using modified United States Public Health Service criteria at baseline and 1, 2, and 3 years. The data were analyzed using non-parametric tests ($p = 0.05$).
Results: Eighty Class II restorations were evaluated. After 3-years, 4 restorations (5%) failed, 1 SDR + CeramX, and 3 CeramX restorations. The annual failure rate (AFR) of the restorations was 1.7%. The SDR + CeramX group revealed an AFR of 0.8%, and the CeramX group an AFR of 2.5% ($p > 0.05$). Regarding anatomical form and marginal adaptation, significant alterations were observed in the CeramX group after 3-years ($p < 0.05$). The changes in the color match were observed in each group over time ($p < 0.05$).
Conclusions: The use of SDR demonstrated good clinical durability in deep Class II resin composite restorations.

Keywords: Bulk-fill; Clinical; Composite resins; Longevity; Posterior

INTRODUCTION

In dentistry, resin composites are frequently used for the restoration of posterior teeth besides anterior teeth due to esthetics and enhanced mechanical properties [1,2]. However, the posterior resin composite restorations might be failed because of different causes, such as mainly material fracture and recurrent caries [3]. The fracture is an important reason for resin composite restoration failure from the second year of restoration, and the cause of failure that appeared in later years is caries [3]. The material-dependent factors have a crucial influence on the survival of the restoration [4].

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Most of the resin composites are nowadays methacrylate-based and polymerize through a free radical reaction [5,6]. A rigid polymer network forms since increasing the cross-linking of the polymer chains during the polymerization [7]. Moreover, the shrinkage stresses occur as a consequence of the polymerization shrinkage by the conversion of monomer molecules into the polymers [7]. The polymerization shrinkage stress may lead to marginal defects, cusp fractures, microleakage, post-operative sensitivity, and secondary caries by concentrating at the adhesive interface [8]. The cure depth of the resin composite also has a great influence on the clinical success of the restoration because of affecting the physical properties of the material [9].

Various modified placement and polymerization strategies have lately been developed to reduce polymerization shrinkage stress formation on the adhesive interface by decreasing the C-factor and improving the degree of cure [8,10]. The resin composites traditionally are gradually placed in layers of 2 mm with horizontal or oblique technique [11]. These layering approaches might provide optimal polymerization and conversion rate through better light penetration, and decrease the cuspal deflection by reducing polymerization shrinkage stresses and the cavity configuration factor [9,10]. The clinical evidence about the clinical efficacy of these techniques is weak [9-11]. The layering techniques might become time-consuming in the restoration of deep posterior cavities and cause void formation between layers, thus; increasing failure risk [8,9,12]. The application of resin composites with thicker increments causes inadequate cure of the material in the deeper parts, influences adversely the mechanical characteristics of the restoration, and causes elution of more monomer [9,12]. Extensive efforts have been made to develop resin composites that have more improved properties and ease of application [8].

Bulk-fill resin composites have recently been developed to simplify the restorative technique because they may be placed in a single increment of 4–5 mm [5]. The bulk-fill composites are divided into 2 groups, the low- and high-viscosity materials. There is a need for a final occlusal layer of conventional resin composite for the low viscosity bulk-fill resin composites, but it is not required for the high viscous ones [5,11]. The first introduced stress-relieving resin technology-based low viscosity bulk-fill resin composite is SDR (Dentsply/DeTrey, Konstanz, Germany), which is used in 4 mm layers by covering the occlusal surface with a conventional resin composite [6]. The flowable bulk-fill resin composite SDR involves a modulator for the polymerization reaction, which is a patented urethane di-methacrylate (UDMA) and provides a relatively slow radical polymerization rate [6]. The slow polymerization rate allows a slower modulus formation, thus providing stress reduction without reducing the conversion rate [6,13]. The rheology of the material might also ensure its enhanced adaptation to the cavity walls by hindering the occurrence of voids at the tooth-restoration interface [8]. Moreover, using SDR as a base material under conventional resin composite may facilitate the placement of resin composite in deep cavities by overcoming the disadvantages of layering techniques, thus shortening the treatment time required for restoration.

Previous laboratory studies have reported that SDR revealed lower shrinkage stress and shrinkage-rate values in comparison to conventional methacrylate-based resin composites, and the bulk filling technique with SDR showed similar performance with the incremental layering techniques [6,12-14]. A few clinical reports are available about the clinical performance of SDR. According to the clinical evidence, the bulk-filling technique with SDR has shown highly acceptable clinical performance and efficacy comparable with layering techniques [8-

11]. Nonetheless, more clinical studies are necessary to validate the clinical performance and effectiveness of restorative materials. Therefore, this retrospective study aimed to investigate the clinical longevity of the use of SDR as a base under a conventional resin composite in Class II cavities for 3-year and to compare with 2 mm layering technique. The null hypothesis tested was that that the 3-year clinical durability of the restorations made with the bulk-fill technique using SDR and the 2 mm thick oblique layering technique would be similar.

MATERIALS AND METHODS

This retrospective study was designed as a comparative evaluation of Class II resin composite restorations performed using SDR and a conventional resin composite. The study design and protocol were approved by the local ethics committee (2021/126). The patient record files of 40 patients with a mean age of 30.1 years (range 21–40) saved by one of the authors were used for collecting data for this retrospective study. Included in the study were patients who were treated by one same experienced operator between March and August 2017 due to needed only 2 similar size Class II resin composite restorations and attended the practice for follow-up recalls at 1-week, 1, 2, and 3 years. For this study, some participant was already excluded due to high caries risk, poor periodontal health, parafunctional habits, or pregnancy. The patient who had only one and more than 2 Class II cavities needing to be filled was also not included in this study. Two similar deep and extended-sized restorations as possible were made for each patient, due to carious lesions and defective restorations requiring replacement. The randomization of the experimental or control restorative materials was performed using a table of random numbers for each patient before the operative procedure. The participants were not knowledgeable regarding which cavity was restored with the experimental and control material. In the experimental cavity, the flowable resin composite SDR (Dentsply/DeTrey) was inserted into the cavity in 4 mm thickness, and a 2 mm final layer of a nano-hybrid resin composite (CeramX; Dentsply/DeTrey) was placed on the occlusal part. The control restoration was done with a 2-mm incremental layering technique using the nano-hybrid resin composite. All teeth had proximal contact with adjacent teeth and were in occlusion. A total of 40 pairs of restorations was considered to be adequate and comparable with previous studies [8,10].

Clinical procedure and evaluation

Following the isolation of the operative field with a rubber dam, the existing restorations and/or caries were removed under constant water cooling without any bevel preparation on the cavities. The thin metallic matrices (Tor VM, Moscow, Russia) and wooden wedges (KerrHawe, Bioggio, Switzerland) were used. Any base materials were applied in none of the cavities. For selective enamel etching, a 35% phosphoric acid gel (Scotchbond Universal Etchant; 3M Oral Care, St. Paul, MN, USA) was applied on enamel for 15 seconds. Application of the 2-step self-etching adhesive Clearfil SE Bond (Kuraray, Tokyo, Japan) in all cavities was performed according to the manufacturer's instructions (**Table 1**). The adhesive was light-cured by a light-curing unit (Smartlite Focus, 1,000 mW/cm^2; Dentsply/DeTrey) for 10 seconds. The output of the light-curing unit was checked after each patient by a radiometer. In experimental SDR restoration, the flow material was placed in bulk increments up to 4 mm until there was a gap of 2 mm in the occlusal surface and light-cured with the light-curing unit for 20 seconds (Smartlite Focus). The 2 mm superficial occlusal layer of the restoration was finished off with the CeramX resin composite material. In the control cavity, the resin composite CeramX was placed in 2 mm layers with an

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Table 1. The materials, chemical composition and application procedure

Material	Composition	Application procedure
SDR (Dentsply DeTrey, Konstanz, Germany) Lot No.: 01193	**Filler:** Barium-alumino-fluoro-borosilicate glass, strontium alumino-fluoro-silicate glass **Matrix:** modified urethane (68% w) dimethacrylate resin, ethoxylated bisphenol-A dimethacrylate, triethyleneglycol dimethacrylate, camphorquinone, butylated hydroxyl toluene, UV stabilizer, titanium oxide, iron oxide pigments	1. Apply in 4 mm layers 2. Light-cure for 20 seconds
CeramX (Dentsply DeTrey, Konstanz, Germany) Lot No.: 0823	**Filler:** Barium–aluminum-borosilicate glass (1.1–1.5 µm), methacrylate functionalized silicone dioxide nano filler (10 nm) (76% w) **Matrix:** Methacrylate modified polysiloxane, dimethacrylate resin, fluorescent pigment, UV stabilizer, stabilizer, camphorquinone, ethyl-4 (dimethylamino) benzoate, titanium oxice pigments, aluminum silicate pigments	1. Apply in 2 mm layers 2. Light-cure for 20 seconds
Clearfil SE Bond (Kuraray Noritake, Osaka, Japan) Lot No.: 000273	**Primer:** Water, 10-MDP, HEMA, camphorquinone, hydrophilic dimethacrylate **Bond:** 10-MDP, Bis-GMA, HEMA, camphorquinone, hydrophobic dimethacrylate, N,N-diethanol p-toluidine bond, colloidal silica	1. Apply primer and leave in place for 20 seconds 2. Dry with air stream to evaporate the volatile ingredients 3. Apply bond and then create a uniform film using a gentle air stream 4. Light-cure for 10 seconds

Composition as provided by the manufacturers.
Bis-GMA, bisphenol-glycidyl methacrylate; 10-MDP, 10-methacryloyloxydecyl dihydrogen phosphate; HEMA, hydroxyethylmethacrylate.

oblique layering technique and light-cured according to manufacturers' instructions. After the occlusion checking and contouring, the polishing was done using a polishing system (OneGloss; Shofu, Kyoto, Japan).

The restorations were assessed at baseline (1 week after placement of the restorations) and after 1, 2, and 3 years by the following parameters by modified United States Public Health Service (USPHS) criteria (**Table 2**) as in previous studies [8-11]: anatomic form, marginal

Table 2. Modified USPHS criteria for direct clinical evaluation

Category	Score		Criteria
	Acceptable	Unacceptable	
Anatomical form	0		The restoration is contiguous with tooth anatomy
	1		Slightly under- or over-contoured restoration; marginal ridges slightly under contoured; contact slightly open (may be self-correcting); occlusal height reduced locally
		2	Restoration is under contoured, 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 structure; shows traumatic occlusion; restoration causes pain in tooth or adjacent tissue
Marginal adaptation	0		Restoration is contiguous 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
Marginal discoloration	0		No discoloration evident
	1		Slight staining, can be polished away
	2		Obvious staining cannot be polished away
		3	Gross staining
Surface roughness	0		Smooth surface
	1		Slightly rough or pitted
	2		Rough, cannot be refinished
		3	Surface deeply pitted, irregular grooves
Caries	0		No evidence of caries contiguous with the margin of the restoration
		1	Caries is evident contiguous with the margin of the restoration

adaptation, marginal discoloration, surface roughness, color match, and secondary caries. The follow-up registrations were performed blindly by 2 calibrated evaluators. There was a strong congruence between the evaluators. The Cohen's kappa coefficient between evaluators was 0.92, 0.88, 0.92, and 0.90 at the evaluation periods, respectively, revealing that there was a concordance of kappa. The evaluators did not know which experimental, or which control group the scoring concerned during the evaluation periods.

Statistical analysis

The data were analyzed using the SPSS Program, version 20.0 (Statistical Package for the Social Sciences; SPSS, Chicago, IL, USA). The properties of the restorations were characterized by descriptive statistics with cumulative frequency distributions of the scores. The experimental and control restorative techniques at the same evaluation period were compared via the Mann-Whitney U test. The analysis of data acquired by the same restorative techniques at different evaluation times was performed through the nonparametric Friedman's 2-way analysis of variance test. The statistical significance level was set up at 0.05 for all analyses.

RESULTS

During the 3-year follow-up, 80 Class II restorations were evaluated. The distribution of the restored teeth is displayed in **Table 3**. Any of the participants reported any postoperative symptoms at the evaluation times. After 3-years, 4 restorations (5%) were failed; 1 SDR + CeramX, and 3 CeramX restorations. The annual failure rate (AFR) of the restorations was 1.7%. The SDR+ CeramX group showed an AFR of 0.8%, and the CeramX group an AFR of 2.5%. Two of the restoration failures were observed in female participants. The reason and tooth type for the failure of the failed restorations are given in **Table 4**. The main reason for failure was partial fractures in the resin composite. No carious lesions observed were found contiguous with the restorations. The modified USPHS scores of the restorations are given in **Table 5**. There were no statistically significant differences between the experimental and control restoration groups in all evaluation times ($p > 0.05$). However, there were some differences within each group. Regarding anatomical form and marginal adaptation, significant alterations were observed over time in the CeramX group ($p < 0.05$). The color match besides changed significantly during the follow-up in the 2 groups ($p < 0.05$). No significant differences were found in other criteria over time in the 2 groups ($p > 0.05$).

Table 3. Distribution of the restored teeth

Tooth type	Mandibula		Maxilla		Total
	SDR + CeramX	CeramX	SDR + CeramX	CeramX	
Premolars	8	8	10	8	34
Molars	13	11	11	11	46
Total	40		40		80

Table 4. The failed restorations after 3-year, tooth type and reason for failure

Materials	Tooth type	Reason for failure
SDR + CeramX	Maxillary premolar	Resin composite fracture
CeramX	Mandibular premolar	Resin composite fracture
CeramX	Mandibular molar	Resin composite fracture
CeramX	Maxillary molar	Tooth fracture and resin composite fracture

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Table 5. Scores for the evaluated Class II restorations at baseline and after 1, 2, and 3 years of CeramX and SDR + CeramX given as relative frequencies (%)

Criteria	Restoration	Evaluation period	0	1	2	3	4
Anatomical form	SDR + CeramX	Baseline	97.5	2.5	0	0	
	CeramX	Baseline	92.5	7.5	0	0	
	SDR + CeramX	1 year	97.5	2.5	0	0	
	CeramX	1 year	92.5	7.5	0	0	
	SDR + CeramX	2 year	95	5	0	0	
	CeramX	2 year	92.5	7.5	0	0	
	SDR + CeramX	3 year	92.5	5	0	2.5	
	CeramX	3 year	87.5	5	2.5	5	
Marginal adaptation	SDR + CeramX	Baseline	97.5	5	0	0	0
	CeramX	Baseline	95	5	0	0	0
	SDR + CeramX	1 year	97.5	5	0	0	0
	CeramX	1 year	95	5	0	0	0
	SDR + CeramX	2 year	95	5	0	0	0
	CeramX	2 year	90	5	5	0	0
	SDR + CeramX	3 year	92.5	5	0	2.5	0
	CeramX	3 year	87.5	2.5	2.5	7.5	0
Color match	SDR + CeramX	Baseline	65	35	0	0	0
	CeramX	Baseline	62.5	37.5	0	0	0
	SDR + CeramX	1 year	62.5	37.5	0	0	0
	CeramX	1 year	57.5	42.5	0	0	0
	SDR + CeramX	2 year	57.5	42.5	0	0	0
	CeramX	2 year	50	50	0	0	0
	SDR + CeramX	3 year	57.5	40	2.5	0	0
	CeramX	3 year	42.5	50	7.5	0	0
Marginal discoloration	SDR + CeramX	Baseline	100	0	0	0	
	CeramX	Baseline	100	0	0	0	
	SDR + CeramX	1 year	100	0	0	0	
	CeramX	1 year	100	0	0	0	
	SDR + CeramX	2 year	97.5	2.5	0	0	
	CeramX	2 year	95	5	0	0	
	SDR + CeramX	3 year	95	5	0	0	
	CeramX	3 year	92.5	5	2.5	0	
Surface roughness	SDR + CeramX	Baseline	100	0	0	0	
	CeramX	Baseline	100	0	0	0	
	SDR + CeramX	1 year	97.5	2.5	0	0	
	CeramX	1 year	97.5	2.5	0	0	
	SDR + CeramX	2 year	95	5	0	0	
	CeramX	2 year	95	5	0	0	
	SDR + CeramX	3 year	95	5	0	0	
	CeramX	3 year	92.5	7.5	0	0	
Caries	SDR + CeramX	Baseline	100	0			
	CeramX	Baseline	100	0			
	SDR + CeramX	1 year	100	0			
	CeramX	1 year	100	0			
	SDR + CeramX	2 year	100	0			
	CeramX	2 year	100	0			
	SDR + CeramX	3 year	100	0			
	CeramX	3 year	100	0			

The experimental and control restorative techniques at the same evaluation period were compared via the Mann-Whitney U test. The analysis of data acquired by the same restorative techniques at different evaluation times was performed through the nonparametric Friedman's 2-way analysis of variance test.

DISCUSSION

In the present study, the 3-year clinical longevity of the use of SDR in large and deep Class II cavities was evaluated by comparing with the nano-hybrid resin composite restoration built up with a 2 mm layering technique. A 0.8% AFR was observed in the bulk-filled restorations whereas the resin composite-only group was showed a 2.5% AFR. There was no statistical difference among the restorations with and without SDR during all evaluation periods. Therefore, the null hypothesis that the 3-year clinical durability of the restorations made with the bulk-fill technique using SDR and the 2 mm thick oblique layering technique would be similar was accepted.

The standard 2-mm incremental placement technique is frequently used to acquire adequate light penetration and reduce shrinkage stress in conventional resin composite restorations despite the incremental filling techniques have some disadvantages during clinical procedures [9,10]. It has been reported that the oblique layering technique induced more stress concentration than the horizontal filling technique at the interface [15,16]. Nevertheless, the stress-decreasing influence of these techniques is also not clear [11]. A previous study has additionally shown that additional increments enhanced the risk of cuspal deformation on the weakened cusps [16]. The bulk-fill resin composites have been developed to overcome the disadvantages of layering techniques and ease the resin composite restoration procedure [5]. One of the first introduced bulk-fill resin composites, the flowable resin composite SDR was employed in this study. SDR may be used in a single increment of 4 mm thanks to its higher translucency and having the modified UDMA [6,13,17]. SDR has UDMA incorporating a photoactive group, which allows a comparatively slow radical polymerization rate [6]. Previous studies have concluded that SDR showed a lower polymerization shrinkage stress and shrinkage rate than conventional resin composites because of the incorporation of the polymerization modulator, which has a high molecular weight to the center of the polymerizable group of the monomer [6,18-20]. The low shrinkage stress might also provide higher dentin bond strength to SDR compared with conventional resin composites [17,21]. Furthermore, it has been reported that the use of SDR decreased cuspal deflection in Class II cavities in comparison with resin composite restorations which were made with an oblique layering technique [14].

The interfacial adaptation is also an essential factor for the longevity of a restoration besides shrinkage stress [22]. The poor interfacial adaptation might lead to microleakage, postoperative sensitivity, and secondary caries [8]. It has been reported that the SDR ensured better adaptation to the cavity walls than the conventional resin composite due to its flowability [22,23]. Besides, the enhanced depth of cure influences the clinical success of the bulk-filled resin composites. The bulk filling technique might not provide adequate post-cure depth when the material translucency is low, resulting in lower mechanical properties of the material [24]. The increased translucency of SDR might provide enough curing efficacy up to a single increment of 4 mm doing so increasing the longevity of restorations by obtaining satisfactory mechanical and physical properties [6,13,17]. However, the occlusal capping layer on SDR with a conventional resin composite is necessary because the modulus of elasticity and hardness of SDR is lower than the conventional resin composites due to its lower filler loading [25]. Although the occlusal capping layer is necessary for SDR, the use of a conventional resin composite together with SDR might reduce treatment time in 6 mm and deeper cavities comparing the conventional layering techniques. The low elasticity modulus of SDR might also increase the longevity of the restoration by absorbing and relieving the occlusal stresses.

A 3-year period might be not sufficient time to assess the clinical performance of resin composite restorations [3]. However, only a few clinical studies are available, which were performed to investigate the clinical performance of the bulk-filled resin composite SDR. These studies have concluded that the bulk-filling with SDR demonstrated similar durability as the restorations performed with conventional 2 mm layering technique, and the difference between the 2 restoration groups in each cavity class (Class I and II) was not significant [8-11]. In the present study, only deep Class II cavities were included because of the observed low failure rate of Class I restorations [10]. The AFRs for restorations in this study were similar to the AFRs found in previous studies, which have reported AFRs varying between 1.7-3.3% for restorations performed with the 2-mm incremental layering technique [26-31]. In the present study, the CeramX group showed an AFR of 2.5%, SDR + CeramX group showed an AFR of 0.8%. Previous randomized clinical trials in which evaluated the performance of SDR with 4 mm layering technique have reported AFRs varying between 0%–2.2% in Class II cavities [8-11].

In the present study, a significant alteration was found in the color match in each group during the follow-up, as reported in previous studies [8,9], but some minor discrepancies in the color match were clinically acceptable. The group in which restorations were performed using CeramX with a 2-mm layering technique presented significant alterations in anatomical form and marginal adaptation over time. Following 3-years, 1 SDR + CeramX and 3 CeramX restorations were failed. It may be due to the low elasticity modulus of SDR, decreasing polymerization shrinkage stresses and, thereby, maintaining the marginal integrity, as attributed in previous studies [2,32]. The lower polymerization stresses of the bulk-fill resin composites might particularly promote better marginal adaptation for restorations [5,6]. The enhanced deep of cure of SDR might also provide higher mechanical properties for the restorations [10,11]. A previous study has concluded that the occurrence of catastrophic failures was observed in the conventional nano-hybrid resin composite restorations with a 2 mm layering technique due to not-optimal conversion in the deeper layers whereas no catastrophic failure occurred in the bulk filling technique with SDR [8]. In this study, the main reason for failure was partial fractures in the material. It has been reported that the material fracture more occurred in bruxing participants [9,10]. However, bruxing-risk participants were not included in the present study. Furthermore, the decreases in the polymerization shrinkage stress thanks to bulk-fill resin composites may affect postoperative sensitivity [33]. Nevertheless, in this study, the participants reported no postoperative sensitivity during any evaluation periods. The result of this study is in agreement with previous studies in which the use of SDR showed good and acceptable clinical durability [8-11].

An important factor contributing to the increased longevity of resin composite restorations is the bonding efficiency of the adhesives and adhesive strategy [3]. In this study, the mild 2-step self-etch adhesive Clearfil SE Bond defined as a gold-standard 2-step self-etch adhesive [34] was used with the selective etching technique. Because it has been reported that this adhesive showed highly good clinical performance when used with selective acid-etching of the enamel cavity margins [35].

In this study, the modified USPHS criteria were employed to investigate the survival of restorations, as in several clinical studies [8-11]. The kappa test showed good agreement between the evaluators, as in a previous study [2]. There are some limitations in the present study. Only 40 patients were treated and evaluated. The patients who had good oral health and low caries risk were included. Besides, the patients who had parafunctional habits were excluded. Therefore, further clinical studies should be performed to investigate the performance of SDR placed in other types of cavities and patients with parafunctional habits and high caries risk. Moreover, longer-term clinical studies are necessary to verify the clinical performance of SDR.

CONCLUSIONS

Within the scope of this study, although the long-term results are not still available, the following conclusion might be drawn: The clinical longevity of the use of SDR in Class II cavities for 3-year was similar to 2-mm incremental oblique layering technique. The use of SDR may provide an advantage in the reduction of the required time for resin composite restoration procedures in deep posterior cavities.

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