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ORIGINAL ARTICLE

TWO-YEAR CLINICAL EVALUATION OF SMART DENTIN REPLACEMENT FLOWABLE RESIN COMPOSITE AS A LINER UNDER CLASS II RESIN COMPOSITE RESTORATIONS

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ABSTRACT:

Objectives: To evaluate in Vivo the effect of Smart Dentin Replacement (SDR) resin-based composite as a liner under Class II nano hybrid resin composite restorations after two years. **Methods:** Forty-five patients with Class II carious lesions were selected. A total of 90 Class II cavities were prepared in premolar/molar teeth. The cavities were equally divided into three groups. Group I was restored with nanohybrid RBC (Esthet.x-HD), group II was restored with Esthet.x-HD/SurFil SDR flowable composite and group III was restored with Esthet.x-HD/Filtek z350 XT flowable composite. The patients were recalled at 6,12 and 24 month and restorations were evaluated using Modified United States Public Health Criteria (USPHS criteria). **Results:** There were no significant differences (p >0.05) between the tested groups. **Conclusions:** SDR as 4 mm bulk fill dentin replacement showed good performance as a liner under nano hybrid composite resin restorations.

Keywords: Clinical evaluation, Nano-hybrid resin composite, Bulk Fill, Flowable liner

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INTRODUCTION

Resin-composite is one of the most common and widely used materials in dentistry. It is known that patients' requests and clinicians' interest in esthetic restorations are not limited to anterior teeth, but posterior tooth-colored restorations have grown considerably over the last decade. Efforts to overcome clinical deficiencies found in the early resin-composites have been refocused from the filler content to the matrix resin.[1–5] With the objective of increasing wear resistance and gloss retention, resin composite restoratives based on nanofiller technology have been introduced to the dental profession and progressed from nanofilled to nanohybrid.[6] Flowable composites developed in the 1990s as an important advancement in dental restorative materials.[7,8] Recently, clinical reports have not been as successful as expected. Post-operative sensitivity for example, did not improve as claimed.[9-12] Therefore, it is concluded that the use of flowables in stress bearing areas is not recommended.[13,14]

Smart Dentin Replacement (SDR) is designed to be used as a base in class I and II restorations. SDR materials behave like flowable composite, but can be placed in 4-mm increments and should be covered by a 2-mm layer of conventional resin composite. SDR material allows intimate adaptation to the prepared cavity walls.[15]

Although flowable resin composite materials have been repeatedly discussed to act as stress breakers or adaptation promoters16, clinical investigations could not confirm this issue so far.17-19 Therefore, the objective of the present study was to investigate in vivo the effect of SDR flowable RBC as a liner under class II resin composite restorations.

MATERIALS AND METHODS

In this study, two flowable lining materials, SureFil SDR and Filtek Z350 XT Flow were used. The restorative system used was the two step etch and rinse Prime & Bond NT adhesive system with a nano-hybrid Esthet x HD resin dental composite as shown in table 1.

The restorative materials were used in accordance with manufacturers' instructions and only one operator performed all the procedures of specimen's preparations and all restorative procedures. A light emitting diode (LED) visible-light curing unit (bluephase C8, IvoclarVivadent AG, Schaan, Liechtenstein) was used, and the power density of the light (800 mW/cm2) was checked every 10 specimens with a digital readout dental radiometer (bluephase meter, IvoclarVivadent AG, Schaan, Liechtenstein).

Table 1: Restorative materials were used in the study.

Brand Name	Specification	Manufacturer	Composition
Esthet.x HD	Nano- hybrid resin composite	Dentsply Caulk, Milford, DE, USA	**Matrix**: U-BisGMA,BisEMA and EGDMA **Filler**: Borosilicate/aluminum/barium glass and silica
SureFil SDR Flow	Bulk- Fill flowable resin composite	Dentsply Caulk, Milford, DE, USA	**Matrix**: Polymerization modulator, dimethacrylate resins, UDMA **Filler**: Ba-B-F-Al silicate glass, SiO2, amorphous , Sr-Al silicate glass ,TiO2
Filtek z350xt Flow	Nano-filled flowble resin composite	3M ESPE; St Paul, MN, USA	**Matrix**:BisGMA, TEGDMA, BisEMA 6, functionalized dimethacrylate **Filler**: Ceramic, SiO2, ZrOx
Prime & Bond NT	Two- step- etch and rinse	Dentsply Caulk, Milford, DE, USA	Di- and Trimethacrylate resins PENTA (dipentaerythritolpenta acrylate monophosphate) Nanofllers-Amorphous Silicon Dioxide Photoinitiators Stabilizers Cetylaminehydrofluoride Acetone

Forty five patients, ranging in age from 20 to 40 years (with a mean age of 30), were enrolled from the Outpatient Clinic at Colleague of Dentistry, Prince Sattam Bin Abd El Aziz University, which were attended for dental care. Each patient signed a written informed consent according to the regulations of our institution's ethics committee, following an explanation at the beginning of the study related to the nature and objectives of the clinical trial. The inclusion criteria were:

- Good general health and oral hygiene, the Gingival Index was scored zero.[17]
- Presence of primary caries, at least two comparable lesions in vital premolars or molars that required moderate sized class II restorations. A moderate-sized restoration was considered to extend between one quarter and no more than one third of the way between the central fissure and the cusp tip and had a proximal portion with the vertical margins that just obviously extended into the inter proximal embrasure and the cervical margin restricted in enamel. A tooth was considered vital if it was clinically and radio graphically free from any signs or symptoms of periapical pathology and normally responded to routine vitality testing. [18]
- Normal functional occlusion with at least one cusp in occlusal contact.
- Patient must be able to return for periodic recall examination. [19]

The teeth were randomly assigned for three restorative systems, group I, group II, or group III. The distribution of the restorations according to their location was found to be 70% in premolars while the other 30% in molars.

Restorative procedures

The restorations were applied by using rubber dam isolation (Powder Free Dental Dams, Royal Shield, Selangor DarulEhsan, Malaysia; Rubber Dam Clamps, Hu-Friedy, Chicago, IL, USA). Rubber dam was placed after preparation of the cavity. Local anesthesia (Mepecaine-l, Alexandria Co. for Pharmaceuticals. Alexandria Egypt) was administered for all patients to prevent patient discomfort during the restorative procedures.

A cavity was prepared using a straight fissure diamond instrument (Komet, 830L, Komet, Lemgo, Germany) on a high-speed air turbine and constant water cooling (120.000rpm). The cavity was prepared with no undercuts, no extension for prevention, none of the cavity preparations involved any cusps, all of the gingival margins were placed supragingival, to be included with enamel, all the facial and lingual margins in the proximal box were beveled, and at the occlusal outline, a butt-joint margin was left. Control of the excavated cavity floor was mainly conducted by probing with a graduated periodontal explorer and by means of the color of the underlying dentin. 17

After the preparations were completed, transparent Toflemire matrix band was applied and wedged with TDV reflecting wedge to seal the gingival margin. Then the restorative systems for each group were applied as recommended by the manufacturers.

Group I (Esthet.x-HD), each cavity was blotted with cotton bellet for drying, then enamel surface was first etched with 37% phosphoric acid gel, and then the dentin was conditioned during the last 15 s. of the 30 s, etching time. After that the cavity was rinsed thoroughly with copious water for 10 s, and then dried with a dry cotton bellet. Prime & Bond NT adhesive was applied to thoroughly wet all the cavity walls for 20 s. Excess solvent was removed by gently drying with clean, dry oil free air from a dental syringe for at least 5 s, and light cured for 20 s. Resin composite was applied into the bonded cavity in an incremental technique. The thickness of each increment was not exceeding 2mm. The first proximal increment was horizontally applied to the gingival floor and adapted to the cavity margins using a Teflon coated condenser (OptraSculpt/IvoclarVivaDent). Then a contact forming instrument (OptraContact/IvoclarVivaDent) was placed into the composite material along the matrix band and pressed against the adjacent tooth. This layer light cured according to manufacturer's instructions for 20 s. The contact forming instrument was removed so a contact bridge of dental composite was created and helped in holding the matrix and creating a tight contact, the restoration was completed incrementally. The restoration was then cured

for additional 20 s on each side (buccal and lingual/palatal) after matrix removal.

Group II (Esthet.x-HD/SureFil SDR Flow), the cavity walls were etched, and conditioned with 37% phosphoric acid gel then bonded as mentioned before. SDR flowable resin composite was applied, in a first layer, to all the cavity walls which not exceed 4 mm in all directions and light cured for 20 s for each cavity portion (i.e. occlusal cavity and proximal cavity). The residual height of the cavity was restored with Esthet.x HD resin composite in increments of 2 mm thickness.

Group III (Esthet.x-HD/Filtek z350xt Flow), the cavities were etched with 37% phosphoric acid gel then bonded as mentioned before. Cavities were first lined with Filtek z350xt flowable resin composite and polymerized for 20 s. The residual height of the cavity was restored in a conventional oblique layering technique of 2 mm thickness. The increments were separately light-cured for 20s.

Articulating paper (Bausch; Nashua, NH, USA) was used to establish appropriate occlusal morphology and contact. For approximal finishing and polishing, aluminum oxide finishing strips were used. The quality of the interproximal contacts was checked with dental floss.

Following matrix and rubber dam removal, all the restorations were finished using serial grits of diamond instruments under water-cooling to remove gross excess and flexible points impregnated with silicone dioxide (Astropol, IvoclarVivadent) to obtain smooth surface.

Evaluations

The restorations were evaluated at baseline (1 weak after restoration), 6, 12, and 24 month by two independent evaluators. Evaluators were not involved in the filling procedures. When disagreement occurred during evaluations, the restorations were re-evaluated by both evaluators and a consensus was obtained.

Restorations were evaluated using Modified United States Public Health Criteria (USPHS criteria).[20]

All evaluations were carried out under a dental operating light, using flat surfaced mirror and Sharpe dental explorer. Each restorative was assessed for postoperative sensitivity one week after placement and at each follow up examination. To detect secondary caries, the presence of softness, opacity, etching, or white spots are considered as evidence of undermining or demineralization in areas where the explorer catches or resist removal after insertion.[27] Furthermore, periapical radiographs were taken at each follow up period. An evaluation sheet was used to record the patient scores at each follow up visit.

Comparison between different materials at the same time was performed with Chi-Square test followed by the Kruskall–Wallis test (K.W.). A cumulative failure score (failure for marginal integrity and/ or anatomy, radiography or vitality) was used to calculate and compare survival curves for the different materials.

RESULTS

After 24-month of follow up examinations, 82(91.1%) restorations of 90 were evaluated. Two patients (three restorations) were unavailable at 6-month recalls and two patients (five restorations) were unavailable at 12-month recalls and 24-month recalls. Reasons for not attending each recall visit were checked. For patients that were not attending at 6-month recalls, the restored teeth for one patient were root canal treated after two months of restoration while the other patient moved away; however, no negative appreciation for restorative procedures that were performed reported by this patient. At 12-months recalls and 24-month recalls, the reason for the two patients not attending each recall visit was accident they had. Kruscal Wallis test used to compare between the three tested composite systems at the three time intervals as shown in Table 2. Figs. 1,2, 3& 4; illustrate left lower second premolar restored with nano-hybrid resin composite, lined with SDR flowable resin composite; at base line and 24 month recalls.

Table 2: Results of Kruscal Wallis test comparing evaluated restorations at base- Line, 6-month, 12- month, and 24-month recall (level of significance P≤0.05).

Recall times	Test values	Retention	Marginal discoloration	Secondary caries	Marginal adaptation	Postoperative sensitivity	Interproximal contact
Base line	Chi square	0.000	0.000	0.000	0.000	0.303	0.000
	p value	1.000	1.000	1.000	1.000	0.864	1.000
6 month	Chi square	0.000	0.000	0.000	0.000	0.000	0.000
	p value	1.000	1.000	1.000	1.000	1.000	1.000
12 month	Chi square	0.000	0.303	0.000	1.054	0.000	0.000
	p value	1.000	0.864	1.000	0.901	1.000	1.000
24 month	Chi square	0.000	0.303	0.000	1.054	0.000	0.303
	p value	1.000	0.864	1.000	0.901	1.000	0.864

Table 3: Results of Friedman test comparison of each evaluated restoration type at different recall times.

Materials	Test values	Retention	Marginal discoloration	Secondary caries	Marginal adaptation	Postoperative sensitivity	Interproximal contact
group I	Chi square	1.019	3.179	1.019	3.071	4.693	3.048
	p value	0.797	0.786	0.797	0.800	0.584	0.384
group II	Chi square	1. 019	3.179	1.019	5.176	7.019	2.069
	p value	0.797	0.786	0.797	0.521	0.319	0.558
group III	Chi square	1.019	3.179	1.019	6.663	10.078	2.105
	p value	0.797	0.786	0.797	0.353	0.121	0.551

Friedman repeated measure analysis of variance was used to compare between different recall examinations as shown in Table 3. All restorations showed only minor changes and no difference was detected between their performance at base line and after 24- month recall. Paired Wilcoxon test was performed at level of significant p =0.05 to highlight differences between each two recall examinations.

Retention

Retention rates were 100% for group I (Esthet-x HD), group II (SureFil SDR/Esthet-x HD) and for group III (Filtek z350 XT Flow/Esthet-x HD). There was no significant difference between the restorative materials concerning retention P > 0.05.

Marginal Discoloration

At base line and at 6-month recall, all the restoration systems evaluated had predominant alpha score. At the 12-month and at the 24-month recall, two restorations for group I, one restoration for group II and one restoration for group III, showed superficial discoloration and scored bravo. No statistically significant difference was found regarding marginal discoloration (p>0.05).

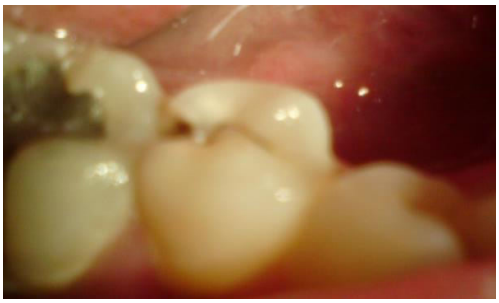

Figure 1: Photograph of pre-operative carious right lower second premolar

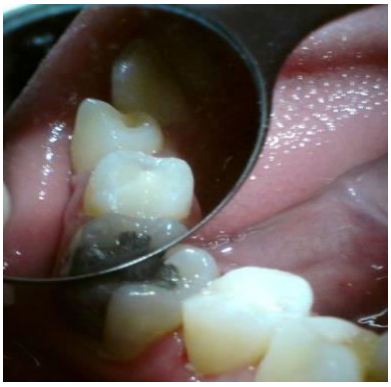

Figure 2: Photograph of prepared class II right lower second premolar

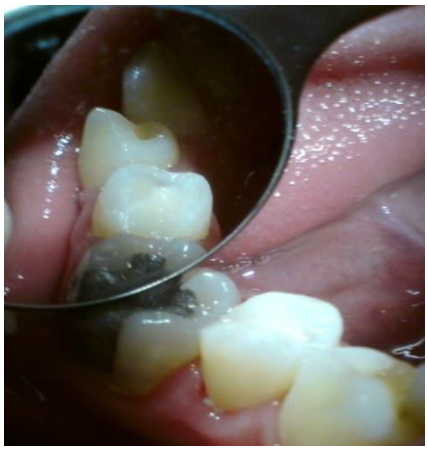

Figure 3: Photograph of restored right lower second premolar

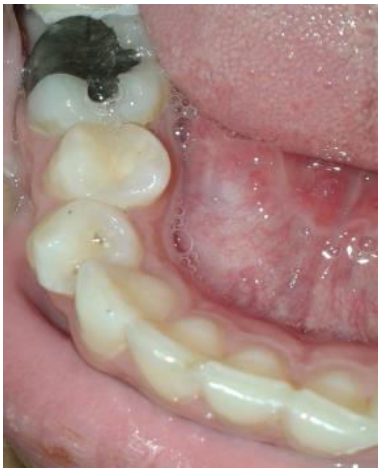

Figure 4: Photograph of restored right lower second premolar after 24-month recall

Secondary Caries

No secondary caries was observed after 24-month of clinical service.

Marginal Adaptation

For all restorations, no marginal defects were recorded at the enamel margins after 6- month clinical service and they were rated Alpha. At 12- month recall, small detectable V-shaped enamel marginal defects (Bravo) were recorded for three restorations for group I. At 24-month recall, three restorations for group I and one restoration for group III were rated Bravo for marginal defects .No significant difference was found between the tested restorative systems (p >0.05).

Postoperative Sensitivity

None of the restorations was sensitive to air or tactile contact postoperatively except two restorations for group I that were relieved after a short time. None of the restorations was sensitive to air or tactile contact postoperatively for all tested groups at 6-month, 12-month nor at 24-month recall.

Inter-proximal Contact

There was no significant difference between the tested restorations concerning inter-proximal contact. The inter-proximal contact of three restorations for group I at 24-month recall were loose but clinically acceptable, no food impaction or trauma to the papilla. Two restorations were rated Bravo and one restoration was rated Charlie.

The survival rates of premolar restorative composites tested over 24-month evaluation time was100%for group I,II and III. For molar restorations, the survival rates of restorative composites tested over 24-month evaluation time was 95.6% for group I and 100% for group II and III.

DISCUSSION

In vitro studies cannot answer questions about in vivo longevity of tooth - colored restorations. Oral environmental condition variables like temperature changes, occlusal stress, and bacterial flora and pH alterations makes reproduction of oral physiology difficult. Therefore, only the clinical environment may helpt in assessing dental materials or restorative techniques.[20]

Clinical trials require objective, reliable and relevant criteria to assess the performance of composite restorations. Composite restoration quality was evaluated using a system of clinical parameters; developed by Gunnar Ryge and known as (USPHS) criteria or Ryge criteria or direct evaluation criteria.[20]

The restorative systems were evaluated for 24-month which may be considered to provide time information on the performance of restorations, particularly in terms of catastrophic failure and may be considered to be particularly appropriate for newly introduced materials such as that used in the present study.[17]

Although dental resin composites have been used extensively in posterior teeth, it is recommended to be used in small to medium sized cavities, not extensive restorations, in order to reduce direct occlusal contacts. On the basis of this fact, the clinical cases were selected to be ranged between small to medium sized cavities. A butt-joint preparation in the occlusal cavities is preferred in this study, to a beveled cavo-surface outline. A beveled preparation results in a thin margin of composite material which could fracture. In the present study, the nano-hybrid resin composite was inserted using an incremental technique, with the increments thickness of no more than 2mm to compensate of polymerization contractions and their stresses, thus securing adhesion to cavity walls. All the restorations were performed under rubber dam isolation to prevent salivary contamination.

In this study, the results revealed a 4.4 % failure rate of the nano-hybrid resin composite restorations without liner due to fracture of composite restoration especially in molar teeth while, there was no failure in nano- hybrid restorations lined with SDR or that lined with nano-flowable composite restorations. These results may be due to decreased masticatory forces in the anterior sectors of the dental arch than the posterior sectors. The failure rate recorded for nano-hybrid restorations without liner was 4.4% to achieve the American Dental Association acceptance criteria, which stated that, at two years no more than 5% of restorations can be considered clinically unacceptable. Therefore, with regard to this criterion, it can be concluded that; nano-hybrid restorations without liner, nano-hybrid restorations lined with SDR and nano-hybrid restorations lined with nano-flowable composites performed well. The results of the current study agree with Ernst CP et al.[21] who reported that no statistically significant difference in the overall survival rate between the groups with and without flowable composite was found. Also, Efes BG et al.[22] reported that the clinical performance of occlusal restorations using either ormocer or nanofill composite did not benefit from the additional use of the flowable composite. In addition, Van Dijken JW & Pallesen U.[23] reported that, the use of flowable resin composite as an intermediate layer did not result in improved effectiveness of the Class II restorations. Also, Stefanski S & van Dijken JW.[24] found that, the nanofilled resin composite showed a good clinical performance with a 2.2% failure rate after 2 years. No differences were observed between the restorations with and without the nano-filled flowable resin intermediary layer. In spite of these results were accepted with the American Dental Association acceptance criteria, the failure rate recorded with nano-hybrid resin composite restorations may be attributed to the absence of the stress breaking effects of flowable resin composite lining materials.

Retention

Usually, failure of retention occurs more typically at the weakest link, namely the tooth-resin interface which remains the area of potential weakness. In the present study, there was no loss of retention reported over 24-month follow up, indicating that the bond strength at the restoration/tooth structure interface is satisfactory in all the tested groups. This results were confirmed by Krämer N 25 who reported that no loss of retention of nano-hybrid composite over six years follow up, while disagree with Stefanski S & van Dijken JW 24 who reported that 2.2% failure due to loss of retention of nanohybrid composite without flowable resin composite liner was observed.

Marginal discoloration

Problems associated with using composites are usually a direct or indirect result of polymerization shrinkage. On account of the polymerization shrinkage, stresses are generated within the restoration and at the margins, and if these stresses exceed the bond strength gap formation, micro-leakage may occur at the tooth restoration interface, which may cause ingress of cariogenic bacteria, interfacial staining, and visible marginal discoloration.[18]

Regarding to marginal discoloration criteria, the majority of scores were Alpha, while Bravo scores were only recorded at the 12 and 24 month of examination in 5% of nano-hybrid resin composite restorations without liner ,2% of nano-hybrid resin composite lined with SDR and nano-hybrid resin composite lined with Filtek z350 XT flow restorations. Marginal discoloration might indicate that, polymerization stresses exceed the bond strength at the restoration/tooth structure interface, and consequently develop marginal leakage. The results of this study consistent with Krämer N,[26],Ernst CP et al [21] and Arhun N et al [27] whom reported no significant marginal discoloration of nano-filled composite and micro-hybrid composite over the follow up periods. Also Celiket al 28 reported no marginal discoloration of both nano-filled, and nano-hybrid posterior composite after 12 month follow up. While, the results inconsistent with Manhart et al [29] who reported a significant increase in marginal discoloration in nano-hybrid posterior composite.

Interproximal contact

For dental resin composites, the wear process is controlled mainly by filler properties and the interfacial bonding strength.[18,19]

According to anatomic form and inter proximal form criteria, no significant differences were found between the materials at 6, 12, and 24- month follow up. The inter-proximal contact of three restorations for group I at 24-month recall were loose but clinically acceptable, no food impaction or trauma to the papilla. Two restorations were rated Bravo and one restoration was rated Charlie. This failure occurred in molar region only and showed as fracture of composite resin restoration. This may attributed to increased masticatory forces in molar region.

Ernst et al [21] and Celik et al [28] whom reported good anatomic form of both the nano-filled resin composite versus a nano-hybrid resin composite over the follow up periods. Also the results agree with, Krämer N et al 26 who reported that 97% were rated optimal for anatomic form of nan-ohybrid resin composite over two years follow up.

Secondary caries

The bacterial accumulation on the surfaces of restorative materials can developed secondary caries and periodontal diseases. Composite restorative materials are modified by environmental influences that could change the profile of bacterial accumulation.

In the present study, there was no secondary caries; all restorations behaved well in this regard. This may be a result of the adequate restorative technique, good adhesive systems, and good oral hygiene of the patients. The results of this study consistent with Ernst CP et al [21], Krämer N et al [26] and Celik et al [28] whom reported that no secondary caries of both the nano-filled resin composite and a nano-hybrid resin composite in over the follow up periods. And also, Krämer N et al. [25] reported no secondary caries of nano-hybrid resin composite over two years follow up.

Marginal adaptation

There was no evidence of crevice along the margins of all restored cavities either at base line or at 6- month recall and they were rated alpha score. At 12 and 24- months, 5% of nano-hybrid restorations without liner and 2.6% of nano-hybrid restorations lined with Filtek z350 XT Flow showed evidence of crevice along the margins and they were rated bravo. The fracture of thin flashes of resin composite material extended on non-instrumented enamel surfaces adjacent to the cavity margins, insufficient restorations and little breakouts of composite caused by occlusal discrepancies may be reasons for catching explorers. The results confirmed by Palaniappan S et al [30] ,Ernst et al [21] and Krämer N et al [25] whom reported good marginal adaptation of both nano-filled, and nano-hybrid composite over the follow up periods. All the failed restorations were recorded at the disto-buccal cavity margins of the mandibular first molars. These results may be explained on the basis of the masticatory forces of posterior sectors and anatomic differences of the restored teeth (functioning cusp). On the other hand, the results inconsistent with Manhart et al [29] who reported a significant increase in deterioration of marginal integrity in nano-hybrid composite.

Postoperative sensitivity

Postoperative sensitivity seemed to be a problem related to resin composite restorations. Postoperative sensitivity has been attributed to several factors, including; operative trauma, dentin etching, desiccation, leakage, bacterial penetration to the pulp, occlusal discrepancies, deformation of cusps by shrinkage stress, and deformation of composite by occlusal forces. Obliteration of the exposed dentin tubules by a dental adhesive should eliminate possible thermal and mechanical oral stimuli.[23]

Many studies have indicated that up to 30% of the study populations have reported postoperative sensitivity following the placement of a posterior resin restoration. The good postoperative sensitivity in this study at each recall visit was related to the excellent two-step etch and rinse adhesive systems, using sharp cutting bur under abundant irrigation with cold water spray, rubber dam isolation, application of flowable composite as a liner, careful drying of the cavity, incremental placement of resin composite and occlusal adjustment .

The results of the present study were in accordance with Stefanski S & van Dijken JW et al [24] who reported slight symptoms of postoperative sensitivity at baseline for teeth restored with nano-filled and nano-hybrid restorations. They explained this by the large size of restorations in their study. However, after one and two year, no postoperative sensitivity was found.

While the results were inconsistent with Krämer N al [26] who reported slight symptoms of postoperative sensitivity at baseline and after 6 months of both nano-filled, and nano-hybrid composite, while Celik et al [28] and Ernst et al 21 whom reported no postoperative sensitivity of both nano-filled, and nano-hybrid posterior composite at any time intervals over the follow up, and Krämer N et al [25] who reported no postoperative sensitivity of nano-hybrid composite over two years follow up.

CONCLUSION

Based on the limitations of this study, we can conclude that SDR resin-based flowable composite showed a satisfactory clinical performance as a liner under resin – based composite restorations.

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