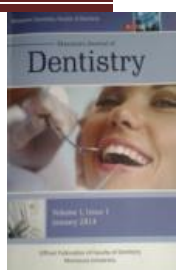


# Clinical Investigation of Nano-hybrid Resin Composite Lined with Smart Dentin Replacement Flowable Resin Composite

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***Abstract:***
**Objectives:** To investigate *in Vivo* the effect of Smart Dentin Replacement (SDR) resin-based composite as a liner under Class II nano hybrid resin composite restorations.
**Methods:** Forty-five patients wih 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 18 months 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 for clinical investigations.
**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 composite resin, Bulk Fill, Flowable liner.*

## *Introduction*

Despite the major developments in new restorative materials, all resin-based composites present a certain degree of volume reduction due to the polymerization shrinkage. Assuming that these materials are bonded to prepared dental cavities, this volume contraction will lead to internal stress generation, which in turn, compromises the mechanical and chemical stability of the restoration and may lead to the loss of marginal integrity [1]. As a consequence, marginal leakage of saliva and its components will occur resulting in post-operative sensitivity, discolored margins, recurrent caries and fractures of the restoration margins [2]. These clinical consequences are the main reasons for restoration substitution, and explain why polymerization shrinkage is recognized as the main limitation of these materials [3,4].

Polymerization shrinkage of resin based composites and the associated stress generated in the dental tissues through the bonded interfaces of the restoration is manifested clinically as cusp deflection [5]. Tooth deformation is indicative of a combination of stresses in the tooth, in the restoration or across the tooth-restoration interface [6]. The size and configuration (C-factor) of the cavity influence the amount of cuspal deflection and the highest deflection values have been recorded for mesio-occluso-distal (MOD) cavities [7]. Post-operartive sensitivity by fluid flow in exposed dentinal tubules has been associated with cusp deflection [8] due to the formation and/or propagation of enamel cracks [9] or by gap formation at the interface between the tooth and the resin based composite restoration as a result of bending and/or insufficient bond strength [10].

Long term adhesion of bonded dental biomaterials to tooth hard tissues is an important factor for clinical success at least with materials shrinking on polymerization [11-14]. Therefore, a tight marginal seal still has to be the primary goal for the clinician, because once happened; gap formation cannot be counteracted with restorative materials that prevent demineralization along with cavity margins [15,16].

Smart Dentin Replacement (SDR) is a one component, fluoride-containing, visible light cured, radiopaque resin composite restorative materials. It is designed to be used as a base in class I and II restorations. SDR material has handling characteristics typical of a flowable composite, but can be placed in 4-mm increments with minimal polymerization stresses, being mandatorily covered by a 2-mm layer of conventional resin composite. SDR material has a self-leveling feature that allows intimate adaptation to the prepared cavity walls [17].

Although flowable resin composite materials have been repeatedly discussed to act as stress breakers or adaptation promoters [18], clinical investigations could not confirm this issue so far [19-22]. Therefore, the objective of the present study was to investigate in vivo the effect of SDR flowable RBC as a liner under class II nano hybrid resin composite restorations.

## *Patients 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 steps etch and rinse Prime & Bond NT adhesive system with a nano hybrid Esthet.x HD resin dental composite.

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).

***Patient Selection***

Forty five patients, ranging in age from 20 to 40 years (with a mean age of 30), were enrolled from the Outpatient Clinic at Faculty of Dentistry Mansoura 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. Presence of primary caries, at least three 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 interproximal embrasure and the cervical margin restricted in enamel. A tooth was considered vital if it was clinically and radiographically free from any signs or symptoms of periapical pathology and normally responded to routine vitality testing [23]. Normal functional occlusion with at least one cusp in occlusal contact. Patient must be able to return for periodic recall examination [24].

The teeth were randomly assigned for three restorative systems, group I, group II, or group III. The randomization was performed by noting each tooth to be restored on one paper and the type of restorative system on a second. First, a tooth number was drawn blindly. Subsequently, a restorative system was allocated to this tooth by blind drawing [25]. 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 design was prepared using a straight fissure-shaped diamond instrument (Komet, 830L, Komet, Lemgo, Germany) on a high-speed air turbine and constant water cooling (120.000 rpm). The common characteristics of these cavity designs were: a) no undercuts, no extension for prevention, b) none of the cavity preparations involved any cusps, c) all of the gingival margins were placed supragingival, to be included with enamel d) all the facial and lingual margins in the proximal box were beveled, and e) at the occlusal outline, a butt-joint margin was left in order to minimize the resin composite surface exposed to occlusal load. 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 [26].

After the preparations were completed, transparent Toflemire matrix band (Peason Dental Supply Company; 13161 Telfair Ave, Sylmar, California 91342) was applied and wedged with TDV reflecting wedge (Peason Dental Supply Company; 13161 Telfair Ave, Sylmar, California 91342) 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 pellet. 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/Ivoclar VivaDent). Then a contact forming instrument (OptraContact/ Ivoclar VivaDent) 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 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 z350 xt Flow), the cavities were etched with 37% phosphoric acid gel then bonded as mentioned before. Cavities were first lined with Filtek z350 xt 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 (3M Dental Products, St. Paul, MN, USA) 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 18 months 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). 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. 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 18-months 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 18-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 18-months recalls, the reason for the two patients not attending each recall visit was the current events in Egypt especially after 30 of June 2013. Kruscal Wallis test used to compare between the three tested composite systems at the three time interval as shown in Table 1. Chi-square test was performed at level of significant $p = 0.05$ to highlight differences between each two investigated composite restorative systems. There was no significant difference among the restorations at all the recall times in term of evaluation criteria.

***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 18-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 ($p>0.05$).

***Secondary Caries***

No secondary caries was observed after 18-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 18- 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 18-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 18-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 18-month evaluation time was 100% for group I,II and III. For molar restorations, the survival rates of restorative composites tested over 18-month evaluation time was 95.6% for group I and 100% for group II and III.

## *Discussion*

SDR or SureFil SDR was introduced to the market as flowable resin composite claiming that it would allow a 4 mm bulk placement in one layer due to reduced polymerization stress [15], being mandatorily covered by a 2 mm layer of conventional resin composite [16].

Improvements in resin-based composite technology have increased the acceptance of this class of materials among dental professionals, particularly for restoring posterior teeth. Laboratory tests might provide useful information to the potential performance of a filling material and its' handling, but such tests cannot adequately evaluate the clinical performance of a material or clinical handling characteristics. Besides, in vitro studies cannot answer questions about in vivo longevity of these tooth colored restorations. The complexity of some 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 be determinant in assessing dental materials or restorative techniques [17,18].

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 (1980) is

known as (USPHS) criteria or Ryge criteria or Direct evaluation criteria [19].

The restorative systems were evaluated for 18-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 [18].

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 anrterior 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. [19] 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.[14] 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 [19]. 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 [14] 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 nanofilled flowable resin intermediary layer. In spite of these results were accepted with the American Dental Association acceptance criteria, the failure rate recorded with nanohybrid resin composite restorations may be attributed to the absence of the stress breaking effects of flowable resin composite lining materials.

## *Conclusion*

SDR as 4 mm bulk fill dentin replacement showed good performance as a liner under nano hybrid composite resin restorations.

***Table 1****: Results of Chi-square test comparing evaluated molar restorations at base- Line, 6-month, 12- month, and 18- 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 |
| 18 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 |

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