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Clinical Assessment of Postoperative Hypersensitivity of Posterior Composite Restorations: Effect of a Cavity Liner

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ABSTRACT

Despite the improvements of resin composites restorative materials and techniques, postoperative hypersensitivity following placement of composite restoration yet remains a problem for both the dentist and the patient. Aim: To evaluate the effectiveness of a Novaseal cavity liner in preventing the occurrence of postoperative hypersensitivity (POH) in class I and II posterior composite restorations. Materials and Methods: A total of 296 posterior composite restorations were placed in 148 patients of both genders (mean age~27.7 ±8.02 Yrs). Each patient has homologous contralateral occlusal or proximal-occlusal caries lesions in premolars and molars teeth. All teeth were restored with a total-etch adhesive system; Tetric® N-Bond and Tetric® N-Ceram resin composite (Ivoclar Vivadent). For each patient, one tooth was chosen at random to be restored with a layer of Novaseal cavity liner, and the contralateral tooth was restored without a liner. POH to various stimuli was evaluated at weeks 1, 4, & 13 post-treatment using the Visual Analog Scale (VAS). Data were statistically analyzed by Chi-Square and Fischer Exact tests. Results: No statistically significant difference in the occurrence of POH was observed between the restorations performed with or without Novaseal cavity liner (P>0.05). Out of 296 restorations placed with the two restorative techniques; only five restorations; 5/296 (1.7%) reported POH to cold at week 1. Among those; three restorations; 3/148 (2%) placed with cavity liner, reported mild and moderate POH (VAS=2, 3 & 5), and two restorations; 2/148 (1.4%) placed without a liner reported mild POH (VAS=3). No POH was reported at weeks 4 and 13 for the two restorative techniques. Conclusions: Novaseal cavity liner could not totally prevent POH in class I and II posterior composite restorations. POH can occur irrespective of the use of a cavity liner.

التقييم السريري لحساسية ما بعد الحشو للترميمات المركبة للاسنان الخلفية: تأثير بطانة التجويف

 2 نعيمة بالتمر 1 و خالد عويدات 2 و إسراء بورقيعة 3 و عمر زيو 4 و عاطف عمر ابوصلاح 2

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المفتاحية:	الكلمات
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ف والثاني موات الخلفية

فرط الحساسي	مقدمة: على الرغم من التحسينات في المواد والتقنيات لمركبات الراتينج، فإن فرط الحساسية بعد وضع الترميم
بطانة التجويف	لمركبات الراتينج لا يزال يمثل مشكلة لكل من طبيب الأسنان والمريض. الهدف: تقييم فعالية بطانة تجويف
الصنف الأول	Novaseal في منع حدوث فرط الحساسية بعد الحشوالترميمي (POH) في الفئتين الأولى والثانية من
المركبات الحش	الترميمات المركبة الخلفية. المواد والطرق: تم وضع ما مجموعه 296 ترميمًا خلفيًا مركبًا في 148 مريِضًا من كلا

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الجنسين (متوسط العمر حوالي 27.7 ± 8.02 عامًا). كل مربض لديه آفات متجانسة أو تسوس قربب في الضواحك والأضراس. تمت ترميم جميع الأسنان باستخدام total-etch adhesive system ؛ و مركب راتنج Tetric® N-Ceram (Ivoclar Vivadent) و Tetric® N-Bond. لکل مربض ، تم اختیار سن واحد بشكل عشوائي ليتم ترميمه بطبقة من بطانة تجويف Novaseal ، وتم ترميم السن المقابل بدون بطانة. تم تقييم POH للمنهات المختلفة في الأسابيع 1 و 4 و 13 بعد العلاج باستخدام مقياس النظير البصري (VAS). تم تحليل البيانات إحصائيا بواسطة اختبارات Chi-Square و Fischer. النتائج: لم يلاحظ أي فرق معتد به إحصائياً في حدوث POH بين الترميمات التي أجربت مع أو بدون بطانة تجويف Novaseal (P> 0.05). من أصل 296 ترميمًا تم وضعها باستخدام طريقتين للترميم؛ خمسة ترميمات فقط؛ أبلغت 296/5 (1.7٪) عن برودة POH في الأسبوع الأول. ثلاثة ترميمات 148/3 (2٪) وضع مع بطانة تجويف، أبلغ عن خفيف ومتوسط POH (VAS = 2 ، واثنين من الترميمات ، 148/2 (1.4) وضعت بدون بطانة خفيفة (POH (VAS = 3. لم يتم الإبلاغ عن أى POH في الأسابيع 4 و 13. الاستنتاجات: لا يمكن أن تمنع بطانة التجويف Novaseal تمامًا POH في الفئتين الأولى والثانية من الترميمات المركبة الخلفية. يمكن أن يحدث POH بغض النظر عن استخدام بطانة التجويف.

1. Introduction

The use of resin composite restorations has increased significantly and has become a well-established and successful dental procedure.¹ Improvements of material properties and techniques as well as increasing the demand for aesthetic restorations have contributed to the establishment of this restorative material. In addition, good clinical performance has encouraged dental clinicians to restore various cavity sizes in anterior and posterior teeth with resin However despite these developments, composite composites.² restorations may exhibit discoloration, marginal leakage, cuspal deflection, recurrent caries, and postoperative hypersensitivity (POH), which can lead to restoration failure.³⁻⁵ This sensitivity is described as discomfort and pain of short duration in a tooth arisen with hot, cold, sweet, and acid stimuli that occur a week or more after placement of a resin composite restoration, and disappear when the stimulus is removed.^{6, 7, 8} Literature reported that patients experienced POH were in a range of 0-47% particularly for Class I and II posterior composite restorations.^{3, 8-20} There are various reasons for the occurrence of POH included; inadequate water coolants during cavity preparation that leads to excessive heat generation and dentine dehydration.²¹ Infection caused by bacterial invasion.²¹ Operator skills, properties of restorative material, modes of light-curing, and cavity depth are also found to be influencing the incidence of POH.^{10, 18, 22}

Another important issue related to the resin composite restoration and connected with the POH problem is the fact that light-cured composites undergo polymerization shrinkage, which may induce stresses internally and at tooth/restoration interface.^{23, 24} If the stresses exceed the bond strength; bond failure and micro-gaps are formed between the composite and the tooth structure that filled with fluids due to microleakage.²⁴⁻²⁶ As the tooth is exposed to either hot or cold stimuli, contraction and expansion of the fluid in marginal gaps lead to fluid movements within dentinal tubules resulting in POH.^{21, 26} Various clinical approaches have been proposed to reduce the polymerization shrinkage stresses and consequently to decrease or minimize POH; for example; incremental packing technique for placement of the resin composite,27 modifying the light activation protocol,²⁴ and application of stress absorbing material such as low elastic modulus resin composite, or flowable composite.^{15, 28}

Furthermore, it has been reported that POH can be minimized by the application of a lining material underneath the composite restoration.^{4, 8, 29} The idea behind using a cavity liner was to seal and protect the dentine-pulp complex from thermal and electrical stimuli,³⁰ and to enhance a remineralization stimulative effect on the pulp to form a reparative dentine.³¹⁻³³ Furthermore, cavity liner used to protect the pulp from toxic effects of chemical agents leaching from some components of adhesive systems or resin composite such as residual monomer, TEGDMA, and HEMA.^{30, 31, 34} In addition to

bacterial leakage into a cavity.35 Currently, several dental products are available on the market that

the antibacterial properties of some lining materials that can inhibit

can be used as cavity liners. Some of these liners have been reported to minimize the occurrence of POH such as calcium hydroxide, glass ionomers (GIs), resin-modified glass ionomers (RMGIs), and selfetch adhesive system.^{4, 8, 36} However, evidence as to the importance and effectiveness of such a liner to provide the best protection, and to reduce POH is varied, and that clinical studies showed diverse results.8, 37 Therefore, this clinical study aimed to evaluate the effectiveness of a Novaseal cavity liner in preventing the occurrence of POH of class I and class II posterior composite restorations at week 1-, 4-, 13- postoperatively.

2. Materials and Methods

Study design and patient selection: A split-mouth design was used where the same patient served as his or her own control. i.e. each patient received two composite restorations in two contralateral posterior teeth. One tooth was restored with the use of a Novaseal cavity liner as an intermediary layer, while the contralateral tooth was restored without a cavity liner. A total of 296 posterior composite restorations were placed in 148 adult patients of both genders at Alraja Dental Clinic in Benghazi City. Informed consent from the patients was obtained after giving a brief explanation of the kind of investigation that was to be conducted. Research approval has been obtained by the Committee on Ethics in Research, school of dentistry, Libyan International Medical University (Certificate Reference No. Dent-1-2021). Inclusion criteria included male and female patients, age; 16-50 years old. Each patient has homologous two contralateral premolars or molars teeth with occlusal or proximal-occlusal (Class I and II) mid-sized caries lesions with no history of sensitivity to cold or hot, no pain, and no tenderness on percussion. Patients who were taking analgesics, or teeth with secondary caries, defective or fractured restoration, and old restorations that needed refilling were excluded from the study. In addition, teeth with deep carious lesions or severe destruction of the tooth crown were also excluded.

Cavity preparation and restorative procedure After clinical and radiographic assessment of the carious lesion, local anesthesia was given. According to the size of the caries lesions; diamond bur (# SF-S11, SF-21 Toboom Shanghai Precise Abrasive Tool Co., Ltd) was used to remove the carious enamel and dentine with a high-speed handpiece under constant water coolant. No bevels were placed on the enamel cavosurface margins of the preparations. Once preparation is completed; the cavity depth, width, and length were measured using a 1-mm marking periodontal probe (William probe) to the nearest millimeter and recorded. The cavity depth was measured from the enamel cavosurface margin to the deepest point in the preparation. The maximum and the narrowest dimensions were

considered as length and width of the preparation at the enamel cavosurface margin.⁶ The dimensions of the two contralateral cavity preparations were approximate of similar size (within 1 mm of each other). A rubber dam was then placed to isolate the operating field.

For Class II cavity preparation a Tofflimire Universal Matrix Retainer and band (DentArt, Dental instrument MFG Co, Pakistan) and interdental wood wedges (PD Produits Dentaires SA, Switzerland) were placed before acid etching and bonding procedures. The cavity preparation walls were acid etched with 37% phosphoric acid semi gel (Meta Biomed Co Ltd., Korea) then thoroughly rinsed off with water, and gently air-dried with compressed air without desiccation. A layer of a Novaseal cavity liner (light-curing lining material-President Dental, Germany) was placed at random in one cavity in each pair. It was applied over the dentine surface on the pulpal floor of the occlusal cavity (class I) and axial wall of proximal-occlusal (class II) cavity preparation. The bonding system Tetric® N-Bond (Ivoclar Vivadent AG, Schaan, Liechtenstein) was then applied with a microbrush and light-cured for 10s,38 using LED light-curing unit (Mini LED, Satelec, France). Nanohybrid resin composite restorative material Tetric® N-Ceram (Ivoclar Vivadent AG, Schaan, Liechtenstein) was incrementally placed in the cavity preparation. Each increment of less than 2-mm thick was obliquely shaped inside the preparation in a way to contact only with part of the cavity floor and one side of the cavity wall,³⁹ and then light-cured using the same LED curing unit with a light intensity of 600 mW/cm².

Except for the placement of the Novaseal cavity liner in one cavity of each pair; the restorative procedure was the same for both cavities. All teeth were restored using the same adhesive bonding system and the same resin composite restorative material. The selection of the tooth to be restored with or without an application cavity liner was done randomly with the help of a coin toss. In general, the tooth on the right side received the composite restoration first. The coin toss decided if the right tooth will receive a cavity liner or not, and consequently, the contralateral tooth received the alternative restorative procedure. After completing the restoration, the rubber dam was removed. The occlusal adjustment was done in maximum intercuspation and eccentric movements using an articulating paper with the patient seated and the occlusal plane parallel to the ground. The identified high spots were carefully removed using extra-fine grit diamond burs EX-17EF, FO-23EF (Toboom Shanghai Precise Abrasive Tool Co., Ltd) under air-water coolant, and then polished with polishing tips to eliminate any surface scratches (Enhance Dentsply Caulk). All clinical work was done by one clinician to control operator variability. One tooth was restored at each clinical visit.

Evaluation of Postoperative Hypersensitivity (POH): Patients were recalled at 1-, 4-, and 13-week post-treatment to assess the occurrence of POH by verbally questioning the patient regarding sensitivity to cold, hot, sweet stimuli, mastication, and clenching. Their answers about the presence and degree of severity in sensitivity

were measured using the Visual Analogue Scale (VAS).^{40, 41} The VAS is presented as a 10-centimeter horizontal line labeled by two ends. The label at the beginning is "no pain at all" (score 0), whereas the label at the other end is "pain as bad as it could be" (score 10). Patients were asked to choose the mark that represented their degree of tooth sensitivity on the line, which was assigned to be one of four categorical scores: None; (0), Mild (1-3), Moderate (4-6), and Severe (7-10). All the readings (marks) stated by the patients were recorded and then the amount of pain was assessed. Data was collected, computerized, and statistically analyzed using SPSS version 19 and differences in reported POH to various stimuli concerning presence or absence of cavity liner were analyzed using Chi-Square and Fischer Exact tests. The level of significance was set as P<0.05. **3. Results**

A total of 196 (66.2%) class I, and 100 (33.8%) class II direct composite restorations were evaluated throughout the study periods. 148 restorations were made with the application of a Novaseal cavity liner and the contralateral 148 restorations were done without cavity liner. 242 (81.25%) were molars and 54 (18.75%) were premolars. 152 teeth in the maxilla and 144 teeth in the mandible (Table 1).

The mean age of patients was 27.7 ± 8.02 (range 16-50) years old, 111 (75.70 %) females and 37 (24.30 %) males. The high percentage of composite restorations was received by the age group of 26-35 years old followed by the age group of 16-25, and then 36-45 years old. The mean and standard deviation for depth, width, and length of the cavity preparations were 2.78 ± 0.35 , 2.50 ± 0.45 , and 6.41 ± 3.77 mm respectively. Detailed numbers, frequencies, and percentages of restored teeth with the two restorative techniques are described in Table 1. The number and distributions of teeth are graphically illustrated in Figure 1.

Results of the Chi-Square and Fisher's Exact test revealed no significant difference was observed in the occurrence of POH between the two restorative techniques at week 1 post-treatment (P>0.05). Out of 296 composite restorations placed with the two treatment modalities, only five restorations (1.7%) presented with mild and moderate POH to cold stimuli. Among those five restorations; three restorations were placed with a Novaseal cavity liner and two restorations placed without a liner. Those Three restorations (3/148, 2%) restored with Novaseal cavity liner reported mild and moderate sensitivity (VAS=2, 3 & 5) in UR7, LL6, and UR6 respectively. Two restorations (2/148, 1.4%) made without a liner reported mild sensitivity to cold (VAS=3) in UL7 and UL6. Four of those restorations were class I, and one was class II restoration. At week 4 post-treatment, the occurrence and severity of POH were totally eliminated, none of the patients reported pain for either of the restorative techniques. Also, no POH was reported at week 13 posttreatment. In addition, there was no POH to hot, sweet, mastication, and clinching as reported by patients throughout the study period. No severe or spontaneous pain was reported from any of the restorations placed during the study period.

	With a Novaseal cavity liner		Without a Novaseal cavity liner		
	Premolars	Molars	Premolars	Molars	Total
Maxilla	22 (28.95%)	54 (71.05%)	22 (28.95%)	54 (71.05%)	152
Mandible	5 (6.94%)	67 (93.06%)	5 (6.94%)	67 (93.06%)	144
Total	27 (18.24%)	121 (81.76%)	27 (18.24%)	121 (81.76 %)	296

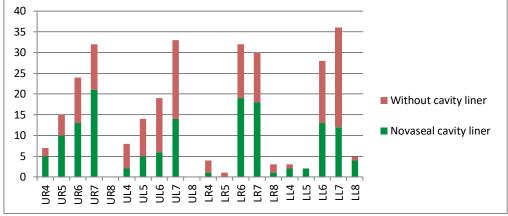


Figure 1: Number and distribution of teeth restored with and without a Novaseal cavity liner

4. Discussion

POH immediately following restorative treatment considers an irritating experience for both; the patient and the clinician.^{10, 11} Literature reported that a mild degree of POH is expected, and it resolves within the first few weeks after restoration placement.^{1, 9, 11} However in some cases, it may continue for a longer time and may lead to restoration failure.^{9, 42} In this situation the management remains challenging to the clinician,^{10, 11} as he/she has to depend on his/her judgment when deciding whether to monitor and observe, amend, or replace the restoration.^{15, 19}

The selection of occlusal and proximal cavity preparations of posterior teeth in the current study is based on the fact that among different classes of composite restorations; class I and class II posterior composite restorations are more prone to clinical failure. This is due to the technique sensitivity of restorative procedures in posterior teeth in a complex oral environment, materials properties,⁹ cavity size,^{10, 19} and residual stresses from polymerization shrinkage that may cause debonding, enamel cracks, gap formation, and POH.^{21, 23}

A split-mouth design was used in this clinical study. This design was introduced in dentistry by Ramfjord et al.,43 in 1968 who randomly assigned the periodontal treatment methods to half of each patient's dentition. There are several advantages for this design; it may control variations within individuals and hence potentially increase the power of the study.44 Lesser number of patients was needed compared to the whole mouth design. In addition, since pain threshold and pain response varies among patients, the splint-mouth design allows the use of contralateral posterior teeth for each patient, therefore each patient acted as his/her own control. On the other hand, the enrollment of patients is hard sometimes because of the need of having symmetrical conditions or very similar extent of the disease in the mouth and this may bias the patients" selection into employing those with an advanced disease condition or deprived oral habits.¹¹ In the current study, difficulty sometimes was experienced during patient selection due to the need to have two contralateral teeth with a very similar degree of caries condition and extension.

The POH was evaluated using the Visual Analogue Scale (VAS).^{40,} ⁴¹ The VAS is a numeric pain assessment scale for sensitivity to cold, hot, sweets, mastication/chewing, and clenching. It is a frequently used method to measure pain intensity in clinical pain research, ⁴⁰ and has been used to measure POH in previous studies.^{6,7,20} It is a simple, reliable and valid method and provides a high degree of resolution. It considers the most sensitive single-item method that makes VAS the ideal tool for describing pain intensity and therefore to guide and monitoring pain treatment.^{40, 41} Occurrence of POH was asked to be reported for a variety of stimuli, however cold sensitivity was the only reported stimuli that caused POH. No POH was reported to hot, sweet, and mastication stimuli. Mastication and clenching hypersensitivity were included in an attempt to distinguish the POH of restoration in hyperocclusion (clenching sensitivity) from hypersensitivity of a restoration related to mastication which is considered a form of POH related to gap formation between the restoration and dentine due to polymerization shrinkage.^{6, 23, 24}

Novaseal cavity liner investigated in this study could not totally prevent the occurrence of POH and that there were no significant differences between composite restorations placed with or without a cavity liner. Novaseal is a light-curing, radiopaque, single component cavity liner contains glass-ionomer and fluoride. This material has been recently presented to the dental practitioners by (President Dental GmbH Zehentstadlweg, Munchen Germany). It also contains the preparation of acrylic resin, glass powder, silica, aliphatic dimethacrylate, aromatic dimethacrylate, polycarboxylic polyethacrylate.⁴⁵ Manufacturers claimed that this lining material is indicated as a protective agent and can be set under all kinds of restorative materials.⁴⁵ It has the advantages of quick and hygienic application, with high compressive strength and fluoride release, and high biocompatibility.⁴⁵

Since the material contains glass ionomer and fluoride, several dentists recommended the use of glass ionomers (GIs) and resinmodified glass ionomers (RMGIs) products as cavity liners to reduce the incidence of POH.^{4, 7, 29} This is because these materials have the ability to provide good bonding to tooth structure, as well as the excellent adaptation and sealing of the dentinal tubules owing to the low viscosity nature of these materials.^{32, 33} However, clinical studies investigated the efficacy of cavity liner in reducing POH showed diverse results.^{8, 10, 21, 29, 37} The vast variation in the results could be due to differences in the cavity depth and size, type of adhesive bonding system, type of resin composite materials and restorative technique used. In addition to, differences in skills, knowledge, and experience of the operator, the number of the clinicians performing the clinical restorative procedures.

Our results were in agreement with some investigators who found no relationship between the occurrence of POH and presence or absence of cavity liner.^{14, 21, 29} Sobral *et al.*,²¹ suggested that POH can occur irrespective of the use of a cavity liner, dentine bonding agent, cavity disinfectant or a dentinal desensitizer.²¹ Furthermore, results of the current study were similsr to other clinical studies that found that glass-ionomer¹⁰, and RMGI⁴⁶ cavity lining layer exhibited no benefit in reducing POH in occlusal composite restorations.^{10, 46} However Akpata and Sadiq⁸ found a reduction in POH with RMGI as compared with the use of bonding agent-alone underneath the resin composite restoration.

The low occurrence of POH obtained in the current study goes in line with some investigators who found no incidence or very low percentage of POH throughout the study periods.^{3, 14, 16, 17} Comparable findings were also obtained by other researchers who found that posterior composite restorations had sensitivity to cold at week 1 post-treatment.^{11, 12, 13, 14} On the other hand, a higher incidence of POH was reported by Bhatti et al.,¹⁸ where 13% of class I composite restorations had POH. It is worth mentioning that, throughout the study period; there was no incidence of severe POH, and no restoration needed replacement. In addition, none of our patients needed any additional intervention since the POH was eliminated gradually.

The explanations for the low occurrence of POH experienced in this study among the two treatment modalities could be attributed to

many reasons; first, the experimental caries teeth were carefully diagnosed and selected. Care was taken to select both contralateral teeth with similar dimensions of the cavity preparation especially regarding the depth of the cavities, being within 3mm. Second, proper clinical procedures were performed during cavity preparation and restorative techniques. The restorative procedures were undertaken in best clinical conditions under rubber dam isolation to avoid moisture, and bacterial contamination that could be contributed to the low incidence of POH.²¹ Extreme care was taken during removal of the caries tissues, using new burs, an intermittent cutting, and light pressure with generous water spray to avoid dehydration of dental tissues and therefore to minimize POH. Furthermore, care was also taken to insert resin composite using incremental packing technique to reduce the polymerization contraction stress and therefore to minimize POH.^{23, 24}

In addition, all restorations were performed using one adhesive system and one resin composite restorative material. Tetric® N-Bond is a light-curing, nano-filled single-component adhesive used in combination with the total-etch technique. It is applied as a homogeneous layer for complete coverage and improved adhesion to the tooth structure, claimed by the manufacturer. It seemed that adhesive material almost fully sealed the dentinal layer and that prevented the rapid outward flow of dentinal tubule fluids and therefore, minimized the occurrence of POH. Furthermore, during the restorative procedure, care was taken to avoid excess adhesive liquid that might irritate soft tissues surrounding the tooth; this might add another explanation to the good results obtained in this study. In this context, Kaurani and Bhagwat,²⁶ documented that the use of a 2step self-etch adhesive system significantly reduced POH. Furthermore, one operator had performed all clinical procedures to minimize the technical and procedural variations regards to the skills, capability, and experience in handling and manipulating materials and technique.21

The reported POH in teeth restored with a resin-based cavity liner was also documented in the literature,^{47, 48} and the reasons for this sensitivity could be attributed to: inadequate seal and closure of the dentinal tubules and consequently POH.⁴⁹ In addition to the harmful chemical effects of some components of this material such as the monomers, BisGMA, and TEGDMA on dental pulp cells.⁵⁰ It has been reported that some components of the adhesive resin-based liners are found to be toxic in cell cultures which may damage the pulp in the short term.^{50, 51} In addition to the polymerization contraction of the organic resins (Bis-GMA and TEGDMA), and temperature rise of these materials during the polymerization process,^{20, 52} are clinically manifested as hypersensitivity. Last but not least, the presence of residual unpolymerized monomers that are more likely to signify a biological risk for the pulp and consequently might lead to POH in a group treated with Novaseal cavity liner.³⁴ These are the possible clarifications for the failures that occurred with the Novaseal cavity liner as resin-contained material though they were very few cases.

Therefore, the success of adhesive restorative treatment in the daily clinical practice relies on improvement of the material properties and restorative technique, as well as the skills, knowledge, and experience of the operator³ It is the responsibility of clinicians to stay side by side with current guiding principles and limitations of resin composite materials to avoid inconvenience and annoying experience of OPH. The high success rate of either using or not using cavity liner was possibly associated with the careful inclusion criteria applied during the selection of the cases along with the proper diagnosis of pulp condition. In addition to the proper clinical restorative procedure and the good marginal seal promoted by the resin composite restoration.³³

5. Conclusions: Within the limitations of this study and based on the results obtained, the following conclusions were drawn. Novaseal cavity liner could not totally prevent the occurrence of POH reported by patients in Class I and Class II posterior composite restorations. i.e. POH can occur irrespective of the use of a cavity liner. POH experienced by the patients was a transient problem and eliminated gradually over time.

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