ID Design Press, Skopje, Republic of Macedonia
Open Access Macedonian Journal of Medical Sciences. 2019 Jul 30; 7(14):2335-2342.
https://doi.org/10.3889/oamjms.2019.656
eISSN: 1857-9655
Dental Science

Evaluation of Post-Operative Sensitivity of Bulk Fill Resin Composite versus Nano Resin Composite: A Randomized Controlled Clinical Study

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Citation: Afifi SMH, Haridy MF, Farid MR. Evaluation of Bulk Fill Resin Composite Post-Operative Sensitivity versus Nano Resin Composite: A Randomized Controlled Clinical Study. Open Access Maced J Med Sci. 2019 Jul 30; 7(14):2335-2342. https://doi.org/10.3889/oamjms.2019.656

Keywords: Postoperative sensitivity; Class II posterior restorations; Bulk fill resin composite; Incremental Nano resin composite; Adhesive system

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Received: 22-Apr-2019; **Revised:** 01-Jun-2019; **Accepted:** 02-Jun-2019; **Online first:** 26-Jul-2019

Funding: This research did not receive any financial support

Competing Interests: The authors have declared that no competing interests exist

Abstract

BACKGROUND: Despite recent advances in restorative dentistry adhesive restorations may cause postoperative sensitivity which leads to restoration failure.

AIM: This study aimed to compare and evaluate the incremental and bulk fill resin Composite postoperative sensitivity in class II posterior restorations bonded with two adhesive systems (self-etch and etch-and-rinse).

METHODS: Sixty patients were randomly selected, their age range from twenty-five to forty years old, divided into two groups according to the packing technique of resin composite material; incremental Tetric Evoceram and Tetric Evoceram bulk-fill resin composite. Thirty patients (n = 30) for incremental Tetric Evoceram resin composite restorations and according to the adhesive systems used they were equally divided (n = 15 teeth).Thirty patients (n = 30) for Tetric Evoceram bulk-fill resin composite restorations and according to the adhesive systems used (etch and rinse or self-etch), they were equally divided (n = 15 teeth). Post-operative pain assessed at 24 hours, 1 week and 1 month using the Visual Analog Scale Score (VAS). Each patient was instructed to put a mark on the VAS line at home to point out the intensity of pain at each assessment period. The problem of measuring the pain that pain tolerance of individuals may be different from the others. This may be due to different reasons, and it is not always because of a problem in the restoration

RESULTS: After 1 day, 1 week as well as 1 month, no statistically significant disagreement between the two resin composite types using self-etch adhesive strategy and total-etch adhesive strategy. Also, when the two adhesive systems were compared using Bulk Fill resin composite and incremental Nano resin composite no statistically significant disagreement between the two adhesive systems after 1 day, 1 week as well as 1 month.

CONCLUSION: The post-operative hypersensitivity is related to many factors as the procedure of cavity preparation, adhesive approach, and type of resin composite used and placement technique of the resin composite.

Introduction

New technologic development is continuing to minimise the shrinkage and polymerisation stress of resin composites. The recent group of bulk-fill resin composites provide the effectual use of 4 or 5 mm thick increment as the first increment of the restoration claiming full conversion of this increment with minimal polymerization stresses providing leak-proof margin to minimize microleakage and a remove it an easy quick application of the composite in difficult compound and complex restorations [1]. The lack of marginal integrity of resin composite restorations results in dentinal sensitivity and secondary caries formation. Dentinal sensitivity present as a sharp, well-defined pain. [2]

Studies have shown that bulk-fill resin composite has some degree of conversion, high depth of cure resins, and low volumetric shrinkage [3]. Furthermore, clinical researches have reported that the postoperative sensitivity increases lead to cuspal deflection and increase stresses at the interface when placing 4or 5 mm-thick increments of resin composite [4].

Self-etch (single step) and etch-and-rinse adhesives using phosphoric acid were used with resin

composite; after rinsing phosphoric acid, postoperative sensitivity may increase due to resin monomers can't be infiltrated into the dematerialised dentin and also can't seal dentin tubules so hydration of dentin should be managed. Self-etch adhesives don't demand multiple steps for bonding which may lower postoperative sensitivity when compared to etch and rinse technique [5]. However, the result of different adhesive techniques on postoperative sensitivity in posterior teeth is still debatable [6].

The aim of this double-blind, randomised clinical trial was to assess and compare the clinical results of postoperative sensitivity after incremental nano resin composite and bulk-fill resin composite placement techniques in posterior restorations bonded with two different adhesive systems.

Material and Methods

Ethical considerations and approval

This study was approved by the Ethics Committee of Scientific Research-Faculty of Dentistry-Cairo University, Approval no: 150405.

Registration

This study was registered at the ClinicalTrials.gov; registration number is NCT03792178.

Study design

Trial Design: Randomized clinical trial.

Participants

All patients were enrolled from the Operative dentistry clinic, Faculty of Dentistry Cairo University. The selection was completed according to the patients need for class II cavity preparations followed by final resin composite restorations. A total of patients was enrolled for this study from April 2016 till April 2017. Medical and dental histories were taken from all patients (Table 1).

Table 1: Inclusion and Exclusion criteria

Inclusion criteria	Exclusion criteria
Patients must not show any signs of voluntary dental pain.	Increasing pre-operative sensitivity of the selected teeth.
The existence of molar and premolar class II teeth requiring resin composite restorations for the treatment of primary carious lesions	Teeth with very deep caries.
The selected teeth should have an occlusal contact with natural or crowned antagonist teeth	Patients have old restorations.
The selected teeth should have a proximal contact with the adjacent teeth.	Teeth with spontaneous pain.
Shallow and mid-sized cavity depths will be included in the study.	Patients with temporomandibular joint problems involving pain.
	Patients are taking analgesics.

Sample size calculation

The total sample size of 42 will be effective to observe this effect size of 0.2, a power of 80%, and a significance level of 5%. This number has been raised to a total sample size of 48, to modify for using a nonparametric test. The number is raised again to sample size of 60 (30 for each group) to permit for losing around 25%. The sample size was calculated using G * Power program (University of Düsseldorf, Düsseldorf, Germany) [7].

Randomisation

Randomisation was accomplished using (https://www.randomizer.org/) in the Center of Evidence-Based Dentistry, Cairo University. Each patient will choose a number from sequentially numbered opaque sealed envelopes after cavity preparation. They will be then allocated into one of the set-ups using a randomisation table (Random.org). All patients who give consent for participation and who fulfil the inclusion criteria will be randomised.

Allocation concealments

Concealed allocation carried out using a set of random numbers placed in sealed opaque envelopes. The operator unlocked the envelope containing the procedure to be carried out on each patient. Sealed envelopes waiting for new subjects remained in a secured place and stated to the operator as the sessions are scheduled.

Implementation

The allocation sequence produced by the statistician who forwarded the sealed opaque envelops to the operator the day before the intervention and the envelope was opened containing the procedure that accomplished on each patient immediately before intervention.

Blinding

Double-blinded study since the participant and the investigator be unaware of the type of resin composite, self-etch adhesive and total-etch that is used. The 2 types of resin composite had the same shade guide. The investigator is blinded since each type of resin composite, the self-etch adhesive and total-etch was given a code that is known only by the data manager, and is placed in very similar bottles.

Intervention

Wholly clinical steps were achieved by only one operator.

Procedure methodology

After consent was acquired, collect the data of the patients retrospectively by using a well-designed questionnaire. The questionnaire involved Medical history, dental history, age, gender, nationality, social status, Occupation [8].

Cavity preparations were done, Participants were stated a short explanation about the examinations and all consent to participate and sign a consent form, Sensitivity tests were performed with hot gutta-percha stick and cold (ice stick) stimuli in order to initiate pulp condition and determine whether there was be any abnormal pulpal responses which could jeopardize the final sensitivity results [9].

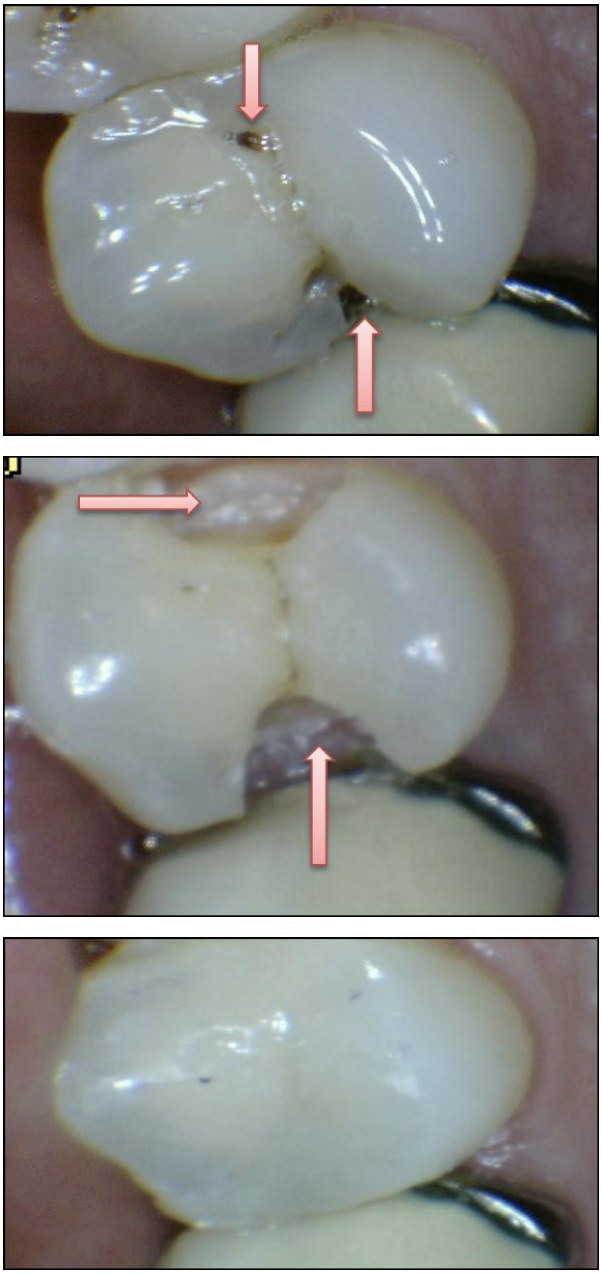

Figure 1: Clinical Case 1. Arrows showing Cl. II (Mesial and distal surface) in upper 4 (top); Arrow showing prepared cavity after caries removal and excavation (middle); Tooth after Tetric Evoceram Bulk Fill resin composite placement and finishing (bottom)

Periapical radiographs were taken for each selected tooth to evaluate cavity proximity to the pulp and any sign of periapical radiolucency. A Local anaesthetic was used for the operative procedures; the working field throughout the whole procedure was be insulated with cotton rolls and saliva aspirator [10].

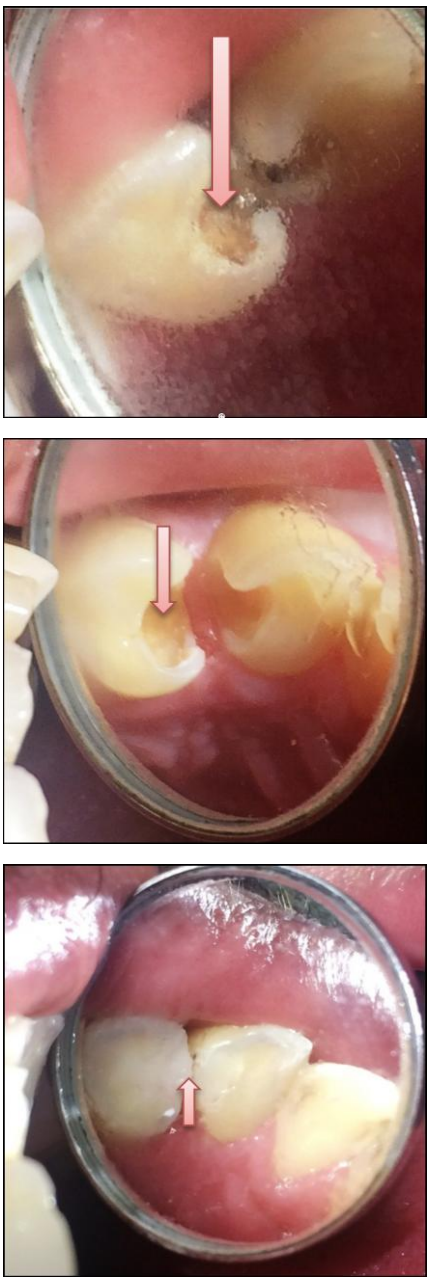

Figure 2: Clinical case 2. Arrows showing Cl.II (Mesial surface) in left upper 4 (top); Arrow showing prepared cavity after caries removal and excavation (middle); Tooth after Tetric Evoceram universal nano-hybrid resin composite incremental (bottom)

The cavo surface angle of the prepared cavity was entirely in enamel without any beveling. The depth of each cavity preparation was estimated against the mesial and distal marginal ridges, using a periodontal probe to be 3 mm and 5 mm but not greater than 5 mm in occlusal and proximal parts respectively with no lining material under resin composite restorations. The cavity was cleaned with a

water spray from the dental unit. Tooth surfaces were treated with the total self-etch and self-etch adhesives according to the directions provided by the manufacturer.

Sectional matrices (Palodent plus, Dentsply) were placed before the restorative procedure.

The treated cases Separated into 2 equal groups according to the packing technique of resin composite material; incremental Tetric Evoceram and Tetric Evoceram bulk-fill resin composite were as follows:

Group A: Incremental Tetric Evoceram resin composite restorations and they equitably divided according to the adhesive Strategies used (Total etch or single-step self-etch adhesive strategy).

Group B: Tetric Evoceram bulk-fill resin composite restorations and they equitably divided according to the adhesive strategies used (Total etch or single-step self-etch adhesive strategy).

Post-operative pain assessed at 24 hours, 1 week and 1 month using the Visual Analog Scale Score (VAS). The VAS is a measurement instrument for subjective characteristics or reaction that cannot be directly measured (Figure 3). A 10 cm line with the anchor words “no sensitivity” at one end and “intolerable sensitivity” at the other end. Each patient was instructed to mark a vertical mark on the VAS rule at home to point out the intensity of pain at each assessment period [11].

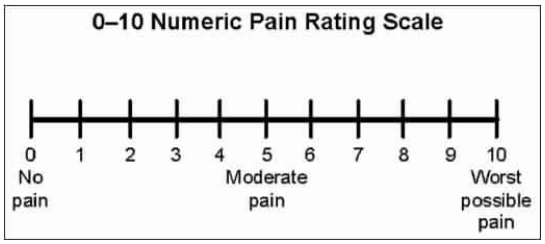

Figure 3: Visual Analog Scale

Statistical analysis

Data were analysed using IBM SPSS advanced statistics (Statistical Package for Social Sciences), version 21 (SPSS Inc., Chicago, IL). Numerical data were described as median and range, while qualitative data were described as number and percentage. To evaluate and compare the post-operative sensitivity of patients with class II cavities using bulk-fill resin composite containing self-etch adhesive and free self-adhesive versus those with Nano resin composite containing self-etch adhesive and free self-etch adhesive, Mann-Whitney nonparametric test was performed. To compare the different measurements within each group, Friedman repeated-measures analysis of variance on ranks was done. To adjust for inflation of the type I error, these tests were followed by the Bonferonni corrections. A p-value less than or equal to 0.05 was considered statistically significant. All tests will be two-tailed.

Results

After 1 month of follow up was found that when the two resin composite types using single-step self-etch adhesive and total-etch adhesive strategies were evaluated; there was no statistically significant difference between the two resin composite types after 1 day, 1 week as well as 1 month. When the two adhesive systems were compared using Bulk Fill composite & incremental Nano resin composite there was no statistically notable difference between the two adhesive systems after 1 day, 1 week as well as 1 month.

Using Bulk Fill composite with self-etch adhesive; there was a statistically notable reduce in the prevalence of hypersensitivity after 1 week. There were no cases with hypersensitivity after 1 week as well as 1 month. Using Bulk Fill composite with Total etch adhesive; there was a statistically notable reduce in prevalence of hypersensitivity after 1 week as well as from 1 week to 1 month.

Using Incremental Nano resin composite with self-etch adhesive; there was a statistically notable reduce in the prevalence of hypersensitivity after 1 week as well as from 1 week to 1 month. Using Incremental Nano resin composite with total-etch adhesive; there was a statistically notable reduce in prevalence of hypersensitivity after 1 week as well as from 1 week to 1 month.

Table 2 shows the frequencies, percentages and results of Chi-square and Fisher's exact tests for comparison between the prevalence of hypersensitivity after using the two resin composite types. Results showed postoperative sensitivity recorded in three patients at one day using bulk fill packing technique with self-etch adhesive system, at one week and one month all cases had no sensitivity.

Table 2: Show the frequencies, percentages and results of Chi-square and Fisher's exact tests for comparison between the prevalence of hypersensitivity after using the two composite types

Adhesive system	Time	Bulk Fill (n = 15)		Incremental Nano Resin (n = 15)		P-value
		N	%	N	%	
Self-etch	1 day	3	20.0	6	40.0	0.427
	1 week	0	0.0	3	20.0	0.224
	1 month	0	0.0	0	0.0	Not computed
Total etch	1 day	4	26.7	7	46.7	0.256
	1 week	2	13.3	4	26.7	0.651
	1 month	0	0.0	2	13.3	0.483

*: Significant at P ≤ 0.05.

For bulk fill packing technique with the total-etch adhesive system; at one day four patients had sensitivity; at one week two patients only had

sensitivity, at one month all cases had no sensitivity. However post-operative sensitivity recorded in four patients at one day using Incremental Nano resin composite packing technique with self-etch adhesive system, at one week two patients had sensitivity and at one month all cases had no sensitivity.

For Incremental Nano resin composite packing technique with a total-etch adhesive system, seven patients recorded postoperative sensitivity at one day, four patients at one week and two patients at one month. Results showed that bulk-fill composite had less post-operative sensitivity when compared to incremental Nano resin composite.

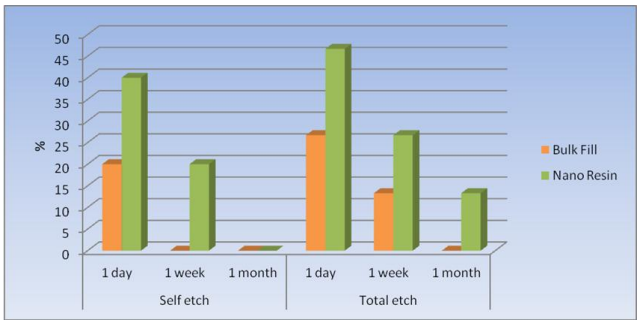

Figure 4: Bar chart representing the prevalence of hypersensitivity after using the two composite types

Table 3 reveals the frequencies, percentages and results of Chi-square and Fisher's exact tests for comparison between prevalence of hypersensitivity after using the two adhesive systems.

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Composite type	Time	Self-etch (n = 15)		Total etch (n = 15)		P-value
		n	%	n	%	
Bulk Fill	1 day	3	20.0	4	26.7	0.666
	1 week	0	0.0	2	13.3	0.483
	1 month	0	0.0	0	0.0	Not computed
Incremental	1 day	6	40.0	7	46.7	0.713
Nano Resin	1 week	3	20.0	4	26.7	1.000
	1 month	0	0.0	2	13.3	0.483

*: Significant at P ≤ 0.05.

Results revealed that when Bulk Fill composite was used; there was no statistically notable difference between the two adhesive systems after 1 day as well as 1 week. After 1 month, all cases had no sensitivity when incremental Nano resin composite was used; there was no statistically significant difference between the two adhesive systems after 1 day, 1 week as well as 1 month.

Results showed that postoperative sensitivity was reduced using a one-step self-etch adhesive strategy compared to total etch adhesive strategy.

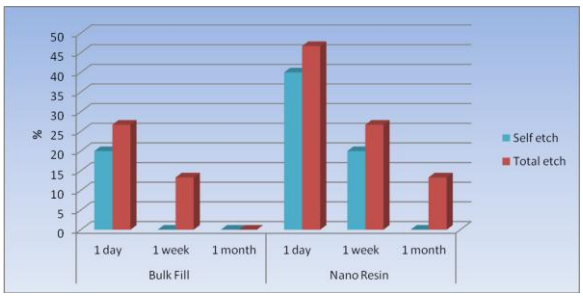

Figure 5: Bar chart representing the prevalence of hypersensitivity after using the two adhesive systems

Table 4 shows the frequencies, percentages and results of Cochran's Q test for comparison between the prevalence of hypersensitivity at different follow up times within each group.

Table 4: Frequencies, percentages and results of Cochran's Q test for comparison between the prevalence of hypersensitivity at different follow up times within each group

Group	1 day (n = 15)		1 week (n = 15)		1 month (n = 15)		P-value
	n	%	N	%	N	%	
Bulk Fill with Self etch	3	20.0 ^{A}	0	0.0 ^{B}	0	0.0 ^{B}	0.050*
Bulk Fill with Total etch	4	26.7 ^{A}	2	13.3 ^{B}	0	0.0 ^{C}	0.050*
Nano Resin with self-etch	6	40.0 ^{A}	3	20.0 ^{B}	0	0.0 ^{C}	0.011*
Nano Resin with Total etch	7	46.7 ^{A}	4	26.7 ^{B}	2	13.3^{C}	0.022*

*: Significant at P ≤ 0.05; Different superscripts in the same row are statistically significantly different.

Results showed that Bulk fills with self-etch, Bulk Fill with Total etch and Nano Resin composite with self-etch had no postoperative sensitivity after one month in all cases. Bulk Fill with Self etch had postoperative sensitivity in three patients at one day then subside from one week to one month. Bulk Fill with Total etch and Nano resin composite with self-etch had postoperative sensitivity from one day to one week then subside at one month. However, incremental Nano resin composite with Total etch showed postoperative sensitivity at one day in seven patients (46.7%) decreased to four patients at one week (26.7%) decreased to two patients at one month (13.3%).

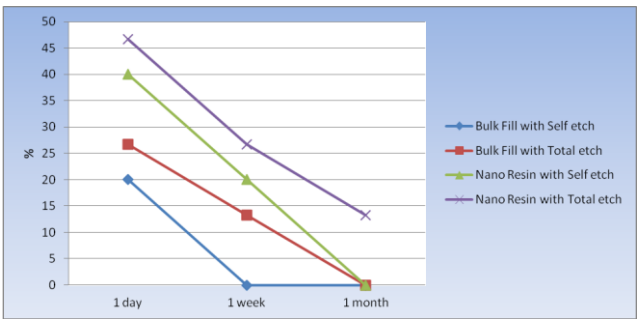

Figure 6: Line chart representing the prevalence of hypersensitivity at different follow up periods within each group

Discussion

Post-operative sensitivity, discoloured margins, recurrent caries and fractures of the restoration margins may be due to marginal leakage of saliva and its components. These clinical results are the major reasons for substitution of restorations and describe why polymerisation shrinkage is acknowledged as the major limitation of these materials. Dentin bonding agents and glass ionomer cement has been used to minimise contraction gap formation and the potential for bacterial leakage [12].

The formation of a hybrid layer that is infiltrated with adhesive resins results in effective dentin bonding. Nano-leakage occurred due to incomplete resin penetration in the hybrid layer permits to occur. Nano-leakage pathways may cause bond failure by stimulating hydrolysis of collagen fibrils and/or degradation of polymerised resins [13].

Therefore, the objective of this study was to assess and compare the post-operative sensitivity of Bulk fill composite placement and incremental Nano resin composite with different dentin adhesives strategy (total-etch or single-step self-etch).

In this randomised clinical trial, risk and intensity of postoperative sensitivity manifested when applying the bulk-fill technique and the conventional 2 mm incremental technique. An ideal resin composite that it can be cured in a single increment, promoting placing should be considered and may be referred to some effects of the bulk fill material which makes it very close to incrementally cured resin composite, except that higher depth of cure can reach [14], [15].

Higher translucency was found in the material used in this study (Tetric N-Ceram Bulk Fill) which can affect its superior depth of cure by increasing deeper blue-light penetration and minimise light scattering [16], [17].

To obtain a reliable adhesive-restoration interface over time, several new adhesive systems have been developed [18].

Knowing the success and longevity of various adhesives enables practitioners to choose the most appropriate material for clinical use. One-step self-etch adhesives systems that have become popular in restorative dentistry as they are easy to use and demonstrate low technique sensitivity with the simplified total-etch adhesives (one bottle) which are still popular among clinicians in routine clinical use. By using agents from the same manufacturer, certain chemical variations are eliminated, allowing a more controlled evaluation of the progression from etch-and-rinse through two-step agents and an assessment of any concomitant clinical advantage [19], [20].

A Method has been described to measure postoperative sensitivity; visual Analog Scale Score (VAS). The VAS is an instrument that measures subjective characteristics or attitudes that cannot be directly measured. When responding to a VAS item, respondents specify their level of agreement to a statement by indicating a position along a continuous line between two end-points. A 10 cm line with the anchor words “no sensitivity” at one end and “intolerable sensitivity” at the other end [21].

In the present study, comparing and evaluating incremental and bulk fill postoperative sensitivity in posterior composite restorations showed that on using the self-etch adhesive system; there was no statistically notable difference between the different resin composite types after 1 day as well as 1 week. After 1 month, all cases had no sensitivity. Using total-etch adhesive system; there was no statistically significant difference between the two resin composite types after 1 day, 1 week as well as 1 month.

The lack of postoperative sensitivity in the current study could be the result of the manufacturer’s instruction for adhesive application in addition to the low polymerisation shrinkage and polymerisation shrinkage stresses of both materials. These results were in agreement with Sancakli et al., who reported that outcome of post-operative sensitivity determined by both operator skill and experience [22].

Ashgar et al. attributed the low post-operative sensitivity to the lower post-gel shrinkage of bulk-fill composites. However, it was reported that post-operative sensitivity is a patient-related factor, such as pain experience and amount of discomfort that can vary between patients [23].

In the present study, comparing postoperative sensitivity of the different bonded adhesive strategy using Bulk Fill composite; there was no statistically notable difference between the different adhesive systems after 1 day as well as 1 week. After 1 month, all cases had no sensitivity. Using incremental Nano resin composite; there was no statistically significant difference between the two adhesive systems after 1 day, 1 week as well as 1 month. The outcome of the present study is in check with the latest systematic review of the Literature Reis A et al., that systematic review concluded that presence of postoperative sensitivity immediately after the restorative procedure does not influence by the type of adhesive strategy used in bonding procedures in posterior resin composite restorations [24].

Favour our results are those by Berkowtiz G et al., who found that postoperative sensitivity did not affect by the cavity depth. Browning WD et al., reported that immediate postoperative sensitivity was not affected by either the adhesive strategy (etch-and-rinse / self-etch) or the filling technique (incremental / bulk) and 20.3% was the overall risk of it, but related to other many factors during cavity preparations and restorations procedures [25], [26].

Agreement our results are those by Blanchard et al., who found that the type of dentin bonding agent used play an important role in greatest sensitivity associated with [27].

The results demonstrated that low post-operative sensitivity is due to the careful application of the treatment steps, the right use of adhesive materials by following the manufacturer's instructions, and clinical placement techniques that might depend on resin composite materials used.

Limitations: Further clinical researches are needed with extended follow-up periods to assess long-term postoperative sensitivity.

In conclusion, the post-operative hypersensitivity is related to many factors as the procedure of cavity preparation, adhesive approach, and type of resin composite used & placement technique of the composite. Etch & Rinse approach provides high bond strength with noticeable postoperative hypersensitivity. The self-etch approach proved the minimal post-operative hypersensitivity with simplified bonding steps. Bulk fill composite with bulk packing in 4mm thickens increment together with self-etch adhesive is considered as practical approach in class II cavity restorations regarding time saving, simplicity & least post-operative hypersensitivity.

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