

Clinical Performance of Posterior Restorations of Bulk Fill Resin Composite without Preheating Versus Repeated Preheating for One, Five and Ten times: A Randomized Controlled Clinical Trial

Protocol

Submitted to Conservative Dentistry Department, Faculty of Dentistry, Cairo University, in partial fulfillment of the requirement for a PhD Degree in Restorative and Esthetics Dentistry

By

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I. Administrative information:

1. Title:

Clinical Performance of Posterior Restorations of Bulk Fill Resin Composite without Preheating Versus Repeated Preheating for One, Five And Ten times: A Randomized Controlled Clinical Trial

2. Protocol Registration:

To be registered in www.clinicaltrials.gov

3. Protocol version:

First version

4. Funding:

Self-funding

5. Roles and responsibilities:

5a) Names, Affiliations, and Roles of protocol contributions

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***Medical Biostatistics Unit (MBU)**

Medical Biostatistics Unit of Faculty of Dentistry, Cairo University, Responsible for reviewing sample size calculation for the trial

***Research Ethics Committee (REC)**

Research Ethics Committee of Faculty of Dentistry, Cairo University; Reviewing this protocol to protect the ethical rights of the participants in the trial.

***Research Plan Committee (RPC)**

Research Plan Committee of Conservative Dentistry Department, Faculty of Dentistry, Cairo University; Ensuring that this protocol considered within the Department research plan.

5b) Name and contact information for the trial sponsor

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II. Introduction:

6 .a. Background and rationale:

Research question:

In restoring posterior teeth, is there difference in clinical performance when using no heated, one, five and ten time preheated bulk fill resin composite?

Statement of the problem:

Dental resin composites are widely used for adhesive restorative procedures nowadays due to the significant improvement in their physical and mechanical properties. However, volumetric shrinkage is still an inherent drawback of the polymerization of the resin matrix (**Erhardt et al., 2020**).

Preheating improves adaptation, polymerization shrinkage and degree of conversion without affect mechanical properties of resin composite restorations (**Yang et al., 2019**).

In clinical situation, composite resin syringe is repeatedly used for restoration of several cavities and if preheating is applied, this syringe will undergo several heating cycles so repeated preheating effect on composite resin should be tested (**Oskoe et al., 2017**).

Rationale for conducting the research:

Up to present no randomized clinical trials were conducted to evaluate the effect of repeated preheating of conventional bulk-fill resin composite in posterior restorations. Thus the purpose of the current study is to assess the clinical performance of posterior restorations of bulk fill resin composite without preheating with repeated preheating for one ,five and ten times. The expected benefit is to decrease postoperative sensitivity (**Oskoe et al., 2017**) and evaluate clinical performance of posterior teeth restorations after one year (**Thyab, 2020**).

Review of literature:

Preheating resin composite restorations before application is a new trend in the field of dentistry. Preheating increases, the flowability of the composite and reduces its viscosity, providing better adaptation to cavity walls, especially for high-viscosity materials. Preheating the resin composite reduces microleakage, thereby increasing the durability of the restoration. Preheating also increases the temperature of the composite because the higher thermal energy enhances the mobility of the radicals and monomers, resulting in a higher degree of monomer conversion and an improved polymerization rate (**Elkaffas et al., 2019**).

D'amario et al. (2015) conducted an in vitro study to assess and compare the flexural strength, flexural elastic modulus and Vickers microhardness of three resin composites Enamel Plus HFO (Micerium), Opallis (FGM), and Ceram X Duo (Dentsply DeTrey). In which a total of 180 specimens

one group of specimens of each material was fabricated under ambient laboratory conditions ($21^{\circ}\text{C} \pm 1^{\circ}\text{C}$), whereas in the other groups the composites were cured after 1, 10, 20, 30, or 40 preheating cycles to a temperature of 39°C in a commercially available preheating device (ENA HEAT composite heating conditioner). Vickers microhardness was assessed on 10 cylindrical specimens from each group. They found that regardless of the material, the number of heating cycles was not a significant factor and was unable to influence the three mechanical properties tested. However, a significant main effect of the employed material on the marginal means of the three dependent variables was detected. They concluded that the preheating procedure did not negatively influence the mechanical properties of the resin composites even when highly repeated.

Dionysopoulos et al. (2016) conducted an in vitro study to evaluate the polymerization efficiency of bulk fill resin-based ,after preheating Eight bulk fill RBCs were investigated, Four high-viscosity bulk fill RBCs (X-tra fil – XF, EverX Posterior – EXP, Tetric EvoCeram Bulk Fill – TEB and Beautifil Bulk Restorative – BBR) and four flowable bulk fill RBCs (X-tra base – XB, Beautifil Bulk Flowable – BBF, Filtek Bulk Fill – FB and Venus Bulk Fill – VB) and a conventional nanohybrid resin composite (Filtek Z550 – FZ) was used as a control . Five specimens for each material were prepared for Vickers hardness measurements. The results showed that as the depth increases microhardness values reduce. The Vickers hardness measurements 24 h after photopolymerization revealed higher values compared to those obtained immediately after photopolymerization. There was an increase in microhardness of the RBC materials when preheated at 54°C in comparison with the room temperature specimens. They concluded that polymerization efficiency of bulk fill RBCs is affected by their composition and increases with temperature and post-irradiation polymerization.

Campbell et al. (2017) conducted a randomized controlled trial of postoperative sensitivity with Warm and room temperature composite. One group had room temperature composite restorations placed and the second had composite preheated to 39°C . They found that there was no detectable difference in postoperative sensitivity between preheated and room temperature composite restorations. They concluded that there is no detectable difference in postoperative sensitivity between preheated and room temperature composite restorations for the restorations in this trial, when teeth are restored with resin composite.

Metalwala et al. (2018) conducted an in vitro study to assess the effect of preheating temperature on the rheological properties of four nanohybrid dental resin composites [Herculite Ultra (Kerr),Tetric EvoCeram (Ivoclar Vivadent), Filtek Supreme Ultra (3 M) and Grandio (Voco)]. Measurements were obtained at three different temperatures 25, 37 and 60°C . Preheating the composite material resulted in enhanced flow and greater adaptability. They found that preheating the nanohybrid dental composites considerably improves their flowability and can improve clinical placement and adaptation. Finally they concluded that preheating the nanohybrid dental composites considerably improves their flowability, which provides increased mechanical characteristics and seal strength.

Karacan and Ozyurt (2019) measured the intra-pulpal temperature increase when placing room temperature or preheated bulk-fill composite. Total number of 30 extracted human lower third molars were selected and class II (MOD) cavities in each tooth were prepared, resulting in a remaining dentin thickness of 1 mm. A K-type thermocouple was placed inside the pulp chamber. In first group bulk-fill composite (Filtek bulk-fill posterior [3M-ESPE], that was stored at room temperature. In the second group, the composites were preheated in an oven for 15 minutes at 54°C. In the third group, the composites were preheated in an oven for 15 minutes at 60°C. They found that preheating does not represent a significant problem in terms of intrapulpal temperature increase. Even if the preheating process results in increases with the increase of intrapulpal temperature, this temperature increase is not the critical factor that causes harm to the pulp.

Winarta et al. (2020) conducted an in vitro study to analyze the effect of repeated preheating on the mechanical properties of a composite resin with different fillers. Microhybrid, nanohybrid, and nanofill composite resins were preheated (ten times, twenty times, and not heated as a control. The specimens were divided into two groups: Group 1 was immediately tested using a universal testing machine. Group 2 was soaked in 37°C artificial saliva for 24 h before testing. Each specimen was tested using the universal testing machine with the pressure side with a 1 mm/s crosshead speed. They found that nanohybrid composite resin had the most stable diametral tensile strength after repeated preheating, whereas nanofill composite had the weakest strength. They concluded that repeated preheating did not significantly affect the diametric tensile strength of composite resin.

6.b.Explanation for choice of comparator:

Bulk fill resin composite without preheating will be used as a control. The technique would be faster than placing numerous increments. Using of bulk fill reduce the technique sensitivity and shorting time of insertion (**Elmarakby, 2020**).

Preheating of bulk fill resin composite improve adaptation, polymerization shrinkage and degree of conversion (**Lempel et al., 2019**).

7. Objectives:

a.Aim of the study:

Compare the clinical performance of bulk fill resin Composite without preheating with one, five and ten times preheating bulk fill resin composite in posterior teeth after one year.

b.Hypothesis:

The null hypothesis of this study is that there is no significant difference in clinical performance of the restoration during restoring posterior teeth when using bulk-fill without preheating and after repeated preheating for one , five and ten times in restoration of posterior teeth.

Primary objective: Clinical Evaluation of restoration (marginal integrity) using Modified US Public Health Service Criteria (USPHS)

Secondary objectives: Clinical Evaluation of restoration (Marginal discoloration, secondary caries and Postoperative Sensitivity) [Time Frame: 1 year] Modified US Public Health Service Criteria (USPHS)

C.PICOTS

P (Population): Carious molar teeth.

I (Intervention):

Intervention 1: restoration with one-time preheated conventional bulk-fill resin composite, **X-tra fill (VOCO, GERMANY)** at 68°C (Yang et al., 2020).

Intervention 2: Restoration with five time preheated conventional bulk-fill resin composite, **X-tra fill (VOCO, GERMANY)** at 68°C (Yang et al., 2020).

Intervention 3: Restoration with ten time preheated conventional bulk-fill resin composite, **X-tra fill (VOCO, GERMANY)** at 68°C (Yang et al., 2020).

C (Control): Restoration with conventional no heated bulk-fill resin composite, **X-tra fill (VOCO, GERMANY)**

O (Outcome):

Primary outcome: marginal integrity

Secondary outcomes:

Clinical performance of the restoration by Modified US Public Health Service Criteria (USPHS).

T :(Time)

T1= 3 months

T2=6 months

T3=9 months

T2= 12 months

	Outcome	Measuring device	Measuring unit
primary	(marginal integrity) by Modified US Public Health Service Criteria (USPHS)	Modified USPHS Ryge criteria(van Dijken et al., 2019)	Scoring system (Ordinal) : -Alfa -Bravo -Charlie -Delta
secondary	Modified US Public Health Service Criteria (USPHS) Retention, color matching, marginal discoloration, secondary caries, surface texture, anatomic form and postoperative sensitivity	Modified USPHS Ryge criteria(van Dijken et al., 2019)	Scoring system (Ordinal) : -Alfa -Bravo -Charlie -Delta

S: (study design): Randomized controlled clinical trial.

8. Trial design:

Type of trial: four parallel groups

Allocation ratio: 1:1:1:1

Framework: Superiority

III. Methods

A) Participants, interventions & outcomes

9. Study settings:

Patient selection and the procedures will be carried in Conservative clinic at Faculty of Dentistry, Cairo University, Cairo, Egypt.

10. Eligibility criteria:

The participants will be chosen according to the following eligibility criteria:

Inclusion Criteria	Exclusion criteria
<p><u>a)Inclusion Criteria of participants</u> 1-Patient age between (18-60) years old. 2-Patient is capable of informed consent. 3-Patients with a high level of oral hygiene.</p>	<p><u>a)Exclusion criteria of participants</u> 1-Participants with general systematic illness. 2-Experience with allergic reactions against any component of used materials. 3-Concomitant participation in another research study. 4-Patients receiving Orthodontic treatment. 5- Pregnant or lactating females. 6-patient with heavy Bruxism habits.</p>
<p><u>b)Inclusion Criteria of teeth:</u> 1- vital teeth 2-Carious molar teeth.</p>	<p><u>b)Exclusion criteria of the teeth</u> 1-The tooth to be filled is an abutment tooth for a removable prosthesis. 2- The tooth to be filled is periodontally involved (grade 2 or grade 3 mobile). 3-Endodontically treated tooth. 4-tooth with previous restoration 5-Exposed tooth.</p>

11. Interventions

Medical and dental history will be obtained from all patients participating in this research. Clinical and radiographic evaluation for each tooth included in this study will be recorded (Appendix, B).

Control group:

Restoration with no heated bulk fill composite, , **X-tra fill (VOCO, GERMANY)**

Intervention groups :

Restoration with preheated bulk fill composite preheated for one ,five and ten times at 68°C using Therma flo (VISTA APEX,USA)(Yang et al., 2020).

a-Procedures:

- 1-Preoperative periapical x-ray will be taken for the tooth to be restored.
 - 2- The clinical diagnosis of vitality tests will be confirmed by cold and hot tests.
 - 3- Anaesthesia will be given.
 - 4-Isolation of the teeth by rubber dam application
 - 5-cavity preparation will be done with fissured bur with round end (880 Oekodental Germany) of 6mm length and 1.4mm width to the DEJ.
 - 6-Partial caries removal will be done by excavator.
 - 7- Selective etch technique by applying 37% phosphoric acid Eco-etch(IvoclarVivadent) to enamel margins of the cavity for 15 seconds then rinse for 15 seconds.
 - 8- Applying Futura bond M+ (Voco ,Germany) then light curing for 20 seconds using 3M Eliper curing unite.
 - 9-application of bulk fill composite Xtra fill (VOCO ,GERMANY)
- In the control group: application of bulk fill resin composite without preheating.
- In the experimental groups: application of preheated bulk fill resin composite restoration with one-five and ten times according to the group number at 68°C using Therma flo (VISTA APEX,USA)
- Intervention1: one-time preheated
- Intervention 2: five times preheated
- Intervention 3: ten times preheated
- 10-checking the occlusion by using the articulating paper.
 - 11-finishing and polishing.
 - 12-Patient will be return for follow up after 3, 6, 9 and 12 months.

B-Criteria for discontinuing:

If very severe pain exists that can't be relieved and patient can't withstand, the tooth may be endodontically treated or extracted and the patient will be excluded from the study.

C-Strategies to improve adherence:

Phone calls to patients will be done to remember for follow up visits.

12. Outcomes: Modified USPHS Ryge criteria (van Dijken et al., 2019)

Criterion	Code	Definition
Fractures and retention*	A	Restoration retained, no fractures / cracks.
	B	Hairline cracks and/or chipping (not affecting the marginal integrity or proximal contact).
	C	Partial or complete loss of restoration.
Marginal discoloration	A	No marginal discoloration.
	B	Minor marginal discoloration without staining toward pulp, only visible using mirror and operating light.
	C	Deep discoloration with staining toward pulp, visible at a speaking distance of 60-100 cm.
Marginal integrity	A	Restoration adapts closely to the tooth structure, there is no visible crevice.
	B	There is a visible crevice, the explorer will penetrate, without dentin exposure.
	C	The explorer penetrates into crevice in which dentin or the base is exposed.
Surface texture	A	As smooth as the surrounding enamel.
	B	Rougher than surrounding enamel. Improvement by finishing is feasible.
	C	Very rough, could become anti-esthetic and/or retain biofilm. Improvement by finishing is not feasible.
Anatomic form	A	Anatomic form ideal.
	B	Restoration is under-contoured, without dentin or base exposure.
	C	Restoration is under-contoured, with dentin or base exposure. Anatomic form is unsatisfactory. Restoration needs replacement.
Post-operative sensitivity	A	No postoperative sensitivity.
	B	Short-term and tolerable postoperative sensitivity.
	C	Long-term or intolerable postoperative sensitivity. Restoration replacement is necessary.
Secondary caries	A	No active caries present.
	B	Non-cavitated active caries is present in contact with the restoration.
	C	Cavitated active caries is present in contact with the restoration.
Proximal contact*	A	Normal proximal contact, floss can be inserted.
	B	Moderate proximal contact, without damage to tooth, gingiva or periodontal structures, floss can be inserted more easily.
	C	Proximal contact absent, clear damage to tooth, gingiva or periodontal structures.
Radiographic evaluation*	A	No pathology, harmonious transition between restoration and tooth.
	B	Small excess and /or presence of step positive/negative in the margin of the restoration or an adhesive line can be observed.
	C	Marginal gap not adjustable and/or suspicion of secondary caries or fracture of tooth or restoration.

13. Participant timeline

Procedure	Staff Member	Before 1 st visit	1 st visit	3months	6months	9months	12months
Enrolment	MS	√					
Allocation	MS	√					
Cavity preparation	II		√				
Restoration placement	II		√				
outcome assessment	ME,OA			√	√	√	√

14. Sample size:

This power analysis used marginal integrity scores after 12 months as the primary outcome. The effect size $w_1 = (0.53)$ was calculated based upon the results of Tetric N Ceram Bulk fill published by (Alkurdi and Abboud, 2016). The effect sizes $w_2 = (0.7)$, $w_3 = (0.8)$ and $w_4 = (0.9)$ were calculated based upon expert opinion estimating Alpha scores = 85%, 90%, 95% and Bravo scores = 15%, 10% and 5%, respectively. Using alpha (α) level of (5%) and Beta (β) level of (20%) i.e. power = 80%; the minimum estimated sample size was a total of 68 subjects. Sample size was increased to 84 subjects (21 subjects per group) to compensate for a dropout rate of 25%. Sample size calculation was performed using G*Power Version 3.1.9.2

15. Recruitment:

Patients will be recruited by (MM) from the outpatient clinic of conservative dentistry department in Faculty of Dentistry, Cairo University, as there is a high and continuous patient flow from which the eligible participants could be chosen until reaching the target sample size.

B) Assignment of interventions

16. Allocation:

16a. Randomization:

Simple randomization will be made by generating random numbers using Random Sequence Generator, Randomness and Integrity Services Ltd (<https://www.random.org/>) by (MS).

16b. Allocation concealment mechanism:

Patients will choose between random numbers placed in an opaque sealed envelope that will be arranged by (MS), who will not be further involved in any of the phases of the clinical trial. Whether the intervention or the comparator treatment group would be chosen, it will be recorded on a computer by (II). And (HH). and all records will be kept with the main supervisor (MI)

16c. Implementation

(MS) will generate the random allocation sequence. The researcher will enroll the patients, but (MS) will assign the intervention/Control identification procedures to respective teeth.

17. Masking/blinding:

- Participants will be blinded as they won't be told which restoration technique will be used.

- The outcome assessors (ME) (OA) will be blinded to the material used. This will be performed
Therefore it is necessary that the assessors won't be included in the preclinical assessment. will be only allowed to know the number of the participant.

- Data analyst (KK) will be blinded, he will receive data excel sheets with symbols.

C) Data collection, management, and analysis:

18. Data collection methods

18.a.i. Baseline data collection:

For every patient, medical and dental history will be taken. Examination charts will be filled

18.a.ii. Outcome data collection:

Modified USPHS criteria for dental restoration will be evaluated by two assessors (ME& OA) at 3,6,9 and 12months, if both assessors differ in score, they will discuss the outcome, if they did not agree, a third assessor will resolve the conflict. To achieve inter-examiners reliability, at the beginning of the study, the assessors will perform a profound assessment training program by performing repeated assessments of restorations using modified USHPS criteria. The main supervisor (MI) will supervise the training program to ensure that the assessors (ME& OA) will be calibrated before starting their evaluation.

18.b. Patient retention:

A record of patient's phone number will be included in every patient's chart. Phone call will be diverted to each patient in order to remind him/her for the time of his/her visit. If the patient did not reply for any reason, another visit will be scheduled within a week.

19. Data management:

Participant files are to be electronical stored in numerical order and stored in a secure and accessible place and manner with (IM). Participant files will be maintained in storage till completion of the study

20. Statistical methods:

Data will be analyzed using IBM SPSS advanced statistics (Statistical Package for Social Sciences), version 21 (SPSS Inc., Chicago, IL). Numerical data will be described as mean and standard deviation or median and range. Categorical data will be described as numbers and percentages. Data will be explored for normality using Kolmogorov-Smirnov test and Shapiro-Wilk test. Comparisons between two groups for normally distributed numeric variables will be done using the Student's t-test while for non-normally distributed numeric variables will be done by Mann-Whitney test. Comparisons between categorical variables will be performed using the chi square test. Pain over time will be assessed by Friedman test. A p-value less than or equal to 0.05 will be considered statistically significant. All tests will be two tailed.

D) Data monitoring:**21. Monitoring**

The main and co-supervisors (MI, HH) will monitor this study to prevent any risk of bias from trial members also to ensure blinding of the assessors and maintain patient safety and rights

22. Harms

Adverse reaction is low and rarely occurs. Pain will be relieved by analgesics and if very severe pain exists that can't be relieved and patient can't withstand, the tooth may be endodontically treated or extracted.

23. Audit

Auditing will be performed by the evidence based committee, Faculty of dentistry, Cairo University at the beginning and half of the study to confirm that the coordinators are skillful in data entry, the overall quality and completeness of the data. Furthermore, auditing is important to review data that is related to participant enrolment, consent, eligibility and allocation to study groups to confirm that the data is accurate.

IV. Ethics and dissemination

24. Research ethics approval

This protocol has the template of informed consent forms with two languages (Arabic and English) with explanation for the steps of treatment that will be done and harms (Appendix A). This template will be approved by ECs (Ethical Committees) before starting the trial.

25. Protocol amendments

If there are any modifications or adjustments in the protocol, ethical committees will be informed of that and will be reported in the study. Intention to treat analysis will be followed as all patients that are eligible for the trial and have been allocated in the randomization sequence will be treated normally and statistically analyzed. Such amendment will be agreed upon by the council of the department of Evidence Based Dentistry, Faculty of Dentistry, Cairo University.

26. Informed consent

The research operator(II) will introduce the template of informed consent with Arabic language to every patient with detailed explanation about aim, steps, advantage and side effect of the treatment, so every patient will receive information sheets of the trial with Arabic language (Appendix A). The operator will take signed consent from patients who will participate in this trial.

27. Confidentiality

All personal information about participants will be acquired during taking patient history (personal, medical and dental), eligibility screening, and data collection. All information will be stored securely in locked file cabinets in areas with limited access.

28. Declaration of interest

There is no conflict of interest.

29. Access to data

The results of the interventional trial can be verified only by the Project Chief Investigators, who will have direct full access to their own site's complete final data sets.

30. Post-trial care

Patients will be followed up after the restorative work to maintain the oral hygiene measures. When there is any evidence of restoration failure, patients will be treated by immediate restoration replacement by different restorative option to the tooth.

31. Dissemination policy

Patients will be informed after the trial which technique is better than the other. Colleagues in conservative dentistry department Cairo University will be informed of results of the study. Full protocol will be published online in www.clinicaltrials.gov to keep the integrity of the research methods and to avoid repetition.

Thesis will be discussed and defended in front of a professional judgment committee.

The results of this clinical trial will be internationally published.

V. Appendices

32. Informed consent

Appendix A: Informed Consent Model of(REC) Faculty of Dentistry, Cairo University will be used in this study



Application Form

Human Subjects

Clinical Performance of Posterior Restorations of Bulk Fill Resin Composite without Preheating Versus Repeated Preheating for One, Five And Ten times: A Randomized Control Clinical Trial

Master PHD/D others

Full name of the researcher(s): Islam Ibrahim Mohammed

Research objective: This study will be conducted to compare the clinical performance of bulk fill resin Composite without preheating with one, five and ten times preheating bulk fill resin composite in posterior teeth after one year.

Procedure in brief:

*Preoperative steps: The patients will be subjected to full examination and diagnosis using dental charts.

***Operative steps:**

- 1-Preoperative periapical x-ray will be taken for the tooth to be restored.
 - 2- The clinical diagnosis of vitality tests will be confirmed by cold and hot tests.
 - 3- Anaesthesia will be given.
 - 4-Isolation of the teeth by rubber dam application
 - 5-cavity preparation will be done with fissured bur with round end (880 Oekodental Germany) of 6mm length and 1.4mm width to the DEJ.
 - 6-Partial caries removal will be done by excavator.
 - 7- Selective etch technique by applying 37% phosphoric acid Eco-etch(Ivoclar Vivadent) to enamel margins of the cavity for 15 seconds then rinse for 15 seconds.
 - 8- Applying Futura bond M+ (Voco ,Germany) then light curing for 20 seconds using 3M Eliper curing unite.
 - 9-application of bulk fill composite Xtra fill (VOCO ,GERMANY)
- In the control group: application of bulk fill resin composite without preheating.
In the experimental groups: application of preheated bulk fill resin composite restoration with one-five and ten times according to the group number at 68°C using Therma flo (VISTA APEX,USA)
- Intervention1: one-time preheated
Intervention 2: five times preheated
Intervention 3: ten times preheated



- 10-checking the occlusion by using the articulating paper.
- 11-finishing and polishing.
- 12-Patient will be return for follow up after 3, 6, 9 and 12 months.

Number of visits & follow up period: restoration will be evaluated at 3,6,9 and 12 months

Direct benefit of the research to the human volunteer :Decrease the postoperative sensitivity of resin composite restorations

Scientific value and social benefits: assess the clinical performance of posterior restorations of bulk fill resin composite without preheating with repeated preheating for one ,five and ten times. The expected benefit is to decrease postoperative sensitivity and evaluate clinical performance of posterior teeth restorations after one year.

Expected risk to the human subjects: the ordinary side effects associated with any restorative treatment and no of the study variable has side effect on the patient and in case of any side effect due to the restorative treatment, the participant will directly contact the operator.

Signature: Islam Ibarhim Mohammed

20	3	22
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Appendix B : Diagnostic form to be completed for each patient

Diagnostic sheet

I- Personal Data:

Name:

Gender:

Age:

Marital status:

Occupation:

Address:

Phone number:

II- Chief Complaint:

.....
.....

Character of Pain:

- Nature:
- Onset:
- Duration:
- Location:
- Initiated by:
- Relieved by:

III - Medical History:

- Diseases:
- Medications:

IV- Dental History:

V- Clinical Examination:



VI-Final Diagnosis:

33.Statement of originality

Up to present no randomized clinical trials were conducted to evaluate the effect of repeated preheating of conventional bulk-fill resin composite in posterior restorations.

VI. References

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