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Clinical Research

36-Month Randomized Clinical Trial Evaluation of Preheated and Room Temperature Resin Composite

AA Elkaffas • RI Eltoukhy • SA Elnegoly • SH Mahmoud

Clinical Relevance

The results of this study confirmed that clinicians can consider using preheated composites in dental practices. The study also found evidence of better clinical performance regarding marginal staining when applying preheated composites. Considering that postoperative sensitivity was reduced over time, its use in routine care can be considered a good practice.

SUMMARY

Objective: This study evaluated the effect of preheating resin composites (RCs) on the clinical performance of class I restorations during a 36-month period using a split-mouth, double-blinded randomized design.

Methods and Materials: A total of 35 patients were selected. Every patient received one pair of class I nanofilled resin composite (RC, Filtek Z350 XT) posterior restorations (n=70). One side of the mouth received preheated composites; on the other side, the composite was placed in a nonheated state following the manufacturer's instructions. These restorations were evaluated at 1-week (baseline), 12-months, 24-months, and 36-months using the FDI World Dental Federation criteria. The statistical analyses were also performed using the Wilcoxon and Friedman tests with the level of significance set at 0.05.

Results: After 36 months, 33 patients attended the recall visits, and 66 restorations were evaluated. The Friedman and Wilcoxon signed-rank tests revealed insignificant differences between both groups (p>0.05) for all FDI parameters. However, a significant difference was detected for staining as a criterion at 36 months (p=0.01). Moreover, a significant difference in the staining was detected when the baseline and 36 months were compared

Ali A Elkaffas, Dr, clinical assistant professor, Operative Dentistry Department, Faculty of Dentistry, Mansoura University, Mansoura Aldakhlia, Egypt

Radwa I Eltoukhy, Dr, clinical assistant professor, Operative Dentistry Department, Faculty of Dentistry, Mansoura University, Mansoura, Aldakhlia, Egypt

Salwa A Elnegoly, professor and chairman of Dental Biomaterial, Faculty of Dentistry, Mansoura, Aldakhlia, Egypt

*Salah H Mahmoud, clinical professor and chairman of Operative Dentistry Department, Faculty of Dentistry, Mansoura University, Mansoura, Aldakhlia, Egypt

*Corresponding author: Algomhoria Street, Mansoura, Aldakhlia, Egypt PO Box 35516; e-mail: Salahmahmoud2010@yahoo.com

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in the nonheated RC group (p=0.001). For esthetic, functional, and biological properties, the nonheated composite exhibited 93.9%, 100%, and 100% of the clinically accepted scores, respectively, and the preheated group presented 100% for all properties. Four restorations had postoperative sensitivity at baseline for nonheated (11.4%) and five for preheated (14.2%), but the postoperative sensitivity scores were considered highly acceptable at 12-, 24-, and 36-months.

Conclusions: After 36 months, preheated nanofilled RCs showed an acceptable clinical performance similar to that of the nonheated ones in class I restorations, but with better resistance to marginal staining.

INTRODUCTION

Composite materials, with their excellent mechanical and esthetic properties, have been successfully utilized for many years as dental restorative materials.[1] Preheating resin composites (RCs) has a crucial effect on the polymerization of multifunctional monomers, which are the prime components of methacrylate-based restorative materials.[2] Furthermore, the mobility of free radicals and monomers is enhanced by increasing the polymerization temperature, and a higher overall conversion thus occurs, which, in turn, leads to improved mechanical, physical, and surface properties of preheated RCs.[3]

Composition and microstructure are accountable for the mechanical properties of RCs.[4] Adequate clinical performances together with the enhanced mechanical properties of RCs have also made them more suitable for posterior restorations.[5] Hence, practitioners might consider preheating RCs for increasing handling characteristics, with the expectation that mechanical properties will be improved.[6]

Laboratory research suggests that preheating RCs before placement can have significant clinical advantages,[7] such as improved rheological properties and reduced film thickness,[8] enhanced adaptation and reduced microleakage,[9] greater monomer conversion during polymerization,[7,10,11] reduced curing time,[7] increased hardness,[9,12] and enough flowability to lute porcelain laminate veneers.[13] Despite these improved properties, the technique of preheating RCs is not widely accepted. One possible reason for the reluctance of dental clinicians to use preheated RCs is the lack of sufficient clinical evidence when using this technique. Thus, the rationale behind this study was to prove whether or not a preheating procedure provides more advantages regarding clinical situations.[14]

The preliminary assessment of any restorative material is conducted using laboratory investigations, but clinical studies are more important in evaluating its performance.[15,16] Thus, several variables (mastication forces, temperature fluctuations, humidity variations, and salivary enzymes) could influence the overall performance of a restorative material.[17] The majority of studies performed on preheated RCs are laboratory ones demonstrating improved properties when dental RCs are preheated.[18-21] These improved rheological properties, increased hardness, improved adaptation, and reduced microleakage may or may not reduce postoperative sensitivity. Hitherto, a review of the literature has revealed that there is only one reported randomized controlled clinical trial of postoperative sensitivity to evaluate the clinical performance of preheated RCs.[14]

Thus, the present study was designed to provide further evidence in this particular research perspective, and this study aimed to evaluate the effect of preheating RCs on the clinical performance of class I restorations in a 36-month period. The formulated null hypothesis was that there is no significant difference in the clinical performance of preheated RCs in comparison with nonheated RCs in a 36-months period in class I restorations.

The research question was as follows: Do preheated RCs in class I restorations present better clinical performances than nonheated RCs according to the FDI World Dental Federation criteria?

METHODS AND MATERIALS

Restorative Materials and Curing Device

A nanofilled RC restorative system (Filtek Z350 XT) with Single Bond Universal adhesive (3M ESPE, St Paul, MN, USA) was utilized in the present study and applied according to the manufacturer's instructions. Table 1 presents its specifications. A light curing unit (LED Bluephase C5, Ivoclar, Vivadent, Amherst, NY, USA) with an output density of 655 mW/cm^2 was applied. The intensity of the light curing unit was measured periodically using Demetron LED light meters (Demetron Research Corp, Danbury, CT, USA).

Study Design

The description of the experimental design followed the Consolidated Standards of Reporting Trials statement.[22] The present study was a double-blind (patients and examiner) randomized clinical trial anticipating the split-mouth design.

Table 1: *Restorative Materials and Application Procedures According to the Manufacturer's Instructions*

Restorative System	Manufacturer	Composition	Lot Number	Application Procedure
Filtek Z350 XT	3M ESPE, St Paul, MN, USA	Treated silanized ceramics; silane- treated silica; urethane dimethacrylate; bisphenol A polyethylene glycol diether dimethacrylate; bisphenol A-glycidyl methacrylate; ceramics of zirconia; polyethylene glycol; dimethacrylate; triethylene glycol; and dimethacrylate	N625490	Resin composite applied incrementally up to two increments and each increment was photopolymerized individually
Single Bond universal Adhesive	3M ESPE, St Paul, MN, USA	Methacryloyloxydecyl dihydrogen phosphate; phosphate monomer; dimethacrylate resins; hydroxyethyl methacrylate; methacrylate-modified polyalkenoic acid copolymer; filler; ethanol; water; initiators; silane	517577	Adhesive was applied using etch-and-rinse strategy. Total etching with 36% phosphoric acid (enamel 30 s, dentin 15 s) followed by rinsing with water for 20 s and drying with air free of moisture and oil, without drying out for 5 s. Adhesive application to tooth surface by scrubbing action (20 s), drying of the adhesive (5 s), and light curing (10 s)

Patient Selection

Thirty-five adult patients seeking dental treatment in the Operative Department Clinic at the Faculty of Dentistry, University of Mansoura were enrolled in the present study with a total of 70 class I restorations. No advertisement was made for participant recruitment, forming a sample of convenience. Additionally, each patient signed a consent form before participating in the present study. The study was conducted from October 2017 to June 2020 as a part of a doctoral dissertation, and the trial was registered by ClinicalTrials.gov. No protocol deviations emerged during the trial.

Sample Size Calculation

The sample size was calculated on the basis of the clinical success rate (100% retention rate in 36-months) of posterior class I restorations restored with nanofilled composites observed in a previous study.[23] According to several parameters, including a significance level of 5%, the power of the test was calculated to be 80% and the equivalent limit to be 15%. Based on these data, a sample size of 30 subjects was appropriate, and allowing for a 20% drop-out, a sample size with a total of 35 subjects was set.

Eligibility Criteria

The inclusion criteria included the presence of primary caries involving occlusal surfaces only and International Caries Detection and Assessment System (ICDAS) 2 or 3 with cavities no more than one-third of the intercuspal distance. No third molars were selected. Patients needed to have good oral hygiene; the selected tooth needed to give a positive response to testing with an electric pulp tester and with normal and full occlusion, having opposing natural teeth with no restorations. High caries risk patients with extremely poor oral hygiene and patients involved in orthodontic treatment or periodontal surgery, and periodontally involved teeth (chronic periodontitis) and abutments were excluded. Moreover, patients with heavy bruxism habits, clenching, and evidence of wear facets on teeth were excluded. Tables 2 and 3 exhibit the data regarding the characteristics of patients and restored cavities.

Random Sequence Generation and Allocation Concealment

Each patient received one pair of class I posterior restorations, a preheated and a nonheated RC

Table 2: *Number of Lesions According to Sex and Age of Patients*

Characteristics of Patients	Number of Lesions
Sex	
Female	19
Male	14
Age, y	
20-25	20
25-30	8
30-35	5

Table 3: *Characteristics of Restored Cavities*

Characteristics of Restored Tooth	Number of Lesions	
	Nonheated	Preheated
Teeth distribution		
Premolars	12	13
Molars	23	22
Dental arch distribution		
Upper	15	12
Lower	20	23
Pulp protection		
Yes	0	0
No	35	35
Presence of antagonist		
Yes	35	35
No	0	0
Width		
Small	10	8
Medium	16	19
Large	9	8
Depth		
Shallow	2	3
Medium	33	32
Deep	0	0
Reason for restoration		
Fracture	2	1
Caries	26	29
Caries and fracture	2	0
Esthetics	5	5

restoration, each in different sides of the mouth (split-mouth design). Hence, they were placed randomly in the two cavities of each pair (35 pairs) and determined by using online software (www.sealedenvelope.com). A blocked list was generated, and a randomization code was performed according to two treatment possibilities (preheated and nonheated). The cavities within the pair were also chosen to match each other concerning size and localization. However, the patients remained blind to the allocation at all times. A staff member not involved in the clinical trial prepared the envelopes.

Clinical Procedures

One experienced operator prepared, restored, and finished 70 class I nanofilled Filtek Z350 XT RC restorations either preheated or nonheated, and the adhesive cavity design was utilized. Initially, the patients were given local anesthesia with 1.8 mL of 2% lidocaine hydrochloride and phenylephrine 1:2500 (SS White 100, SS White, Petropolis, Brazil) before the restorative procedures to reduce discomfort. Fissure carbide burs and round diamond stones (Komet, Brasseler GmbH Co. KG, Lemgo, Germany) were utilized to prepare cavities at a high speed with copious water cooling followed by excavation of remaining caries using tungsten carbide burs (Komet, Brasseler GmbH Co. KG) at a low speed and sharp excavators. After the shade selection, a rubber dam with high suctioning was also utilized to isolate the operative field. The enamel was selectively etched with 36% phosphoric acid gel (Scotchbond Etchant, 3M ESPE, St Paul, MN, USA) for 30 seconds while the dentin was etched for 15 seconds. The preparation was then thoroughly rinsed for 20 seconds and gently air dried. A disposable brush was used to apply the adhesive by a scrubbing action for 20 seconds followed by gently air drying for 3-5 seconds and then light cured using a light curing unit for 10 seconds.

A device called Therma-flo RC warming kit (Vista, WI, USA) was applied for the heating of RCs according to the manufacturer's instructions. The warming device was operated for 30 minutes until it reached 68°C, and then the syringe tube was placed inside a heating chamber for 5 minutes to reach the temperature of the warming device. The syringe was then removed from the device, and the RCs were applied immediately using gold-plated instruments. The teeth were restored incrementally up to two increments in the form of oblique layers, with each increment being up to 2 mm. Consequently, each increment was light cured for 25 seconds, and the restorations were finished and contoured at the same visit using low-speed fine-grit diamond finishing stones (Komet, Brasseler GmbH Co. KG) and copious

amounts of water as a coolant. Furthermore, the occlusal morphology was established using articulating paper (Bausch, Nashua, NH, USA). The polishing procedures were performed immediately using Soflex discs (3M ESPE) in a recommended order (coarse, medium, fine, and superfine) with water coolant to obtain a smooth surface.

Calibration Procedures for Clinical Evaluation

In October 2017, two examiners who did not participate in the placement of the restorations were trained for the evaluation process using an online calibration tool (www.e-calib.info). An inter-examiner and intra-examiner agreement before the beginning of the evaluation of at least 90% was requested.[24]

Blinding

The examiners not involved in the placement of restorations and the participants were both blinded to the intervention; hence, this study was categorized as a double-blind study.

Clinical Evaluation

All the restorations were evaluated clinically two weeks after finishing and polishing procedures (baseline) and after 12-, 24-, and 36-months using the World Dental Federation FDI criteria.[25] The clinical intraoral photographs were taken at all recall periods, and the standardized case report for each patient was applied to record the FDI parameters during the evaluation procedures. After each observation, the case report forms were sent to the research staff to ensure that all the evaluators were blinded to the group assignment along with the follow-up recall visits.

Only the clinically relevant measures of the performances for RCs in class I restorations were evaluated. The primary clinical endpoints were marginal adaptation, surface and marginal staining, restoration retention, and fractures, but the following secondary outcomes were also evaluated: surface luster, color match, postoperative sensitivity, tooth integrity, patient's view, and recurrence of caries. The parameters that required clinical visibility were evaluated using a magnifying dental loupe with a magnification of 4.3× and a working distance of 40 cm (EyeMag Pro F, Carl Ziess Meditec Ag, Germany) with a powerful illumination intensity from a light source attached to the loupe (EyeMag Light II, Carl Ziess Meditec Ag). The primary and secondary clinical endpoints were also ranked using the following scores according to the FDI criteria: (clinically very good, clinically good, clinically satisfactory, clinically unsatisfactory, and clinically poor).

Statistical Analysis

The statistical package program (IBM-SPSS version 26.0, IBM, Armonk, NY, USA) was utilized for the tabulation, coding, and analysis of the data. Descriptive statistics were also applied to describe the evaluated data distributions. Additionally, the Friedman test was used for intragroup comparisons between the baseline and other periods, whereas the Wilcoxon signed-rank test was utilized to compare both groups in each period. The comparisons were also performed for all the criteria evaluated with a significance level of 5%, and the Cohen kappa statistic was used to measure the agreement between the examiners.

RESULTS

All the restorative procedures were implemented exactly as planned, and no further modifications were performed. Recall rates were 100% for baseline, 12, and 24 months. At 36-months, the recall rate was 94.3%; two patients did not attend due to health problems. Table 4 shows the clinical scores according to the FDI evaluation criteria. Regarding the agreement between the examiners, the overall Cohen κ statistics revealed a satisfactory agreement between all the examiners at baseline (0.94), 12-months (0.95), 24-months (0.96), and 36-months (0.93). Staining (marginal and surface) was detected in three restorations in the nonheated group (9.6%) and marked staining was observed in two restorations in the same group (6.5%). Therefore, staining showed a significant difference between the nonheated RC and preheated RC groups (p=0.01). Additionally, a significant difference in staining was detected when the 1-week (baseline) and 36-month time point were compared in the nonheated RC group (p=0.001). Four restorations had postoperative sensitivity at baseline for the nonheated group (11.4%) and five for the preheated group (14.2%), but the postoperative sensitivity scores were considered highly acceptable at the 12-, 24-, and 36-month evaluation periods. Generally, the Friedman and Wilcoxon signed-rank tests revealed insignificant differences between the preheated and nonheated RC groups (p>0.05) for all the FDI parameters except that a significant difference was detected for the staining criterion at 36-months. For esthetic, functional, and biological properties, the nonheated composite revealed 93.9%, 100%, and 100% of the clinically accepted scores, and the preheated group presented 100% clinically accepted scores for all the properties.

DISCUSSION

Studying the preheating effect on the mechanical properties of nanofilled RCs in class I restorations

Table 4: *Summary of FDI Clinical Criteria Findings of Nonheated and Preheated Filtek Z350 XT RC over a 36-Month Follow-up Period*

Esthetic Properties	Nonheated Z350 XT					Preheated Z350XT			
	Score	Baseline	12-M	24-M	36-M	Baseline	12-M	24-M	36-M
Surface luster	1	35	30	25	22	35	29	24	21
	2	0	5	10	11	0	6	11	12
Staining									
Surface	1	35	34	33	24	35	35	35	32
	2	0	1	2	4	0	0	0	1
	3	0	0	0	3	0	0	0	0
	4	0	0	0	2	0	0	0	0
Marginal	1	35	34	33	23	35	35	35	32
	2	0	1	2	5	0	0	0	1
	3	0	0	0	3	0	0	0	0
	4	0	0	0	2	0	0	0	0
Color match and translucency	1	30	30	29	26	30	30	29	26
	2	5	5	6	7	5	5	6	7
Functional properties									
Marginal adaptation	1	35	35	35	32	35	35	35	32
	2	0	0	0	1	0	0	0	1
Biological properties									
Postoperative (hypersensitivity) and tooth vitality	1	31	35	35	32	30	35	35	32
	2	2	0	0	1	3	0	0	1
	3	2	0	0	0	2	0	0	0

Abbreviations: 1, clinically very good; 2, clinically good; 3, clinically satisfactory; 4, clinically unsatisfactory.

provides valuable information to clinicians to promote using RCs in a more flowable form. The class I restorations were selected to easily standardize the cavity dimensions and C-factors. Hence, in a clinical situation, the viscosity of RCs is reduced upon preheating, offering a more flowable state that can be injected into cavity preparations rather than using conventional hand instruments for RC manipulation.[26] Thus, a warm RC technique guarantees better handling properties, gaining the advantages of the outstanding mechanical, wear, and surface properties of nanofilled RCs.[27]

The authors[28] reported a 50% drop in temperature within two minutes in the RC samples upon the removal from the heating device. Hence, the authors suggested that clinicians must work very quickly to ensure the least temperature drop possible when using a heating device for the best clinical performance.[28] Stabilizing the temperature until the light curing process is thus of ultimate importance. Consequently, the RC temperature was strictly standardized in the present study, as the insertion time to the mold or cavity preparation was 40 seconds and the curing time was 25 seconds but the overall 65 seconds may have reduced the RC temperature.

Several *in vitro* studies have demonstrated the possibility of preheating to enhance the physical and mechanical properties of RCs.[29] However, the data regarding the clinical performance of preheated RCs compared with nonheated RCs are scarce; thus, the present study is of interest. Multiple factors affect the oral environment as temperature changes, such as bacterial flora, pH alterations, and occlusal stresses. These factors differ from patient to patient, which makes reproducing oral physiology profoundly difficult. Thus, the present study anticipated the split-mouth design. Although *in vitro* studies may give useful information regarding the physical and mechanical properties of restorative materials, they still cannot estimate the clinical handling properties or the clinical

performance of restorative materials. Subsequently, the clinical oral environment is considered the most useful way to assess restorative techniques and restorative dental materials.[30] The clinical evaluation process requires reliable, relevant, and objective criteria for assessing the clinical performance of restorative materials precisely.[25] Hence, the FDI clinical evaluation criteria were chosen.[25]

A significant difference was found between nonheated and preheated RCs at the 36-month recall period regarding marginal staining, where preheated RCs performed better. This could be attributed to the increased flowability of RCs upon preheating, enhancing marginal adaptation. These findings were confirmed by the results of Wagner and others, who concluded that the preheating procedure reduced microleakage and improved the adaptation of RC restoration to tooth structure.[31] Additionally, Yang and others proved that preheated RCs at 50°C for class I cavity preparations showed no microleakage at the tooth restoration interface, whereas nonheated RCs showed minor microleakage detected at occlusal margins.[32]

These findings also agree with Loguercio and others, who revealed 11% marginal staining in subjects after a 3-year follow-up when restored with nanofilled RCs using Single Bond Universal (3M ESPE) adhesives in the etch-and-rinse mode.[33] Yazici and others proved that a high incidence of marginal staining (14%) was evident in nanofilled RCs after a 3-year follow-up period when used in class I restorations.[23]

Regarding postoperative sensitivity, the majority of the cases scored 1 in relation to postoperative sensitivity. Thus, no difference was found between nonheated and preheated RCs, but significant differences were found regarding postoperative sensitivity over time in both groups.

These findings are in agreement with Campbell and others as they concluded that there is no detectable difference regarding postoperative sensitivity between room temperature and preheated RC restorations. That study also proved that when teeth were restored with RCs, postoperative sensitivity was significantly reduced from 24 hours after placement to that recorded after two weeks and that recorded one month later.[14] Additionally, these findings agree with Zanatta and others, who revealed 8.5% postoperative sensitivity in subjects at the baseline when restored with nanofilled RCs using Single Bond Universal adhesive in the etch-and-rinse mode.[34]

Moreover, these results observed postoperative sensitivity over a 36-month period and proved the significant decline of postoperative sensitivity over the whole review period as concluded by previous studies.[23,33,34] These secondary outcomes validate the sensitivity of the protocol used in the present study. Furthermore, a comprehensive literature review confirmed that this is the first attempt to measure postoperative sensitivity clinically using preheated RCs over a 36-month period.

Clinical data on the effect of the heating of RCs on the clinical performance of class I restorations are lacking, making comparison of our study results difficult. Thus, further studies are required to confirm our findings. In a literature review, one clinical trial evaluated the effect of composite preheating on postoperative sensitivity for 1 month.[14] Our study verified that there were no significant differences between the nonheated and preheated RCs for all the parameters, except for marginal staining. Hence, the null hypothesis stating that there is no significant difference in the clinical performance of preheated RCs in comparison with nonheated RCs for a 36-month follow-up period in class I restorations was partially rejected. One of the major limitations of this clinical investigation is that 36 months could be a short period for observing substantial changes. Thus, a long-term clinical evaluation may be able to better assess the effect of preheating nanofilled RCs.

CONCLUSIONS

After 36 months, the preheated nanofilled RCs showed acceptable clinical performance similar to that of the nonheated resin in class I restorations with better resistance to marginal staining.

Regulatory Statement

This study was conducted in accordance with all the provisions of the human subjects oversight committee guidelines and polices of the ethical committee of Mansoura University. The approval code issued for this study is A1810022136.MCEPRCRCL.

Conflict of Interest

The authors do not have any financial interests in the companies whose materials are included in this article.

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