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Temperature change of the pulpal floor and restoration with preheated bis-GMA free and containing resin composite (a randomized clinical trial)

AlShimaa Nasser^{1*}, Nermin A. Mahmoud² and Mona I. Riad³

Abstract

Background: Preheating is one of several innovative approaches and improvements developed to increase the durability and clinical behavior of resin composites. Development of preheated composites is to reduce its viscosity in order to improve resin composite adaptation and placement ease. The purpose of this clinical trial was to study the effect of preheating Bis-GMA free and Bis-GMA-containing resin composites at different temperatures on the pulpal floor and restoration temperature. A total of twenty individuals (N = 40) have two carious posterior teeth that need to be restored were randomly assigned to one of two groups based on the type of restorative materials used: (group 1) Bis-GMA-containing resin composite VisCalor bulk (VCB), and (group 2) Bis-GMA-free resin composite Admira Fusion x-tra (AFX). Preheating temperatures of 50 °C and 70 °C were utilized to separate each group into two subgroups. Class I or II cavities were prepared. Thermometer device with two separate K-type temperature probes was used to measure the base line temperature values at the pulpal floor before beginning the restorative procedure (C_0), pulpal floor during packing of preheated composite (C_1), the top composite surface after packing and before curing (C_2), pulpal floor after curing of the preheated composite (C_3), and top composite surface after curing (C_4). One-way ANOVA and the Kruskal–Wallis test were used to analyze the data.

Results: The measured temperature of pulpal floor for both preheated VCB or AFX at 50 °C or 70 °C revealed significant increasing from base line measured temperature to during packing as well as after curing with (P-value < 0.001). There was no significant difference for mean composite surface temperature for both preheated materials at 50 °C or 70 °C whether before or after curing.

Conclusions: Preheating of bulk fill Bis-GMA free and containing resin composite rises both the pulpal floor and the restoration temperature; meanwhile, the rise in temperature was limited. The application of the curing unit caused the greatest temperature rise.

¹ Department of Operative Dentistry, Faculty of Dentistry, Nahda University, New Bani Suef city 62521, Bani Suef Government, Egypt Full list of author information is available at the end of the article *Clinical Relevance* The preheating of bulk fill resin composite at 50 °C and 70 °C prior to curing yielded a limited rise in both pulpal floor of posterior cavities and on resin composite restorations. Preheating of Bis-GMA-free resin composite is recommended, as it reduces the temperature rise with the benefit of lowering the viscosity.



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Keywords: Preheating, Bulk-fill composite, Bis-GMA-free resin composite, Pulpal floor temperature, Restoration temperature

Background

Resin-based composites (RBCs) have become the most widely used materials for direct tooth restoration, owing to their superior esthetic properties as compared to alternative traditionally used materials, as well as significant improvements in physical and mechanical capabilities (Devoto et al. 2010). Polymerization shrinkage, postoperative sensitivity, inadequate proximal contact, limited wear resistance, and a lack of proper adaptability in specific clinical settings are all issues that resin composites face (Mohammadi et al. 2016). Bisphenol-A glycidyl methacrylate (Bis-GMA) is the most widely used monomer in dental composites, sealants, and cements. Because Bis-GMA has a higher viscosity than other dimethacrylates, this causes low degree of conversion (DC). Highly filled RBCs have a high viscosity, which might cause a lack of adaptation to prepared cavity, poor marginal integrity, and eventual restoration failure. Reducing resin composite viscosity is the ways to improve restoration adaptability to the cavity (Yang et al. 2019). As a countermeasure, Bis-GMA substitutional monomer component have been developed to enhance longevity and biocompatibility. One possibility is to use an Ormocer-based dental composite material (Organic Modified Ceramic), which is made up of inorganic-organic co-polymers (Kalra et al. 2012). The first motivation for the development of preheated composite is to reduce its viscosity to improve handling properties, better flowability, marginal adaptation, and reduce microleakage (Clelland et al. 2005). Preheating high viscosity bulk fill composites could be a promising approach to achieve a momentary viscosity lowering close to that of a flowable composite while maintaining the mechanical properties benefits of highly filled resin composites (Alshali et al. 2015). VisCalor bulk fill resin composite created especially for preheating and have improved handling properties (Lopes et al. 2020). When a preheated composite is placed directly into a prepared cavity, the heat from the restoration may pass to the prepared dentin surface, potentially elevating intrapulpal temperature and putting the tissue's health at risk (Whalen and Bouschlicher 2003).

Therefore, it seems valuable to evaluate clinically the effect of preheating Bis-GMA-free resin composite at different temperatures and compare it with Bis-GMA-containing resin composite on pulpal floor temperature with preheated composite. The null hypothesis tested in the current study was that the pulpal floor temperature with

preheated bulk fill Bis-GMA-free resin composite was similar to that of Bis-GMA-containing resin composite.

Methods

Ethical regulation

This study was reviewed and approved by the IRBs/ECs [institutional review boards/ethical committees] in the Faculty of Dentistry-Minia University with serial no. (490), and also registered and approved on (www. Clinicaltrials.gov) with trial number: (NCT05140447). Patients had to sign a documented informed consent form outlining the study's objectives. Moreover, the study adheres to CONSORT guidelines.

Study design, randomization and allocation

This study was four-armed, parallel-design randomized clinical trial and was conducted in the clinic of Operative Dentistry Department, Faculty of Dentistry, Minia University, Egypt. All volunteers who gave consent for participation and fulfilled the eligibility criteria were randomized. Twenty patients were selected; each patient has 2 carious posterior teeth which were restored with the same type of resin composite with two different heating temperature of resin composite in each tooth. The total sample size was forty teeth (N=40). Randomization was carried out via computer sequence generation (www.random.org) and was used to provide a sequence for groups A and B with randomized participant numbers (10 numbers in each group). When they were observed consent, each patient was given a number from a series of consecutively numbered dark sealed envelopes. The allocation sequence was generated by one contributor other than the operator. The researcher was responsible for all activities associated with the research. Blinding of the operator was not possible; because the tested materials were supplied in two forms syringe and compules. The operator was blinded until randomization into two groups to avoid bias regarding the application of resin composite to which molar. Patients were assigned to one of two groups based on the type of restorative materials utilized (A): group (A1) was restored by Bis-GMA-containing resin composite VisCalor bulk (VCB), and group(A2) was restored by Bis-GMA-free resin composite Admira Fusion x-tra (AFX) (Table 1). According to the preheating temperatures used, each group was split into two subgroups, each with ten teeth (T): The first subgroup (T1) was preheated at 50° C, and the second subgroup (T2) was preheated at 70 °C.

Table 1 Materials, specification, composition, manufacturers, and batch number

Material	Specification	Composition	Manufacturer	Batch number
VisCalor bulk	Thermoviscous bulk-fill (Nano-hybrid composite) (Universal shade)	Matrix: Bis-GMA (Bis-GMA: Bisphenol A glycidyl methacrylate), aliphatic dimethacrylate Filler: Inorganic filler Filler content%: 83 (w/w)	VOCO, Cuxhaven, Germany service@voco.de	2046140
Admira Fusion x-tra	Nano-hybrid ORMOCER® (organically modified ceram- ics) bulk-fill composite (Uni- versal shade)	Matrix: ORMOCER® Filler: glass ceramics, silica nanoparticles, pigments Filler content%: 84 (w/w)		1942580
Futurabond M+	Universal adhesive system (All in one)	HEMA (2-Hydroxyethyl methacrylate)		1929088
Meta Etch	Etchant agent	37% phosphoric acid etching gel	Meta Biomed, Korea dental@meta-biomed.com	MET1906071

Sample size calculation

Pulpal floor temperature was used as the primary outcome, while composite surface temperature was used as the secondary outcome in this power analysis. A pilot study was conducted on three patients in each group, and results of the pilot study were used for sample size calculation. Based upon the results of the pilot study, the effect size (f) for repeated-measures ANOVA design was 0.6. 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 20 patients. Sample size calculation was performed using G*Power version 3.1.9.2.

Patients selection

A random sample was selected among population treated in the Clinic of Operative Dentistry Department, Faculty of Dentistry, Minia University. This clinical trial was performed from April 2021 to September 2021. All restorative procedure and all temperature measurement was taken immediately in a single visit as this test has no follow-up periods. The patients were selected according to the following exclusion and inclusion criteria:

Inclusion criteria of participants

Healthy men and women between the ages of 25 and 45 with proper oral hygiene.

In the preoperative radiograph, at least two posterior class I carious lesions away from the pulp,

there was no preoperative pain, and the teeth were in normal occlusion.

Before being enrolled, all patients had to sign a written consent form, and there was a decent possibility of recall.

Exclusion criteria of participants

Patient with severe periodontitis or severe erosion damage.

patients with a preexisting medical condition or who had had therapeutic irradiation to the head and neck

If the patient used analgesics or antibiotics during the last 12 h before operation, it could affect their pain perception.

Patients with bruxism, clenching, or non-carious lesions such as attrition, erosion, abrasion, or abfraction.

More mobility than grade I.

Immature teeth or non-restorable teeth.

Periodontal pathosis.

External or internal root resorption can be seen on radiographs.

Alcoholic and smoker patients.

Pregnancy.

Physical disabilities.

Patients were unable to return for a recall appointment.

Cavity preparation

The subject was anesthetized by (Mepecaine-L: Mepevacaine 31.36 mg/1.8 ml). Rubber dam was applied; then the cavities were prepared by carbide bur No. 245 (Blue white carbide bur, Kerr, Switzerland) mounted in a high-speed handpiece (NSK panaflir FX, Japan) with copious air water spray. Caries removal was done using large round bur (Mani, Germany) operated in low-speed handpiece (NSK low speed handpiece, Japan), and excavation of soft caries was done using large spoon excavator (Excavator double ended. Dentsply, maillefer, lot: 1548935, Switzerland) in a sweeping motion. A periodontal probe was used to measure the pulpal floor depth, which ranged from 3 to 4 mm. X-ray was taken after cavity preparation.

Restorative procedure

The 37 percent phosphoric acid etching gel was placed for 15 s to the prepared cavity tooth enamel only (selective etching), washed with water for 15 s, and then gently air-dried for 5 s to leave the cavity almost moist. Bonding procedure (Futurabond M+, Voco, Cuxhaven, Germany) (Table 1) was done according to the manufacturer's instructions. Temperature values were recorded in Celsius (°C) and measured by two separate K-type thermocouple temperature probes attached to a portable mini-type digital thermometer device (UNI-T Mini Type K/J Dual Input Thermometer, UT320D, P/N: 110401106698X, China) (Fig. 1). The device used in industrial application; petroleum, chemical, steel, paper, thermoelectricity, nuclear power and other



Fig. 1 K-type temperature probe and thermometer device

production industries and not specified in dental uses. This device can be adjusted in one of three different moods to record the temperature: minimum, maximum, and average, and this helps to measure the temperature at specific point without being affected by a decrease in temperature over time. In the present study, the maximum mood was used. Modification added to the first probe by isolating its end with a shrinkable plastic tube (Fig. 2) and left its tip to be the only part of the probe touching the pulpal floor. This heat shrink tube is adjusted to the probe after cutting it into the required length from a continuous tube and then subjected to the heat from the dental torch and confirmed that the heat shrink is in tight contact with the probe.

The first probe was placed at the pulpal floor to measure: (C_0) : pulpal floor temperature before beginning the restorative procedure, (C₁) pulpal floor temperature during placement of preheated composite, and (C_3) : pulpal floor temperature after curing of the preheated composite. The second probe was placed at the top surface of the preheated resin composite to measure (C_2) : top composite surface after packing and before curing and (C₄): top composite surface after curing. The syringe of AFX adjusted into the composite heater (ceramic one input voltage 220v, output voltage 12v, power 24w, china) while the compule of VCB loaded in the dispenser gun then placed into the heater. Both materials preheated for 15 min (Lopes et al. 2020) in the composite heater. The resin composite was packed into the prepared cavity while the isolated probe resting on the pulpal floor, C_1 and C_2 temperature values, was recorded and then composite cured for 10 s for VCB and 20 s for AFX according to the manufacturer's instructions by light-curing unit (LCU) with intensity of (1000 mw/cm²). C₃ and C₄ recorded after curing and then the probe was removed and the empty space from the probe was filled with resin composite then cured.

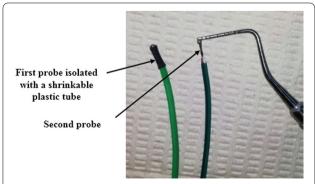


Fig. 2 Two separate K-type thermocouple probe one of them was isolated with heat shrinkable plastic tube

Rubber dam was removed, and the restorations were finished and polished.

Statistical analysis

The data were analyzed in several stages. To begin, descriptive statistics for each group's findings was used. The distribution of numerical data was checked for normality, and normality tests were used (Kolmogorov-Smirnov and Shapiro-Wilk tests). For parametric data (temperature measurement), one-way ANOVA test was used. Repeated-measures ANOVA test was utilized to compare between composite types, preheating temperatures, site of measurement as well as to compare between temperatures before and after curing. When the ANOVA test was significant, Bonferroni's post hoc test was applied for pair-wise comparisons. When nonparametric data (temperature change) were used, the Kruskal-Wallis test was applied first, followed by Dunn's test for pair-wise comparisons when the Kruskal-Wallis test was significant. To compare temperature variations at the pulpal floor and composite surface, the Wilcoxon signed-rank test was performed. To compare qualitative variables in various groups, the Chi-square test was applied. The significance level was set at P < 0.05. IBM SPSS Statistics for Windows was used to conduct the statistical analysis, version 23.0. Armonk, NY: IBM Corp.

Results

Table 2 shows the measured temperature at the pulpal floor and on resin composite restoration when the resin composite materials were preheated at different temperatures. At the pulpal floor with preheating temperature 50 °C, there was no statistically significant difference at base line temperature between the two composite types

(P-value = 0.931). Whether before or after curing at 50 °C, VCB showed statistically significantly higher mean pulpal floor temperature than AFX, where the mean \pm SD values of VCB and AFX before curing were (34.3 \pm 0.97) and (32.66 \pm 1.11), respectively. P-value between VCB and AFX before curing was (P-value = 0.002). The mean \pm SD values of VCB and AFX after curing were (37.41 \pm 0.96), and (35.57 \pm 2.18), respectively. P-value between VCB and AFX after curing was (P-value = 0.020).

With preheating temperature 70 °C there was no statistically significant difference at base line temperatures between mean pulpal floor of the two composite types (P-value=0.601), while before or after curing at 70 °C there was no statistically significant difference between both materials, where the mean \pm SD values of VCB and AFX before curing were (35.25 \pm 1.36) and (34.3 \pm 1.02), respectively. P-value between VCB and AFX before curing was (P-value=0.067). The mean \pm SD values of VCB and AFX after curing were (36.53 \pm 1.61) and (38.04 \pm 1.8), respectively. P-value between VCB and AFX after curing was (P-value=0.054).

At composite surface, the preheating to 50° C whether before or after curing, there was no statistically significant difference between mean composite surface temperatures of the two composite, where the mean \pm SD values of VCB and AFX at 50 °C before curing were (32.53 \pm 0.86) and (31.93 \pm 1.12), respectively. The P-value between VCB and AFX before curing was (*P*-value=0.129). The mean \pm SD values of VCB and AFX at 50 °C after curing were (33.39 \pm 0.8) and (33.22 \pm 0.96), respectively. The P-value between VCB and AFX after curing was (*P*-value=0.661).

With preheating temperature 70 °C before curing, VCB showed statistically significantly higher mean

Table 2 Comparison of the repeated measures and descriptive statistics temperature measurements (°C) of the two different resin composite types using the ANOVA test

Site	Preheating temperature	Curing	VisCalor (n = 10)		Admira (n = 10)		P-value
			Mean	SD	Mean	SD	
Pulpal floor	50 °C	Base line	31.6	1.19	31.6	1.04	0.931
		Before curing	34.3	0.97	32.66	1.11	0.002*
		After curing	37.41	0.96	35.57	2.18	0.020*
	70 °C	Base line	32.5	0.81	32.2	1	0.601
		Before curing	35.25	1.36	34.3	1.02	0.067
		After curing	36.53	1.61	38.04	1.8	0.054
Composite surface	50 °C	Before curing	32.53	0.86	31.93	1.12	0.129
		After curing	33.39	0.8	33.22	0.96	0.661
	70 °C	Before curing	33.3	0.51	32.43	0.85	0.031*
		After curing	33.74	0.86	33.92	0.82	0.643

^{*}Significant at $P \le 0.05$

composite surface temperature than AFX (33.3 ± 0.51) and (32.43 ± 0.85) , respectively, with (P-value=0.031). After curing, there was no statistically significant difference between mean composite surface temperatures of the two composite types where the mean \pm SD values of VCB and AFX at 70 °C after curing were (33.74 ± 0.86) and (33.92 ± 0.82) , respectively. The P-value between VCB and AFX after curing was (P-value=0.643).

From Table 3 and Fig. 3, the measured temperature at the pulpal floor and on resin composite restoration before and after curing revealed that at the pulpal floor, both VCB and AFX composites, whether preheated at 50° or 70 °C, there was a significant increase in mean pulpal floor temperature after curing where the mean \pm SD values of VCB at 50 °C before and after curing were (34.3 \pm 0.97) and (37.41 \pm 0.96), respectively, with (*P*-value < 0.001). The mean \pm SD

values of VCB preheated at 70 °C before and after curing were (35.25 \pm 1.36) and (36.53 \pm 1.61), respectively, with (*P*-value < 0.001). Pair-wise comparisons revealed that there was a statistically significant increase in temperature from base line to before curing as well as after curing. With AFX composite the mean \pm SD values preheated at 50 °C before and after curing were (32.66 \pm 1.11) and (35.57 \pm 2.18), respectively, with (*P*-value < 0.001). The mean \pm SD values of AFX preheated at 70 °C before and after curing were (34.3 \pm 1.02) and (38.04 \pm 1.8), respectively, with (*P*-value < 0.001). Pair-wise comparisons revealed that there was a statistically significant increase in temperature from base line (C₀) to before curing (C₁) as well as after curing (C₃).

At composite surface, with VCB composite preheated at 50 °C, there was a statistically significant increase in mean composite surface temperature after

Table 3 Results of repeated measures and descriptive statistics temperature measurements (°C) before and after curing were compared using the ANOVA test

Site	Composite type	Preheating temperature	Base line (n = 10)		Before curing (n = 10)		After curing (n = 10)		<i>P</i> -value
			Mean	SD	Mean	SD	Mean	SD	
Pulpal floor	VisCalor	50 °C	31.6 ^C	31.6 ^C	34.3 ^B	0.97	37.41 ^A	0.96	< 0.001*
		70 °C	32.5 ^C	32.5 ^C	35.25 ^B	1.36	36.53 ^A	1.61	< 0.001*
	Admira	50 °C	31.6 ^C	31.6 ^C	32.66 ^B	1.11	35.57 ^A	2.18	< 0.001*
		70 °C	32.2 ^C	32.2 ^C	34.3 ^B	1.02	38.04 ^A	1.8	< 0.001*
Composite surface	VisCalor	50 °C	-	-	32.53	0.86	33.39	0.8	0.004*
		70 °C	-	-	33.3	0.51	33.74	0.86	0.121
	Admira	50 °C	-	-	31.93	1.12	33.22	0.96	< 0.001*
		70 °C	-	-	32.43	0.85	37.41 ^A	0.96	< 0.001*

^{*}Significant at P \leq 0.05, Different superscripts in the same row indicate significant difference

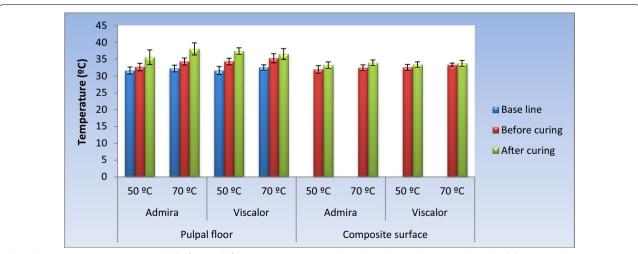


Fig. 3 Temperature measurements (°C) before and after curing are represented as a bar chart with mean and standard deviation values

curing where the mean \pm SD values before and after curing were (32.53 \pm 0.86) and (33.39 \pm 0.8), respectively, with (*P*-value=0.004). There was no statistically significant change in mean composite surface temperature after curing of VCB preheated at 70 °C where the mean \pm SD values before and after curing were (33. 3 \pm 0.51) and (33.74 \pm 0.86), respectively, with (*P*-value=0.121). At composite surface, with AFX composite whether preheated at 50 °C or 70 °C, there was a statistically significant increase in mean composite surface temperature after curing where the mean \pm SD values of AFX preheated at 50 °C before and after curing were (31.93 \pm 1.12) and (33.22 \pm 0.96), respectively, with (*P*-value<0.001).

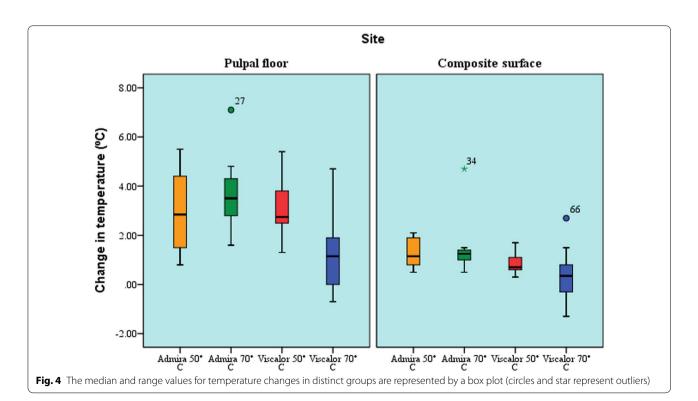
The mean \pm SD values of AFX preheated at 70 °C before and after curing were (32.43 \pm 0.85) and (33.92 \pm 0.82), respectively, with (*P*-value < 0.001).

Table 4 and figure 4 show the difference between groups; at the pulpal floor there was a significant difference between temperature changes in different groups (P-value = 0.023). Pair-wise comparisons between the groups revealed that AFX preheated at 70 °C showed the statistically significantly highest median temperature rise at the pulpal floor. There was no statistically significant difference between VCB preheated at 50 °C and AFX preheated at 50 °C, and both showed statistically significantly lower median temperature rise at the pulpal floor.

Table 4 Descriptive statistics comparison and results of Kruskal–Wallis test between temperature changes (°C) of the different groups and Wilcoxon signed-rank test for comparison between changes at pulpal floor and composite surface

Site	VisCalor 50° (n = 10)	VisCalor 70° (n = 10)	Admira 50° (n = 10)	Admira 70° (n = 10)	<i>P</i> -value
Pulpal floor					0.023*
Median (range)	2.75 (1.3–5.4) ^B	1.15 (-0.7–4.7) ^C	2.85 (0.8–5.5) ^B	3.5 (1.6–7.1) ^A	
Mean (SD)	3.11 (1.18)	1.28 (1.66)	2.91 (1.75)	3.74 (1.53)	
Composite surface					0.018*
Median (range)	0.7 (0.3-1.7) ^B	0.35 (-1.3–2.7) ^B	1.15 (0.5–2.1) ^A	1.25 (0.5–4.7) ^A	
Mean (SD)	0.86 (0.39)	0.44 (1.09)	1.29 (0.6)	1.49 (1.17)	
<i>P</i> -value	< 0.001*	0.306	0.044*	0.001*	

Significant at $P \le 0.05$, Different superscripts in the same row indicate statistically significant difference



VCB preheated at 70 °C showed the statistically significantly lowest median temperature rise at the pulpal floor.

At the composite surface, the temperature changes in different groups were significant (P-value = 0.018). When the groups compared in pair-wise, the results showed that there were no significant differences between VCB preheated at 50 °C and VCB preheated at 70 °C and both showed the lowest median temperature rise values at the composite surface. There was no statistically significant difference between AFX preheated at 50 °C and AFX preheated at 70 °C and both showed the significant highest median temperature rise values at the composite surface.

When the groups are compared in pair-wise comparisons, the pulpal floor and composite surface for VCB preheated at 70 °C revealed that there was no significant difference between temperature rise at pulpal floor and composite surface. As regards AFX preheated at 50 °C, AFX preheated at 70 °C as well as VCB preheated at 50 °C pulpal floor showed statistically significantly higher median temperature rise than composite surface.

Discussion

The current clinical trial was aimed to compare the effect of preheating at 50 °C and 70 °C on two bulk fill resin composite restorative materials one containing Bis-GMA (VCB) and the other free Bis-GMA (AFX) on the temperature change of the pulpal floor and restoration surface. The expelled of bisphenol-A out from resinous matrix could enhance its cytotoxic properties. Bisphenol-A glycidyl methacrylate (Bis-GMA) monomer is routinely used in manufactured resin composites (El-Askary et al. 2017). As a result, an alternative to Bis-GMA has been developed, such as Ormocer resin composite (organic modified ceramic). Due to their greater three dimensions cross-linked ceramic polysiloxane monomers, Ormocer composite materials are thought to get low polymerization shrinkage than Bis GMA resin composite restorative materials. (Kalra et al. 2012). Compared to standard dimethacrylate resins, they have decreased or no cytotoxicity (El-Askary et al. 2017).

To improve the handling properties of dental resinbased composites (RBCs), chairside pre-heating has been adopted. It minimizes microleakage and gap formation by lowering the viscosity of composites, resulting in enhanced flowability and marginal adaptability (Yang et al. 2020). The temperature range of 54–68 °C is regarded safe because it does not harm the pulp tissue (Gavic et al. 2015), (El-Deeb et al. 2015), and (Karacan and Ozyurt 2019). Moreover, resin composite can be preheated at 50–70 °C (Trugillo et al. 2004; Prasanna et al. 2007; Uctasli et al. 2008; Silva-Júnior et al. 2018).

K-type thermocouple is the most widely used sensor in temperature measurement, it can measure temperature ranging from -50 °C to +1300 °C. It was used by many authors (Daronch et al. 2007; El-Deep et al. 2015; Karacan and Ozyurt 2019; and Erhardt et al. 2020) in laboratory measurement of intrapulpal temperature with preheated composite. They measured the intrapulpal temperature on extracted teeth (in vitro study), and the metal probe of the K-type thermocouple was fitted inside the pulp chamber through the molar root after removing of the pulp tissues. In this clinical trial, they believe that depending on empty pulp chamber it gives no indication what really happens in the temperature of the pulp tissues due to resin composite preheating. Rueggeberg et al. 2010 used a typical photoactivated hybrid resin composite (Esthet-X) at room temperature (23.6 °C) or preheated to 54.7 °C, to assess the temperature of the prepared tooth surface throughout a restorative treatment on only three patients. Temperature data at the tooth pulpal floor were recorded using a customized handheld temperature measuring probe equipped with K-type thermocouples. To our knowledge, this is the first clinical trial to measure the temperature of the pulpal floor of the cavity believing that a higher increase in the temperature due to preheating can affect the pulp tissues causing harm. Similarly, measuring the resin composite temperature after curing might be effective as rapid returning to intraoral temperature is important to avoid pulp affection.

In the current study the whole metal probe was modified and covered with shrinkable non-conductive plastic tube leaving only the tip that touches the pulpal floor for measurement. This was done to overcome the problem that there was no specific device to pass through the restoration measuring only the pulpal floor temperature without measuring the temperature of the preheated resin composite. Also to prevent the probe from sticking to the resin composite while packing. This heat shrinkable tubing is commonly used for electrical and mechanical insulation, sealing, and connecting application (Barth 2005). When heated, heat shrink tubing is a mechanically expanding extruded plastic tube, often made of the thermoplastic materials nylon or polyolefin, that contracts exclusively in one plane (its diameter), (Luo et al. 2014).

In the present study, the mean values of the recorded baseline temperature of the pulpal floor before the bonding procedure ranged from 31.5 to 32.5 °C with no statistically significant difference in all groups and this was consistent with Rueggeberg et al. 2010 where the temperature was 30.5 °C, not 37 °C like the intraoral temperature, while this low temperature 30.5 °C acted to rapidly cool warmed composite but it has negative effect on increasing the viscosity, reducing the potential for composite flow that enhances the restoration adaption to prepared tooth surfaces (Rueggeberg et al. 2010).

The result of pulpal floor temperature on this clinical trial showed that there was significant difference between VCB preheated at 50 °C and AFX during packing and after curing while VCB showed the higher mean value. In the contrary, when both testing materials were preheated at 70 °C, there was a nonsignificant difference between both testing materials either before and after curing (Table 2). The varied matrix compositions seem to be a reason for these findings between VCB and AFX that results in differences in the degree of convergence which lead to exothermic variances between two materials (Al-Qudah et al. 2007). Moreover, increased heat is a sign of a high conversion rate (Knežević et al. 2005). These results were in accordance with (Daronch et al. 2006) whom reported that increasing the conversion of dimethacrylate monomers is caused by increasing polymerization temperature, but only up to a certain point. Following that point, monomer conversion reduces as the temperature rises. This limit is reached near 90 °C for monomers like Bis-GMA or BisEMA. Reactant evaporation and photoinitiator degradation cause a decrease in monomer conversion when the temperature is too high.

Comparing the pulpal floor temperature before (C_1) and after curing (C_3) to the baseline (C_0) temperature, there was significant difference in both testing materials when preheated at 50 °C and 70 °C (Tables 3 and 4). There was a significant increase in the pulpal floor temperature from base line (C₀) to (C₁), where the highest recorded value of C₀ was 32.5 °C and highest recorded value of C₁ was 35.25 °C where the increasing was only 2.75 degrees Celsius. These results were in agreement with (Akarsu and Aktuğ Karademir 2019) who reported that the application of heat to tooth structures might result in increasing pulpal floor temperature and can cause varying degrees of pulpal damage. Chiang et al. 2008 reported that the enamel may be considered as a origin of heat because it has the fastest early temperature rise. Furthermore, investigations revealed that enamel and dentin had poor thermal conductivity and diffusivity (Lin et al. 2010). Dentin tubule fluids volume and blood flow rate, as well as the tooth's potential to perform as a heat origin in the occurrence of a temperature change, all have a significant impact on the tooth's thermal properties (Raab 1992). There was a significant increase in the pulpal floor temperature from (C_1) to (C_3) , where the highest recorded value of C₁ was 35.25 °C and the highest recorded value of C₃ was 38.04 °C where the increasing was only 2.79 °C. The light exposure causes significant intra-pulpal temperature changes, with light energy, exposure length, and light source being some of the characteristics related to greater temperature variations (Yazici et al. 2006; Armellin et al. 2016). All of the curing units resulted in a statistically significant increase in pulpal temperature. In high-energy curing modes, the pulpal temperature climbed by more than 5.0 °C, while in low-energy curing modes it increased by 2.5 °C. Furthermore, researchers showed a strong correlation between high energy density and increased pulpal temperature (Vinagre et al. 2019).

Even after the curing light has been switched off, the temperature of heat energy in the pulp eventually dissipates, which arrives to a higher temperature in the pulp chamber. Dentin has not only the potential to transmit heat energy but also the tendency to preserve it due to its low thermal diffusivity (Chiang et al. 2008). The thermal energy of dentin should only be considered when incremental strands of resin composite are serially positioned in a cavity followed by exposure to the LCU, and it is logical to assume that many exposures to LCU above a short time will lead to higher heat storage in dentin. (Runnacles et al. 2015).

The pulpal floor temperature rises in both testing materials from the baseline (C_0) to after curing (C_3) was in the range of 4-6 degrees only. The highest recorded value of C1 was 35.25 °C, and the highest recorded value of C3 was 38.04 °C The application of heat to tooth structures might result in varying degrees of pulpal damage. Temperatures between 42 and 42.5 °C are required for reversible dental pulp damage (Pohto and Scheinin 1958). At 5.5 °C, 15% of pulps have necrosis, which is the most well-known temperature threshold associated with pulpal injury. This threshold was observed in a monkey study by Zach (1965), who used a soldering iron at 275 °C to produce temperature variations, which did not correlate to the temperature changes that occur during dental procedures (Erhardt et al. 2020). With temperature rises ranging from 8.9 to 14.7 °C, Baldissara et al. (1997) observed neither clinical or histological pulp injury in people using various techniques. Heat-induced pulp cell degeneration occurs when the pulpal temperature is raised over 42 °C or 43 °C, according to other researchers (Amano et al. 2006; Kitamura et al. 2005). As a result, Jakubinek et al. (2008) and Tunc (2007) concluded that those temperatures were critical for pulp viability. However, the current research results can support all previous studies reported that the greatest temperature change caused by the application of the curing unit.

The findings of this clinical investigation revealed a statistically significant difference in the temperature rises at the Admira Fusion x-tra restoration before and after curing when preheated at 50 °C and 70 °C, while after curing showed the highest mean values. At composite surface, with VisCalor bulk preheated at 50 °C after curing, the mean composite surface temperature increased statistically significantly. There was no statistically significant difference in mean composite surface temperature

after curing of VCB preheated at 70 °C. The materials were supplied in two forms where the VCB supplied in compules and AFX supplied in syringe. The preheated compules actual delivery temperature was lower than the heating device's preset temperature. Furthermore, when a resin composite heated at 60 °C and then separated from the heat source, the temperature decreased 50% in 2 min and 90% in 5 min. As a result, to keep the temperature from lowering too far, the operator must intervene quickly. To gain the benefits of increased monomeric conversion, the operator should deliver the material, adjust it, remove excess and shape it as needed, then light-cure it while it is still warm (Daronch et al. 2007).

The degree of rising temperature during photopolymerization is affected by a number of factors, including the type of light curing unit, power output, exposure time, nearness between the tooth and/or composite surface and the light guide tip end, composite shade, and thickness of both the composite material and remaining dentin (El-Deeb et al. 2015). The majority of the temperature rise in the preheated composite was caused by exothermic photopolymerization and heat produced by the LCU (Daronch et al. 2007; Fróes-Salgado et al. 2010). Researchers and physicians have long been concerned about the buildup of heat during photopolymerization.

Significant temperature gains during light curing can be attributed to the increased irradiance and/or a longer exposure period when comparing different forms of LCU (Rueggeberg et al. 2017).

The current study's findings that the hypothesis was accepted as there was a nonsignificant difference in the pulpal floor and restoration temperatures between Bis-GMA containing and free when both preheated at 50 °C and 70 °C.

Conclusions

Within the confines of this study's limitations, it is possible to draw the following conclusions:

The pulpal floor temperature did not reach even the normal body temperature with preheating Bis-GMA free and containing resin composite to 50 °C.

Pulpal temperature rise was greater with the application of the curing light more than preheating resin composite.

Temperature rise of both the pulpal floor or restoration with preheating either Bis-GMA free or containing resin composite even to 70 °C is not the most important factor that harms the pulp so may be utilized with considerable safety when it comes to causing pulp damage.

Abbreviations

Bis-GMA: Bisphenol-A glycidyl methacrylate; AFX: Admira Fusion x-tra; VCB: VisCalor bulk; HEMA: 2-Hydroxyethyl methacrylate; ORMOCER: Organically modified ceramics; DC: Degree of convergence; RBCs: Resin-based composites; LCU: Light curing unit.

Supplementary Information

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Additional file 1. CONSORT check list and Flow diagram of the study (Consolidated Standards of Reporting Trial).

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Not applicable.

Author contributions

AN, MR, and NA performed the study design. AN performed the whole methodology. AN, MR, and NA analyzed the data. AN was the major contributor in writing the manuscript. All the authors read and approved the final manuscript.

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Availability of data and materials

The authors state that the data supporting the study's findings are included in the article.

Declarations

Ethics approval and consent to participate

This study was reviewed and approved by the IRBs/ECs [institutional review boards/ethical committees] in the Faculty of Dentistry-Minia University with serial no (490), and also registered and approved on (www. Clinicaltrials.gov) with trial number: (NCT05140447). Patients were told to follow general instructions and sign a printed informed consent form that explained the study's purpose.

Consent for publication

Consent was obtained for publication from the department and patients.

Competing interests

There are no interests involved.

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