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A new preheating thermoviscous composite for restoration of non-carious cervical lesions: a 6-month randomized clinical trial

Um novo compósito termoviscoso de pré-aquecimento para restauração de lesões cervicais não cariosas: ensaio clínico randomizado de 6 meses

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ABSTRACT

Objective: This double-blind, split-mouth randomized clinical trial evaluate the clinical performance of a new preheating (PHT) thermoviscous composite compared to a non-heating (NHT) composite resin in restorations of non-carious cervical lesions (NCCLs) over a period of 6-month. **Material and Methods:** 120 restorations were performed on NCCLs with two restorative materials (n = 60). After prophylaxis, the teeth were isolated with retraction cord isolation/cotton rolls and one universal adhesive was applied in the selective enamel etching strategy. For the PHT group heating was carried out at 68°C using a heater bench for 3 min. On the other side, for the NHT group, no heating was applied. Both restorative materials were placed in the caps dispenser and inserted in the NCCLs. The restorations were evaluated after 6-month of clinical performance according to the FDI criteria. Statistical analysis was performed with Chi-square test for all FDI parameters ($\alpha = 0.05$). **Results:** Three restorations only in the NHT group were lost/fractured after six months follow-up. The retention rates (confidential interval 95%) for six months were 97.5% (88.6% - 99.0%) for the NHT group and 100% (93.9% - 100%) for the PHT group ($p > 0.05$). Twenty-two restorations (8 for NHT and 14 for PHT) presented small marginal adaptation defects at the six-months follow-up ($p > 0.05$). Twenty-six restorations were found to have biofilm retention in the six-month recall (11 for NHT and 15 for PHT; $p > 0.05$). Regarding all others FDI parameters evaluated, all restorations were considered clinically acceptable. **Conclusion:** The clinical performance of the new preheating thermoviscous was found to be promise after 6-month of clinical evaluation when applied in NCCLs.

KEYWORDS

Composite resin; Viscosity; Temperature; Clinical trial; Preheating.

RESUMO

Objetivo: Este ensaio clínico randomizado, duplo-cego e boca dividida avaliou o desempenho clínico de um novo compósito termoviscoso com pré-aquecimento (PHT) em comparação com uma resina composta sem aquecimento (NHT) em restaurações de lesões cervicais não cariosas (LCNCs) durante um período de 6 meses. **Material e Métodos:** 120 restaurações foram realizadas em LCNCs com dois materiais restauradores (n = 60). Após a profilaxia, os dentes foram isolados com isolamento de fio retrator/rolos de algodão e um adesivo universal foi aplicado na estratégia de condicionamento seletivo do esmalte. Para o grupo PHT o aquecimento foi realizado a 68°C usando um aquecedor de bancada por 3 min. Por outro lado, para o grupo NHT, nenhum aquecimento foi aplicado. Ambos os materiais restauradores foram colocados no dispensador de cápsulas e inseridos nas LCNCs. Após 6 meses, o desempenho clínico das restaurações foi avaliado de acordo com os critérios FDI. A análise estatística foi realizada com teste Qui-quadrado para todos parâmetros da FDI ($\alpha = 0,05$). **Resultados:** Apenas três restaurações no grupo NHT foram perdidas/fraturadas após seis meses de acompanhamento. As taxas de retenção (intervalo confiança 95%) por seis meses foram de 97,5% (88,6% - 99,0%) para o grupo NHT e 100% (93,9% - 100%) para

o grupo PHT ($p > 0,05$). Vinte e duas restaurações (8 para NHT e 14 para PHT) apresentaram pequenos defeitos de adaptação marginal aos seis meses de acompanhamento ($p > 0,05$). Vinte e seis restaurações apresentaram alguma retenção de biofilme aos seis meses de acompanhamento (11 para NHT e 15 para PHT; $p > 0,05$). Em relação a todos os outros parâmetros de FDI avaliados, todas as restaurações foram consideradas clinicamente aceitáveis. **Conclusão**: O desempenho clínico do novo compósito termoviscoso de pré-aquecimento mostrou-se promissor após 6 meses de avaliação clínica quando aplicado em LCNCs.

PALAVRAS-CHAVE

Resina composta; Viscosidade; Temperatura; Ensaio clínico; Pré-aquecimento.

INTRODUCTION

Composite resins are versatile materials that can be used on anterior teeth due to their aesthetic properties and used for restorations in posterior teeth due to their greater mechanical properties [1], usually related to the viscosity of composites [2,3]. Viscosity mainly depends on the composite resin's chemical composition, i.e., type of organic matrix and size, type and concentration of filler particles [4,5]. Keeping other variables constant, the greater the monomers' filler loading content and molecular weight, the greater the composite resin's viscosity and mechanical properties [4,5].

However, highly viscous composites may fail to adapt well to the cavity preparation, leading to poor marginal integrity and gap formation [6-8]. Flowable composite resins can overcome these problems because they are low-viscosity restorative materials that differ from regular-viscosity composite resins, as they have a lower filler load and less viscous resin content [9]. Unfortunately, the majority of flowable composites available in the market do not present adequate mechanical properties for use in areas submitted to high masticatory stress [8,10-12].

Ideally, the composite resin should have flowable properties during application, allowing for better adaptability to all cavity walls, but as soon as application ends, its viscosity should increase to prevent it from flowing out of the cavity and make it suitable for carving and contouring [2]. Therefore, a balance between high mechanical properties and good handling characteristics is essential for the success of a composite resin restoration [9]. Therefore, manufacturers have developed several alternatives, one of which is the SonicFill system (Kerr, Orange, CA, USA) [13,14] and other approach is to preheat the composite resin [15-17].

Preheating improves the composite resin's degree of conversion and mechanical properties and, in the same way, makes the composite resin (regular or high viscosity) more fluid during application [17]. In the dental market, some devices are available, but the most common are the Calset heater (AdDent Inc., Danbury, CT, USA) and ENA heat (Micerium, Avegno GE, Italy), with operating temperatures ranging from 37°C to 68°C.

More recently, a new thermoviscous bulk-fill material (VisCalor bulk, Voco GmbH, Germany) has been developed that allows for preheating up to 68°C (Caps Warmer, Voco GmbH, Cuxhaven, Germany) before application. According to Yang et al. [18,19], preheating is beneficial in terms of placement and causes no adverse effects through premature polymerization. They also found lower rates of internal voids with the technique [20,21], which guarantee a high degree of conversion and, consequently, elevated mechanical properties for VisCalor bulk compared to other composites [22,23]. In fact, VisCalor bulk-fill combines a flowable composite's fluidity during application as the material is heated with the sculptability of an encapsulated bulk-fill composite, as it can be placed in increments of up to 4 mm [24].

Despite all these favorable in vitro results for preheated composite resins [25], a closer analysis of clinical studies to evaluate the effects of preheated and non-preheated composite resins produced controversial results [26,27]. However, to the extent of the authors' knowledge, no clinical study has been conducted to compare the clinical performance of this new thermoviscous composite resin to that of non-heated composite resins. Therefore, the aim of this double-blind, split-mouth randomized clinical trial was to compare the clinical behavior of a preheating thermoviscous composite resin using a Caps heating device to that of a non-heated composite resin in NCCL restorations.

MATERIAL AND METHODS

Ethics approval and protocol registration

The clinical investigation was approved (4.656.880) by the Scientific Review Committee and by the Committee for the Protection of Human Participants of the State University of Ponta Grossa, PR, Brazil. It was registered in the Brazilian Clinical Trials Registry (REBEC) under the identification number RBR-6d6gxxz.

The experimental project was conducted according to the CONSORT statements [28] with extension for projects within pairs [29]. Readers can find the explanatory document about these CONSORT extensions in the following website: www.consort.org.

Trial design, settings, locations of data collection and recruitment

This study is a split-mouth, double-blind randomized clinical trial. It was performed between October 2021 to November 2021. The 6-month data was collected from April 2022 to May 2022. The authors decided to form a convenience sample, and no advertisement was made for recruiting participants. While patients sought treatment for various reasons at the private clinic, when identified they were informed about the research that was taking place at the site, once they understood the objectives of the study, and signed the informed consent, they were recruited for the study.

Eligibility criteria

All participants were examined by two calibrated operators to verify that they met the inclusion and exclusion criteria of the study. The evaluations were carried out using a set of mouth mirror, an explorer and a periodontal probe. Participants needed to be in good general health, at least 18 years old, have an acceptable level of oral hygiene and have at least 20 teeth under occlusion.

Participants included at least two comparable NCCLs (in size, shape and dimensions) to be restored. These lesions must be non-retentive, deeper than 0.5 mm, and involve both enamel and dentin of vital teeth without mobility. Participants who had a cavo-superficial margin involving more than 50% of the enamel were excluded. Patients with extremely poor oral hygiene or using orthodontic devices, severe or chronic periodontitis or heavy bruxism were excluded from the study, as they needed to receive other treatments before the restorative intervention. In addition, participants with a known allergy to resin-based materials or any other material used in this study, pregnant or lactating women, or participants in chronic use of anti-inflammatories, analgesics and psychotropics were not included in the study.

Sample size calculation

The annual retention rate for composite resin after three years of clinical service is around 80% [30]. With a α of 0.05, a power of 90%, and an equivalence test of 25%, a minimum sample size of 56 restorations per group, in order to detect a 25% difference between the test groups. Sixty restorations were carried out per group, to compensate for possible losses.

Randomization and allocation concealment

Randomization was performed on an interindividual basis so that each subject received two restorations. These randomization schemes were carried out using tools available on the website *www.sealedenvelope.com*

A researcher not involved in the research protocol (blind) performed the randomization process. Each participant was randomized at the time of the intervention. For this purpose, the operator sent a message through a social communication network (WhatsApp, LLC) for the research, 15 min before starting the intervention. The researcher realizes the randomization for the patient and immediately send to operator. This ensures the concealment of the random sequence. In all cases, the tooth with the largest number of teeth (FDI numbering system) received the treatment described first, while the tooth with the next number in sequence received the treatment mentioned in second place.

Blinding

The evaluators were not involved with the restorative procedures and, therefore, were blinded to evaluating groups. Despite, some heat was used in one of the restorative groups, the patient was also consider blinded to the assignment of the groups, characterizing the double-blind study. Due to the significant difference between the materials to be used and evaluated, it was not possible to blind the operators.

Interventions: restorative procedure

All participants selected according to the inclusion and exclusion criteria had their NCCLs previously evaluated in relation to the degree of sclerotic dentin, measuring according to the criteria described by Swift et al. [31]. The dimensions of the cavities (height, width and depth) were measured with a millimeter probe, the geometry of the cavity was also evaluated by profile photography and labeled at <45º, 45º-90º, 90º <135º and >135º) [32]. The presence of an antagonist and the presence of friction facets were observed and recorded. Preoperative sensitivity was also assessed by applying an air jet for 10 seconds with a dental syringe placed 2 cm from the tooth surface and with an explorer. The evaluation of the presence of biofilm was also carried out using the millimeter probe, going through all the cervical. These characteristics were recorded to allow comparison of baseline characteristics of cavities between experimental groups.

In order to calibrate the restorative procedures, the study coordinator performed a restoration of each group to identify all the steps involved in the restorative technique. Then, the other three operators, residing in the faculty of dentistry and with more than five years of clinical experience, placed the four restorations in a clinical setting, two from each group, under the supervision of the study coordinator. Restoration failures were shown to operators before starting the study. After this point, the operators were considered calibrated to perform the restorative procedures. The same operators restored all teeth in the study.

All NCCLs (Figure 1A) were cleaned through prophylaxis using pumice and water using a brush (Figure 1B), followed by rinsing and drying. Before the restorative procedures, the operators performed the anesthesia related to the teeth corresponding to be restored with a 3% solution of articaine hydrochloride (Articaine, Nova DFL, Rio de Janeiro, RJ, Brazil). Then, the color was selected using a color guide present in the composites kit (Admira Fusion, Voco GmbH, Cuxhaven, Germany), according to the color selection, the corresponding color was used to select the color of the other group (VisCalor bulk, Voco GmbH, Cuxhaven, Germany) (Table I). The patient was submitted to the mouth expander and cheeks and the isolation of the NCCLs was performed using an insertion spatula to insert the retraction cord (Ultrapak # 0, Ultradent, South Jordan, UT, USA) (Figure 1C and 1D), associated to cotton rolls. No hemostatic liquids were necessary during this study. Selective enamel conditioning (Vococid, Voco GmbH,

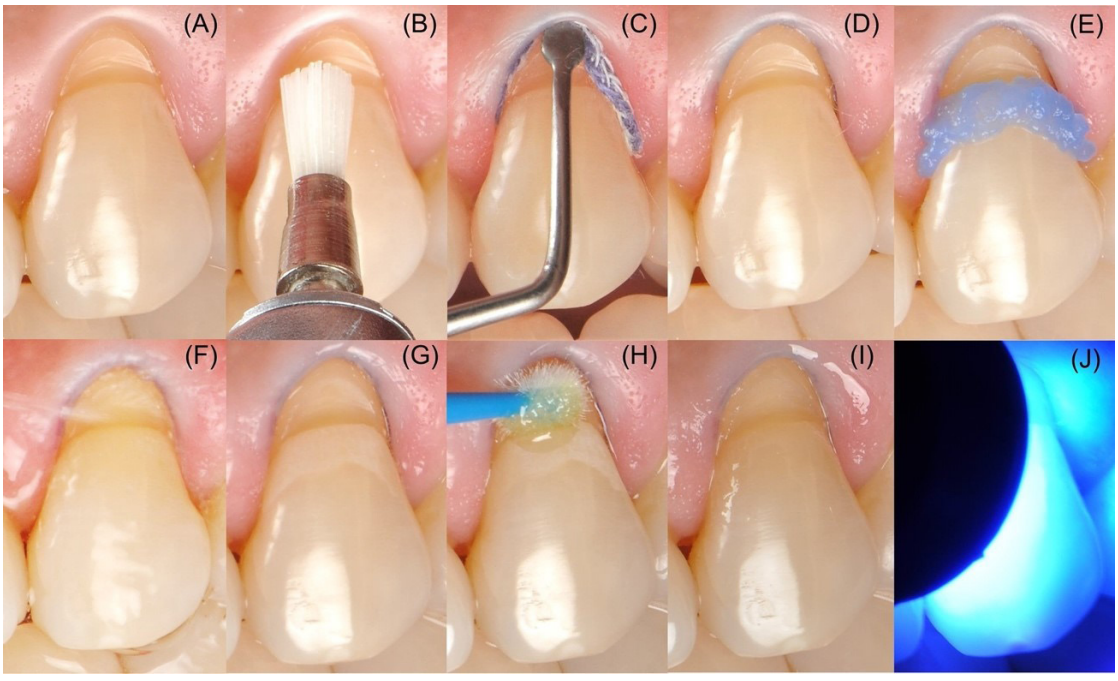

Figure 1 - Initial appearance of NCCLs (A); Prophylaxis (B); Isolation of the NCCLs was performed using an insertion spatula and retraction cord (C); Appearance after isolation (D); Selective enamel conditioning (E); Rinsing (F); Drying (G). Applied universal adhesive system (H); Drying (I); Light curing of the adhesive (J).

Table I - Manufacture information of investigated composites

Material	Manufacturer	Color/Batch Number	Resin system	Application mode
Admira Fusion	Voco GmbH, Cuxhaven, Germany	U / 1610473	Organically modified ceramic ORMOCER®	1. The capsule is inserted into the Caps dispenser (Caps dispenser, Voco GmbH, Cuxhaven, Germany).
		A1 / 1608454	Resin matrix: aromatic and aliphatic dimethacrylates, methacrylate-functionalized polysiloxane	2. Placed in increments of 2 mm.
		A2 / 1607524	Inorganic filler: barium aluminum borosilicate glass ceramic filler, silicon dioxide nanoparticles (0.02-1 µm). SiO_2. Filler wt. 84%.	3. Light-curing of each increment is performed with an irradiance of 1200 mW/cm² for 20 seconds.
		A3 / 1606252	Photoinitiator: camphorquinone.	
			Synergist: NI	
VisCalor bulk	Voco GmbH, Cuxhaven, Germany	U / 2020095	Resin matrix: Bisphenol-A-glycidyl dimethacrylate, aliphatic dimethacrylate.	1. The capsule is inserted into the Caps dispenser (Caps dispenser, Voco GmbH, Cuxhaven, Germany).
		A1 / 2020153	Inorganic filler: NI. Filler wt. 83%.	2. Heated to 68°C using a bench heater (Caps Warmer, Voco GmbH, Cuxhaven, Germany) for 3 minutes.
		A2 / 2020239		3. Placed in increments of 4 mm.
		A3 / 2021097		Light-curing of each increment is performed with an irradiance of 1200 mW/cm² for 40 seconds.

NI: not defined by the manufacturer.

Cuxhaven, Germany) (Figure 1E), followed by rinsing (Figure 1F) and drying (Figure 1G). The universal adhesive system (Futurabond U, Voco GmbH, Cuxhaven, Germany) was applied in the self-etching mode only to dentin, applying according to the manufacturer's instructions in all cavities. The adhesive was manipulated, and the first application was made with a microbrush (Single Tim, Voco GmbH, Cuxhaven, Germany) (Figure 1H) followed drying by an air jet for 10 seconds (Figure 1I). Following, a second coat was application as the previous one and, at the end, the light curing of the adhesive was carried out with an irradiance of 1200 mW/cm² (Valo, Ultradent, South Jordan, UT, USA) for 20 seconds (Figure 1J). Then, the cavities were restored with one of the two compounds described below:

NHT group: in this group non-heating, a one dose composite resin Admira Fusion (Voco GmbH, Cuxhaven, Germany) (Figure 2A) was applied. The restorative material was placed in the Caps dispenser (Caps dispenser, Voco GmbH, Cuxhaven, Germany) (Figure 2B) and inserted in 2 mm increments (Figure 2C). After the correct accommodation of the composite in the cavity (Figure 2D), the light curing of each increment was carried out with an irradiance of 1200 mW/cm² (Valo, Ultradent, South Jordan, UT, USA) for 20 seconds (Figure 2E).

PHT group: in this group preheating, a one dose thermo-viscous bulk-fill composite resin VisCalor bulk (Voco GmbH, Germany) (Figure 2F) was applied. The restorative material was placed in the Caps dispenser (Caps dispenser, Voco GmbH, Cuxhaven, Germany) (Figure 2G) was heated to 68°C using a bench heater (Caps Warmer, Voco GmbH, Cuxhaven, Germany) for 3 minutes (Figure 2H). After heated, inserted in a single increment (up to 4 mm) in the cavity (Figure 3I), the handling of the resin was up to 20 seconds until it took on its most rigid shape, the resin was accommodated in the cavity with the help of an instrument (Figure 3J). The light curing of each increment was carried out with an irradiance of 1200 mW/cm² (Valo, Ultradent, South Jordan, UT, USA) for 40 seconds (Figure 3K).

After filling the cavity, the restorations were adjusted and polished with a sequence of polishing discs (Solf-lex, 3M Oral Care, St. Paul, MN, USA) (Figure 3L).

Calibration procedures and clinical evaluation

For training purposes, two experienced dentists who were not involved with the restoration procedures performed the clinical evaluation. For training purposes, the examiners observed 10 photographs that were

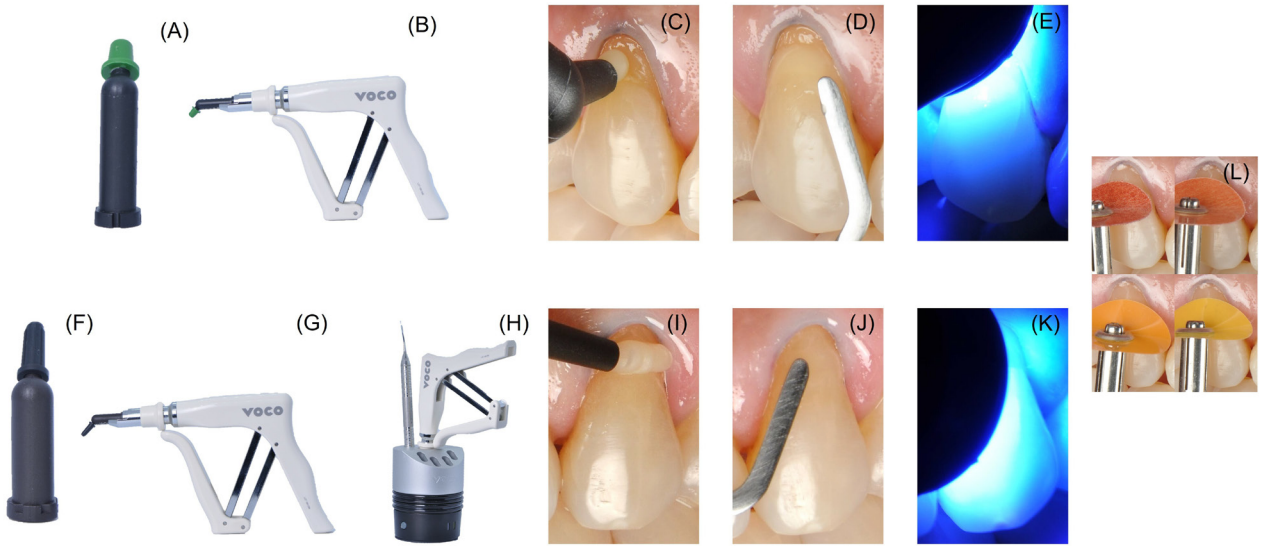

Figure 2 - Composite resin Admira Fusion (A); Caps dispenser (B); Inserted in 2 mm increments (C); Accommodation of the composite in the cavity (D); Light curing of the composite (E); Composite resin VisCalor bulk (F); Caps dispenser (G); Heated to 68°C using a bench heater for 3 minutes (H); Inserted in a single increment in the cavity (I); Accommodation of the composite in the cavity (J); Light curing of the composite (K); Adjusted and polished with a sequence of polishing discs (L).

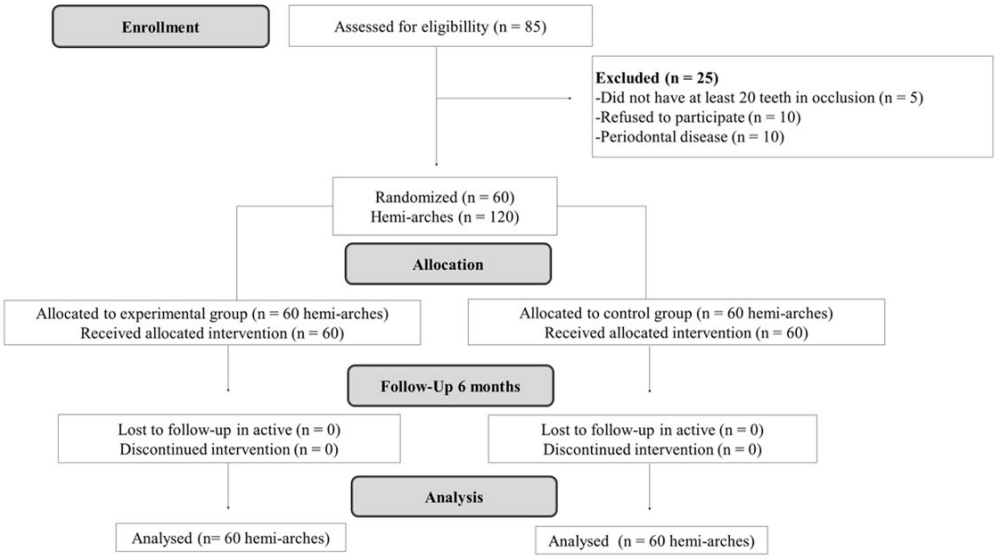

Figure 3 - CONSORT Flow Diagram.

representative of each score for each criterion. They evaluated 10 to 15 subjects each on 2 consecutive days. These subjects had cervical restorations and they did not participate in this project. An intraexaminer and interexaminer agreement of at least 85% was necessary before the beginning of the evaluation [32,33].

The restorations at baseline and after 6 months were evaluated by World Federation criteria (FDI) [34,35]. The primary outcome was restoration retention and fracture, and the secondary outcomes were: surface gloss/luster and roughness; surface and marginal staining; marginal adaptation; color match; esthetic anatomical form; recurrence of initial pathology; tooth cracks and fractures; effect of the restoration on the periodontium; postoperative sensitivity; recurrence of caries; tooth Integrity; periodontal response and oral health. Examiners were kept blind to earlier evaluations during the follow-up recalls. Seven days and 6 months after the restorative procedure, spontaneous postoperative sensitivity was evaluated. Patients were asked if they experienced any pain during the first seven days after restorations.

Variables were classified according to the FDI criteria as clinically very good, clinically good, clinically sufficient/satisfactory, clinically unsatisfactory but repairable, and clinically poor (replacement required) [34,35]. Both examiners evaluated all the restorations once and independently. When there was disagreement during such assessments, the examiners reached a consensus before dismissing the patient.

Statistical Analysis

The statistical analyses followed the intention-to-treat [28]. Descriptive statistics were used to describe the distributions of the evaluated criteria. After 6-month of clinical evaluation, the two restorative materials were statistically evaluated by Chi-square test for the primary outcome (retention/fracture), as well as all the secondary outcomes (surface gloss/luster and roughness; surface and marginal staining; marginal adaptation; color match; esthetic anatomical form; recurrence of initial pathology; tooth cracks and fractures; effect of the restoration on the periodontium; postoperative sensitivity; recurrence of caries; tooth Integrity; periodontal response and oral health). Cohen's kappa statistics were used to test inter-examiner agreement. In all statistical tests, the significance level was pre-set at 5%.

RESULTS

Twenty-five out of 85 patients examined for eligibility were not enrolled in the study because they did not fulfill the inclusion criteria (Figure 3). Thus, a total of 60 subjects (30 male and 30 female) were selected. One hundred and twenty restorations were placed: 60 for each group (Figure 3). All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table II. The overall Cohen kappa statistics showed excellent agreement between the examiners during the six months (0.96) follow-up recall. All research subjects were evaluated at baseline and 6-month recall.

To confirm the blinding of participants, after the restorative procedure, the participants were asked if they felt any discomfort regarding the temperature during the restorative procedure. None participant complained about the difference betwenn both restorative procedure. This

Table II - Characteristics of the Research Subjects and the Noncarious Cervical Lesions (NCCLs) per Group

Characteristics of Research Subjects	Number of Subjects	
Gender Distribution		
Male	30	
Female	30	
Age distribution, (Years)		
20-29	1	
30-39	12	
40-49	19	
>49	28	
Characteristics of NCCLs lesions	**Number of Lesions**	
	NHT	**PHT**
Shape (degree of angle)		
<45	0	0
45-90	15	13
90-135	26	25
>135	19	22
Cervico-incisal height (mm)		
<1.5	7	5
1.5-2.5	19	28
2.5-4.0	30	23
>4.0	4	4
Degree of sclerotic dentin		
1	11	10
2	24	22
3	16	20
4	9	8
Presence of antagonist		
Yes	60	60
No	0	0
Attrition facet		
Yes	16	20
No	44	41
Pre-operative sensitivity (spontaneous)		
Yes	9	12
No	51	48
Pre-operative sensitivity (air dry)		
Yes	28	26
No	32	34
Pre-operative sensitivity (touch)		
Yes	14	13
No	46	47
Tooth distribution		
Anterior		
Incisor	2	1
Canines	10	12
Posterior		
Premolar	36	29
Molar	12	18
Arc distribution		
Maxillary	37	40
Mandibular	23	20
Presence of biofilm		
0	48	52
1	7	6
2	3	2
3	2	0

intervention confirm that the temperature did not compromise the blinding of the participants.

Retention/Fracture

Three restorations were lost or fractured after 6 months of clinical evaluation for NHT group (Table III). The retention rates (confidential interval 95%) for 6 months were 97.5% (88.6% - 99.0%) for the NHT group and 100% (93.9% - 100%) for the PHT group, with no statistical difference between both groups ($p = 0.08$).

Marginal adaptation

Twenty-two restorations were considered small discrepancies in marginal adaptation in the six-month recall using FDI criteria (8 for NHT and 14 for PHT; Table III), with no statistical difference between them ($p = 0.84$).

Oral health

Twenty-six restorations were found to have biofilm retention in the six-month recall using FDI criteria (11 for NHT and 15 for PHT; Table III), with no statistical difference ($p = 0.38$).

Other parameters

No restorations had postoperative sensitivity in both periods of evaluation. Also, no restoration showed any discrepancy in all other parameters of FDI after 6 months of clinical evaluation. Usually, the restorations showed a very good clinical performance, which can be seen in Figure 4, after 6 months of clinical performance.

DISCUSSION

Although the preheating of composite resins is not a new technique [15,16] and a wide range of in vitro studies have shown improved properties when preheating composite resins were compared to non-heated composite resins [25], the authors found only a few clinical studies evaluating this technique [26,27].

Dentists could be reluctant to use preheated composites due to the impression that preheating could be responsible for some damage in the pulp tissue, leading to greater postoperative sensitivity [36]. However, previous clinical studies have not confirmed these expectations [26,27]. In these studies, the authors examined whether preheating a composite resin leads to a change in postoperative sensitivity, mainly in posterior restorations. In the end, they found no significant difference in postoperative sensitivity between restorations performed with and without preheating.

Actually, Campbell et al. and Elkaffas et al. evaluated class I and II restorations [26,27], and to the authors' knowledge, this was the first study designed to evaluate the effect of preheating in the clinical performance of composite resin restorations in NCCLs. It seems important because

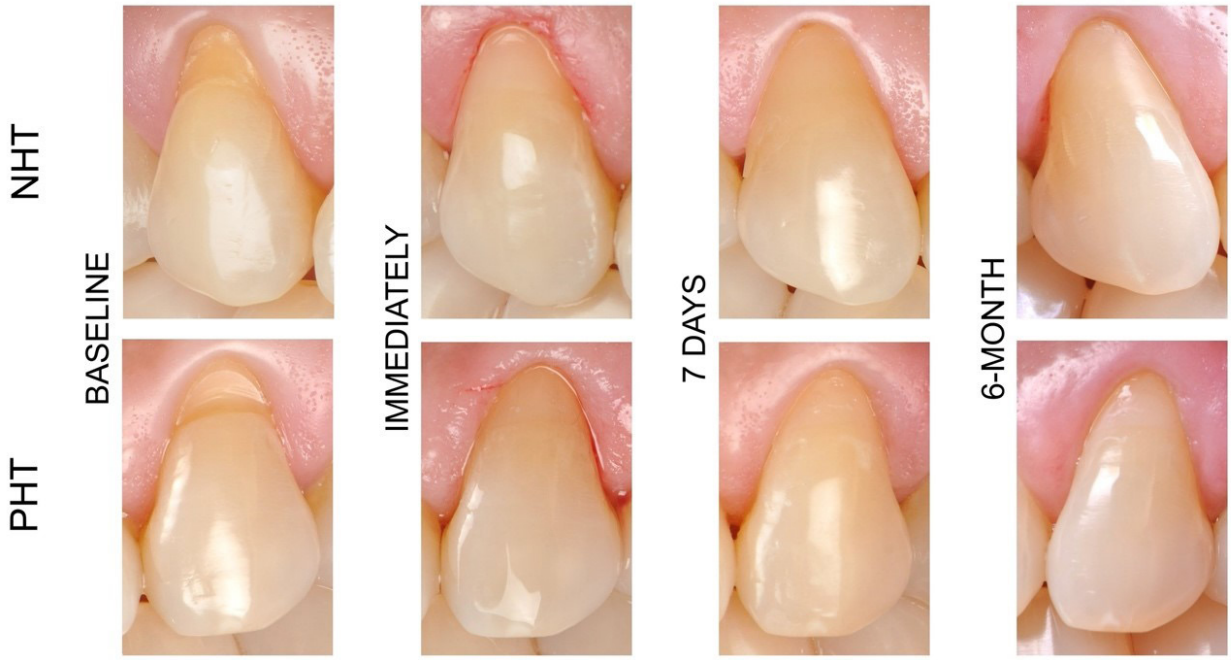

Figure 4 - Clinical follow-up of restorations in different groups and times.

Table III - Number of evaluated restorations for each experimental group classified according to the World Dental Federation (FDI) criteria

FDI Criteria	(*)	Baseline		6 months	
		NHT	PHT	NHT	PHT
Fractures and retention	A	60	60	56	56
	B	0	0	1	3
	C	0	0	0	1
	D	0	0	1	0
	E	0	0	2	0
Surface gloss/lustre and roughness	A	60	60	55	58
	B	0	0	2	2
	C	0	0	0	0
	D	0	0	0	0
	E	0	0	0	0
Surface and Marginal staining	A	60	60	56	59
	B	0	0	1	1
	C	0	0	0	0
	D	0	0	0	0
	E	0	0	0	0
Marginal adaptation	A	60	60	49	46
	B	0	0	8	14
	C	0	0	0	0
	D	0	0	0	0
	E	0	0	0	0
Color match	A	60	60	50	54
	B	0	0	6	4
	C	0	0	1	2
	D	0	0	0	0
	E	0	0	0	0
Esthetic anatomical form	A	60	60	57	60
	B	0	0	0	0
	C	0	0	0	0
	D	0	0	0	0
	E	0	0	0	0
Recurrence of initial pathology	A	60	60	57	60
	B	0	0	0	0
	C	0	0	0	0
	D	0	0	0	0
	E	0	0	0	0
Tooth cracks and fractures	A	60	60	57	60
	B	0	0	0	0
	C	0	0	0	0
	D	0	0	0	0
	E	0	0	0	0
Effect of the restoration on the periodontium	A	60	60	57	60
	B	0	0	0	0
	C	0	0	0	0
	D	0	0	0	0
	E	0	0	0	0
Postoperative sensitivity	A	60	60	57	60
	B	0	0	0	0
	C	0	0	0	0
	D	0	0	0	0
	E	0	0	0	0
Recurrence of caries	A	60	60	57	60
	B	0	0	0	0
	C	0	0	0	0
	D	0	0	0	0
	E	0	0	0	0
Tooth Integrity	A	60	60	57	60
	B	0	0	0	0
	C	0	0	0	0
	D	0	0	0	0
	E	0	0	0	0
Periodontal response	A	60	60	57	60
	B	0	0	0	0
	C	0	0	0	0
	D	0	0	0	0
	E	0	0	0	0
Oral health	A	60	60	46	45
	B	0	0	8	14
	C	0	0	3	1
	D	0	0	0	0
	E	0	0	0	0

A = Clinically very good; B = Clinically good; C = Clinically sufficient / satisfactory; D = Clinically unsatisfactory; E = Clinically poor.

NCCLs are always close to gingival tissue, which could be damaged with higher temperatures [37]. At the same time, NCCLs are more often considered in terms of distance to pulp chamber [38]. The results of the present study showed that no participants noticed the difference between the temperatures used in the two groups.

The present study's results indicate a high retention rate for both groups (100% for the preheating group and 97.5% for non-heating group). Although only short-term clinical data has been reported, the observed success rate should be attributed to the composition of universal adhesive used. Several clinical studies have shown that universal adhesives with ultra-mild/mild pH and containing the acidic functional monomer 10-MDP (10-methacryloyloxydecyl dihydrogen phosphate), such as Futurabond U, yield better clinical results than universal adhesives with a high pH and without 10-MDP [39-42]. It is noteworthy that all restorations were completed with universal adhesive applied in the self-etch mode associated with the selective enamel etching, because this strategy has shown better clinical performance that only self-etching [30,43].

Regarding other clinical factors, a few restorations (24% in the preheating group and 13% in the non-heating group) showed small defects related to the marginal adaptation, with no difference between groups. This seems to be an advantage when preheating was used, mainly because the increase of the flowability of composite when preheating improves the marginal adaptation of the cavity. These findings align with those by Elkaffas et al. [27], who found that the difference between preheating and non-preheating composite resin restorations performed in posterior restorations were non-significant, even after 36 months of clinical evaluation. However, in the mentioned study, only 3% of the restorations showed marginal defects [27]. Several methodological differences (including cavity type and composite resin used) between the present study and the previous one help explain these differences. However, one of the most important is the evaluation criteria used. Elkaffas et al. [27] used the United States Public Health Service criteria, and the authors of the present study used a more sensitive and standardized criteria, known as FDI criteria [44]. This fact justify the report of these defects has been increasingly observed when FDI was used, as observed in previous studies [39,42,45]. However, it is noteworthy that most of these defects are clinically acceptable and easily solved with a repolishing of the restorations [46].

One important limitation of the present study is the short-term evaluation, which helps explain the two techniques' similar clinical performance. Elkaffas et al. [27] only observed a few favorable results for resin restorations with preheated composites after 3 years of clinical evaluation, with less marginal staining in the former than in non-heating composite resin restorations. However, considering a few clinical studies evaluating the preheating technique, this technique's popularity among clinicians and lack of clinical studies in NCCLs, the authors of the present study believe publishing the present study is important.

Actually, as NCCLs are consider the best model to test the clinical effectiveness of adhesive techniques [47], the authors believe that is important to evaluate the effect of preheating in NCCLs restorations. Observe that, due to the multifactorial etiology, it's difficult to diagnose and treat NCCLs exclusively formed from an abrasion, erosion or abfraction. However, some of these factors associated to the etiology of the NCCLs could be partially responsible for interfering in the results of the restorations in NCCLs. For instance, occlusal wear (wear facets) very common in abfraction lesions was correlated with lower retention rate of adhesive restorations in NCCLs [48,49]. Future studies need to be done to evaluate the effect of different NCCLs characteristics (shape, size, etc) on the clinical performance of adhesive restorations on NCCLs.

It's worth to mention that, in terms of use a preheating composite, one important disadvantage is the necessity of investment in a device for heating. Although some devices are available in the marketing, usually these devices are still expensive. However, the authors believe that, in the near future, with the increase of the demand, the prices of heat-set can be more affordable. Finally, future long-term clinical follow-up studies need to be conducted to determine whether the effect of preheating composite resin restorations will improve composite resin restorations' clinical performance in NCCLs.

CONCLUSION

The clinical performance of the new preheated thermoviscous composite resin was found to be safe and showed similar clinical

performance in non-carious cervical lesions after six months of clinical evaluation, compared to non-heated composite resins.

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Author's Contributions

MWF, TSC, LGB, RNV, TPM, PMK, AR, ADL: Conceptualization, Methodology, Investigation. MWF, RNV, AR, ADL: Data Curation. MWF, TSC, LGB, RNV: Writing – Original Draft Preparation. TPM, PMK, AR, ADL: Writing – Review & Editing, Supervision. AR, ADL: Formal Analysis, Resources, Project Administration and Funding Acquisition.

Conflict of Interest

The authors have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subject's oversight committee guidelines and policies of The State University of Ponta Grossa. The approval code for this study is 4.656.880; 2021.

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